

**THIS PRELIMINARY PROPOSED RULE LANGUAGE AND ACCOMPANYING DISCUSSION IS BEING RELEASED TO SUPPORT INTERACTIONS WITH STAKEHOLDERS AND THE ADVISORY COMMITTEE ON REACTOR SAFEGUARDS (ACRS). THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS DOCUMENT AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.**

**AN IMPORTANT NOTE FOR THIS ITERATION IS THAT THE STAFF IS ACTIVELY ASSESSING VARIOUS ALTERNATIVE DESIGN/LICENSING APPROACHES TO ADDRESS COMMENTS THAT THE RULEMAKING SHOULD SUPPORT METHODOLOGIES THAT ARE LESS RELIANT ON PROBABILISTIC RISK ASSESSMENTS (PRA). THE DEVELOPMENT OF THIS SUBPART PRIMARILY REFLECTS A RISK-INFORMED OR PRA-CENTERED APPROACH. THE STAFF IS DEVELOPING ALTERNATIVE APPROACHES AND RELATED PRELIMINARY RULE SECTIONS FOR A FUTURE ITERATION THAT CAN BE CONSIDERED BY AND DISCUSSED WITH STAKEHOLDERS, NRC MANAGEMENT, AND THE COMMISSION.**

**THE STAFF IS PRIMARILY SEEKING INSIGHTS REGARDING THE CONCEPTS IN THIS PRELIMINARY LANGUAGE AND SECONDARILY SEEKING INSIGHTS RELATED TO DETAILS SUCH AS NUMERICAL VALUES FOR VARIOUS CRITERIA.**

**STAFF DISCUSSION OF SUBPART H (Licenses, Certifications, and Approvals) – PRELIMINARY RULE LANGUAGE (August 2021)**

**SUBPART H - Licenses, Certifications, and Approvals**

<b>Preliminary Language</b>	<b>Discussion</b>
	<p>There are several issues in Subpart H that relate to issues being addressed in the ongoing rulemaking on <a href="#">“Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing”</a> (Docket ID NRC-2009-0196) for Parts 50 and 52. Reconciliation of similar issues between that rulemaking and the Part 53 rulemaking will occur at a later date. This first iteration of Subpart H largely reflects the current version of Parts 50 and 52.</p>

**§ 53.1100 Filing of application for licenses, certifications or approvals; oath or affirmation.**

*(a) Serving of applications.*

(1) Each filing of an application for a standard design approval, standard design certification, or license to construct and/or operate, or manufacture, a commercial nuclear plant (including an early site permit) under this part, and any amendments to the applications, must be submitted to the U.S. Nuclear Regulatory Commission in accordance with § 53.040 of this chapter, as applicable.

(2) Each applicant for a construction permit, early site permit, combined license, or manufacturing license under this part shall, upon notification by the presiding officer designated to conduct the public hearing required by the Atomic Energy Act, update the application and serve the updated copies of the application or parts of it, eliminating all superseded information, together with an index of the updated application, as directed by presiding officer. Any subsequent amendment to the application must be served on those served copies of the application and must be submitted to the U.S. Nuclear Regulatory Commission as specified in § 53.040 of this chapter, as applicable.

(3) The applicant must make a copy of the updated application available at the public hearing for the use of any other parties to the proceeding, and shall certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements of this part.

(4) At the time of filing an application, the Commission will make available at the NRC Web site, <http://www.nrc.gov>, a copy of the application, subsequent amendments, and other records pertinent to the matter which is the subject of the application for public inspection and copying.

(5) The serving of copies required by this section must not occur until the application has been docketed under § 2.101(a) of this chapter. Copies must be submitted to the Commission, as specified in § 53.040 of this chapter, as applicable, to enable the Director, Office of Nuclear Reactor Regulation to determine whether the application is sufficiently complete to permit docketing.

*(b) Oath or affirmation.* Each application for a standard design

From § 50.30. Deleted paragraphs § 50.30(a)(2). Paragraph § 50.30(d) moved to § 53.XXX on OLs.

<p>approval or license, including, whenever appropriate, a construction permit or early site permit, or amendment of it, and each amendment of each application must be executed in a signed original by the applicant or duly authorized officer thereof under oath or affirmation.</p> <p>(c) [Reserved]</p> <p>(d) [Reserved]</p> <p>(e) <i>Filing fees.</i> Each application for a standard design approval or commercial nuclear plant license under this part, including, whenever appropriate, a construction permit, combined license, operating license, manufacturing license, or early site permit, other than a license exempted from part 170 of this chapter, shall be accompanied by the fee prescribed in part 170 of this chapter. No fee will be required to accompany an application for renewal, amendment, or termination of a construction permit, operating license, combined license, or manufacturing license, except as provided in § 170.21 of this chapter.</p> <p>(f) <i>Environmental report.</i> An application for a construction permit, operating license, early site permit, design certification, combined license, or manufacturing license for an commercial nuclear plant shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.</p>	
<p><b>§ 53.1110 Combining applications.</b></p> <p>An applicant may combine in one application several applications for different kinds of licenses under the regulations in this chapter.</p>	<p>From §§ 50.31 and 52.8.</p>
<p><b>§ 53.1120 Elimination of repetition.</b></p> <p>An applicant may incorporate by reference in its application information contained in previous applications, statements, or reports filed with the Commission, provided, however, that such references are clear and specific.</p>	<p>From § 50.32.</p>
<p><b>§ 53.1130 Contents of applications; general information.</b></p> <p>Each application shall state, unless otherwise indicated in this subpart:</p> <p>(a) Name of applicant;</p> <p>(b) Address of applicant;</p> <p>(c) Description of business or occupation of applicant;</p> <p>(d)(1) If applicant is an individual, state citizenship.</p>	<p>From § 50.33. Paragraph (f) on financial qualifications moved to Subpart J. Deleted paragraph (h) on earliest and latest dates for completion of construction. This is addressed separately in the Subpart H section on CPs.</p>

<p>(2) If applicant is a partnership, state name, citizenship and address of each partner and the principal location where the partnership does business.</p> <p>(3) If applicant is a corporation or an unincorporated association, state:</p> <p>(i) The state where it is incorporated or organized and the principal location where it does business;</p> <p>(ii) The names, addresses and citizenship of its directors and of its principal officers;</p> <p>(iii) Whether it is owned, controlled, or dominated by an alien, a foreign corporation, or foreign government, and if so, give details.</p> <p>(4) If the applicant is acting as agent or representative of another person in filing the application, identify the principal and furnish information required under this paragraph with respect to such principal.</p> <p>(e) The type of license applied for, the use to which the facility will be put, the period of time for which the license is sought, and a list of other licenses, except operator's licenses, issued or applied for in connection with the proposed facility.</p> <p>(f) [Reserved]</p> <p>(g)(1) Except as provided in paragraph (g)(2) of this section, if the application is for an operating license or combined license for a commercial nuclear plant, or if the application is for an early site permit for a commercial nuclear plant and contains plans for coping with emergencies under § 53.1185(b)(2)(ii) of this chapter, the applicant shall submit radiological emergency response plans of State and local governmental entities in the United States that are wholly or partially within the plume exposure pathway emergency planning zone (EPZ),<sup>1</sup> as well as the plans of State governments wholly or partially within the ingestion pathway EPZ.<sup>2</sup> If the application is for an early site</p>	<p>Paragraphs (g) and (i) will be updated following completion of the rulemaking on "<a href="#">Emergency Preparedness Requirements for Small Modular Reactors and Other New Technologies</a>" (Docket ID NRC-2015-0225).</p>
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<sup>4</sup> Emergency planning zones (EPZs) are discussed in NUREG–0396, EPA 520/1–78–016, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light-Water Nuclear Power Plants," December 1978.

