

1st Iteration - Part 53 Framework B Preliminary Proposed Rule Language

June 2022

This document is the 1st iteration of the preliminary proposed rule language that the NRC staff has publicly released in support of Part 53 Framework B, previously known as Part 5X. The NRC staff previously released the 2nd iteration of Part 53 Framework A in May 2022 (ADAMS Accession No. ML22125A000). The NRC staff expects to adopt further changes in addition to those reflected in this consolidated version of the preliminary proposed rule language for Framework B. Therefore, the absence in this document of changes made in response to a particular comment submittal by any stakeholder should not be construed to mean that the comment is no longer under consideration by the NRC staff. Rather, this consolidated preliminary proposed rule language 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 proposed rule language provided in this document and continues to welcome public participation in the Part 53 rulemaking activities.

This iteration presents the consolidated Part 53 preliminary proposed rule language for Framework B, which is the set of preliminary proposed regulatory requirements in Subparts N through U. The preliminary proposed rule language is a work-in-progress; the rule text will continue to be revised by the NRC staff to address formatting, consistency in terminology, and other editorial details. The staff has also released a supporting document that outlines the development and provisions for Framework B. This document can be found in ADAMS under Accession No. ML22160A039 or on regulations.gov under docket ID NRC-2019-0062.

While the NRC will consider all comments received in further developing the preliminary proposed rule language, it will not provide written responses to those comments. Once the proposed rule is issued in the *Federal Register*, the public will have an opportunity to provide comments, and the agency will respond in writing to all public comments on the proposed rule when issuing a final rule.

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Subpart N – Definitions

§ 53.3010a Definitions.

As used in Framework B of this part —

Anticipated operational occurrences (AOOs) mean those conditions of normal operation which are expected to occur one or more times during the life of the commercial nuclear reactor. As examples, these include but are not limited to loss of power to all coolant pumps, tripping of the turbine generator set, isolation of the main condenser, and loss of all offsite power.

Design bases means that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be (1) restraints derived from generally accepted "state of the art" practices for achieving functional goals, or (2) requirements derived from analysis (based on calculation and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals.

Reactor coolant pressure boundary means, for a light-water reactor subject to the requirements of Framework B of this part, all those pressure-containing components, such as pressure vessels, piping, pumps, and valves, which are:

- (1) Part of the reactor coolant system, or
- (2) Connected to the reactor coolant system, up to and including any and all of

the following:

- (i) The outermost containment isolation valve in system piping which penetrates primary reactor containment,
- (ii) The second of two valves normally closed during normal reactor operation in system piping which does not penetrate primary reactor containment,

(iii) The reactor coolant system safety and relief valves.

For nuclear power reactors of the direct cycle boiling water type, the reactor coolant system extends to and includes the outermost containment isolation valve in the main steam and feedwater piping.

Safety-related structures, systems, and components for light-water reactors means those structures, systems and components that are relied upon to remain functional during and following design basis events to assure:

(1) The integrity of the reactor coolant pressure boundary

(2) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(3) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in § 53.4730(a)(1)(vi).

For non-light-water reactors, *safety-related structures, systems, and components* means those structures, systems and components that are relied on to remain functional during and following design basis accidents to assure:

(1) the capability to perform safety functions determined in accordance with §§ 53.4730(a)(5)(ii) and 53.4730(a)(36), including cooling to maintain the integrity of required systems and barriers such that these requirements and any other applicable requirements are met; or

(2) the capability to shut down the reactor and maintain it in a safe shutdown condition; or (3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in § 53.4730(a)(1)(vi).

Subpart O – Construction and Manufacturing Requirements

§ 53.4100 Construction and manufacturing - scope and purpose.

This subpart applies to those construction and manufacturing activities authorized by a Construction Permit (CP), Combined License (COL), Manufacturing License (ML), or Limited Work Authorization (LWA) issued under Framework B of this part.

§ 53.4105 Reporting of defects and noncompliance.

Each construction permit and manufacturing license issued under Framework B of this part is subject to the terms and conditions in this section, and each combined license issued under Framework B of this part is subject to the terms and conditions in this section until the date that the Commission makes the finding under § 53.5052(g) of this chapter.

(a) *Definitions.* The definitions in 10 CFR 21.3 apply to this section.

(b) *Posting requirements.*

(1) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of this section and the regulations in part 21 of this chapter; Section 206 of the Energy Reorganization Act of 1974 (ERA); and procedures adopted under the regulations. These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to the license are conducted.

(2) If posting of the regulations or the procedures adopted under them is not practical, the licensee may, in addition to posting Section 206 of the ERA, post a notice

which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

(c) *Procedures.* The holder of a construction permit, a combined license, or a manufacturing license subject to this section must adopt appropriate procedures to –

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (c)(2) of this section, in all cases within 60 days of discovery, to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.

(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from the discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in paragraph (d)(5) of this section. The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(3) Ensure that a director or responsible officer of the holder of a construction permit, combined license, or manufacturing license subject to this section is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraph (c)(1) or (c)(2) of this section, if the construction or manufacture of a facility or activity, or a basic component supplied for such a facility or activity –

(i) Fails to comply with the AEA, as amended, or any applicable regulation, order, or license of the Commission, relating to a substantial safety hazard;

(ii) Contains a defect; or

(iii) Undergoes any significant breakdown in any portion of the quality assurance program conducted under the requirements of Subpart U to this part which could have produced a defect in a basic component. These breakdowns in the quality assurance program are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction, installation or manufacture.

(d)(1) The holder of a construction permit, combined license, or manufacturing license subject to this section that obtains information reasonably indicating that the facility or manufactured reactors fail to comply with the AEA, as amended, or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard must notify the Commission of the failure to comply through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(2) The holder of a construction permit, combined license, or manufacturing license subject to this section that obtains information reasonably indicating the existence of any defect found in the construction or manufacture, or any defect found in the final design of a facility as approved and released for construction or manufacture, must notify the Commission of the defect through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(3) The holder of a construction permit, combined license, or manufacturing license subject to this section that obtains information reasonably indicating that the quality assurance program has undergone any significant breakdown discussed in paragraph (c)(3)(iii) of this section must notify the Commission of the breakdown in the quality assurance program through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(4) When acting as a dedicating entity, the holder of a construction permit, combined license, or manufacturing license subject to this section is responsible for

identifying and evaluating deviations; reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and maintaining auditable records for the dedication process.

(5) The notification requirements of this paragraph apply to all defects and failures to comply associated with a substantial safety hazard regardless of whether extensive evaluation, redesign, or repair is required to conform to the criteria and bases stated in the safety analysis report, construction permit, combined license or manufacturing license. Evaluation of potential defects and failures to comply and reporting of defects and failures to comply under this section satisfies the construction permit holder's, combined license holder's, and manufacturing license holder's evaluation and notification obligations under 10 CFR part 21, and satisfies the responsibility of individual directors or responsible officers or holders of construction permits issued under § 53.4900, holders of combined licenses (until the Commission makes the finding under § 53.5052(g)), or holders of manufacturing licenses to report defects, and failures to comply associated with substantial safety hazards under section 206 of the ERA. The director or responsible officer may authorize an individual to provide the notification required by this section, provided that this must not relieve the director or responsible officer of his or her responsibility under this section.

(e) *Notification – timing and where sent.* The notification required by paragraph (d) of this section must consist of –

(1) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816-5151 or by telephone at (301) 816-5100 within 2 days following receipt of information by the director or responsible corporate officer under paragraph (c)(3) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling

the NRC Operations Center. This paragraph does not apply to interim reports described in paragraph (c)(2) of this section.

(2) Written notification submitted to the Document Control Desk, U.S. Nuclear Regulatory Commission, by an appropriate method listed in § 53.040, with a copy to the appropriate Regional Administrator at the address specified in appendix D to 10 CFR part 20 and a copy to the appropriate NRC resident inspector, if applicable, within 30 days following receipt of information by the director or responsible corporate officer under paragraph (c)(3) of this section, on the identification of a defect or failure to comply.

(f) *Content of notification.* The written notification required by paragraph (e)(2) of this section must clearly indicate that the written notification is being submitted under § 53.4105 and include the following information, to the extent known.

(1) Name and address of the individual or individuals informing the Commission.

(2) Identification of the facility, the activity, or the basic component supplied for the facility or the activity within the United States which contains a defect or fails to comply.

(3) Identification of the firm constructing or manufacturing the facility or supplying the basic component which fails to comply or contains a defect.

(4) Nature of the defect or failure to comply and the safety hazard which is created or could be created by the defect or failure to comply.

(5) The date on which the information of a defect or failure to comply was obtained.

(6) In the case of a basic component which contains a defect or failure to comply, the number and location of these components in use at the facility subject to the regulations in this part.

(7) In the case of a completed reactor manufactured under Framework B of this part, the entities to which the reactor was supplied.

(8) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(9) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to other entities.

(g) *Procurement documents.* Each holder of a construction permit, combined license, or manufacturing license subject to this section shall ensure that each procurement document for a facility, or a basic component specifies the provisions of 10 CFR part 21 or 10 CFR 53.4105 that apply, as applicable.

(h) *Coordination with 10 CFR part 21.* The requirements of § 53.4105 are satisfied when the defect or failure to comply associated with a substantial safety hazard has been previously reported under 10 CFR part 21, under 10 CFR 73.71, under § 53.4105, or under § 53.6030.

(i) *Records retention.* Each holder of a construction permit, combined license, or manufacturing license subject to this section must prepare and maintain records necessary to accomplish the purposes of this section, specifically –

(1) Retain procurement documents, which define the requirements that facilities or basic components must meet in order to be considered acceptable, for the lifetime of the facility or basic component.

(2) Retain records of evaluations of all deviations and failures to comply under paragraph (c)(1) of this section for the longest of:

(i) Ten (10) years from the date of the evaluation; or

(ii) Five (5) years from the date that an early site permit is referenced in an application for a combined license; or

(iii) Five (5) years from the date of delivery of a manufactured reactor.

(3) Retain records of all interim reports to the Commission made under paragraph (c)(2) of this section, or notifications to the Commission made under paragraph (d) of this section for the minimum time periods stated in paragraph (i)(2) of this section;

(4) Suppliers of basic components must retain records of:

(i) All notifications sent to affected licensees or purchasers under paragraph (d)(4) of this section for a minimum of ten (10) years following the date of the notification;

(ii) The facilities or other purchasers to whom the basic components or associated services were supplied for a minimum of fifteen (15) years from the delivery of the basic component or associated services.

(5) Maintaining reports in accordance with this section satisfies the recordkeeping obligations under 10 CFR part 21 of the entities, including directors or responsible officers thereof, subject to this section.

§ 53.4110 Construction.

(a) *Management and control.* Licensees must ensure that the following plans, programs, and organizational units are developed and implemented to manage and control the construction activities:

(1) Programs to ensure that the construction of a commercial nuclear plant supports the eventual compliance with the technical requirements in § 53.4756, for an early site permit, § 53.4909 for a construction permit, or § 53.5016 for a combined license.

(2) An organization, headed by qualified personnel, responsible for managing, controlling, and evaluating the adequacy of the construction activities.

(3) Approved procedures describing the qualifications for personnel in key positions in the licensee's management and control organization and the organizational responsibilities, authority, and interfaces with other parts of the licensee's organization.

(4) Procedures to evaluate the applicability of other national and international construction experience to the planned and ongoing construction activities and to ensure the applicable experience will be provided to those constructing the plant.

(5) A fitness-for-duty program, under 10 CFR part 26.

(6) A Quality Assurance (QA) Program meeting the requirements of Subpart U to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the commercial nuclear plant.

(7) A radiation protection program, in accordance with 10 CFR part 20, that includes measures for monitoring the dose to individuals working with radioactive materials brought onto the site, as applicable.

(8) An information security program in accordance with 10 CFR 73.21, 73.22 and 73.23, as applicable.

(9) A cyber security program established in accordance with 10 CFR 73.54 or 73.110, as applicable.

(b) *Construction activities.* No person may begin the construction of a commercial nuclear plant on a site on which the facility is to be operated under Framework B of this part until that person has been issued either a construction permit or combined license, an early site permit authorizing activities under § 53.4740, or a limited work authorization under Framework B of this part.

(1) Licensees must meet the following requirements:

(i) As appropriate, considering the types and quantities of radioactive materials being brought onto the site:

(A) The licensee must maintain and follow a special nuclear material (SNM) material control and accounting (MC&A) program, a measurement control program, and other material control procedures that include corresponding record management requirements as required by the provisions of 10 CFR 70.32. Prior to initial receipt of SNM onsite, the licensee shall implement a SNM MC&A Program in accordance with 10 CFR part 74.

