determinations, including the determination that the application is consistent with the certification information. This information may be acquired by appropriate arrangements with the design certification applicant.

Subpart C—Combined Licenses

§ 52.71 Scope of subpart.

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

§ 52.73 Relationship to other subparts.

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

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

§ 52.75 Filing of applications.

(a) Any person except one excluded by § 50.38 of this chapter may file an application for a combined license for a nuclear power facility with the Director, Office of New Reactors or Director, Office 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.

[72 FR 49517, Aug. 28, 2007, as amended at 73 FR 5724, Jan. 31, 2008]

§ 52.77 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33.

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

(a) The application must contain a final safety analysis report 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 of the facility as a whole. The final safety analysis report shall include the following information, at a level of information sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a combined license:

(1)(i) The boundaries of the site;

(ii) The proposed general location of each facility on the site;

(iii) The seismic, meteorological, hydrologic, and geologic characteristics of the proposed site with appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity, and time in which the historical data have been accumulated;

(iv) The location and description of any nearby industrial, military, or transportation facilities and routes;

(v) The existing and projected future population profile of the area surrounding the site;

(vi) A description and safety assessment of the site on which the facility is to be located. The assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in paragraphs (a)(1)(vi)(A) and (a)(1)(vi)(B) of this section. In performing this assessment, an applicant shall assume a fission product release[5] 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 site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. 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[6] total effective dose equivalent (TEDE).

(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; and

(2) A description and analysis of the structures, systems, and components 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 reactors will reflect through their design, construction, and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The descriptions 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 and proposed operation 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;

(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

[5] 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.

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

performing this assessment, an applicant shall assume a fission product release[7] from the core into the containment assuming that the facility is operated at the ultimate power level contemplated;

(3) 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;

(4) The design of the facility including:

(i) The principal design criteria for the facility. Appendix A to part 50 of this chapter, ''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;

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

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

(5) 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;

(6) 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;

(7) 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(b)(1) and (b)(2) of this chapter;

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

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

(10) A description of the program, and its implementation, required by § 50.49(a) of this chapter for the environmental qualification of electric equipment important to safety and the list of electric equipment important to safety that is required by 10 CFR 50.49(d);

(11) A description of the program(s), and their implementation, necessary to ensure that the systems and components meet the requirements of the ASME Boiler and Pressure Vessel Code and the ASME Code for Operation and Maintenance of Nuclear Power Plants in accordance with 50.55a of this chapter;

(12) A description of the primary containment leakage rate testing program, and its implementation, necessary to ensure that the containment meets the requirements of appendix J to 10 CFR part 50;

(13) A description of the reactor vessel material surveillance program required by appendix H to 10 CFR part 50 and its implementation;

(14) A description of the operator training program, and its implementation, necessary to meet the requirements of 10 CFR part 55;

[7] 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.

(15) A description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of § 50.65 of this chapter;

(16)(i) 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(d) of this chapter;

(ii) A description of the process and effluent monitoring and sampling program required by appendix I to 10 CFR part 50 and its implementation.

(17) The information with respect to compliance with technically relevant positions of the Three Mile Island requirements in § 50.34(f) of this chapter, with the exception of §§ 50.34(f)(1)(xii), (f)(2)(ix), and (f)(3)(v);

(18) 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;

(19) Information necessary to demonstrate that the plant complies with the earthquake engineering criteria in 10 CFR part 50, appendix S;

(20) 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;

(21) Emergency plans complying with the requirements of § 50.47 of this chapter, and 10 CFR part 50, appendix E;

(22)(i) All emergency plan certifications that have been obtained from the State and local governmental agencies with emergency planning responsibilities must state that:

(A) The proposed emergency plans are practicable;

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

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

(ii) If certifications cannot be obtained after sustained, good faith efforts by the applicant, then the application 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.

(23) [Reserved]

(24) If the application is for a nuclear power reactor design which differs significantly from light-water reactor designs that were licensed before 1997 or use simplified, inherent, passive, or other innovative means to accomplish their safety functions, the application must describe how the design meets the requirements in § 50.43(e) of this chapter;

(25) A description of the quality assurance program, applied to the design, and to be applied to the fabrication, construction, and testing, of the structures, systems, and components of the facility. Appendix B to 10 CFR part 50 sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant must include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 have been and will be satisfied, including a discussion of how the quality assurance program will be implemented;

(26) The applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements for operation;

(27) Managerial and administrative controls to be used to assure safe operation. Appendix B to 10 CFR part 50 sets forth the requirements for these controls for nuclear power plants. The information on the controls to be used for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 will be satisfied;

(28) Plans for preoperational testing and initial operations;

(29)(i) Plans for conduct of normal operations, including maintenance, surveillance, and periodic testing of structures, systems, and components;

(ii) Plans for coping with emergencies, other than the plans required by § 52.79(a)(21);

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

(31) For nuclear power plants to be operated on multi-unit sites, an evaluation of the potential hazards to the structures, systems, and components important to safety of operating units resulting from construction activities, as well as a description of the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation are not exceeded as a result of construction activities at the multi-unit sites;

