this paragraph unless there exists significant new information that substantially affects the earlier determination or other good cause.

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

(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 50.54(f) and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

§ 52.147 Duration of design approval.

A standard design approval issued under this subpart 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 50 or a combined license or manufacturing license under part 52 that references the final design approval and is docketed before the date of expiration of the design approval.

Subpart F—Manufacturing Licenses

§ 52.151 Scope of subpart.

This subpart sets out the requirements and procedures applicable to Commission issuance of a license authorizing manufacture of nuclear power reactors to be installed at sites not identified in the manufacturing license application.

§ 52.153 Relationship to other subparts.

(a) A nuclear power reactor manufactured under a manufacturing license issued under this subpart may only be transported to and installed at a site for which either a construction permit under part 50 of this chapter or a combined license under subpart C of this part has been issued.

(b) Subpart B of this part governs the certification by rulemaking of the design of standard nuclear power facilities. Subpart E of this part governs the NRC staff review and approval of standard designs for a nuclear power facility. A manufacturing license applicant may reference a standard design certification or a standard design approval in its application. These subparts may also be used independently of the provisions in this subpart.

§ 52.155 Filing of applications.

(a) Any person, except one excluded by 10 CFR 50.38, may file an application for a manufacturing license under this subpart with the Director of New Reactors or the Director of Nuclear Reactor Regulation, as appropriate.

(b) The application must comply with the applicable filing requirements of §§ 52.3 and 50.30 of this chapter.

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

§ 52.156 Contents of applications; general information.

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

§ 52.157 Contents of applications; technical information in final safety analysis report.

The application must contain a final safety analysis report containing the information set forth below, with a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that the manufacturing conforms to the design and to reach a final conclusion on all safety questions associated with the design, permit the preparation of construction and installation specifications by an applicant who seeks to

use the manufactured reactor, and permit the preparation of acceptance and inspection requirements by the NRC:

(a) The principal design criteria for the reactor to be manufactured. Appendix A of 10 CFR part 50, ''General Design Criteria for Nuclear Power Plants,'' 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;

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

(c) A description and analysis of the structures, systems, and components of the reactor to be manufactured, with emphasis upon the materials of manufacture, performance requirements, the bases, with technical justification therefor, upon which the performance requirements have been established, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations. Items such 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:

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

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

(3) 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;

(d) The safety features that are engineered into the reactor 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 reactor design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release[11] 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:

(1) 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[12] total effective dose equivalent (TEDE);

[11] 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.

[12] 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 intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, 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

Continued

(2) 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; and

(e) 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.

(f) Information necessary to establish that the design of the reactor to be manufactured complies with the technical requirements in 10 CFR Chapter I, including:

(1) 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 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;

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

(3) 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 §§ 50.60 and 50.61 of this chapter;

(4) An analysis and description of the equipment and systems for combustible gas control as required by § 50.44 of this chapter;

(5) The coping analysis, and any design features necessary to address station blackout, as described in § 50.63 of this chapter;

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

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

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

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

(10) [Reserved]

(11) 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, as described in § 50.34a(e) of this chapter;

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

(13) If the applicant seeks to use risk-informed treatment of SSCs in accordance with § 50.69 of this chapter, the information required by § 50.69(b)(2) of this chapter;

(14) The information necessary to demonstrate that the manufactured reactor complies with the earthquake engineering criteria in appendix S to 10 CFR part 50;

(15) Information sufficient to demonstrate compliance with the applicable requirements regarding testing, analysis, and prototypes as set forth in § 50.43(e) of this chapter;

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

(17) A description of the quality assurance program applied to the design, and to be applied to the manufacture of, the structures, systems, and components of the reactor. Appendix B to 10 CFR part 50, ''Quality Assurance Criteria for Nuclear Power Plants and

provide assurance of low risk of public exposure to radiation, in the event of an accident.

Fuel Reprocessing Plants,'' sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program must include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 have been and will be satisfied; and

(18) Proposed technical specifications applicable to the reactor being manufactured, prepared in accordance with the requirements of §§ 50.36 and 50.36a of this chapter;

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

(20) The interface requirements between the manufactured reactor and the remaining portions of the nuclear power plant. These requirements must be sufficiently detailed to allow for completion of the final safety analysis;

(21) Justification that compliance with the interface requirements of paragraph (f)(20) of this section is verifiable through inspections, testing, or analysis. The method to be used for verification of interface requirements must be included as part of the proposed ITAAC required by § 52.158(a);

(22) A representative conceptual design for a nuclear power facility using the manufactured reactor, to aid the NRC in its review of the final safety analysis required by this section and to permit assessment of the adequacy of the interface requirements in paragraph (f)(20) of this section;

(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) [Reserved]

(25) If the reactor is to be used in modular plant design, a description of 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;

(26) A description of the management plan for design and manufacturing activities, including:

(i) The organizational and management structure singularly responsible for direction of design and manufacture of the reactor;

(ii) Technical resources directed by the applicant, and the qualifications requirements;

(iii) Details of the interaction of design and manufacture within the applicant's organization and the manner by which the applicant will ensure close integration of the architect engineer and the nuclear steam supply vendor, as applicable;

(iv) Proposed procedures governing the preparation of the manufactured reactor for shipping to the site where it is to be operated, the conduct of shipping, and verifying the condition of the manufactured reactor upon receipt at the site; and

(v) The degree of top level management oversight and technical control to be exercised by the applicant during design and manufacture, including the preparation and implementation of procedures necessary to guide the effort;

(27) Necessary parameters to be used in developing plans for preoperational testing and initial operation;

(28) 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;

(29) The information necessary to demonstrate how operating experience insights have been incorporated into the manufactured reactor design;

(30) For applications for light-water-cooled nuclear power plants, an evaluation of the design to be manufactured 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; and

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

(32) For applications for manufacturing licenses which are subject to 10 CFR 50.150(a), the information required by 10 CFR 50.150(b).

[72 FR 49517, Aug. 28, 2007, as amended at 74 FR 28147, June 12, 2009]

§ 52.158 Contents of application; additional technical information.

The application must contain:

(a)(1) *Inspections, tests, analyses, and acceptance criteria (ITAAC).* The proposed inspections, tests, and analyses that the licensee who will be operating the reactor shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met:

(i) The reactor has been manufactured in conformity with the manufacturing license; the provisions of the Act, and the Commission's rules and regulations; and

(ii) The manufactured reactor will be operated in conformity with the approved design and any license authorizing operation of the manufactured reactor.

(2) If the application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are covered by the design certification.

(3) If the application references a standard design certification, the application may include a notification that a required inspection, test, or analysis in the design certification ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The FEDERAL REGISTER notification required by § 52.163 must indicate that the application includes this notification.

(b)(1) An environmental report as required by 10 CFR 51.54.

(2) If the manufacturing license application references a standard design certification, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the reactor.

§ 52.159 Standards for review of application.

Applications filed under this subpart will be reviewed according to the applicable standards set out in 10 CFR parts 20, 50 and its appendices, 51, 73, and 100 and its appendices.

§ 52.161 [Reserved]

§ 52.163 Administrative review of applications; hearings.

A proceeding on a manufacturing license is subject to all applicable procedural requirements contained 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 proposed action in § 2.105 of this chapter, *provided, however,* 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 constructing and/or operating the manufactured reactor or an evaluation of alternative energy sources. All hearings on manufacturing licenses are governed by the hearing procedures contained in 10 CFR part 2, subparts C, E, G, L, and N.

[72 FR 49517, Aug. 28, 2007, as amended at 78 FR 34249, June 7, 2013]

§ 52.165 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.