(B) Procedures must be in place to receive, possess, use, and store source, byproduct, and SNM in accordance with applicable portions of 10 CFR parts 30, 40, and 70.

(C) A plant staff training program associated with the receipt of radioactive material must be approved and implemented prior to initial receipt of byproduct, source, or SNM (excluding exempt quantities as described in 10 CFR 30.18).

(ii) For construction of a commercial nuclear plant involving multiple reactor units, applicants must identify potential hazards to the structures, systems and components important to safety of operating nuclear facilities from construction activities. A discussion shall also be included of any managerial and administrative controls that will be used during construction to assure the safety of the operating unit.

(iii) Procedures must be in place prior to the start of construction activities that describe how construction will be controlled so as not to impact other features important to the design, such as dewatering, slope stability, backfill, compaction, and seepage.

(iv) For LWA holders, a plan must be developed for redress of activities performed under the LWA should one of the following situations arise:

(A) LWA work activities are terminated by the holder of the LWA;

(B) The LWA is revoked by the NRC; or

(C) The Commission denies the associated construction permit or combined license application.

(2) *On-site fresh fuel.*

(i) For a CP holder or LWA holder, or for a COL holder before the Commission makes the finding under § 53.5052, onsite fresh fuel must be stored in compliance with 10 CFR 73.67.

(ii) For an OL holder or for a COL holder after the Commission makes the finding under § 53.5052:

(A) Onsite fresh fuel must be in stored within a protected area in compliance with 10 CFR 73.55 or 73.100.

(B) Before fuel is brought within a protected area, a cyber security program that meets the requirements of 10 CFR 73.54 or 73.110, a physical security program that meets the requirements of 10 CFR 73.55 or 73.100, and an access authorization program that meets the requirements of 10 CFR 73.56 and 73.120 must be established.

(C) Fire protection measures for work and storage areas (including adjacent fire areas that could affect the work or storage area) must be implemented before initial receipt of byproduct, source, or non-fuel SNM (excluding exempt quantities as described in 10 CFR 30.18). The fire protection measures for areas associated with new fuel (including all fuel handling, fuel storage, and adjacent fire areas that could affect the new fuel) must be implemented before receipt of fuel. Prior to the receipt of fuel, a formal letter of agreement must be in place with the local fire department specifying the nature of arrangements in support of the fire protection program.

(c) *Inspection and acceptance*

(1) The licensee must have a process for accepting individual or groups of SSCs upon completion of construction and protecting them from damage or tampering as other construction activities continue.

(2) The post construction acceptance process must address the inspections, tests, analyses, and acceptance criteria specified in the combined license under

§ 53.5040 or the equivalent verifications needed to support the issuance of an operating license under § 53.4987.

§ 53.4120 Manufacturing.

(a) *Management and control.* Holders of manufacturing licenses must ensure that the following plans, programs, and organizational units are developed and implemented to manage and control the manufacturing activities within the scope of the ML:

(1) Programs to ensure that the manufacturing of a reactor, portions of a reactor, or a manufactured reactor module complies with the manufacturing license issued under Framework B of this Part. The holder of the manufacturing license must be the entity with design authority for the manufactured reactor or manufactured reactor module covered by the manufacturing license.

(2) An organizational and management structure responsible for managing, controlling, and evaluating the adequacy of the reactor design and manufacturing activities.

(3) Approved procedures describing the qualifications for personnel in key positions in the licensee's management and control organization and the organizational responsibilities, authority, and interfaces with other parts of the licensee's organization.

(4) A program to evaluate the applicability of other national and international design and manufacturing experience to the planned and ongoing manufacturing activities.

(5) A fitness for duty program, in accordance with 10 CFR part 26.

(6) A QA program meeting the requirements of Subpart U of this part, to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the manufactured reactor or manufactured reactor module.

(7) A radiation protection program, in accordance with 10 CFR part 20, that includes measures for monitoring the dose to individuals if the manufacturing activities include working with radioactive materials.

(8) An information security program in accordance with 10 CFR 73.21, 73.22 and 73.23, as applicable.

(b) *Manufacturing activities.* Holders of manufacturing licenses must meet the following requirements:

(1) The manufacturing process must be conducted within facilities that are controlled by a manufacturing license holder. This licensee must establish access controls to the portions of each facility involved in the manufacturing processes governed by the ML.

(2) Manufacturing processes must be performed in accordance with the ML and the referenced codes and standards that have been endorsed or otherwise found acceptable by the NRC.

(3) A post manufacturing inspection and acceptance process must be established and implemented before transporting a manufactured reactor or portions of a manufactured reactor for installation at a commercial nuclear plant and prior to and following the loading of fresh fuel into a manufactured reactor module. The process must consider the results of inspections, tests, and analyses that have been performed and the acceptance criteria that are necessary and sufficient to conclude that manufacturing activities have been completed in accordance with the ML.

(c) *Control of radioactive materials.* As appropriate considering the types and quantities of radioactive materials being brought into the manufacturing facility:

(1) Procedures must be in place to receive, transfer, possess, and use source, byproduct, and SNM in accordance with the applicable portions of 10 CFR parts 30, 40 and 70.

(2) A fire protection program must be established and implemented before the initial receipt of byproduct, source, or SNM (excluding exempt quantities as described in 10 CFR 30.18) other than fuel. The fire protection measures for areas associated with fueling a manufactured reactor module (including all fuel handling, fuel storage and adjacent areas where a fire could affect the fresh fuel) must be implemented before receipt of fresh fuel at the manufacturer's facility. Prior to the receipt of fuel at the manufacturer's facility, a formal letter of agreement must be in place with the local fire department specifying the nature of arrangements in support of the fire protection program.

(3) An emergency plan for responding to the radiological hazards of an accidental release of radioactive material and to limit the health effects of the associated chemical hazards of licensed material must be approved and implemented prior to the receipt of byproduct, source, or SNM (excluding exempt quantities as described in 10 CFR 30.18).

(4) A plant staff training program associated with the receipt of radioactive material must be approved and implemented before initial receipt of byproduct, source, or special nuclear material (excluding exempt quantities as described in 10 CFR 30.18).

(5) Prior to the receipt of fresh fuel for a manufactured reactor module at the manufacturer's facility, the following measures must be in place:

(i) A physical security program for the storage of fresh fuel in accordance with 10 CFR 73.67.

(ii) A material control and accounting program in accordance with 10 CFR part 74.

(iii) Measures to monitor criticality accidents in accordance with §§ 70.61 and 70.64 of this chapter and to detect potential criticality accidents in accordance with § 53.440(m).

(6) Procedures shall be in place to describe how the facility design and manufacturing process will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. Manufacturing licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the facility site, including the subsurface, under § 20.1406 of this chapter.

(d) *Fuel loading*

(1) If the ML authorizes fuel loading into a manufactured reactor module at the manufacturing facility, the following must be in place prior to the receipt of SNM:

(i) Radiation monitoring instrumentation and alarms.

(ii) Criticality monitoring instrumentation and alarms.

(iii) Procedures, equipment, and personnel qualified to handle fresh fuel, load it into the reactor, monitor the reactivity, and secure the fuel and reactor assembly for shipment.

(2) The storage, movement, and loading of fresh fuel into the manufactured reactor module within the manufacturing facility must comply with the requirements of §§ 70.61, 70.62 and 70.64 of this chapter.

(3) The loading of fresh fuel into a manufactured reactor module and any changes to the configuration of reactivity-related systems for the manufactured reactor module will be performed by a certified fuel handler meeting the requirements in subpart P.

(e) *Transportation.*

(1) A holder of a manufacturing license may not transport or allow to be removed from the places of manufacture the manufactured reactor or major portions thereof as defined in the ML except to the site of a licensee with a combined license. The combined

license must authorize the construction of a nuclear power facility using the manufactured reactor(s).

(2) A holder of a manufacturing license shall include, in any contract governing the transport of a manufactured reactor or major portions thereof as defined in the ML from the places of manufacture to any other location, a provision requiring that the person or entity transporting the manufactured reactor to comply with all NRC-approved shipping requirements in the manufacturing license.

(3) Procedures governing the preparation of the manufactured reactor or major portions thereof as defined in the ML for transport and the conduct of the transport must be documented and approved prior to transport. The procedures must implement the protective measures and restrictions described in the ML to protect the reactor from damage, contamination, or accidental criticality, if containing fuel.

(4) The packaging and shipping of any fueled manufactured reactor module must be done in compliance with 10 CFR parts 71 and 73.

(f) Acceptance and installation at the site.

(1) Installation at the site must follow the regulations in § 53.4110.

(2) Upon arrival at the site, the manufactured reactor may not be installed in its final place of use unless the CP or COL holder inspects the reactor, using approved procedures, and verifies it is in acceptable condition in compliance with the ML. These inspections must confirm that all interface requirements between the manufactured reactor, portions of a manufactured reactor, or a manufactured reactor module and the remaining portions of the commercial nuclear power plant are met. Prior to installation at the site, the holder of the combined license must verify that:

(i) The manufactured reactor, portions of a manufactured reactor, or a manufactured reactor module has arrived with no damage or contamination that could affect its safe operation.

(ii) The manufactured reactor, portions of a manufactured reactor, or a manufactured reactor module conform to the manufacturing license referenced in the COL;

(iii) The manufactured reactor or manufactured reactor module are consistent with the interface requirements included in the COL and the commercial nuclear plant can be operated safely in conformity with the approved design.

Subpart P – Requirements for Operation

§ 53.4200 Operational objectives.

Each holder of an operating license or combined license under Framework B of this part must define, implement, and maintain controls for plant SSCs, responsibilities of plant personnel, and plant programs during the operating life of each commercial nuclear plant. Each such licensee must maintain the capabilities and reliabilities of facility structures, systems, and components to ensure that these structures, systems, and components can perform their specified safety functions if called upon during design-basis events. Each such licensee must ensure that plant personnel have adequate knowledge and skills to perform their assigned duties. Each such licensee must implement plant programs during operations to ensure that plant safety is maintained during normal operations and design-basis events.

§ 53.4210 Maintenance, repair, and inspection programs.

The requirements of this section are applicable during all conditions of plant operation, including normal shutdown operations.

(a)(1) Each holder of an operating license under Framework B of this part or a combined license under Framework B of this part after the Commission makes the finding under § 53.5052(g) , shall monitor the performance or condition of structures, systems, and components, against licensee-established goals, in a manner sufficient to provide reasonable assurance that these structures, systems, and components, as defined in paragraph (b) of this section, are capable of fulfilling their intended functions. These goals shall be established commensurate with safety and, where practical, take into account industrywide operating experience. When the performance or condition of a structure, system, or component does not meet licensee-established goals, appropriate corrective action shall be taken. For a commercial nuclear reactor for which the licensee has submitted the certifications specified in § 53.6075(a), this section shall only apply to the extent that the licensee shall monitor the performance or condition of all structures, systems, and components associated with the storage, control, and maintenance of spent fuel in a safe condition, in a manner sufficient to provide reasonable assurance that these structures, systems, and components are capable of fulfilling their intended functions.

(2) Monitoring as specified in paragraph (a)(1) of this section is not required for a structure, system, or component when the licensee has documented a demonstration that its performance or condition is being effectively controlled through the performance of appropriate preventive maintenance, such that the structure, system, or component remains capable of performing its intended function.

(3) Performance and condition monitoring activities and associated goals and preventive maintenance activities shall be evaluated at appropriate times in the facility's operating cycle such that the interval between evaluations does not exceed 24 months. The evaluations shall take into account, where practical, industrywide operating experience. Adjustments shall be made where necessary to ensure that the objective of

preventing failures of structures, systems, and components through maintenance is appropriately balanced against the objective of minimizing unavailability of structures, systems, and components due to monitoring or preventive maintenance.

(4) Before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee must assess and manage the increase in risk that may result from the proposed maintenance activities. The scope of the assessment may be limited to structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety.

(b) The scope of the monitoring program specified in paragraph (a)(1) of this section must include:

(1) Safety-related structures, systems, and components; and

(2) Non-safety-related structures, systems, and components:

(i) That are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures; or

(ii) Whose failure could prevent safety-related structures, systems, and components from fulfilling their safety-related function; or

(iii) Whose failure could cause a reactor scram or actuation of a safety-related system.

§ 53.4213 Technical specifications.

(a) Each operating license or combined license under Framework B of this part must include technical specifications in accordance with the requirements of this section. The technical specifications must be derived from the analyses and evaluation included in the safety analysis report, and amendments thereto, submitted pursuant to

§ 53.4730(a)(23). The Commission may include such additional technical specifications as the Commission finds appropriate.