<sup>2</sup> If the State and local emergency response plans have been previously provided to the NRC for inclusion in the facility docket, the applicant need only provide the appropriate reference to meet this requirement.

<p>permit that, under § 53.1185(b)(2)(i), proposes major features of the emergency plans describing the EPZs, then the descriptions of the EPZs must meet the requirements of this paragraph. Generally, the plume exposure pathway EPZ for a commercial nuclear plant shall consist of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ shall consist of an area about 50 miles (80 km) in radius. The exact size and configuration of the EPZs surrounding a particular commercial nuclear plant shall be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. The size of the EPZs also may be determined on a case-by-case basis for gas-cooled reactors and for reactors with an authorized power level less than 250 MW thermal. The plans for the ingestion pathway shall focus on such actions as are appropriate to protect the food ingestion pathway.</p> <p>(2) [To be added when EP for SMR and ONT final rule is published.]</p> <p>(h) [Reserved]</p> <p>(i) A list of the names and addresses of such regulatory agencies as may have jurisdiction over the rates and services incident to the proposed activity, and a list of trade and news publications which circulate in the area where the proposed activity will be conducted and which are considered appropriate to give reasonable notice of the application to those municipalities, private utilities, public bodies, and cooperatives, which might have a potential interest in the facility.</p> <p>(j) If the application contains Restricted Data or other defense information, it shall be prepared in such manner that all Restricted Data and other defense information are separated from the unclassified information.</p> <p>(k) [Reserved]</p>	<p>In paragraph (i), the staff has not limited this requirement to commercial nuclear plants generating electricity, as it is currently in Part 50.</p>
<p><b>§ 53.1135 Environmental conditions.</b></p> <p>(a) Each construction permit, early site permit, and combined license under part 53 of this chapter may include conditions to address environmental issues during construction. These conditions are to be set out in an attachment to the permit or license, which is incorporated in and made a part of the permit or license. These conditions will be</p>	<p>From § 50.36(b).</p>

<p>derived from information contained in the environmental report submitted pursuant to § 53.1100(f) of this chapter as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.</p> <p>(b) Each license authorizing operation of a commercial nuclear plant, including a combined license under part 53 of this chapter, and each license for a commercial nuclear plant for which the certification of permanent cessation of operations required under § 50.82(a)(1) or § 52.110(a) of this chapter has been submitted, which is of a type described in § 50.21(b)(2) or (3) or § 50.22 or is a testing facility, may include conditions to address environmental issues during operation and decommissioning. These conditions are to be set out in an attachment to the license which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report or the supplement to the environmental report submitted pursuant to §§ 51.50 and 51.53 of this chapter as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.</p>	
<p><b>§ 53.1140 Agreement limiting access to Classified Information.</b></p> <p>As part of its application and in any event before the receipt of Restricted Data or classified National Security Information or the issuance of a license, construction permit, early site permit, standard design approval, or manufacturing license, or before the Commission has adopted a final standard design certification rule, the applicant shall agree in writing that it will not permit any individual to have access to any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The agreement of the applicant becomes part of the license, construction permit, or standard design approval.</p>	<p>From § 50.37.</p>

<p><b>§ 53.1150 Ineligibility of certain applicants.</b>  Any person who is a citizen, national, or agent of a foreign country, or any corporation, or other entity which the Commission knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government, shall be ineligible to apply for and obtain a license.</p>	<p>From § 50.38.</p>
<p><b>§ 53.1160 Public inspection of applications.</b>  Applications and documents submitted to the Commission in connection with applications may be made available for public inspection in accordance with the provisions of the regulations contained in part 2 of this chapter.</p>	<p>From § 50.39.</p>
<p><b>§ 53.1162 Relationship between sections.</b></p>	<p>This section will be added at a later date to include text from the Part 52 "Relation to other subparts," as applicable, as well as explain relationships between Part 50 licensing processes.</p>
<p><b>§ 53.1165 Site suitability reviews</b></p>	<p>The NRC staff is interested in stakeholder input as to whether the Part 50 Appendix Q and Part 2 Subpart F site suitability review process should be carried forward into Part 53.</p>
<p><b>§ 53.1170 Limited work authorizations</b>  (a) <i>Requirement for construction permit, early site permit authorizing limited work authorization activities, combined license, or limited work authorization.</i> No person may begin the construction of a commercial nuclear plant on a site on which the facility is to be operated until that person has been issued either a construction permit or combined license under this Part, an early site permit under this Part authorizing the activities under paragraph (b) of this section, or a limited work authorization under paragraph (b) of this section.  (b) <i>Request for limited work authorization.</i> (1) Any person to whom the Commission may otherwise issue either a license or permit related to an commercial nuclear plant may request a limited work authorization allowing that person to perform the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of the foundation,</p>	<p>Paragraph (a) from § 50.10(c).</p> <p>Paragraph (b) from § 50.10(d).</p> <p>In Part 53, the definition of construction from § 50.10 is contained in the subpart A definitions.</p>

including placement of concrete, any of which are for an SSC of the facility for which either a construction permit or combined license is otherwise required under paragraph (a) of this section.

(2) An application for a limited work authorization may be submitted as part of a complete application for a construction permit or combined license in accordance with 10 CFR 2.101(a)(1) through (a)(5), or as a partial application in accordance with 10 CFR 2.101(a)(9). An application for a limited work authorization by the holder of an early site permit must be submitted as a complete application in accordance with 10 CFR 2.101(a)(1) through (a)(4).

(3) The application must include:

(i) A safety analysis report required by 10 CFR 53.1260 [CP], or 10 CFR 53.1280 [COL] of this chapter, as applicable, a description of the activities requested to be performed, and the design and construction information otherwise required by the Commission's rules and regulations to be submitted for a construction permit or combined license, but limited to those portions of the facility that are within the scope of the limited work authorization. The safety analysis report must demonstrate that activities conducted under the limited work authorization will be conducted in compliance with the technically-relevant Commission requirements in 10 CFR Chapter I applicable to the design of those portions of the facility within the scope of the limited work authorization;

(ii) An environmental report in accordance with § 51.49 of this chapter; and

(iii) A plan for redress of activities performed under the limited work authorization, should limited work activities be terminated by the holder or the limited work authorization be revoked by the NRC, or upon effectiveness of the Commission's final decision denying the associated construction permit or combined license application, as applicable.

(c) *Issuance of limited work authorization.* (1) The Director of the Office of Nuclear Reactor Regulation may issue a limited work authorization only after:

(i) The NRC staff issues the final environmental impact statement for the limited work authorization in accordance with subpart A of part 51 of this chapter;

Paragraph (c) from § 50.10(e).

(ii) The presiding officer makes the finding in §§ 51.105(c) or 51.107(d) of this chapter, as applicable;

(iii) The Director determines that the applicable standards and requirements of the Act, and the Commission's regulations applicable to the activities to be conducted under the limited work authorization, have been met. The applicant is technically qualified to engage in the activities authorized. Issuance of the limited work authorization will provide reasonable assurance of adequate protection to public health and safety and will not be inimical to the common defense and security; and

(iv) The presiding officer finds that there are no unresolved safety issues relating to the activities to be conducted under the limited work authorization that would constitute good cause for withholding the authorization.

(2) Each limited work authorization will specify the activities that the holder is authorized to perform.

