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 50.90 and 50.92.

(f) *Information requests.* Except for information requests seeking to verify compliance with the current licensing basis of the early site permit, information requests to the holder of an early site permit 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 50.54(f), and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

Subpart B—Standard Design Certifications

§ 52.41 Scope of subpart.

(a) This subpart sets forth the requirements and procedures applicable to Commission issuance of rules granting standard design certifications for nuclear power facilities separate from the filing of an application for a construction permit or combined license for such a facility.

(b)(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 (b)(1) of this section or uses simplified, inherent, passive, or other innovative means to accomplish its safety functions.

§ 52.43 Relationship to other subparts.

(a) This subpart applies to a person that requests a standard design certification from the NRC separately from an application for a combined license filed under subpart C of this part for a nuclear power facility. An applicant for a combined license may reference a standard design certification.

(b) Subpart E of this part governs the NRC staff review and approval of a final standard design. Subpart E may be used independently of the provisions in this subpart.

(c) Subpart F 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 F may be used independently of the provisions in this subpart. However, an applicant for a manufacturing license under subpart F may reference a design certification.

§ 52.45 Filing of applications.

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

(b) The application must comply with the applicable filing requirements of §§ 52.3 and §§ 2.811 through 2.819 of this chapter.

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

§ 52.46 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33(a) through (c) and (j).

§ 52.47 Contents of applications; technical information.

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, before 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.

(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 as a whole, and must include the following information:

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

(2) A description and analysis of the structures, systems, and components (SSCs) of the facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which these requirements have been established, and the evaluations required to show that safety functions will be accomplished. It is expected that the standard plant will reflect through its design, construction, and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The description shall be sufficient to permit understanding of the system designs and their relationship to the safety evaluations. Such items as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent. The following power reactor design characteristics will be taken into consideration by the Commission:

(i) Intended use of the reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;

(ii) The extent to which generally accepted engineering standards are applied to the design of the reactor;

(iii) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials; and

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release[3] from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem[4] total effective dose equivalent (TEDE);

[3] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

[4] A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE;

(3) The design of the facility including:

(i) The principal design criteria for the facility. Appendix A to 10 CFR part 50, general design criteria (GDC), establishes minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of nuclear power units;

(ii) The design bases and the relation of the design bases to the principal design criteria;

(iii) Information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the design will conform to the design bases with an adequate margin for safety;

(4) An analysis and evaluation of the design and performance of structures, systems, and components with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of emergency core cooling system (ECCS) cooling performance and the need for high-point vents following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of §§ 50.46 and 50.46a of this chapter;

(5) The kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in part 20 of this chapter;

(6) The information required by § 20.1406 of this chapter;

(7) The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter;

(8) The information necessary to demonstrate compliance with any technically relevant portions of the Three Mile Island requirements set forth in 10 CFR 50.34(f), except paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v);

(9) For applications for light-water-cooled nuclear power plants, an evaluation of the standard plant design against the Standard Review Plan (SRP) revision in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in design features, analytical techniques, and procedural measures proposed for the design and those corresponding features, techniques, and measures given in the SRP acceptance criteria. Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. The SRP is not a substitute for the regulations, and compliance is not a requirement.

(10) The information with respect to the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations described in 10 CFR 50.34a(e);

(11) Proposed technical specifications prepared in accordance with the requirements of §§ 50.36 and 50.36a of this chapter;

intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. This dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

(12) An analysis and description of the equipment and systems for combustible gas control as required by 10 CFR 50.44;

(13) The list of electric equipment important to safety that is required by 10 CFR 50.49(d);

(14) A description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in 10 CFR 50.60 and 50.61;

(15) Information demonstrating how the applicant will comply with requirements for reduction of risk from anticipated transients without scram events in § 50.62;

(16) A coping analysis, and any design features necessary to address station blackout, as required by 10 CFR 50.63;

(17) Information demonstrating how the applicant will comply with requirements for criticality accidents in § 50.68(b)(2)–(b)(4);

(18) A description and analysis of the fire protection design features for the standard plant necessary to comply with 10 CFR part 50, appendix A, GDC 3, and § 50.48 of this chapter;

(19) A description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Appendix B to 10 CFR part 50, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 were satisfied;

(20) The information necessary to demonstrate that the standard plant complies with the earthquake engineering criteria in 10 CFR part 50, appendix S;

(21) Proposed technical resolutions of those Unresolved Safety Issues and medium- and high-priority generic safety issues which are identified in the version of NUREG–0933 current on the date up to 6 months before the docket date of the application and which are technically relevant to the design;

(22) The information necessary to demonstrate how operating experience insights have been incorporated into the plant design;

(23) For light-water reactor designs, a description and analysis of design features for the prevention and mitigation of severe accidents, e.g., challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen combustion, and containment bypass;

(24) A representative conceptual design for those portions of the plant for which the application does not seek certification, to aid the NRC in its review of the FSAR and to permit assessment of the adequacy of the interface requirements in paragraph (a)(25) of this section;

(25) 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 FSAR;

(26) Justification that compliance with the interface requirements of paragraph (a)(25) of this section is verifiable through inspections, tests, or analyses. The method to be used for verification of interface requirements must be included as part of the proposed ITAAC required by paragraph (b)(1) of this section; and

(27) A description of the design-specific probabilistic risk assessment (PRA) and its results.

(28) For applications for standard design certifications which are subject to 10 CFR 50.150(a), the information required by 10 CFR 50.150(b).

(b) The application must also contain:

(1) The 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; and

(2) An environmental report as required by 10 CFR 51.55.

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

(1) An application for certification of a nuclear power reactor design that is an evolutionary change from light-water reactor designs of plants that 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) An application for certification of a nuclear power reactor design that differs significantly from the light-water reactor designs described in paragraph (c)(1) of this section or uses simplified, inherent, passive, or other innovative means to accomplish its safety functions must provide an essentially complete nuclear power reactor design except for site-specific elements such as the service water intake structure and the ultimate heat sink, and must meet the requirements of 10 CFR 50.43(e); and

(3) An application for certification of a modular nuclear power reactor design must describe and analyze the possible operating configurations of the reactor modules with common systems, interface requirements, and system interactions. The final safety analysis must also account for differences among the configurations, including any restrictions that will be necessary during the construction and startup of a given module to ensure the safe operation of any module already operating.

(d) Each applicant for a standard design certification under this part shall protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

[72 FR 49517, Aug. 28, 2007, as amended at 73 FR 63571, Oct. 24, 2008; 74 FR 28147, June 12, 2009]

§ 52.48 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, 51, 73, and 100.

§ 52.51 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 § 52.45 and shall specify the procedures to be used for the rulemaking. The notice of proposed rulemaking published in the FEDERAL REGISTER 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 FEDERAL REGISTER under this paragraph (a), the Commission decides that a legislative hearing should be held, the information required by 10 CFR 2.1502(c) must be included in the FEDERAL REGISTER document for the proposed design certification.

(b) 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 FEDERAL REGISTER 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.

(c) Notwithstanding anything in 10 CFR 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.

§ 52.53 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

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.