(b) Technical specifications must include items in the following categories:

(1) *Safety limits, limiting safety system settings, and limiting control settings.*

(i) Safety limits for commercial nuclear reactors are limits upon important process variables that are found to be necessary to reasonably protect the integrity of certain physical barriers that guard against the uncontrolled release of radioactivity. If any safety limit is exceeded, the reactor must be shut down. The licensee must notify the Commission, review the matter, and record the results of the review, including the cause of the condition and the basis for corrective action taken to preclude recurrence. Operation must not be resumed until authorized by the Commission. The licensee must notify the Commission as required by § 53.6330 and submit a Licensee Event Report to the Commission as required by § 53.6340. Licensees shall retain the record of the results of each review until the Commission terminates the license for the reactor.

(ii) Limiting safety system settings for nuclear reactors are settings for automatic protective devices related to those variables having significant safety functions. Where a limiting safety system setting is specified for a variable on which a safety limit has been placed, the setting must be so chosen that automatic protective action will correct the abnormal situation before a safety limit is exceeded. If, during operation, it is determined that the automatic safety system does not function as required, the licensee must take appropriate action, which may include shutting down the reactor. The licensee must notify the Commission, review the matter, and record the results of the review, including the cause of the condition and the basis for corrective action taken to preclude recurrence. The licensee must notify the Commission as required by § 53.6330 and submit a Licensee Event Report to the Commission as required by § 53.6340. Licensees

must retain the records of the review for a period of three years following issuance of a Licensee Event Report.

(2) *Limiting conditions for operation.*

(i) Limiting conditions for operation are the lowest functional capability or performance levels of equipment required for safe operation of the facility. When a limiting condition for operation of a commercial nuclear reactor is not met, the licensee must shut down the reactor or follow any remedial action permitted by the technical specifications until the condition can be met. The licensee must notify the Commission if required by § 53.6330 and must submit a Licensee Event Report to the Commission as required by § 53.6340. Licensees must retain records associated with preparation of a Licensee Event Report for a period of three years following issuance of the report. For events which do not require a Licensee Event Report, the licensee must retain each record as required by the technical specifications.

(ii) A technical specification limiting condition for operation of a nuclear reactor must be established for each item meeting one or more of the following criteria:

(A) *Criterion 1.* Installed instrumentation that is used to detect, and indicate in the control room, significant abnormal degradation of either a fission product barrier identified as part of § 53.4730(a)(36), or for water-cooled reactors, the reactor coolant pressure boundary.

(B) *Criterion 2.* A process variable, design feature, or operating restriction that is an initial condition of a design-basis accident or transient analysis that either assumes the failure of or presents a challenge to the integrity of a fission product barrier.

(C) *Criterion 3.* A structure, system, or component that is part of the primary success path and which functions or actuates to mitigate a design basis accident or transient that either assumes the failure of, presents a challenge to, or acts as a precursor to identify an issue that would affect the integrity of a fission product barrier.

(D) *Criterion 4.* A structure, system, or component which operating experience or probabilistic risk assessment has shown to be significant to public health and safety.

(3) *Surveillance requirements.* Surveillance requirements are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the limiting conditions for operation will be met.

(4) *Design features.* Design features to be included are those features of the facility such as materials of construction and geometric arrangements, which, if altered or modified, would have a significant effect on safety and are not covered in categories described in paragraphs (b) (1), (2), and (3) of this section.

(5) *Administrative controls.* Administrative controls are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure operation of the facility in a safe manner. Each licensee must submit any reports to the Commission pursuant to approved technical specifications as specified in § 53.040.

(6) *Decommissioning.* This paragraph applies only to commercial nuclear reactors that have submitted the certifications required by § 53.6075(a). Technical specifications involving safety limits, limiting safety system settings, and limiting control system settings; limiting conditions for operation; surveillance requirements; design features; and administrative controls must be developed on a case-by-case basis.

(7) *Initial notification.* Reports made to the Commission by licensees in response to the requirements of this section must be made as follows:

(i) Licensees that have an installed Emergency Notification System must make the initial notification to the NRC Operations Center in accordance with § 53.6330 of this part.

(ii) All other licensees must make the initial notification by telephone to the Administrator of the appropriate NRC Regional Office listed in appendix D, part 20, of this chapter.

(8) *Written Reports.* Holders of an operating license or combined license under Framework B of this part must submit written reports to the Commission in accordance with § 53.6340 of this part for events described in paragraphs (b)(1) and(b)(2) of this section. For all licensees, the Commission may require Special Reports as appropriate.

(c) At the initiative of the Commission or the licensee, any license may be amended to include technical specifications of the scope and content which would be required if a new license were being issued.

(d) The provisions of this section apply to each operating license or combined license under Framework B of this part for which the authority to operate the reactor has been removed by license amendment, order, or regulation.

§ 53.4215 Vibratory ground motion required shutdown.

If vibratory ground motion exceeding that of the Operating Basis Earthquake Ground Motion or significant plant damage occurs, the licensee must shut down the commercial nuclear plant. If systems, structures, or components necessary for the safe shutdown of the commercial nuclear plant are not available after the occurrence of the Operating Basis Earthquake Ground Motion, the licensee must consult with the Commission and must propose a plan for the timely, safe shutdown of the commercial nuclear power plant. Prior to resuming operations, the licensee must demonstrate to the Commission that no functional damage has occurred to those features necessary for continued operation without undue risk to the health and safety of the public and the licensing basis is maintained.

§ 53.4220 General staffing, training, personnel qualifications, and human factors requirements.

(a) Purpose and applicability. The regulations in §§ 53.4220 through 53.4299 address areas related to staffing, training, personnel qualifications, and human factors for applicants for or holders of operating licenses or combined licenses under Framework B of this part. These regulations are organized as follows:

(1) Sections 53.4220 through 53.4239 provide general requirements for operator staffing, training, personnel qualifications, and human factors. The regulations within these sections are applicable to all applicants for and holders of operating licenses or combined licenses for commercial nuclear plants under this part, except where specifically stated otherwise.

(2) Sections 53.4240 through 53.4259 provide operator licensing requirements. The regulations within this section are applicable to those applicants for and holders of operating licenses or combined licenses for commercial nuclear plants under this part who have not yet certified the permanent removal of fuel from the reactor vessel as described under § 53.4670.

(3) Sections 53.4260 through 53.4279 are reserved.

(4) Sections 53.4280 through 53.4299 provide general personnel training requirements. The regulations within this section are applicable to all applicants for and holders of operating licenses or combined licenses for commercial nuclear plants under Framework B of this part.

(b) Definitions. The definitions of § 53.725 apply to Framework B of this part.

§ 53.4222 Communications.

An applicant for a licensed operator or senior licensed operator license, a licensed operator or senior licensed operator, or facility licensee shall submit any communication or report concerning the regulations contained within §§ 53.4220 through 53.4299 under these regulations to the Commission.

§ 53.4224 Information Collection Requirements.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in §§ 53.4220 through 53.4299 under Framework B of this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number XXXX-XXXX.

(b) The approved information collection requirements contained in §§ 53.4220 through 53.4299 under Framework B of this part appear in § 53.727.

§ 53.4226 Defining, fulfilling, and maintaining the role of personnel in ensuring safe operations.

Each licensee or applicant for an operating license or combined license under Framework B of this part must develop, implement, and maintain the following measures to ensure that human actions needed to fulfill safety functions and protect the public health and safety are satisfied:

(a) *Human factors engineering design requirements.* The facility design must reflect state-of-the-art human factors principles for safe and reliable performance in all

locations that human activities are expected for performing or supporting the continued availability of plant safety or emergency response functions.

(b) *Human system interface design requirements.* The facility design must provide for the following to support operators in monitoring plant conditions and responding to plant events:

(1) features for displaying to operators a minimum set of parameters that define the safety status of the plant and are capable of displaying both the full range of important plant parameters and data trends on demand, as well as indicating when process limits are being approached or exceeded,

(2) automatic indication of the bypassed and operable status of safety systems,

(3) direct indication of SSC status that relates to the ability of the SSC to perform its safety function. Examples include relief and safety valve position (i.e., open or closed) for barriers with such devices and ultimate heat sink and cooling system status and availability,

(4) instrumentation to measure, record, and readout key plant parameters related to the performance of SSCs and the integrity of barriers important to fulfilling safety functions. Examples include temperatures and pressures within important systems or structures, core or fuel system conditions (including possible damage states), temperatures and levels associated with cooling functions, combustible gas concentrations, radiation levels in systems and within structures, and radioactive effluent releases,

(5) leakage control and detection in the design of systems that pass-through barriers to the release of radionuclides. An example is an SSC that penetrates a containment structure that might contain radioactive materials that could contribute to the source term during an accident, and

(6) monitoring of in-plant radiation and airborne radioactivity as appropriate for a broad range of routine and accident conditions.

(c) *Concept of operations.* A concept of operations that is of sufficient scope and detail to, at a minimum, address the following, must be provided:

(1) facility goals,

(2) the roles and responsibilities of personnel and automation (or any combination thereof) that are responsible for completing plant functions,

(3) staffing, qualifications, and training,

(4) the management of normal operations,

(5) the management of off-normal conditions and emergencies,

(6) the management of maintenance and modifications, and

(7) the management of tests, inspections, and surveillance tasks.

(d) *Functional Requirements Analysis and Function Allocation.* A functional requirements analysis and function allocation must be provided that are sufficient to satisfy the following:

(1) the functional requirements analysis must address how safety functions and functional safety criteria are satisfied, and

(2) the function allocation must describe how the safety functions will be assigned to human action, automation, active safety features, passive safety features, or inherent safety characteristics.

(e) *Programmatic requirements.*

(1) A description of the program, to begin during construction and follow into operation, for evaluating and applying operating experience must be provided developed and implemented.

(2) A program, to begin during construction and follow into operation, for developing and maintaining plant procedures must be developed and implemented. The

scope of the program must include emergency procedures, reliability analyses, human factors engineering, crisis management, and operator training.

(f) *Staffing plan.* A staffing plan must be developed to include the numbers, positions, and qualifications of operators and senior operators across all modes of plant operations, and the numbers, positions, and responsibilities of personnel providing support in areas such as plant operations, equipment surveillance and maintenance, radiological protection, chemistry control, fire brigades, engineering, security, and emergency response.

(1) The staffing plan must include a description of how engineering expertise will be available to the on-shift operating personnel during all plant conditions, to assist in the event that operators encounter a situation not covered by procedures or training. Engineering expertise includes familiarity with the operation of the facility for which the expertise is provided and one of the following education alternatives:

(i) a bachelor's degree in engineering from an accredited institution; or

(ii) a Professional Engineer's license obtained by the successful completion of the PE examination; or

(iii) a bachelor's degree in engineering technology or physical science from an accredited institution, including course work in the physical, mathematical, or engineering sciences.

(2) Staffing plans must include a description of how the proposed numbers, positions, and qualifications of licensed operators and senior licensed operators across all modes of plant operations will be sufficient to provide assurance that plant safety functions can be maintained. This description must be supported by human factors engineering analysis and assessments.

(3) Staffing plans must include the numbers, positions, and responsibilities of personnel providing support in areas such as plant operations, equipment surveillance

and maintenance, radiological protection, chemistry control, fire brigades, engineering, security, and emergency response. The numbers, positions, and responsibilities of the personnel not directly addressed by the requirements for licensed or certified operators must reflect the evaluations of human factors engineering design requirements and concept of operations in paragraphs (a) and (c) of this section as well as other requirements within this part and Part 73 for security-related matters.

(g) *Training and examination programs.* Develop and implement proposed programs capable of satisfying the operator licensing initial training, operator licensing initial examination, and operator licensing requalification programs required under § 53.4250.

§ 53.4228 General exemptions.

The regulations in §§ 53.4200 through 53.4299 do not require a license for an individual who –

(a) Under the direction and in the presence of a licensed operator or senior licensed operator manipulates the controls of a facility as a part of the individual's training in a facility licensee's training program as approved by the Commission to qualify for an operator license under Framework B this part; or

(b) Under the direction and in the presence of a senior licensed operator manipulates the controls of a facility to load or unload the fuel into, out of, or within the reactor vessel.

§ 53.4230 Conditions for operations staffing for operating or combined licenses under Framework B of this part.

(a) Facility licensees must meet the requirements of §§ 53.4240 through 53.4259.

(b) Except as provided under § 53.4228, the facility licensee may not permit the manipulation of the controls of any facility by anyone who is not an operator or senior operator.

(c) Upon commencing the administration of licensed operator and senior licensed operator licensing examinations as provided under § 53.4250, the licensee must have an operator requalification program. The operator requalification program must, at a minimum, meet the requirements of § 53.4250. The approved operator requalification program shall be subject to the requirements of § 53.6065.