(d) *Effect of limited work authorization.* Any activities undertaken under a limited work authorization are entirely at the risk of the applicant and, except as to the matters determined under paragraph (e)(1) of this section, the issuance of the limited work authorization has no bearing on the issuance of a construction permit or combined license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act. The environmental impact statement for a construction permit or combined license application for which a limited work authorization was previously issued will not address, and the presiding officer will not consider, the sunk costs of the holder of limited work authorization in determining the proposed action (i.e., issuance of the construction permit or combined license).

(e) *Implementation of redress plan.* If construction is terminated by the holder, the underlying application is withdrawn by the applicant or denied by the NRC, or the limited work authorization is revoked by the NRC, then the holder must begin implementation of the redress plan in a reasonable time. The holder must also complete the redress of the site no later than 18 months after termination of construction, revocation of the limited work authorization, or upon effectiveness of the Commission's final decision denying the associated construction permit

Paragraph (d) from § 50.10(f).

Paragraph (e) from § 50.10(g).

<p>application or the underlying combined license application, as applicable.</p>	
<p><b>§ 53.1180 Early site permits</b>  Sections §§ 53.1181-53.1199 set out the requirements and procedures applicable to Commission issuance of an early site permit for approval of a site for one or more nuclear power facilities separate from the filing of an application for a construction permit or combined license for the facility.</p>	<p>From § 52.12.</p>
<p><b>§ 53.1183 Filing of applications.</b>  Any person who may apply for a construction permit or for a combined license under this part, may file an application for an early site permit with the Director, Office of Nuclear Reactor Regulation. An application for an early site permit may be filed notwithstanding the fact that an application for a construction permit or a combined license has not been filed in connection with the site for which a permit is sought.</p>	<p>From § 52.15.</p>
<p><b>§ 53.1185 Contents of applications; technical information.</b>  (a) The application must contain:  (1) A site safety analysis report. The site safety analysis report must include the following:  (i) The specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used;  (ii) The anticipated maximum levels of radiological and thermal effluents each facility will produce;  (iii) The type of cooling systems, including intakes and outflows, where appropriate, that may be associated with each facility;  (iv) The boundaries of the site;  (v) The proposed general location of each facility on the site;  (vi) The external hazards and site characteristics required by subpart D of this part;  (vii) The location and description of any nearby industrial, military, or transportation facilities and routes;  (viii) The existing and projected future population profile of the area surrounding the site;  (ix) An analysis of licensing basis events associated with potential designs and their results, as described in § 53.240, considered</p>	<p>From § 52.17.</p> <p>In paragraph (a)(1)(ix), the phrase “licensing basis events associated with potential designs” is meant to</p>

in the design to determine compliance with the safety criteria in §§ 53.210 and 53.220, or more restrictive alternative evaluation criteria elected under § 53.470 of this part. This analysis description must address the elements in §§ 53.450(e) and 53.450(f), as applicable for the licensing basis events associated with potential designs that the applicant may be considering.

(x) Information demonstrating that site characteristics are such that adequate security plans and measures can be developed;

(xi) A description of the quality assurance program required by § 53.XX applied to site-related activities for the future design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site.

(2) A complete environmental report as required by 10 CFR 51.50(b).

(b)(1) The site safety analysis report must identify physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans. If physical characteristics are identified that could pose a significant impediment to the development of emergency plans, the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment.

(2) The site safety analysis report may also:

(i) Propose major features of the emergency plans, in accordance with the pertinent standards of § 53.820 of this chapter, such as the exact size and configuration of the emergency planning zones, for review and approval by the NRC, in consultation with the Federal Emergency Management Agency (FEMA), as applicable, 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, as applicable, in accordance with the applicable standards of § 53.820 of this chapter. To the extent approval of emergency plans is sought, the application must contain the information required by § 53.1130(g).

(3) Emergency plans submitted under paragraph (b)(2)(ii) of this section must include the proposed inspections, tests, and analyses that the holder of a combined license referencing the early site permit must

acknowledge that the applicant may be considering one or more designs in the evaluation of its proposed site, similar to the plant parameter envelope approach that has been used by ESP applicants under Part 52.

In paragraph (a)(1)(xi), the reference to § 53.XX is to a new QA section that will be added to Subpart D, "Siting Requirements," of Part 53, as the NRC staff inadvertently failed to include such a requirement for siting activities in the first iteration of Subpart D.

Paragraph (b)(2) will be updated following completion of the rulemaking on "Emergency Preparedness Requirements for Small Modular Reactors and Other New Technologies."

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 be operated in conformity with the emergency plans, the provisions of the Act, and the Commission's rules and regulations. Major features of an emergency plan submitted under paragraph (b)(2)(i) of this section may include proposed inspections, tests, analyses, and acceptance criteria.

(4) Under paragraphs (b)(1) and (b)(2)(i) of this section, the site safety analysis report must include, where appropriate, a description of contacts and arrangements made with Federal, State, and local governmental agencies with emergency planning responsibilities. The site safety analysis report must contain any certifications that have been obtained. If these certifications, where appropriate, cannot be obtained, the site safety analysis report must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site. Under the option set forth in paragraph (b)(2)(ii) of this section, the applicant must make good faith efforts, where appropriate, to obtain from the same governmental agencies certifications that:

(i) The proposed emergency plans are practicable;

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

(iii) That these agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(c) An applicant may request that a limited work authorization under 10 CFR 53.1170 be issued in conjunction with the early site permit. The application must include the information otherwise required by 10 CFR 53.1170.

(d) Each applicant for an early site permit under this part must protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

**§ 53.1186 Standards for review of applications.**

From § 52.18.

<p>Applications filed under this subpart will be reviewed according to the applicable standards set out in 10 CFR Part 53. In addition, the Commission shall prepare an environmental impact statement during review of the application, in accordance with the applicable provisions of 10 CFR Part 51. The Commission shall determine, after consultation with FEMA as applicable, whether the information required of the applicant by § 53.1185(b)(1) shows that there is not significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 53.1185(b)(2)(i) are acceptable in accordance with the applicable standards of § 53.820 of this chapter, and whether any emergency plans submitted by the applicant under § 53.1185(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.</p>	
<p><b>§ 53.1188 Administrative review of applications; hearings.</b>  An early site permit is subject to all procedural requirements in 10 CFR Part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the requirements for issuance of a notice of hearing in §§ 2.104(a) and (d) of this chapter, provided that the designated sections may not be construed to require that the environmental report, or draft or final environmental impact statement include an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources. The presiding officer in an early site permit hearing shall not admit contentions proffered by any party concerning an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources if those issues were not addressed by the applicant in the early site permit application. All hearings conducted on applications for early site permits filed under this part are governed by the procedures contained in subparts C, G, L, and N of 10 CFR Part 2, as applicable.</p>	<p>From § 52.21.</p>
<p><b>§ 53.1189 Referral to the Advisory Committee on Reactor Safeguards (ACRS).</b>  The Commission shall refer a copy of the application for an early site permit to the ACRS. The ACRS shall report on those portions of the</p>	<p>From § 52.23.</p>

application which concern safety.	
<p><b>§ 53.1190 Issuance of early site permit.</b></p> <p>(a) After conducting a hearing under § 53.1188 and receiving the report to be submitted by the ACRS under § 53.1189, the Commission may issue an early site permit, in the form the Commission deems appropriate, if the Commission finds that:</p> <p>(1) An application for an early site permit meets the applicable standards and requirements of the Act and the Commission's regulations;</p> <p>(2) Notifications, if any, to other agencies or bodies have been duly made;</p> <p>(3) There is reasonable assurance that the site is in conformity with the provisions of the Act, and the Commission's regulations;</p> <p>(4) The applicant is technically qualified to engage in any activities authorized;</p> <p>(5) The proposed inspections, tests, analyses and acceptance criteria, including any on emergency planning, are necessary and sufficient, within the scope of the early site permit, to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;</p> <p>(6) Issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public;</p> <p>(7) Any significant adverse environmental impact resulting from activities requested under § 53.1185(c) can be redressed; and</p> <p>(8) The findings required by subpart A of 10 CFR Part 51 have been made.</p> <p>(b) The early site permit must specify the site characteristics, design parameters, and terms and conditions of the early site permit the Commission deems appropriate. Before issuance of either a construction permit or combined license referencing an early site permit, the Commission shall find that any relevant terms and conditions of the early site permit have been met. Any terms or conditions of the early site permit that could not be met by the time of issuance of the construction permit or combined license, shall be set forth as terms or conditions of the construction permit or combined license.</p>	<p>From § 52.24.</p>