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

(33) A description of the training program required by § 50.120 of this chapter and its implementation;

(34) A description and plans for implementation of an operator requalification program. The operator requalification program must as a minimum, meet the requirements for those programs contained in § 55.59 of this chapter;

(35)(i) A physical security plan, describing how the applicant will meet the requirements of 10 CFR part 73 (and 10 CFR part 11, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable;

(ii) A description of the implementation of the physical security plan;

(36)(i) A safeguards contingency plan in accordance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan shall include plans for dealing with threats, thefts, and radiological sabotage, as defined in part 73 of this chapter, relating to the special nuclear material and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license shall include the information contained in the applicant's safeguards contingency plan.[8] (Implementing procedures required for this plan need not be submitted for approval.)

(ii) A training and qualification plan in accordance with the criteria set forth in appendix B to 10 CFR part 73.

(iii) A cyber security plan in accordance with the criteria set forth in § 73.54 of this chapter;

(iv) A description of the implementation of the safeguards contingency plan, training and qualification plan, and cyber security plan; and

(v) Each applicant who prepares a physical security plan, a safeguards contingency plan, a training and qualification plan, or a cyber security plan, shall protect the plans and other related Safeguards Information against unauthorized disclosure in accordance with the requirements of § 73.21 of this chapter.

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

(38) 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;

(39) A description of the radiation protection program required by § 20.1101 of this chapter and its implementation.

(40) A description of the fire protection program required by § 50.48 of this chapter and its implementation.

(41) For applications for light-water-cooled nuclear power plant combined licenses, an evaluation of the facility 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

[8] A physical security plan that contains all the information required in both § 73.55 of this chapter and appendix C to 10 CFR part 73 satisfies the requirement for a contingency plan.

procedural measures proposed for a facility 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;

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

(43) Information demonstrating how the applicant will comply with requirements for criticality accidents in § 50.68 of this chapter;

(44) A description of the fitness-for-duty program required by 10 CFR part 26 and its implementation.

(45) The information required by § 20.1406 of this chapter.

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

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

(b) If the combined license application references an early site permit, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the early site permit, *provided, however,* that the final safety analysis report must either include or incorporate by reference the early site permit site safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.

(2) If the final safety analysis report does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application shall include a request for a variance that complies with the requirements of §§ 52.39 and 52.93.

(3) The final safety analysis report must demonstrate that all terms and conditions that have been included in the early site permit, other than those imposed under § 50.36b, will be satisfied by the date of issuance of the combined license. Any terms or conditions of the early site permit that could not be met by the time of issuance of the combined license, must be set forth as terms or conditions of the combined license.

(4) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the final safety analysis report must include any new or additional information that updates and corrects the information that was provided under § 52.17(b), and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. The application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute or would constitute a decrease in effectiveness under § 50.54(q) of this chapter.

(5) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(22) of this section are not required.

(c) If the combined license application references a standard design approval, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the design approval, *provided, however,* that the final safety analysis report must either include or incorporate by reference the standard design approval final safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design approval. In addition, the plant-specific PRA information must use the PRA information for

the design approval and must be updated to account for site-specific design information and any design changes or departures.

(2) The final safety analysis report must demonstrate that all terms and conditions that have been included in the final design approval will be satisfied by the date of issuance of the combined license.

(d) If the combined license application references a standard design certification, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the design certification, *provided, however,* that the final safety analysis report must either include or incorporate by reference the standard design certification final safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the design certification. In addition, the plant-specific PRA information must use the PRA information for the design certification and must be updated to account for site-specific design information and any design changes or departures.

(2) The final safety analysis report must demonstrate that the interface requirements established for the design under § 52.47 have been met.

(3) The final safety analysis report must demonstrate that all requirements and restrictions set forth in the referenced design certification rule, other than those imposed under § 50.36b, must be satisfied by the date of issuance of the combined license. Any requirements and restrictions set forth in the referenced design certification rule that could not be satisfied by the time of issuance of the combined license, must be set forth as terms or conditions of the combined license.

(e) If the combined license application references the use of one or more manufactured nuclear power reactors licensed under subpart F of this part, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the manufacturing license, *provided, however,* that the final safety analysis report must either include or incorporate by reference the manufacturing license final safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the manufacturing license. In addition, the plant-specific PRA information must use the PRA information for the manufactured reactor and must be updated to account for site-specific design information and any design changes or departures.

(2) The final safety analysis report must demonstrate that the interface requirements established for the design have been met.

(3) The final safety analysis report must demonstrate that all terms and conditions that have been included in the manufacturing license, other than those imposed under § 50.36b, will be satisfied by the date of issuance of the combined license. Any terms or conditions of the manufacturing license that could not be met by the time of issuance of the combined license, must be set forth as terms or conditions of the combined license.

(f) Each applicant for a combined license under this subpart 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 13970, Mar. 27, 2009; 74 FR 28147, June 12, 2009]

§ 52.80 Contents of applications; additional technical information.

The application must contain:

(a) The proposed inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in conformity with the combined license,