(d) Apparatus and mechanisms other than controls, the operation of which may affect the reactivity or power level of a reactor must be manipulated only while plant conditions are being monitored by an individual who is an operator or senior operator.

(1) Load-following, as defined by § 53.725(b), must only be permitted if one of the following is immediately capable of refusing demands when they could challenge the safe operation of the plant or when precluded by the plant equipment conditions:

- (i) the actuation of an automatic protection system, or
- (ii) an automated control system; or
- (iii) an operator or senior operator.

(e) Facility licensees that have not yet certified the permanent removal of fuel from the reactor vessel as described under § 53.4670 must designate senior licensed operators to be responsible for supervising the licensed activities of licensed operators.

(f) The facility licensee must maintain the staffing complement described under their approved facility staffing plan until such time as the permanent removal of fuel from the reactor vessel has been certified as described under § 53.4670. The approved staffing plan shall be subject to the requirements of § 53.6065.

(g)(1) Notwithstanding any other provisions of this section, facility licensees must have present, during alteration of the core of a commercial nuclear reactor (including fuel loading or transfer), a person holding a senior licensed operator license or a senior licensed operator license limited to fuel handling to directly supervise the activity and, during this time, the facility licensee shall not assign other duties to this person.

(2) This requirement does not apply to the alteration of the core while the plant is operating.

(h) A holder of an operating license or combined license under Framework B of this part may take reasonable action that departs from a license condition or a technical specification (contained in a license issued under Framework B of this part) in an emergency situation when this action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent.

(j) Any action by the holder of an operating license or combined license under Framework B of this part permitted by paragraph (h) of this section must be approved, as a minimum, by one of the following, as applicable, prior to taking the action:

(1) a senior operator; or

(2) at a commercial nuclear plant that has certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described in § 53.4670, by either a senior operator or a certified fuel handler.

§ 53.4232 Medical requirements.

The rules in § 53.745 apply under Framework B of this part to applicants for or holders of operator or senior operator licenses.

§ 53.4234 Violations.

The rules in § 53.750 apply under Framework B of this part.

§ 53.4236 Criminal Penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in §§ 53.4220 through 53.4282 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in §§ 53.4220 through 53.4282 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 53.4220(b), 53.4222, 53.4224, 53.4228, 53.4234, 53.4236, 53.4240, 53.4248, 53.785(f) (by reference via 53.4250), 53.4254, and 53.4256.

§ 53.4240 Operator licensing.

(a) *Applicability.* Sections 53.4240 through 53.4259 address operator licensing requirements. The regulations within this section are applicable to all applicants for, or holders of, operating licenses or combined licenses for commercial nuclear plants licensed under Framework B of this part and that have not yet certified the permanent removal of fuel from the reactor vessel as described under § 53.4670.

(b) Reserved.

§ 53.4242 Operator license requirements.

The rules in § 53.765 apply under Framework B of this part.

§ 53.4244 Completeness and accuracy of information.

The rules in § 53.770 apply under Framework B of this part.

§ 53.4246 Incapacitation because of disability or illness.

The rules in § 53.775 apply under Framework B of this part.

§ 53.4248 Applications for operators and senior operators.

The rules in § 53.780 apply under Framework B of this part.

§ 53.4250 Training program.

The rules in § 53.785 apply under Framework B of this part with the following exceptions:

(a) The approved operator licensing initial training program of § 53.785(a) shall be subject to the requirements of § 53.6065 of this part.

(b) The approved operator licensing initial examination program of § 53.785(b) shall be subject to the requirements of § 53.6065 of this part.

(c) The approved operator licensing requalification program of § 53.785(c)(1) shall be subject to the requirements of § 53.6065 of this part.

(d) The approved requalification examination program of § 53.785(c)(2) shall be subject to the requirements of § 53.6065 of this part.

§ 53.4252 Conditions of operator and senior operator licenses.

The rules in § 53.790 apply under Framework B of this part.

§ 53.4254 Expiration and renewal of operator and senior operator licenses.

The rules in § 53.792 apply under Framework B of this part with the exception that the communication requirement of § 53.792(b)(1)(ii) must be made in accordance with § 53.4222.

§ 53.4256 Issuance, modification, and revocation of operator and senior operator licenses.

The rules in § 53.795 apply under Framework B of this part.

§§ 53.4260 – 53.4279 (Reserved)

§ 53.4280 Training and qualification of commercial nuclear plant personnel.

(a) *Applicability.* Sections 53.4280 through 53.4299 address personnel training requirements. The regulations within this section are applicable to all applicants for or holders of operating licenses or combined licenses under Framework B this part

(b) Reserved

§ 53.4282 Training and qualification requirements.

The rules in § 53.840 apply under Framework B of this part.

§§ 53.4283 to 53.4299 Reserved

§ 53.4300 Programs.

Programs must be provided for each commercial nuclear plant such that, when combined with associated design features and human actions, plant safety will be maintained during normal operations and design-basis events. The required plant programs must include but are not necessarily limited to the programs described in the following sections of this Subpart. Licensees may combine, separate, and otherwise organize programs and related documents as appropriate for the technologies and organizations associated with the commercial nuclear plant.

§ 53.4310 Radiation protection.

(a) Each licensee under Framework B of this part must develop, implement, and maintain a Radiation Protection Program for operations that is commensurate with the scope and extent of licensed activities under Framework B of this part and sufficient to ensure compliance with the requirements of 10 CFR part 20.

(b) Each licensee under Framework B of this part must develop, implement, and maintain a program for the control of radioactive effluents and for keeping the doses to members of the public from radioactive effluents as low as is reasonably achievable. The program shall be contained in an Offsite Dose Calculations Manual (ODCM), shall be implemented by procedures, and shall include remedial actions to be taken whenever the program limits are exceeded. The ODCM shall:

(1) Contain the methodology and parameters used in the calculation of offsite doses resulting from radioactive gaseous and liquid effluents, in the calculation of gaseous and liquid effluent monitoring alarm and trip setpoints, and in the conduct of the radiological environmental monitoring program; and

(2) Contain the radioactive effluent controls and radiological environmental monitoring activities, and descriptions of the information that should be included in the Annual Radiological Environmental Operating, and Radioactive Effluent Release Reports required by § 53.6345.

(c) Each licensee under Framework B of this part must develop, implement, and maintain a Process Control Program which identifies the administrative and operational controls for solid radioactive waste processing, process parameters, and surveillance requirements sufficient to ensure compliance with the requirements of 10 CFR Part 20, 10 CFR Part 61, and 10 CFR Part 71.

§ 53.4320 Emergency preparedness.

The rules in § 53.855 apply under Framework B of this part.

§ 53.4330 Security programs.

(a) *Physical Protection Program.* Each holder of an operating license or combined license under Framework B of this part must develop, implement, and maintain a physical protection program meeting the following requirements:

(1) The licensee must implement security requirements for the protection of special nuclear material based on the form, enrichment, and quantity in accordance with 10 CFR part 73, as applicable, and implement security requirements for the protection of Category 1 and Category 2 quantities of radioactive material in accordance with 10 CFR part 37, as applicable; and

(2) The licensee must meet the provisions set forth in either 10 CFR 73.55 or 73.100, unless the licensee meets the following criterion:

(i) The radiological consequences from a design basis threat initiated event

involving the loss of engineered systems for decay heat removal and possible breaches in physical structures surrounding the reactor, spent fuel, and other inventories of radioactive materials result in offsite doses below the values in § 53.4730(a)(1)(vi) of this part.

(ii) The licensee must perform a site-specific analysis to demonstrate that the criterion in § 53.4330(a)(2)(i) is met. The licensee must maintain the analysis until the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.4670.

(b) *Fitness for Duty*. Each holder of an operating license or combined license under Framework B of this part must develop, implement, and maintain a fitness for duty (FFD) program that meets the requirements in 10 CFR part 26.

(c) *Access Authorization*. Each holder of an operating license or combined license under Framework B of this part must develop, implement, and maintain an Access Authorization program that meets the requirements in 10 CFR 73.120 if the criterion in § 53.4330(a)(2)(i) is met, or § 73.56, if the criterion is not met.

(d) *Cyber Security*. Each holder of an operating license or combined license under Framework B of this part must develop, implement, and maintain a cyber security program that meets the requirements in 10 CFR 73.110 or 73.54.

(e) *Information Security*. Each holder of an operating license or combined license under Framework B of this part must develop, implement, and maintain an information protection system that meets the requirements of 10 CFR 73.21, 73.22, and 73.23, as applicable.

§ 53.4340 Quality assurance.

Each licensee under Framework B of this part must develop, implement, and maintain a quality assurance program (QAP) in accordance with Subpart U of this part. A written QAP manual must be developed and used to guide the conduct of the program in accordance with generally accepted consensus codes and standards. QA activities must be based upon written procedures.

§ 53.4350 Fire protection.

(a)(1) Each holder of an operating license or combined license under Framework B of this part must have a fire protection program that satisfies the principal design criterion corresponding to criterion 3 of appendix A to part 50 of this chapter. This fire protection program must:

- (i) Describe the overall fire protection program for the facility;
- (ii) Identify the various positions within the licensee's organization that are responsible for the program;
- (iii) State the authorities that are delegated to each of these positions to implement those responsibilities; and
- (iv) Outline the plans for fire protection, fire detection and suppression capability, and limitation of fire damage.

(2) The fire protection program must also describe specific features necessary to implement the requirements described in paragraph (a)(1) of this section such as--

- (i) Administrative controls and personnel requirements for fire prevention and manual fire suppression activities;
- (ii) Automatic fire detection and automatic and manually operated suppression systems; and

(iii) The means to limit fire damage to structures, systems, and components required for any safety function so that the capability to shut down the plant safely is ensured.

(3) The licensee must retain the fire protection program and each change to the program as a record until the Commission terminates the reactor license. The licensee must retain each superseded revision of the procedures for 3 years from the date it was superseded.

(4) Each applicant for a design approval, design certification, or manufacturing license under Framework B of this part must have a description and analysis of the fire protection design features for the standard plant necessary to demonstrate compliance with the design-specific principal design criterion corresponding to criterion 3 of appendix A to part 50 of this chapter.

(b) *Definitions.*

(1) *Safe shutdown.* The phrase "safe shutdown" will be used throughout this section as applying to post-fire safe shutdown functions.

(2) *Alternative or dedicated shutdown capability.* Alternative and dedicated safe shutdown capabilities must be independent of the fire area under consideration. Alternative capabilities are normally controlled from the control room, but control may be transferred to a remote location. Dedicated capabilities must only be controlled from outside the control room.

(3) *Associated circuits.* Circuits in which hot shorts, open circuits, or shorts to ground could prevent operation of safe shutdown equipment and systems unless the safe shutdown equipment and systems are isolated from the circuits.

(c) *General Requirements.*

(1) *Fire protection program.*

(i) Each holder of an operating license or combined license under Framework B of this part must establish a fire protection program. The program must establish the fire protection policy for the protection of structures, systems, and components required for any safety function at each commercial nuclear plant and the procedures, equipment, and personnel required to implement the program at the plant site.

(ii) The fire protection program must be under the direction of an individual who has been delegated authority commensurate with the responsibilities of the position and who has available staff personnel knowledgeable in both fire protection and nuclear safety.

(iii) The goal of the fire protection program is to prevent or limit radiation exposure below 10 CFR Part 20 limits due to a fire.

(iv) The fire protection program must extend the concept of defense-in-depth to fire protection in fire areas required for any safety function, with the following objectives:

(A) To prevent fires from starting;

(B) To detect rapidly, control, and extinguish promptly those fires that do occur;

(C) To provide protection for structures, systems, and components required for any safety function so that a fire that is not promptly extinguished by the fire suppression activities will not prevent the safe shutdown of the plant.

(2) *Procedures.*

(i) Procedures must be established for implementation of the fire protection program.

(ii) In addition to procedures that are required by other parts of this section, the procedures to accomplish the following must be established:

(A) Inspection, testing, and maintenance for fire protection systems and features credited by the fire protection program.

(B) Compensatory actions implemented when fire protection systems and other systems credited by the fire protection program cannot perform their intended function and limits on impairment duration.

(C) Reviews of fire protection program-related performance and trends.

(D) Reviews of physical plant modifications and procedure changes for impact on the fire protection program.

(E) Long-term maintenance and configuration of the fire protection program.

(3) *Post-fire safe shutdown*

(i) The goal of post-fire safe shutdown is to achieve and maintain the fuel in a safe and stable state in the event of a fire in any plant area during any operational mode or configuration.

(ii) The licensee must establish what the safe and stable state is for the design of its commercial nuclear plant.

(iii) The licensee must establish the functions that are required to meet the post-fire safe shutdown goal for the design of its commercial nuclear plant.