<p>(c) The early site permit shall specify those 10 CFR 53.1170(b) activities requested under § 53.1185(c) that the permit holder is authorized to perform.</p>	
<p><b>§ 53.1191 Extent of activities permitted.</b>  If the activities authorized by § 53.1190(c) are performed and the site is not referenced in an application for a construction permit or a combined license issued under this part while the permit remains valid, then the early site permit remains in effect solely for the purpose of site redress, and the holder of the permit must redress the site in accordance with the terms of the site redress plan required by § 53.1185(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 must carry out the redress plan to the greatest extent possible consistent with the alternate use.</p>	<p>From § 52.25.</p>
<p><b>§ 53.1191½ Duration of permit.</b>  (a) Except as provided in paragraph (b) of this section, an early site permit issued under this subpart may be valid for not less than 10, nor more than 20 years from the date of issuance.  (b) An early site permit continues to be valid beyond the date of expiration in any proceeding on a construction permit application or a combined license application that references the early site permit and is docketed before the date of expiration of the early site permit, or, if a timely application for renewal of the permit has been docketed, before the Commission has determined whether to renew the 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.  (d) Upon issuance of a construction permit or combined license, a referenced early site permit is subsumed, to the extent referenced, into the construction permit or combined license.</p>	<p>From § 52.26.</p>
<p><b>§ 53.1192 Limited work authorization after issuance of early site permit.</b>  A holder of an early site permit may request a limited work authorization in accordance with § 53.1185(c) of this part.</p>	<p>From § 52.27.</p>
<p><b>§ 53.1193 Transfer of early site permit.</b></p>	<p>From § 52.28.</p>

<p>An application to transfer an early site permit will be processed under 10 CFR 53.xx.</p>	
<p><b>§ 53.1194 Application for renewal.</b></p> <p>(a) Not less than 12, nor more than 36 months before the expiration date stated in the early site permit, or any later renewal period, the permit holder may apply for a renewal of the permit. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.</p> <p>(b) Any person whose interests may be affected by renewal of the permit may request a hearing on the application for renewal. The request for a hearing must comply with 10 CFR 2.309. If a hearing is granted, notice of the hearing will be published in accordance with 10 CFR 2.309.</p> <p>(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 § 53.1191(b).</p> <p>(d) The Commission shall refer a copy of the application for renewal to the ACRS. The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 53.1195.</p>	<p>From § 52.29.</p>
<p><b>§ 53.1195 Criteria for renewal.</b></p> <p>(a) The Commission shall grant the renewal if it determines that:</p> <p>(1) The site complies with the Act, the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; and</p> <p>(2) Any new requirements the Commission may wish to impose are:</p> <p>(i) Necessary for adequate protection to public health and safety or common defense and security;</p> <p>(ii) Necessary for compliance with the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; or</p> <p>(iii) A substantial increase in overall protection of the public</p>	<p>From § 52.31.</p>

<p>health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.</p> <p>(b) A denial of renewal for failure to comply with the provisions of § 53.1195(a) does not bar the permit holder or another applicant from filing a new application for the site which proposes changes to the site or the way that it is used to correct the deficiencies cited in the denial of the renewal.</p>	
<p><b>§ 53.1196 Duration of renewal.</b> Each renewal of an early site permit may be for not less than 10, nor more than 20 years, plus any remaining years on the early site permit then in effect before renewal.</p>	From § 52.33.
<p><b>§ 53.1197 Use of site for other purposes.</b> 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 must inform the Director, Office of Nuclear Reactor Regulation (Director), of any significant uses for the site which have not been approved in the early site permit. The information about the activities must be given to the Director at least 30 days in advance of any actual construction or site modification for the activities. The information provided could be the basis for imposing new requirements on the permit, in accordance with the provisions of § 53.1199. If the permit holder informs the Director that the holder no longer intends to use the site for a nuclear power plant, the Director may terminate the permit.</p>	From § 52.35.
<p><b>§ 53.1198 Reporting of defects and noncompliance; revocation, suspension, modification of permits for cause.</b> For purposes of 10 CFR part 21 and 10 CFR 53.xx [50.100], an early site permit is a construction permit.</p>	From § 52.37.
<p><b>§ 53.1199 Finality of early site permit determinations.</b> (a) <i>Commission finality.</i> (1) While an early site permit is in effect under §§ 53.1191 or 53.1196, the Commission may not change or impose new site</p>	From § 52.39.

characteristics, design parameters, or terms and conditions, including emergency planning requirements, on the early site permit unless the Commission:

(i) Determines that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued;

(ii) Determines the modification is necessary to assure adequate protection of the public health and safety or the common defense and security;

(iii) Determines that a modification is necessary based on an update under paragraph (b) of this section; or

(iv) Issues a variance requested under paragraph (d) of this section.

(2) In making the findings required for issuance of a construction permit or combined license, or the findings required by § 53.XX [52.103], or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, if the application for the construction permit or combined license references an early site permit, the Commission shall treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit, except as provided for in paragraphs (b), (c), and (d) of this section.

(i) If the early site permit approved an emergency plan (or major features thereof) that is in use by a licensee of a nuclear power plant, the Commission shall treat as resolved changes to the early site permit emergency plan (or major features thereof) that are identical to changes made to the licensee's emergency plans in compliance with § 53.XX of this chapter occurring after issuance of the early site permit.

(ii) If the early site permit approved an emergency plan (or major features thereof) that is not in use by a licensee of a nuclear power plant, the Commission shall treat as resolved changes that are equivalent to those that could be made under § 53.XX of this chapter without prior NRC approval had the emergency plan been in use by a licensee.

(b) *Updating of early site permit-emergency preparedness.* An applicant for a construction permit, operating license, or combined

license who has filed an application referencing an early site permit issued under this subpart must update the emergency preparedness information that was provided under § 53.1185(b) and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements.

(c) *Hearings and petitions.* (1) In any proceeding for the issuance of a construction permit, operating license, or combined license referencing an early site permit, contentions on the following matters may be litigated in the same manner as other issues material to the proceeding:

(i) The nuclear power reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit;

(ii) One or more of the terms and conditions of the early site permit have not been met;

(iii) A variance requested under paragraph (d) of this section is unwarranted or should be modified;

(iv) New or additional information is provided in the application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness; or

(v) Any significant environmental issue that was not resolved in the early site permit proceeding, or any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which significant new information has been identified.

(2) Any person may file a petition requesting that the site characteristics, design parameters, or terms and conditions of the early site permit should be modified, or that the permit should be suspended or revoked. The petition will be considered in accordance with § 2.206 of this chapter. Before construction commences, the Commission shall consider the petition and determine whether any immediate action is required. If the petition is granted, an appropriate order will be issued. Construction under the construction permit or combined license will not be affected by the granting of the petition unless the order is made immediately effective. Any change required by the Commission in

<p>response to the petition shall meet the requirements of paragraph (a)(1) of this section.</p> <p>(d) <i>Variances</i>. An applicant for a construction permit, operating license, or combined license referencing an early site permit may include in its application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the early site permit, or from the site safety analysis report. In determining whether to grant the variance, the Commission shall apply the same technically relevant criteria applicable to the application for the original or renewed early site permit. Once a construction permit or combined license referencing an early site permit is issued, variances from the early site permit will not be granted for that construction permit or combined license.</p> <p>(e) <i>Early site permit amendment</i>. The holder of an early site permit may not make changes to the early site permit, including the site safety analysis report, without prior Commission approval. The request for a change to the early site permit must be in the form of an application for a license amendment, and must meet the requirements of 10 CFR 53.XX.</p>	
<p><b>§ 53.1220 Standard Design Approvals</b>  Sections 53.1220 through 53.1229 sets out procedures for the filing, NRC staff review, and referral to the Advisory Committee on Reactor Safeguards of standard designs for a commercial nuclear plant under this part or major portions thereof.</p>	<p>From § 52.131.</p>
<p><b>§ 53.1223 Filing of applications.</b>  Any person may submit a proposed standard design for a commercial nuclear plant to the NRC staff for its review. The submittal may consist of either the design for the entire facility or the design of major portions thereof.</p>	<p>From § 52.135.</p>
<p><b>§ 53.1224 Contents of applications; general information.</b>  The application must contain all of the information required by 10 CFR 53.1130 (a) through (c) and (j).</p>	<p>From § 52.136.</p>
<p><b>§ 53.1225 Contents of applications; technical information.</b>  If the applicant seeks review of a major portion of a standard design, the application need only contain the information required by this</p>	<p>From § 52.137.  New text added to expand discussion of “major</p>

section to the extent the requirements are applicable to the major portion of the standard design for which NRC staff approval is sought. If an applicant seeks approval of a major portion of the design, the scope of the application for which approval is sought must include all functional design criteria as can be identified at that stage of design. Such applicants must identify conditions related to interfaces with systems outside the scope of the major portion of the standard design for which NRC staff approval is sought, and functional or physical boundary conditions between the major portion of the standard design for which NRC staff approval is sought and the remainder of the standard design. These conditions must be demonstrated when the standard design approval is incorporated into a subsequent construction permit, design certification, manufacturing license, or combined license application.

(a) The application must contain a final safety analysis report (FSAR) that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility, or major portion thereof, for which the applicant seeks design approval, and must include the following information:

(1) *Site Parameters.* The site parameters postulated for the design in accordance with Subpart D of this part, including the design bases external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

(2) *General plant description.* A general description of the plant including reactor type, the intended use of the reactor, nuclear design (e.g., neutron spectrum, reactor control, multi-module reactor control), overall layout of the plant including significant plant features and SSCs, maximum power level, and the nature and inventory of radioactive materials.

(3) *Design features—licensing basis events.* A description of the design features required by § 53.400 that, when combined with associated programmatic controls and human actions, demonstrate that the plant will satisfy the safety criteria defined in §§ 53.210 and 53.220. The description must also demonstrate how design features meet the requirements of § 53.440.

(4) *Design Features and Functional Design Criteria – Normal*

portion” SDAs. Additional discussion regarding SDAs for a major portion of a standard design can be found in the NRC’s ["A Regulatory Review Roadmap for Non-Light Water Reactors,"](#) and the Nuclear Innovation Alliance report “Clarifying ‘Major Portions’ of a Reactor Design in Support of a Standard Design Approval” (ADAMS Accession No. ML17128A507).

*Operations.* A description of the functional design criteria for each design feature required by § 53.425 to demonstrate that the safety criteria defined in § 53.260 are not exceeded during normal operations.

(5) *Functional Design Criteria – Licensing Basis Events.* A description of the functional design criteria required by §§ 53.410 and 53.420 for each design feature required by § 53.400 to demonstrate that the safety criteria defined in §§ 53.210 and 53.220 are met during licensing basis events.

(6) *Programmatic Controls and Interfaces.* (i) A description of the corresponding programmatic controls and interfaces necessary to achieve and maintain the reliability and capability of SSCs relied upon to meet the functional design criteria required by §§ 53.410 and 53.420 and the safety criteria in §§ 53.210 and 53.220, and necessary to maintain consistency with analyses required by § 53.450.

(ii) For an application for a multi-module nuclear power reactor design, the programmatic controls and interfaces must also be described for different modular configurations, as required by § 53.440(i), including any restrictions that will be necessary during the construction and startup of a given module to ensure the safe operation of the overall nuclear plant to be licensed under this part.

(7) *Design Features and Functional Design Criteria for the Protection of Plant Workers.* A description of the design features and functional design criteria required by § 53.430 for each design feature relied upon to demonstrate compliance with § 53.270.

(8) *Programmatic Controls for Protection of Plant Workers.* A description of the corresponding programmatic controls, including monitoring programs, necessary to demonstrate that the worker protection criteria in § 53.270(a) are not exceeded.

(9) *Codes and Standards.* A description of generally accepted consensus codes and standards used to design the design features required to meet the safety criteria defined in §§ 53.210 and 53.220, as required by § 53.440(a), to the extent generally accepted engineering consensus codes and standards are applied to the design of the reactor.

(10) *Materials.* A description of the materials used for safety related (SR) and non-safety related but safety significant (NSRSS) SSCs and a description of the qualification of these materials for their

service conditions over the plant lifetime, as required by with § 53.440(b).

(11) *Safety and Security*. A description of how safety and security were considered together in the design process such that, where possible, security issues were effectively resolved through design and engineered security features, as required by § 53.440(c).

(12) *Probabilistic Risk Assessment*. A description of the probabilistic risk assessment (PRA) required by § 53.450(a) and its results.

(13) *Analyses*. A description of the analyses performed to meet the requirements in § 53.450(b)-53.450(g) that includes the following information:

(i) A description of the analysis of licensing basis events and their results, as described in § 53.240, considered in the design to determine compliance with the safety criteria in §§ 53.210 and 53.220.

This analysis description must include the following:

(A) Address the elements in §§ 53.450(e) and 53.450(f)

(B) In accordance with § 53.460(c):

(1) Describe any human actions that are necessary to prevent or mitigate licensing basis events;

(2) Describe how those human actions are capable of being reliably performed under the postulated environmental conditions present; and

(3) Describe how those human actions would be addressed by programs established in accordance with Subpart F of this part.

(ii) For an application for standard design approval of a multi-module commercial nuclear plant design, the possible operating configurations of the reactor modules, including common systems, interface requirements, and system interactions, as required by 53.440(i).

(iii) (A) The classification of SSCs and human actions according to their safety significance in accordance with § 53.460(a).

(B) For SR and NSRSS SSCs and human actions, the conditions under which they must perform their safety functions required by § 53.230, including environmental conditions.

(C) A description of how SSCs needed to ensure the safety

criteria defined in § 53.210 are designed to withstand the effects of external hazards as required by § 53.510.

(iv) The defense-in-depth measures required by § 53.250.

(v) All plant operating states where there is the potential for the uncontrolled release of radioactive material to the environment, as required by § 53.450(b)(4).