(iv) A system that is not necessary for safe shutdown but is used to mitigate the consequences of other design-basis accidents may be affected by a fire as long as at least one system redundant to that system is not affected by the fire.

(v) The equipment necessary to achieve and maintain the plant in its safe and stable state must be capable of being powered by both onsite and offsite electric power systems, or an independent onsite power system must be provided.

(vi) Passive mechanical components must not require manual realignment post-fire.

(vii) Equipment and systems, including cables and associated circuits, that can be damaged by any fire in a fire area must not be included in the means to achieve and maintain the plant in its safe and stable state in that fire area.

(viii) Shutdown systems installed to ensure post-fire shutdown capability need not be designed to meet seismic Category I criteria, single failure criteria, or other design-basis accident criteria, except where required by other requirements in Framework B or for other reasons, e.g., because of interface with or impact on existing systems, or because of adverse valve actions due to fire damage.

(ix) The safe shutdown equipment and systems for each fire area must be separated or isolated from associated circuits in the fire area so that hot shorts, open circuits, or shorts to ground in the associated circuits will not prevent operation of the safe shutdown equipment.

(4) *Fire hazards analysis.*

(i) A fire hazards analysis must be performed by qualified fire protection and reactor systems engineers to:

(A) consider potential in situ and transient fire hazards;

(B) determine the consequences of fire in any location in the plant on the ability to safely shut down the reactor or on the ability to minimize and control the release of radioactivity to the environment; and

(C) specify measures for fire prevention, fire detection, fire suppression, and fire containment and alternative shutdown capability as required for each fire area containing structures, systems, or components important to safety.

(5) *Fire protection features.* Fire protection features must meet the following general requirements for all fire areas that contain or present a fire hazard to structures, systems, or components important to safety.

(i) In situ fire hazards must be identified and suitable protection provided.

(ii) Transient fire hazards associated with normal operation, maintenance, repair, or modification activities must be identified and eliminated where possible. Those

transient fire hazards that cannot be eliminated must be administratively controlled and suitable protection provided.

(iii) Fire detection and suppression systems, portable fire extinguishers, standpipes, and hose connections must be installed as necessary to protect redundant systems or components necessary for safe shutdown.

(iv) Fire barriers must be installed as necessary to protect redundant systems or components necessary for safe shutdown.

(v) A site fire brigade must be established, trained, and equipped and must be onsite as necessary to protect redundant systems or components necessary for safe shutdown.

(vi) Fire detection and suppression systems must be designed, installed, maintained, and tested by personnel properly qualified by experience and training in fire protection systems.

(vii) Surveillance procedures must be established to ensure that fire barriers are in place and that fire detection and suppression systems and components are capable of performing their intended functions.

(6) *Alternative or dedicated shutdown capability.* In areas where the fire protection features cannot ensure safe shutdown capability in the event of a fire in that area, alternative or dedicated safe shutdown capability must be provided.

(7) *Performance-based methods.*

(i) The fire protection program elements and features described in paragraph (d) of this section may be subject to performance-based methods.

(ii) Prior to receiving an operating or combined license, applicants that wish to use performance-based methods for fire protection program elements and features described in paragraph (d) of this section must include the request in the license application.

(iii) After receiving an operating or combined license, licensees who wish to use performance-based methods for these fire protection program elements and features described in paragraph (d) of this section must submit a request in the form of an application for license amendment under § 53.6010.

(iv) For either (ii) or (iii), the Director of the Office of Nuclear Reactor Regulation, or a designee of the Director, may approve the application if the Director or designee determines that the performance-based approach:

(A) Satisfies the post-fire safe shutdown goal as defined for the specific design;

(B) Maintains safety margins; and

(C) Maintains fire protection defense-in-depth (fire prevention, fire detection, fire suppression, mitigation, and post-fire safe shutdown capability).

(d) Specific Requirements

(1) *Water supplies for fire suppression systems.*

(i) Two separate water supplies must be provided to furnish necessary water volume and pressure to the fire main loop.

(ii) Each supply must consist of a storage tank, pump, piping, and appropriate isolation and control valves. Two separate redundant suction in one or more intake structures from a large body of water (river, lake, etc.) will satisfy the requirement for two separated water storage tanks. These supplies must be separated so that a failure of one supply will not result in a failure of the other supply.

(iii) Each supply of the fire water distribution system must be capable of providing for a period of 2 hours the maximum expected water demands as determined by adding the largest design demand of a water-based suppression system and 500 gpm for manual suppression hose streams.

(iv) The fire water supply must be capable of delivering the design demand with the hydraulically least demanding portion of the fire main loop out of service.

(v) The fire protection water supply system must be dedicated for fire protection use only or designed and maintained to deliver the combined fire and non-fire-related flows.

(vi) Failure of non-fire-related systems connected to the fire water system must not degrade the fire water system.

(2) Fire main loop and hydrants.

(i) An underground yard fire main loop must be installed to furnish anticipated water requirements.

(ii) Sectional isolation valves such as post indicator valves or key operated valves must be installed in the fire main loop to permit isolation of portions of the fire main loop for maintenance or repair without interrupting the water supply to automatic or manual fire suppression systems in any area containing or presenting a fire hazard to safe shutdown equipment or structures, systems, or components required for any safety function.

(iii) Valves must be installed to permit isolation of outside hydrants from the fire main for maintenance or repair without interrupting the water supply to automatic or manual fire suppression systems in any area containing or presenting a fire hazard to safe shutdown equipment or structures, systems, or components required for any safety function.

(iv) Sprinkler systems, manual hose connections, and standpipes must be connected to the fire main so that a single active failure or a crack to the water supply piping to these systems can be isolated so as not to impair both the primary and backup fire suppression systems.

(3) Fire pumps.

(i) Fire pumps must be provided to ensure that 100 percent of the required flow rate and pressure are available assuming failure of the largest pump or pump power source.

(ii) At least one diesel engine-driven fire pump or two or more seismic Category I Class 1E electric motor-driven fire pumps connected to redundant Class 1E emergency power buses capable of providing 100 percent of the required flow rate and pressure must be provided.

(iii) Each pump and its driver and controls must be separated from the remaining fire pumps and from the rest of the plant by rated fire barriers so that a single fire cannot prevent supply of 100 percent of the required flow rate and pressure.

(iv) Individual fire pump connections to the yard fire main loop must be provided and separated with sectionalizing valves between connections.

(v) A method of automatic pressure maintenance of the fire protection water system must be provided independent of fire pumps.

(4) Manual fire suppression.

(i) Standpipe and hose connections must be installed so that at least one effective hose stream will be able to reach any location that contains or presents a fire hazard to structures, systems, or components required for any safety function.

(ii) Access to permit effective functioning of the fire brigade must be provided to all areas that contain or present a fire hazard to structures, systems, or components required for any safety function.

(iii) Provisions must be made to provide water to standpipe and hose connections for manual fire suppression in the event of the design-basis seismic event.

(iv) Standpipe and hose connections must be provided inside containments that are not inerted. Standpipe and hose connections inside a containment may be connected to a high-quality water supply of sufficient quantity and pressure other than

the fire main loop if plant-specific features prevent extending the fire main supply inside containment.

(v) The proper type of hose nozzle must be provided for each area based on the area fire hazards.

(vi) Threads compatible with those used by local fire departments must be provided on all hydrants, hose couplings, and standpipe risers, or offsite fire departments must be provided with adapters that allow interconnection between plant equipment and the fire department equipment, along with training and procedures for their use.

(5) *Fire alarm.*

(i) Alarm initiating devices must be installed.

(ii) Alarm annunciation must allow the alarm system to transmit fire-related alarms, supervisory signals, and trouble signals to the control room or other continuously manned location from which required notifications and response can be initiated.

(iii) Personnel assigned to the alarm station must be permitted to have other duties.

(iv) The following fire-related signals must be transmitted:

(A) Actuation of any fire detection device

(B) Actuation of any fixed fire suppression system

(C) Actuation of any manual fire alarm station

(D) Starting of any fire pump

(E) Actuation of any fire protection supervisory device

(F) Indication of alarm system trouble condition

(v) Means must be provided to allow a person observing a fire at any location in the plant to quickly and reliably communicate to the control room or other suitable continuously manned location.

(vi) Means must be provided to promptly notify the following of any fire emergency in such a way as to allow them to determine an appropriate course of action:

(A) General site population in all occupied areas

(B) Members of the onsite fire brigade, offsite fire departments, and other groups supporting fire emergency response

(vii) Two independent means must be available (e.g., telephone and radio) for notification of offsite emergency services.

(6) *Automatic fire detection.*

(i) Automatic fire detection systems must be installed in all areas of the plant that contain or present a fire hazard to structures, systems, or components required for any safety function, including safe shutdown.

(ii) These fire detection systems must be capable of operating with or without offsite power.

(iii) Licensees must design fire detection systems to be effective following a design-basis seismic event.

(7) *Automatic fire suppression.*

(i) Automatic suppression systems must be installed as determined by the fire hazards analysis described in paragraph (c)(4) of this section and as necessary to protect structures, systems, or components required for any safety function, including safe shutdown equipment.

(ii) Structures, systems, and components required for any safety function, including safe shutdown equipment, that are subject to unacceptable damage by suppression system discharge, must be appropriately protected.

(iii) Drains must be provided to protect structures, systems, and components required for any safety function, including safe shutdown equipment from flooding damage.

(iv) Gaseous suppression systems must be evaluated for potential impacts on the habitability of areas containing structures, systems, and components required for any safety function, including safe shutdown equipment, where operations personnel perform safe shutdown actions or where fire fighting activities may become necessary.

(v) The design of gaseous suppression systems must evaluate and address the following:

(A) gas concentration, distribution, soak time, and ventilation control,

(B) the anoxia and toxicity hazards associated with the gas,

(C) the possibility of damage from secondary thermal shock,

(D) venting during system discharge to prevent over-pressurization versus sealing to prevent loss of agent,

(E) location and selection of the actuating devices, and

(F) the toxic and corrosive characteristics of the thermal decomposition products of the agent.

(vi) Licensees must design fire suppression systems to be effective following a design-basis seismic event.

(8) *Fire protection of safe shutdown capability.*

(i) Fire protection features must be provided for structures, systems, and components required for any safety function. These features must be capable of limiting fire damage so that one train of systems necessary to achieve and maintain safe shutdown conditions from either the control room or emergency control station(s) is free of fire damage.

(ii) Except as provided for in paragraph (8)(iv) of this section, where cables or equipment, including any associated circuits that could prevent operation or cause maloperation due to hot shorts, open circuits, or shorts to ground, of redundant trains of systems necessary to achieve and maintain safe shutdown conditions are located within

the same fire area outside of containment, one of the following means of ensuring that one of the redundant trains is free of fire damage must be provided:

(A) Separation of cables and equipment and associated circuits of redundant trains by a fire barrier having a 3-hour fire resistance rating. Structural steel forming a part of or supporting such fire barriers must be protected to provide fire resistance equivalent to that required of the barrier;

(B) Separation of cables and equipment and associated circuits of redundant trains by a horizontal distance of more than 20 feet with no intervening combustible or fire hazards. In addition, fire detectors and an automatic fire suppression system must be installed in the fire area; or

(C) Enclosure of cable and equipment and associated circuits of one redundant train in a fire barrier having a 1-hour fire resistance rating. In addition, fire detectors and an automatic fire suppression system must be installed in the fire area;

(iii) Inside non-inerted containments, where cables or equipment, including any associated circuits that could prevent operation or cause maloperation due to hot shorts, open circuits, or shorts to ground, of redundant trains of systems necessary to achieve and maintain safe shutdown conditions are present, one of the fire protection means specified above or one of the following fire protection means must be provided:

(A) Separation of cables and equipment and associated circuits of redundant trains by a horizontal distance of more than 20 feet with no intervening combustibles or fire hazards;

(B) Installation of fire detectors and an automatic fire suppression system in the fire area; or

(C) Separation of cables and equipment and associated circuits of redundant trains by a noncombustible radiant energy shield.

(iv) Alternative or dedicated shutdown capability and its associated circuits, independent of cables, systems and components in the area, room, or zone under consideration must be provided:

(A) Where the protection of systems whose function is required for safe shutdown does not satisfy the requirement of paragraph (8)(ii) of this section; or

(B) Where redundant trains of systems required for safe shutdown located in the same fire area may be subject to damage from fire suppression activities or from the rupture or inadvertent operation of fire suppression systems.

In addition, fire detection and an automatic fire suppression system must be installed in the area, room, or zone under consideration.

(9) *Fire brigade.*

(i) A site fire brigade trained and equipped for fire fighting must be established to ensure adequate manual fire fighting capability for all areas of the plant containing structures, systems, or components important to safety.