(vi) Events that challenge plant control and safety systems whose failure could lead to an undesirable end state and/or radioactive material release. These include internal events, such as human errors and equipment failures, and external events, such as earthquakes, identified in accordance with Subpart D of this part, as required by § 53.450(b)(5).

(vii) The analytical codes used in modeling plant behavior in analyses of licensing basis events (e.g., thermodynamics, reactor physics, fuel performance, mechanistic source term) and how these codes are qualified for the range of conditions for which they were used, as required by § 53.450(d).

(viii) If not described in addressing paragraph (14)(i) above, the results of other analyses required by § 53.450(g).

(14) *PRA Maintenance*. A description of a program or process that will be used to maintain and upgrade the PRA in conformance with generally accepted methods, standards, and practices, as required by § 53.450(c).

(15) *Special Treatments*. A description of special treatment (e.g., functional design criteria and programmatic controls) established as required by § 53.460 to provide appropriate confidence that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in §§ 53.210 and 53.220.

(16) *Analytical Margins*. A description of any alternative evaluation criteria more restrictive than those defined in §§ 53.220 and 53.450(e) adopted to demonstrate analytical margins supporting operational flexibilities, if applicable, that are incorporated into design features and programmatic controls, and that are maintained within programs required in other Subparts, as required by § 53.470.

(17) *Design and Analyses Quality Assurance.* A description of measures to ensure that the design criteria, analysis, categorization, and special treatment of SSCs as required by § 53.460 are correctly translated into specifications, drawings, procedures, and instructions, as required § 53.480(a).

(18) *Design and Analyses Interfaces.* A description of measures for the identification and control of interfaces required by § 53.490.

(19) *Design Features and Controls to Address the Minimization of Contamination.* The information required by § 20.1406 of this chapter.

(20) *Interface Requirements.* A description, analysis, and evaluation of the interfaces between the standard design and the balance of the nuclear power plant that may impact the ability of the plant to meet the functional design criteria, performance objectives or the safety criteria required in §§ 53.210 or 53.220.

(b) *Other Application Content.* In addition to the FSAR, the application must also include the following:

(1) *Technical Specifications.* Proposed technical specifications prepared in accordance with the requirements of § 53.720(a) of this chapter for those areas addressed by the design approval.

(2) *Availability Controls (if not included in the FSAR).* A description of the controls on plant operations, including availability controls, to provide reasonable assurance that the configurations and special treatments for NSRSS SSCs provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220.

(3) *Technical Qualifications.* A description of the technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

(4) *Integrity Assessment Program.* A description of a Design Integrity Assessment Program that addresses the elements described in § 53.440(c).

(5) *Safeguards Information.* A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

(c) If there are SSCs of the plant which required research and development to confirm the adequacy of their design, provide a report in

For paragraph (b)(2), the issue of the what is to be included in the application regarding reliability and availability controls is currently being discussed under the technology-inclusive content of application project (TICAP) effort. The staff intends to reflect a similar resolution to this issue in Part 53.

For paragraph (c), the language comes from § 50.34(a)(8).

<p>the application which documents the resolution of any safety questions associated with such SSCs.</p> <p>(d) A description of how the performance of each design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.440(d).</p>	
<p><b>§ 53.1226 Review of applications.</b></p> <p>Applications filed under this section will be reviewed for compliance with the standards set out in 10 CFR parts 20, 53, and 73.</p>	<p>From § 52.139.</p>
<p><b>§ 53.1227 Referral to the Advisory Committee on Reactor Safeguards (ACRS).</b></p> <p>The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application which concern safety.</p>	<p>From § 52.141.</p>
<p><b>§ 53.1228 Staff approval of design.</b></p> <p>(a) Upon completion of its review of a submittal under this section and receipt of a report by the Advisory Committee on Reactor Safeguards under § 53.1227 of this section, the NRC staff shall publish a determination in the <i>Federal Register</i> as to whether or not the design is acceptable, subject to appropriate terms and conditions, and make an analysis of the design in the form of a report available at the NRC Web site, <a href="http://www.nrc.gov">http://www.nrc.gov</a>.</p> <p>(b) Duration of design approval. A standard design approval issued under this section is valid for 15 years from the date of issuance and may not be renewed. A design approval continues to be valid beyond the date of expiration in any proceeding on an application for a construction permit or an operating license under part 53 or a combined license or manufacturing license under part 53 that references the final design approval and is docketed before the date of expiration of the design approval</p>	<p>From §§ 52.143 and 52.147.</p>
<p><b>§ 53.1229 Finality of standard design approvals; information requests.</b></p> <p>(a) An approved design must be used by and relied upon by the NRC staff and the ACRS in their review of any standard design</p>	<p>From § 52.145.</p>

<p>certification or individual facility license application that incorporates by reference a standard design approved in accordance with this paragraph unless there exists significant new information that substantially affects the earlier determination or other good cause.</p> <p>(b) The determination and report by the NRC staff do not constitute a commitment to issue a permit or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board Panel, or presiding officers in any proceeding under part 2 of this chapter.</p> <p>(c) Except for information requests seeking to verify compliance with the current licensing basis of the standard design approval, information requests to the holder of a standard design approval must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with 10 CFR 53.XX [50.54(f) equivalent] and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.</p> <p>(d) The Commission will require, before granting a construction permit, combined license, operating license, or manufacturing license which references a standard design approval, that information supporting required design and analysis application content be completed and available for audit if the information is necessary for the Commission to make its safety determinations, including the determination that the application is consistent with the design approval information. This information may be acquired by appropriate arrangements with the design approval applicant.</p>	
<p><b>§ 53.1230 Standard Design Certifications</b>  Section 53.1230 through 53.1239 sets forth the requirements and procedures applicable to Commission issuance of rules granting standard design certifications for commercial nuclear plants licensed under this part separate from the filing of an application for a construction permit or combined license for such a facility.</p>	<p>From § 52.41.</p>
<p><b>§ 53.1232 Filing of applications.</b>  (a) An application for design certification may be filed notwithstanding the fact that an application for a construction permit,</p>	<p>From § 52.45.</p>

<p>combined license, or manufacturing license for such a facility has not been filed.</p> <p>(b) The application must comply with the applicable filing requirements of § 53.040 and §§ 2.811 through 2.819 of this chapter.</p>	
<p><b>§ 53.1233 Contents of applications; general information.</b></p> <p>The application must contain all of the information required by 10 CFR 53.1130 (a) through (c) and (j).</p>	<p>From § 52.46.</p>
<p><b>§ 53.1235 Contents of applications; technical information.</b></p> <p>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. The Commission will require, before design certification, that information supporting required design and analysis application content be completed and available for audit if the information is necessary for the Commission to make its safety determination.</p> <p>(a) The application must contain a final safety analysis report (FSAR) that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components (SSCs), and must include the following information:</p> <p>(1) <i>Site Parameters.</i> The site parameters postulated for the design in accordance with Subpart D of this part, including the design bases external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.</p> <p>(2) <i>General Plant Description.</i> A general description of the plant including reactor type, the intended use of the reactor, nuclear design (e.g., neutron spectrum, reactor control, multi-module reactor control), overall layout of the plant including significant plant features and SSCs, maximum power level and the nature and inventory of radioactive materials.</p> <p>(3) <i>Design Features-licensing basis events.</i> A description of the</p>	<p>From § 52.47.</p>

design features required by § 53.400 that, when combined with associated programmatic controls and human actions, demonstrate that the plant will satisfy safety criteria defined in §§ 53.210 and 53.220. The description must also demonstrate how design features meet the requirements of § 53.440.

(4) *Design Features and Functional Design Criteria – Normal Operations.* A description of the functional design criteria for each design feature required by § 53.425 to demonstrate that the safety criteria defined in § 53.260 are not exceeded during normal operations.

(5) *Functional Design Criteria – Licensing Basis Events.* A description of the functional design criteria required by §§ 53.410 and 53.420 for each design feature required by § 53.400 to demonstrate that the safety criteria defined in §§ 53.210 and 53.220 are met during licensing basis events.

(6) *Programmatic Controls and Interfaces.* (i) A description of the corresponding programmatic controls and interfaces necessary to achieve and maintain the reliability and capability of SSCs relied upon to meet the functional design criteria required by §§ 53.410 and 53.420 and the safety criteria in §§ 53.210 and 53.220 and necessary to maintain consistency with analyses required by § 53.450.

(ii) For an application for a multi-module nuclear power reactor design, the programmatic controls and interfaces must also be described for different modular configurations, as required by § 53.440(i), including any restrictions that will be necessary during the construction and startup of a given module to ensure the safe operation of the overall nuclear plant to be licensed under this part.

(7) *Design Features and Functional Design Criteria for the Protection of Plant Workers.* A description of the design features and functional design criteria required by § 53.430 for each design feature relied upon to demonstrate compliance with § 53.270.

(8) *Programmatic Controls for Protection of Plant Workers.* A description of the corresponding programmatic controls, including monitoring programs, necessary to demonstrate that the worker protection criteria in § 53.270(a) are not exceeded.

(9) *Codes and Standards.* A description of generally accepted consensus codes and standards used to design the design features

required to meet the safety criteria defined in §§ 53.210 and 53.220, as required by § 53.440(a), to the extent generally accepted engineering consensus codes and standards are applied to the design of the reactor.

(10) *Materials*. A description of the materials used for safety related (SR) and non-safety related but safety significant (NSRSS) SSCs and a description of the qualification of these materials for their service conditions over the plant lifetime, as required by with § 53.440(b).

(11) *Safety and Security*. A description of how safety and security were considered together in the design process such that, where possible, security issues were effectively resolved through design and engineered security features, as required by § 53.440(c).

(12) *Probabilistic Risk Assessment*. A description of the probabilistic risk assessment (PRA) required by § 53.450(a), and its results.

(13) *Analyses*. A description of the analyses performed to meet the requirements in §§ 53.450(b) – 53.450(g), that includes the following information:

(i) A description of the analysis of licensing basis events and their results, as described in § 53.240, considered in the design to determine compliance with the safety criteria in §§ 53.210 and 53.220.

This analysis description must:

(A) Address the elements in §§ 53.450(e) and 53.450(f)

(B) In accordance with § 53.460(c):

(1) Describe any human actions that are necessary to prevent or mitigate licensing basis events;

(2) Describe how those human actions are capable of being reliably performed under the postulated environmental conditions present; and

(3) Describe how those human actions would be addressed by programs established in accordance with Subpart F of this part.

(ii) For an application for standard design certification of a multi-module commercial nuclear plant design, the possible operating configurations of the reactor modules, including common systems, interface requirements, and system interactions as required by § 53.440(i).

(iii) (A) The classification of SSCs and human actions according to their safety significance in accordance with § 53.460(a).

(B) For SR and NSRSS SSCs and human actions, the conditions under which they must perform their safety functions required by § 53.230, including environmental conditions.

(C) A description of how SSCs needed to ensure the safety criteria defined in § 53.210 are designed to withstand the effects of external hazards as required by § 53.510.

(iv) The defense-in-depth measures required by § 53.250.

(v) All plant operating states where there is the potential for the uncontrolled release of radioactive material to the environment, as required by § 53.450(b)(4).

(vi) Events that challenge plant control and safety systems whose failure could lead to an undesirable end state and/or radioactive material release. These include internal events, such as human errors and equipment failures, and external events, such as earthquakes, identified in accordance with Subpart D of this part, as required by § 53.450(b)(4).

(vii) The analytical codes used in modeling plant behavior in analyses of licensing basis events (e.g., thermodynamics, reactor physics, fuel performance, mechanistic source term) and how these codes are qualified for the range of conditions for which they were used, as required by § 53.450(d).

(viii) If not described in addressing paragraph (13)(i) above, the results of other analyses required by § 53.450(g).

(14) *PRA Maintenance*. A description of a program or process that will be used to maintain and upgrade the PRA in conformance with generally accepted methods, standards, and practices, as required by § 53.450(c).

(15) *Special Treatments*. A description of special treatment (e.g., functional design criteria and programmatic controls) established as required by § 53.460 to provide appropriate confidence that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in §§ 53.210 and 53.220.

(16) *Analytical Margins*. A description of any alternative evaluation criteria more restrictive than those defined in §§ 53.220 and 53.450(e) adopted to demonstrate analytical margins supporting operational flexibilities, if applicable, that are incorporated into design features and programmatic controls, and that are maintained within programs required in other Subparts, as required § 53.470.

(17) *Design and Analyses Quality Assurance*. A description of measures to ensure that the design criteria, analysis, categorization, and special treatment of SSCs as required by § 53.460 are correctly translated into specifications, drawings, procedures, and instructions, as required by § 53.480(a).

(18) *Design and Analyses Interfaces*. A description of measures for the identification and control of interfaces required by § 53.490.

(19) *Design Features and Controls to Address the Minimization of Contamination*. The information required by § 20.1406 of this chapter.

(20) *Interface Requirements*. A description analysis, and evaluation of the interfaces between the standard design and the balance of the nuclear power plant that may impact the ability of the plant to meet the functional design criteria, performance objectives or the safety criteria required in §§ 53.210 or 53.220.

(b) *Other Application Content*. In addition to the FSAR, the application must also include the following:

(1) *Environmental report*. An environmental report as required by 10 CFR 51.55.

(2) *Technical Specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.720(a) of this chapter for those areas addressed by the design certification.

(3) *Availability Controls* (if not included in the FSAR). A description of the controls on plant operations, including availability controls, to provide reasonable assurance that the configurations and special treatments for NSRSS SSCs provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220.

(4) *Technical Qualifications*. A description of the technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

(5) *Inspections, tests, analyses, and acceptance criteria*. The

<p>proposed inspections, tests, analyses, and 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, a facility that incorporates the design certification has been constructed and will be operated in conformity with the design certification, the provisions of the Act, and the Commission's rules and regulations;</p> <p>(6) <i>Integrity Assessment Program</i>. A description of a Design Integrity Assessment Program that addresses the elements described in §§ 53.440(c).</p> <p>(7) <i>Safeguards information</i>. A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.</p> <p>(c) If there are SSCs of the plant which required research and development to confirm the adequacy of their design, provide a report in the application which documents the resolution of any safety questions associated with such SSCs.</p> <p>(d) A description of how the performance of each design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.440(d).</p>	
<p><b>§ 53.1236 Review of applications</b></p> <p>(a) <i>Standards for review of applications</i>. Applications filed under this subpart will be reviewed for compliance with the standards set out in 10 CFR parts 20, 51, 53, and 73.</p> <p>(b) <i>Reference to an issued operating license or combined license</i>. In those cases where a design certification application is preceded by the issuance of an operating license or custom combined license for a commercial nuclear plant that is essentially the same as the standard design for which certification is being requested, the review will follow the processes for referencing a standard design approval, to the extent practicable.</p> <p>(c) <i>Administrative review of applications</i>.</p>	<p>From §§ 52.48 and 52.51.</p> <p>Paragraph (b) is a new proposal to include a provision for a design certification applicant to reference an issued operating license or custom combined license. This proposal would provide finality provisions similar to those for a design certification applicant referencing a standard design approval.</p>