(ii) The fire brigade must be at least five members on each shift.

(iii) The brigade leader and at least two brigade members must have sufficient training in or knowledge of plant structures, systems, and components required for any safety function to understand the effects of fire and fire suppressants on safe shutdown capability.

(iv) The qualification of fire brigade members must include an annual physical examination to determine their ability to perform strenuous fire fighting activities.

(v) The shift supervisor must not be a member of the fire brigade.

(vi) The fire brigade leader must be competent to assess the potential safety consequences of a fire and advise control room personnel. Such competence by the brigade leader may be evidenced by possession of an operator's license or equivalent

knowledge of plant structures, systems, and components required for any safety function.

(vii) Fire brigade members must have no other duties related to post-fire safe shutdown.

(viii) An effective emergency communications capability must be provided for the plant fire brigade.

(ix) The minimum equipment provided for the brigade must consist of personal protective equipment such as turnout coats, boots, gloves, helmets, emergency communications equipment, portable lights, portable ventilation equipment, and portable extinguishers.

(x) Self-contained breathing apparatus using full-face positive-pressure masks approved by the National Institute for Occupational Safety and Health (NIOSH) must be provided for fire brigade and control room personnel. At least two masks must be available for each member of the fire brigade. Control room personnel may be furnished breathing air by a manifold system piped from a storage reservoir if practical. Service or rated operating life must be a minimum of one-half hour for the self-contained breathing units.

(xi) At least a 1-hour supply of breathing air in extra bottles must be located on the plant site for each unit of self-contained breathing apparatus. In addition, an onsite 6-hour supply of reserve air must be provided and arranged to permit quick and complete replenishment of exhausted air supply bottles as they are returned. If compressors are used as a source of breathing air, only units approved for breathing air must be used and the compressors must be operable assuming a loss of offsite power. Special care must be taken to locate the compressor in areas free of dust and contaminants.

(10) *Fire brigade training.*

(i) The fire brigade training program must ensure that the capability to fight potential fires is established and maintained.

(ii) The program must consist of an initial classroom instruction program followed by periodic classroom instruction, fire fighting practice, and fire drills.

(iii) *Instruction.*

(A) The initial classroom instruction must include:

(1) Indoctrination of the plant fire fighting plan with specific identification of each individual's responsibilities.

(2) Identification of the type and location of fire hazards and associated types of fires that could occur in the plant.

(3) The toxic and corrosive characteristics of expected products of combustion.

(4) Identification of the location of fire fighting equipment for each fire area and familiarization with the layout of the plant, including access and egress routes to each area.

(5) The proper use of available fire fighting equipment and the correct method of fighting each type of fire. The types of fires covered should include fires in energized electrical equipment, fires in cables and cable trays, hydrogen fires, fires involving flammable and combustible liquids or hazardous process chemicals, fires resulting from construction or modifications (welding), record file fires, and other fires involving hazards related to the specific plant design.

(6) The proper use of communication, lighting, ventilation, and emergency breathing equipment.

(7) The proper method for fighting fires inside buildings and confined spaces.

(8) The direction and coordination of the fire fighting activities (fire brigade leaders only).

(9) Detailed review of fire fighting strategies and procedures.

(10) Review of the latest plant modifications and corresponding changes in fire fighting plans.

(B) The instruction must be provided by qualified individuals who are knowledgeable, experienced, and suitably trained in fighting the types of fires that could occur in the plant and in using the types of equipment available in the nuclear power plant.

(C) Instruction must be provided to all fire brigade members and fire brigade leaders.

(D) Regular planned meetings must be held at least every 3 months for all brigade members to review changes in the fire protection program and other subjects as necessary.

(E) Periodic refresher training sessions must be held to repeat the classroom instruction program for all brigade members over a two-year period. These sessions may be concurrent with the regular planned meetings.

(iv) *Practice*

Practice sessions must be held for each shift fire brigade on the proper method of fighting the various types of fires that could occur in a nuclear power plant. These sessions must provide fire brigade members with experience in actual fire extinguishment and the use of emergency breathing apparatus under strenuous conditions encountered in fire fighting. These practice sessions must be provided at least once per year for each fire brigade member.

(v) *Drills*

(A) Fire brigade drills must be performed in the plant so that the fire brigade can practice as a team.

(B) Drills must be performed at regular intervals not to exceed 3 months for each shift fire brigade. Each fire brigade member should participate in each drill but must participate in at least two drills per year.

(C) A sufficient number of these drills, but not less than one for each shift fire brigade per year, must be unannounced to determine the fire fighting readiness of the plant fire brigade, brigade leader, and fire protection systems and equipment. Persons planning and authorizing an unannounced drill must ensure that the responding shift fire brigade members are not aware that a drill is being planned until it is begun. Unannounced drills must not be scheduled closer than four weeks.

(D) At least one drill per year must be performed on a "back shift" for each shift fire brigade.

(E) The drills must be preplanned to establish the training objectives of the drill and must be critiqued to determine how well the training objectives have been met. Unannounced drills must be planned and critiqued by members of the management staff responsible for plant safety and fire protection. Performance deficiencies of a fire brigade or of individual fire brigade members must be remedied by scheduling additional training for the brigade or members. Unsatisfactory drill performance must be followed by a repeat drill within 30 days.

(F) At 3-year intervals, a randomly selected unannounced drill must be critiqued by qualified individuals independent of the licensee's staff. A copy of the written report from these individuals must be available for NRC review and must be retained as a record as specified in Section (9)(vi).

(G) Drills must as a minimum include the following:

(1) Assessment of fire alarm effectiveness, time required to notify and assemble fire brigade, and selection, placement and use of equipment, and fire fighting strategies.

(2) Assessment of each brigade member's knowledge of his or her role in the fire fighting strategy for the area assumed to contain the fire. Assessment of the fire brigade member's conformance with established plant fire fighting procedures and use of fire fighting equipment, including self-contained emergency breathing apparatus, communication equipment, and ventilation equipment, to the extent practicable.

(3) The simulated use of fire fighting equipment required to cope with the situation and type of fire selected for the drill. The area and type of fire chosen for the drill should differ from those used in the previous drill so that brigade members are trained in fighting fires in various plant areas. The situation selected should simulate the size and arrangement of a fire that could reasonably occur in the area selected, allowing for fire development due to the time required to respond, to obtain equipment, and organize for the fire, assuming loss of automatic suppression capability.

(4) Assessment of fire brigade leader's direction of the fire fighting effort as to thoroughness, accuracy, and effectiveness.

(vi) *Records*. Individual records of training provided to each fire brigade member, including drill critiques, must be maintained for at least 3 years to ensure that each member receives training in all parts of the training program. These records of training must be available for NRC review. Retraining or broadened training for fire fighting within buildings must be scheduled for all those brigade members whose performance records show deficiencies.

(11) *Offsite fire department interface*.

(i) Offsite fire authorities must be offered a plan for their interface during fires and related emergencies onsite.

(ii) Fire fighters from the offsite fire authorities who are expected to respond to a fire at the plant must be offered site specific training and be invited to participate in a drill at least annually.

(iii) Plant security and radiation protection plans must address offsite fire authority response.

(12) *Emergency lighting.* Sufficient emergency lighting must be provided in all areas needed for operation of safe shutdown equipment and in access and egress routes. This emergency lighting may be provided by fixed or portable lights. The sufficiency of the provided lighting must be demonstrated through engineering evaluation.

(13) *Administrative controls.* Administrative controls must be established to minimize fire hazards in areas containing structures, systems, or components required for any safety function. These controls must establish procedures to:

(i) Govern the handling and limitation of the use of ordinary combustible materials, combustible and flammable gases and liquids, high efficiency particulate air and charcoal filters, dry ion exchange resins, or other combustible supplies in areas containing structures, systems, or components required for any safety function.

(ii) Prohibit the storage of combustibles in areas containing structures, systems, or components required for any safety function or establish designated storage areas with appropriate fire protection.

(iii) Govern the handling of and limit transient fire loads such as combustible and flammable liquids, wood and plastic products, or other combustible materials in buildings containing structures, systems, or components required for any safety function during all phases of operation, and especially during maintenance, modification, or refueling operations.

(iv) Designate the onsite staff member responsible for the in-plant fire protection review of proposed work activities to identify potential transient fire hazards and specify required additional fire protection in the work activity procedure.

(v) Govern the use of ignition sources by use of an open-flame permit system to control welding, flame cutting, brazing, or soldering operations. A separate permit must be issued for each area where work is to be done. If work continues over more than one shift, the permit must be valid for not more than 24 hours when the plant is operating or for the duration of a particular job during plant shutdown.

(vi) Control the removal from the area of all waste, debris, scrap, oil spills, or other combustibles resulting from the work activity immediately following completion of the activity, or at the end of each work shift, whichever comes first.

(vii) Maintain the periodic housekeeping inspections to ensure continued compliance with these administrative controls.

(viii) Control the use of specific combustibles in areas containing structures, systems, or components required for any safety function. All wood used in these areas during maintenance, modification, or refueling operations (such as lay-down blocks or scaffolding) must be treated with a flame retardant. Equipment or supplies (such as new fuel) shipped in untreated combustible packing containers may be unpacked in areas containing structures, systems, or components required for any safety function if required for valid operating reasons. However, all combustible materials must be removed from the area immediately following the unpacking. Such transient combustible material, unless stored in approved containers, must not be left unattended during lunch breaks, shift changes, or other similar periods. Loose combustible packing material such as wood or paper excelsior, or polyethylene sheeting must be placed in metal containers with tight-fitting self-closing metal covers.

(ix) Control actions to be taken by an individual discovering a fire, for example, notification of control room, attempt to extinguish fire, and actuation of local fire suppression systems.

(x) Control actions to be taken by the control room operator to determine the need for brigade assistance upon report of a fire or receipt of alarm on control room annunciator panel, for example, announcing the location of the fire over public address system, sounding fire alarms, and notifying the shift supervisor and the fire brigade leader of the type, size, and location of the fire.

(xi) Control actions to be taken by the fire brigade after notification by the control room operator of a fire, for example, assembling in a designated location, receiving directions from the fire brigade leader, and discharging specific fire fighting responsibilities including selection and transportation of fire fighting equipment to fire location, selection of protective equipment, operating instructions for use of fire suppression systems, and use of preplanned strategies for fighting fires in specific areas.

(xii) Define the strategies for fighting fires in all areas containing structures, systems, or components required for any safety function or presenting a hazard to structures, systems, or components required for any safety function. These strategies must designate:

(A) Fire hazards in each area covered by the specific pre-fire plans.

(B) Fire extinguishants best suited for controlling the fires associated with the fire hazards in that area and the nearest location of these extinguishants.

(C) Most favorable direction from which to attack a fire in each area in view of the ventilation direction, access hallways, stairs, and doors that are most likely to be free of fire, and the best station or elevation for fighting the fire. All access and egress routes that involve locked doors should be specifically identified in the procedure with the appropriate precautions and methods for access specified.

(D) Plant systems that should be managed to reduce the damage potential during a local fire and the location of local and remote controls for such management

(e.g., any hydraulic or electrical systems in the zone covered by the specific fire fighting procedure that could increase the hazards in the area because of overpressurization or electrical hazards).

(E) Vital heat-sensitive system components that need to be kept cool while fighting a local fire. Particularly hazardous combustibles that need cooling should be designated.

(F) Organization of fire fighting brigades and the assignment of special duties according to job title so that all fire fighting functions are covered by any complete shift personnel complement. These duties include command control of the brigade, transporting fire suppression and support equipment to the fire scenes, applying the extinguishant to the fire, communication with the control room, and coordination with outside fire departments.

(G) Potential radiological and toxic hazards in fire zones.

(H) Ventilation system operation that ensures desired plant air distribution when the ventilation flow is modified for fire containment or smoke clearing operations.

(I) Operations requiring control room and shift engineer coordination or authorization.

(J) Instructions for plant operators and general plant personnel during fire.

(14) *Bulk storage of flammable gases and flammable and combustible liquids.*

(i) Bulk compressed or cryogenic flammable gas storage must not be permitted inside buildings housing structures, systems, or components required for any safety function.

(ii) Storage of flammable gas must be located outdoors, or in separate detached buildings, so that a fire or explosion will not adversely impact structures, systems, or components required for any safety function.

(iii) Outdoor high-pressure flammable gas storage containers must be located so that the long axis is not pointed at buildings.

(iv) Flammable gas storage cylinders not required for normal operation must be isolated from the system.

(v) Bulk storage of flammable and combustible liquids must not be permitted inside structures containing structures, systems, or components required for any safety function.