<p>(1) 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 § 53.1232 and shall specify the procedures to be used for the rulemaking. The notice of proposed rulemaking published in the <i>Federal Register</i> must provide an opportunity for the submission of comments on the proposed design certification rule. If, at the time a proposed design certification rule is published in the <i>Federal Register</i> under this paragraph (a), the Commission decides that a legislative hearing should be held, the information required by § 2.1502(c) must be included in the <i>Federal Register</i> document for the proposed design certification.</p> <p>(2) Following the submission of comments on the proposed design certification rule, the Commission may, at its discretion, hold a legislative hearing under the procedures in subpart O of part 2 of this chapter. The Commission shall publish a document in the <i>Federal Register</i> of its decision to hold a legislative hearing. The document shall contain the information specified in paragraph (c) of this section and specify whether the Commission or a presiding officer will conduct the legislative hearing.</p> <p>(3) Notwithstanding anything in § 2.390 to the contrary, proprietary information will be protected in the same manner and to the same extent as proprietary information submitted in connection with applications for licenses, provided that the design certification shall be published in Chapter I of this title.</p>	
<p><b>§ 53.1237 Referral to the Advisory Committee on Reactor Safeguards (ACRS).</b></p> <p>The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application which concern safety.</p>	<p>From § 52.53.</p>
<p><b>§ 53.1238 Issuance of standard design certification.</b></p> <p>(a) After conducting a rulemaking proceeding under § 53.1236 on an application for a standard design certification and receiving the report to be submitted by the Advisory Committee on Reactor Safeguards under § 53.1237, the Commission may issue a standard design certification in the form of a rule for the design, which is the</p>	<p>From § 52.54.</p>

<p>subject of the application, if the Commission determines that:</p> <p>(1) The application meets the applicable standards and requirements of the Atomic Energy Act and the Commission's regulations;</p> <p>(2) Notifications, if any, to other agencies or bodies have been duly made;</p> <p>(3) There is reasonable assurance that the standard design conforms with the provisions of the Act, and the Commission's regulations;</p> <p>(4) The applicant is technically qualified;</p> <p>(5) The proposed inspections, tests, analyses, and acceptance criteria are necessary and sufficient, within the scope of the standard design, to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in accordance with the design certification, the provisions of the Act, and the Commission's regulations;</p> <p>(6) Issuance of the standard design certification will not be inimical to the common defense and security or to the health and safety of the public;</p> <p>(7) The findings required by subpart A of part 51 of this chapter have been made; and</p> <p>(8) The applicant has implemented the quality assurance program described or referenced in the safety analysis report.</p> <p>(b) The design certification rule must specify the site parameters, design characteristics, and any additional requirements and restrictions of the design certification rule.</p> <p>(c) After the Commission has adopted a final design certification rule, the applicant shall not permit any individual to have access to or any facility to possess restricted data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95, as applicable.</p>	
<p><b>§ 53.1238<sup>1/3</sup> Duration of certification.</b></p> <p>(a) Except as provided in paragraph (b) of this section, a standard design certification issued under this subpart is valid for 15</p>	<p>From § 52.55.</p>

<p>years from the date of issuance.</p> <p>(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 § 53.XXX [52.103 equivalent] before operation begins under a combined license that references the design certification.</p> <p>(c) An applicant for a construction permit, operating license, combined license, or a manufacturing license may, at its own risk, reference in its application a design for which a design certification application has been docketed but not granted.</p>	
<p><b>§ 53.1238½ Application for renewal.</b></p> <p>(a) Not less than 12 nor more than 36 months before the expiration of the initial 15-year period, or any later renewal period, any person may apply for renewal of the certification. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application. The Commission will require, before renewal of certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if this information is necessary for the Commission to make its safety determination. Notice and comment procedures must be used for a rulemaking proceeding on the application for renewal. The Commission, in its discretion, may require the use of additional procedures in individual renewal proceedings.</p> <p>(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 § 53.1238¼.</p> <p>(c) The Commission shall refer a copy of the application for</p>	<p>From § 52.57.</p>

<p>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 § 53.1238%.</p>	
<p><b>§ 53.1238% Criteria for renewal.</b></p> <p>(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.</p> <p>(b) The Commission may impose other requirements if it determines that:</p> <ol style="list-style-type: none"> <li>(1) They are necessary for adequate protection to public health and safety or common defense and security;</li> <li>(2) They are necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the design certification was issued; or</li> <li>(3) There is a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementing those requirements are justified in view of this increased protection.</li> </ol> <p>(c) In addition, the applicant for renewal may request an amendment to the design certification. The Commission shall grant the amendment request if it determines that the amendment will comply with the Atomic Energy Act and the Commission's regulations in effect at the time of renewal. If the amendment request entails such an extensive change to the design certification that an essentially new standard design is being proposed, an application for a design certification must be filed in accordance with this subpart.</p> <p>(d) Denial of renewal does not bar the applicant, or another applicant, from filing a new application for certification of the design, which proposes design changes that correct the deficiencies cited in the denial of the renewal.</p>	<p>From § 52.59.</p>
<p><b>§ 53.1238% Duration of renewal.</b></p>	<p>From § 52.61.</p>

<p>Each renewal of certification for a standard design will be for not less than 10, nor more than 15 years.</p>	
<p><b>§ 53.1239 Finality of standard design certifications.</b></p> <p>(a)(1), while a standard design certification rule is in effect under § 53.1238, 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:</p> <ul style="list-style-type: none"> <li>(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;</li> <li>(ii) Is necessary to provide adequate protection of the public health and safety or the common defense and security;</li> <li>(iii) Reduces unnecessary regulatory burden and maintains protection to public health and safety and the common defense and security;</li> <li>(iv) Is necessary to correct material errors in the certification information; or</li> <li>(v) Substantially increases overall safety, reliability, or security of facility design, construction, or operation, and the direct and indirect costs of implementation of the rule change are justified in view of this increased safety, reliability, or security.</li> </ul> <p>(2)(i) In a rulemaking under § 53.1238, the Commission will give consideration to whether the benefits justify the costs for plants that are already licensed or for which an application for a permit or license is under consideration.</p> <p>(ii) The rulemaking procedures for changes under § 53.1239(a)(1) must provide for notice and opportunity for public comment.</p> <p>(3) Any modification the NRC imposes on a design certification rule under paragraph (a)(1) of this section will be applied to all plants referencing the certified design, except those to which the modification has been rendered technically irrelevant by action taken under paragraphs (a)(4) or (b)(1) of this section.</p> <p>(4) The Commission may not impose new requirements by plant-specific order on any part of the design of a specific plant referencing</p>	<p>From § 52.63.</p>

the design certification rule if that part was approved in the design certification while a design certification rule is in effect under § 53.1238, 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 § 53.080 are present. In addition to the factors listed in § 53.080, the Commission shall consider whether the special circumstances which § 53.080 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 § 2.335, in making the findings required for issuance of a combined license, construction permit, operating license, or manufacturing license, or for any hearing under § 53.XXX [52.103 equivalent], the Commission shall treat as resolved those matters resolved in connection with the issuance or renewal of a design certification rule.

(b) The Commission will require, before granting a construction permit, combined license, operating license, or manufacturing license which references a design certification rule, that information normally supporting required design and analysis application content be completed and available for audit if the information is necessary for the Commission to make its safety determinations, including the determination that the application is consistent with the certification information. This information may be acquired by appropriate arrangements with the design certification applicant.