(15) *Alternative and dedicated shutdown capability.*

(i) Alternative or dedicated shutdown capability provided for a specific fire area must be able to maintain the post-fire safe shutdown functions of the design and achieve and maintain the safe and stable conditions of the design. During the post-fire shutdown, fission product boundary integrity must not be affected; i.e., there must be no fuel cladding damage, rupture of any primary coolant boundary, or rupture of the containment boundary.

(ii) The shutdown capability for specific fire areas may be unique for each such area, or it may be one unique combination of systems for all such areas. In either case, the alternative shutdown capability must be independent of the specific fire area(s) and must accommodate post-fire conditions where offsite power is available and where offsite power is not available. Procedures must be in effect to implement this capability.

(16) *Fire barriers.*

(i) Each fire barrier must have a specific fire resistance rating.

(ii) Fire barriers must be designed and installed to meet the specific fire resistance rating using assemblies qualified by fire tests.

(iii) Penetrations and openings in fire barriers must be provided with listed penetration seals, fire-rated door assemblies, or listed rated fire dampers, etc., having a fire resistance rating consistent with the designated fire resistance rating of the barrier.

(17) *Fire barrier penetration seal qualification.*

(i) Penetration seal designs must be qualified by tests that are comparable to tests used to rate fire barriers.

(ii) The acceptance criteria for the test must include the following:

(A) The fire barrier penetration seal has withstood the fire endurance or resistance test without passage of flame or ignition of the penetrating items on the unexposed side for a period of time equivalent to the fire resistance rating required of the barrier;

(B) The temperature levels recorded for the unexposed side are analyzed and demonstrate that the maximum temperature is sufficiently below the penetrating item ignition temperature; and

(C) The fire barrier penetration seal remains intact and does not allow projection of water beyond the unexposed surface during the hose stream test.

(18) *Fire doors.*

(i) Fire doors must be self-closing or provided with closing mechanisms and must be inspected semiannually to verify that automatic hold-open, release, and closing mechanisms and latches are operable.

(ii) One of the following measures must be provided to ensure they will protect the opening as required in case of fire:

(A) Fire doors must be kept closed and electrically supervised at a continuously manned location;

(B) Fire doors must be locked closed and inspected weekly to verify that the doors are in the closed position;

(C) Fire doors must be provided with automatic hold-open and release mechanisms and inspected daily to verify that doorways are free of obstructions; or

(D) Fire doors must be kept closed and inspected daily to verify that they are in the closed position.

(iii) The fire brigade leader must have ready access to keys for any locked fire doors.

(19) *Electrical raceway fire barrier systems.*

(i) Each electrical raceway fire barrier system must have a specific fire resistance rating.

(ii) Electrical raceway fire barrier systems must be tested and qualified.

(iii) The electrical raceway fire barrier system must adequately address the design requirements and limitations of supports and intervening items and their impact on the fire barrier system rating.

(iv) The electrical raceway fire barrier system's ability to maintain the protected cables free from fire damage for a specific thermal exposure, barrier design, raceway size and type, cable size, fill, and type must be demonstrated.

(d) Licensees that have submitted the certifications required under § 53.6075 must maintain a decommissioning fire protection program to address the potential for fires that could cause the release or spread of radioactive materials.

(1) The objectives of the decommissioning fire protection program are to

(i) Reasonably prevent these fires from occurring;

(ii) Rapidly detect, control, and extinguish those fires that do occur and that could result in a radiological hazard; and

(iii) Ensure that the risk of fire induced radiological hazards to the public, environment, and plant personnel is minimized.

(2) The licensee must assess the decommissioning fire protection program on a regular basis. The licensee must revise the decommissioning fire protection program as appropriate throughout the various stages of facility decommissioning.

(3) The licensee may make changes to the decommissioning fire protection program without NRC approval if these changes do not reduce the effectiveness of fire protection for structures, systems, and components that could result in a radiological hazard, taking into account the decommissioning plant conditions and activities.

§ 53.4360 Inservice inspection/inservice testing.

(a) Each boiling or pressurized water-cooled commercial nuclear plant licensee must meet the requirements of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code and the ASME Operation and Maintenance Code for inservice inspection and inservice testing as specified in § 50.55a of this chapter.

(b) Each non-light-water-cooled commercial nuclear plant licensee under Framework B of this part must develop, implement, and maintain programs for inservice inspection and inservice testing that meet the requirements of § 53.880.

§ 53.4380 Environmental qualification of electric equipment important to safety for nuclear power plants.

(a) Each holder of an operating license, combined license, or manufacturing license under Framework B of this part, other than a commercial nuclear plant for which the certifications required under § 53.6075 have been submitted, must develop, implement, and maintain a program for qualifying the electric equipment defined in paragraph (b) of this section. For a manufacturing license, only electric equipment

defined in paragraph (b) that is within the scope of the manufactured reactor must be included in the program.

(b) Electric equipment important to safety covered by this section is:

(1) Safety-related electric equipment.¹

(2) Non-safety-related electric equipment whose failure under postulated environmental conditions could prevent satisfactory accomplishment of safety functions by the safety-related equipment.

(3) Certain post-accident monitoring equipment.²

(c) Requirements for (1) dynamic and seismic qualification of electric equipment important to safety, (2) protection of electric equipment important to safety against other natural phenomena and external events, and (3) environmental qualification of electric equipment important to safety located in a mild environment are not included within the scope of this section. A mild environment is an environment that would at no time be significantly more severe than the environment that would occur during normal plant operation, including anticipated operational occurrences.

(d) The licensee must prepare a list of electric equipment important to safety covered by this section. In addition, the licensee must include the information in paragraphs (d)(1), (2), and (3) of this section for this electric equipment important to safety in a qualification file. The licensee must keep the list and information in the file

¹ Safety-related electric equipment is referred to as "Class 1E" equipment in IEEE 323–1974. Copies of this standard may be obtained from the Institute of Electrical and Electronics Engineers, Inc., 345 East 47th Street, New York, NY 10017.

² Specific guidance concerning the types of variables to be monitored for LWRs is provided in Revision 2 of Regulatory Guide 1.97, "Instrumentation for Light-Water-Cooled Nuclear Power Plants to Assess Plant and Environs Conditions During and Following an Accident." Copies of the Regulatory Guide may be purchased through the U.S. Government Publishing Office by calling 202–512–1800 or by writing to the U.S. Government Publishing Office, P.O. Box 37082, Washington, DC 20013–7082. The need for environmental qualification of post-accident monitoring equipment for non-light-water reactors is determined on a case-by-case basis considering factors such as the need for information to confirm plant status and/or to take additional on-site or off-site actions to protect public health and safety.

current and retain the file in auditable form for the entire period during which the covered item is installed in the commercial nuclear plant or is stored for future use to permit verification that each item of electric equipment covered by this section that is important to safely meets the requirements of paragraph (j) of this section.

(1) The performance specifications under conditions existing during and following design basis accidents.

(2) The voltage, frequency, load, and other electrical characteristics for which the performance specified in accordance with paragraph (d)(1) of this section can be ensured.

(3) The environmental conditions, including temperature, pressure, humidity, radiation, chemicals, and submergence at the location where the equipment must perform as specified in accordance with paragraphs (d)(1) and (2) of this section.

(e) The electric equipment qualification program must include and be based on the following:

(1) *Temperature and pressure.* The time-dependent temperature and pressure at the location of the electric equipment important to safety must be established for the most severe design basis accident during or following which this equipment is required to remain functional.

(2) *Humidity.* Humidity during design basis accidents must be considered.

(3) *Chemical effects.* The composition of chemicals used must be at least as severe as that resulting from the most limiting mode of plant operation (e.g., containment spray, combustion products, fluid releases). If the composition of the chemical environment can be affected by equipment malfunctions, the most severe chemical environment that results from a single failure must be assumed.

(4) *Radiation.* The radiation environment must be based on the type of radiation, the total dose expected during normal operation over the installed life of the equipment,

and the radiation environment associated with the most severe design basis accident during or following which the equipment is required to remain functional, including dose-rate effects.

(5) *Aging*. Equipment qualified by test must be preconditioned by natural or artificial (accelerated) aging to its end-of-installed life condition. Consideration must be given to all significant types of degradation which can have an effect on the functional capability of the equipment. If preconditioning to an end-of-installed life condition is not practicable, the equipment may be preconditioned to a shorter designated life. The equipment must be replaced or refurbished at the end of this designated life unless ongoing qualification demonstrates that the item has additional life.

(6) *Submergence* (if subject to being submerged).

(7) *Synergistic effects*. Synergistic effects must be considered when these effects are believed to have a significant effect on equipment performance.

(8) *Margins*. Margins must be applied to account for unquantified uncertainty, such as the effects of production variations and inaccuracies in test instruments. These margins are in addition to any conservatisms applied during the derivation of local environmental conditions of the equipment unless these conservatisms can be quantified and shown to contain appropriate margins.

(f) Each item of electric equipment important to safety must be qualified by one of the following methods:

(1) Testing an identical item of equipment under identical conditions or under similar conditions with a supporting analysis to show that the equipment to be qualified is acceptable.

(2) Testing a similar item of equipment with a supporting analysis to show that the equipment to be qualified is acceptable.

(3) Experience with identical or similar equipment under similar conditions with a supporting analysis to show that the equipment to be qualified is acceptable.

(4) Analysis in combination with partial type test data that supports the analytical assumptions and conclusions.

(g) Reserved.

(h) Reserved.

(i) Reserved.

(j) A record of the qualification, including documentation in paragraph (d) of this section, must be maintained in an auditable form for the entire period during which the covered item is installed in the commercial nuclear plant or is stored for future use to permit verification that each item of electric equipment important to safety covered by this section:

(1) Is qualified for its application; and

(2) Meets its specified performance requirements when it is subjected to the conditions predicted to be present when it must perform its safety function up to the end of its qualified life.

(k) Reserved.

(l) Replacement equipment must be qualified in accordance with the provisions of this section unless there are sound reasons to the contrary.

§ 53.4390 Procedures and guidelines.

(a) Each holder of an operating license or combined license under Framework B of this part must have a program for developing, implementing, and maintaining an integrated set of procedures, guidelines, and related supporting activities to support normal operations and respond to possible unplanned events.

(b) The program required by paragraph (a) of this section must include but is not limited to development, implementation, maintenance, and supporting activities of procedures and guidelines for the following:

(1) Plant operations

(2) Maintenance activities under § 53.4205

(3) Program requirements under this subpart

(4) Emergency operating procedures if human intervention is needed to respond to design basis accidents identified in accordance with the requirements of § 53.4730(a)(5)(i)

(5) Procedures that describe how the licensee will address the following areas if the licensee is notified of a potential aircraft threat:

(i) Verification of the authenticity of threat notifications;

(ii) Maintenance of continuous communication with threat notification sources;

(iii) Contacting all onsite personnel and applicable offsite response organizations;

(iv) Onsite actions necessary to enhance the capability of the facility to mitigate the consequences of an aircraft impact;

(v) Measures to reduce visual discrimination of the site relative to its surroundings or individual buildings within the protected area;

(vi) Dispersal of equipment and personnel, as well as rapid entry into site protected areas for essential onsite personnel and offsite responders who are necessary to mitigate the event; and

(vii) Recall of site personnel.

§ 53.4400 Integrity assessment program.

Each holder of an operating license or combined license licensee under Framework B of this part must develop, implement, and maintain an integrity assessment program to monitor, evaluate, and manage:

(a) The effects of plant aging on SSCs identified in § 53.4400(d). The program may refer to surveillances, tests, and inspections conducted for specific SSCs in accordance with other requirements in Framework B of this part or conducted in accordance with applicable accepted consensus codes and standards;

(b) Cyclic or transient load limits to ensure that SSCs are maintained within the applicable design limits; and

(c) Degradation mechanisms related to chemical interactions, operating temperatures, effects of irradiation, and other environmental factors to ensure that the capabilities and reliabilities of SSCs satisfy the principal design criteria for the commercial nuclear plant.

(d) Plant structures, systems, and components within the scope of this section are--

(1) Safety-related structures, systems, and components; and

(2) Non-safety-related structures, systems, and components:

(i) That are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures; or

(ii) Whose failure could prevent safety-related structures, systems, and components from fulfilling their safety-related function; or

(iii) Whose failure could cause a reactor scram or actuation of a safety-related system.

§ 53.4410 Primary containment leakage rate testing program.

Primary reactor containments for water-cooled power reactors, other than facilities for which the certifications required under § 53.6075(a) have been submitted, shall be subject to the requirements set forth in appendix J to 10 CFR part 50 of this chapter.

Subpart Q – Decommissioning

§ 53.4600 Scope and purpose.

Each applicant for or holder of an operating license or combined license under Framework B of this part must meet the requirements for decommissioning under this subpart. The requirements related to maintaining financial assurance for decommissioning are in §§ 53.4610 through 53.4660. The requirements for transitioning from operations to decommissioning and for the release of property and termination of the license are in §§ 53.4670 through 53.4680.

§ 53.4610 Financial assurance for decommissioning.

(a) This section establishes requirements for indicating to the NRC how an applicant for or holder of an operating license or combined license under Framework B of this part will provide reasonable assurance that funds will be available for the decommissioning process. Reasonable assurance consists of a series of steps as provided in paragraph (b) of this section and §§ 53.4620, 53.4630, and 53.4640. Funding for the decommissioning of commercial nuclear plants may also be subject to the regulation of Federal or State government agencies (e.g., Federal Energy Regulatory

Commission (FERC) and State Public Utility Commissions (PUC)) that have jurisdiction over rate regulation. The requirements of this subpart, in particular § 53.4620, are in addition to, and not a substitution for, other requirements, and are not intended to be used by themselves or by other agencies to establish rates.

(b) Each applicant for an operating license or combined license under Framework B of this part must prepare a plan and an associated decommissioning report that ensures and documents that adequate funding will be available to decommission the facility. Each holder of an operating license or combined license must implement and maintain the plan.

(1)(i) Before the Commission issues an operating license under Framework B of this part, the applicant must update the decommissioning report to certify that it has provided financial assurance for decommissioning in the amount proposed in the application and approved by the NRC in accordance with § 53.4620.

(ii) No later than 30 days after the Commission issues the notice of intended operation under § 53.5052 for a combined license under Framework B of this part, the licensee must update the decommissioning report to certify that it has provided financial assurance for decommissioning in the amount proposed in the application and approved by the NRC in accordance with § 53.4620.

(2) The amount of financial assurance for decommissioning to be provided must be adjusted annually using a rate at least equal to that stated in § 53.4630.

(3) The amount of financial assurance for decommissioning to be provided must be covered by one or more of the methods described in § 53.4640 as acceptable to the NRC.

(4) The amount of financial assurance for decommissioning to be provided must be based on a site-specific cost estimate for decommissioning the facility in accordance

with § 53.4620. A copy of the financial instrument obtained to satisfy the requirements of § 53.4640 must be submitted to the NRC as part of the application for an operating license or combined license under Framework B of this part.

§ 53.4620 Cost estimates for decommissioning.

Cost estimates for decommissioning must be site-specific. Site-specific decommissioning cost estimates must account for the engineering, labor, equipment, transportation, disposal, and related charges needed to support termination of the license. They must include the costs for decontaminating structures, systems, and components and the site environs; removal of contaminated components and materials from the plant and the site environs; disposal costs for removed components and materials in appropriate facilities; and any other associated costs supporting the release of the property and termination of the license. They must also address the approach to annual adjustments required by § 53.4630. Finally, site-specific decommissioning cost estimates must include plans for adjusting levels of funds assured for decommissioning to demonstrate that a reasonable level of assurance will be provided that funds will be available when needed to cover the cost of decommissioning.

§ 53.4630 Annual adjustments to cost estimates for decommissioning.

Each holder of an operating license or combined license under Framework B of this part must annually adjust the cost estimate for decommissioning to account for escalation in labor, energy, and waste burial costs. Licensees may elect to use either a site-specific adjustment factor, approved as part of the plan and associated

decommissioning report required by § 53.4610, in paragraph (a) of this section or the generic adjustment factor in paragraph (b) of this section.

(a) A site-specific adjustment factor must at a minimum address the estimated contributions and escalation of costs for the following aspects of decommissioning:

- (1) labor, materials, and services;
- (2) energy and waste transportation; and
- (3) radioactive waste burial or other disposition.

(b) A generic adjustment factor must be at least equal to $0.65 L + 0.13 E + 0.22 B$, where L and E are escalation factors for labor and energy, respectively, and are to be taken from regional data of U.S. Department of Labor Bureau of Labor Statistics and B is an escalation factor for waste burial and is to be taken from NRC report NUREG-1307, "Report on Waste Burial Charges."

§ 53.4640 Methods for providing financial assurance for decommissioning.

Financial assurance is to be provided by the following methods.

(a) *Prepayment.* Prepayment is the deposit made preceding the start of operation or the transfer of a license under § 53.6070 into an account segregated from licensee assets and outside the administrative control of the licensee and its subsidiaries or affiliates of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, or Government fund with payment by certificate of deposit, deposit of government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement shall be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the prepayment

deposit is managed are regulated and examined by a Federal or State agency. A licensee that has prepaid funds based on a site-specific cost estimate under § 53.4620 may take credit for projected earnings on the prepaid decommissioning trust funds, using up to a 2 percent annual real rate of return through the time of termination of the license. A licensee may use a credit of greater than 2 percent if the licensee's rate-setting authority has specifically authorized a higher rate. Actual earnings on existing funds may be used to calculate future fund needs.

(b) *External sinking fund.* An external sinking fund is a fund established and maintained by setting funds aside periodically in an account segregated from licensee assets and outside the administrative control of the licensee and its subsidiaries or affiliates in which the total amount of funds would be sufficient to pay decommissioning costs. An external sinking fund may be in the form of a trust, escrow account, or Government fund, with payment by certificate of deposit, deposit of Government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement shall be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the external sinking fund is managed are regulated and examined by a Federal or State agency. A licensee that has collected funds based on a site-specific cost estimate under § 53.4620 may take credit for projected earnings on the external sinking funds using up to a 2 percent annual real rate of return from the time of future funds' collection through the time of termination of the license. A licensee may use a credit of greater than 2 percent if the licensee's rate-setting authority has specifically authorized a higher rate. Actual earnings on existing funds may be used to calculate future fund needs. A licensee whose rates for decommissioning costs cover only a portion of these costs may make use of this method only for the portion of these costs that are collected in one of the manners described in

this paragraph. This method may be used as the exclusive mechanism relied upon for providing financial assurance for decommissioning in the following circumstances:

(1) By a licensee that recovers, either directly or indirectly, the estimated total cost of decommissioning through rates established by "cost of service" or similar ratemaking regulation. Public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, that establish their own rates and are able to recover their cost of service allocable to decommissioning, are deemed to meet this condition.

(2) By a licensee whose source of revenues for its external sinking fund is a "non-bypassable charge," the total amount of which will provide funds estimated to be needed for decommissioning pursuant to §§ 53.4620, 53.4660, or 53.6075 of this part.

(c) A surety method, insurance, or other guarantee method.

(1) These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended, or, if written for a specified term, such as 5 years, must be renewed automatically, unless 90 days or more prior to the renewal day the issuer notifies the NRC, the beneficiary, and the licensee of its intention not to renew. The surety or insurance must also provide that the full-face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the NRC within 30 days after receipt of notification of cancellation.

(ii) The surety or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the NRC. An acceptable trustee includes an appropriate State or Federal government agency or an

entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(2) A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to 10 CFR part 30.

(3) For commercial companies that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to 10 CFR part 30. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D to 10 CFR part 30. A guarantee by the applicant or licensee may not be used in any situation in which the applicant or licensee has a parent company holding majority control of voting stock of the company.

(d) For a Federal licensee, a statement of intent containing a cost estimate for decommissioning and indicating that funds for decommissioning will be obtained when necessary.

(e) Contractual obligation(s) on the part of a licensee's customer(s), the total amount of which over the duration of the contract(s) will provide the licensee's total share of uncollected funds estimated to be needed for decommissioning pursuant to §§ 53.4620, 53.4660, or 53.6075. To be acceptable to the NRC as a method of decommissioning funding assurance, the terms of the contract(s) shall include provisions that the buyer(s) of electricity or other products will pay for the decommissioning obligations specified in the contract(s), notwithstanding the operational status either of the licensed plant to which the contract(s) pertains or force majeure provisions. All proceeds from the contract(s) for decommissioning funding will be deposited to the external sinking fund. The NRC reserves the right to evaluate the terms of any

contract(s) and the financial qualifications of the contracting entity or entities offered as assurance for decommissioning funding.

(f) Any other mechanism, or combination of mechanisms, that provides, as determined by the NRC upon its evaluation of the specific circumstances of each licensee submittal, assurance of decommissioning funding equivalent to that provided by the mechanisms specified in paragraphs (a) through (e) of this section. Licensees who do not have sources of funding described in paragraph (b) of this section may use an external sinking fund in combination with a guarantee mechanism, as specified in paragraph (c) of this section, provided that the total amount of funds estimated to be necessary for decommissioning is assured.

§ 53.4645 Requirements for decommissioning trust funds.

(a)(1) Decommissioning trust funds may be used by licensees if—

(i) The withdrawals are for expenses for decommissioning activities consistent with the definition of decommissioning in § 53.020;

(ii) The expenditure would not reduce the value of the decommissioning trust below an amount necessary to place and maintain the reactor in a safe storage condition if unforeseen conditions or expenses arise; and

(iii) The withdrawals would not inhibit the ability of the licensee to complete funding of any shortfalls in the decommissioning trust needed to ensure the availability of funds to ultimately release the site and terminate the license.

(2) Initially, 3 percent of the amount determined in accordance with § 53.4620 may be used for decommissioning planning. For licensees that have submitted the certifications required under § 53.6075 and commencing 90 days after the NRC has received the post-shutdown decommissioning activities report (PSDAR) required by

§ 53.4660, an additional 20 percent may be used. An updated site-specific decommissioning cost estimate must be submitted to the NRC prior to the licensee using any funding in excess of these amounts.

(b) Licensees that are not "electric utilities" as defined in § 53.020 that use prepayment or an external sinking fund to provide financial assurance shall provide in the terms of the arrangements governing the trust, escrow account, or Government fund, used to segregate and manage the funds that—

(1) The trustee, manager, investment advisor, or other person directing investment of the funds:

(i) Is prohibited from investing the funds in securities or other obligations of the licensee or any other owner or operator of any commercial nuclear plant or their affiliates, subsidiaries, successors or assigns, or in a mutual fund in which at least 50 percent of the fund is invested in the securities of a licensee or parent company whose subsidiary is an owner or operator of a foreign or domestic commercial nuclear plant. However, the funds may be invested in securities tied to market indices or other non-nuclear sector collective, commingled, or mutual funds, provided that this subsection shall not operate in such a way as to require the sale or transfer either in whole or in part, or other disposition of any such prohibited investment that was made before the publication date of this rule, and provided further that no more than 10 percent of trust assets may be indirectly invested in securities of any entity owning or operating one or more commercial nuclear plants.

(ii) Is obligated at all times to adhere to a standard of care set forth in the trust, which either shall be the standard of care, whether in investing or otherwise, required by State or Federal law or one or more State or Federal regulatory agencies with jurisdiction over the trust funds, or, in the absence of any such standard of care, whether in investing or otherwise, that a prudent investor would use in the same circumstances.

The term "prudent investor," shall have the same meaning as set forth in the Federal Energy Regulatory Commission's "Regulations Governing Nuclear Plant Decommissioning Trust Funds" at 18 CFR 35.32(a)(3), or any successor regulation.

(2) The licensee, its affiliates, and its subsidiaries are prohibited from being engaged as investment manager for the funds or from giving day-to-day management direction of the funds' investments or direction on individual investments by the funds, except in the case of passive fund management of trust funds where management is limited to investments tracking market indices.

(3) The trust, escrow account, Government fund, or other account used to segregate and manage the funds may not be amended in any material respect without written notification to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the proposed effective date of the amendment. The licensee shall provide the text of the proposed amendment and a statement of the reason for the proposed amendment. The trust, escrow account, Government fund, or other account may not be amended if the person responsible for managing the trust, escrow account, Government fund, or other account receives written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period.

(4) Except for withdrawals being made under paragraph (a) of this section or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made from the trust, escrow account, Government fund, or other account used to segregate and manage the funds until written notice of the intention to make a disbursement or payment has been given to the Director, Office of Nuclear Reactor Regulation, or

Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other account may be made following the 30-working day notice period if the person responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than for payment of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under § 53.4640 until final decommissioning has been completed. After decommissioning has begun and withdrawals from the decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.

(c) Licensees that are "electric utilities" under § 53.020 that use prepayment or an external sinking fund to provide financial assurance shall include a provision in the terms of the trust, escrow account, Government fund, or other account used to segregate and manage funds that except for withdrawals being made under paragraph (a) of this section or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made from the trust, escrow account, Government fund, or other account used to segregate and manage the funds until written notice of the intention to make a disbursement or payment has been given the Director, Office of Nuclear Reactor

Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other account may be made following the 30-working day notice period if the person responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than for payment of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under § 53.4640 until final decommissioning has been completed. After decommissioning has begun and withdrawals from the decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.

(d) A licensee that is not an "electric utility" under § 53.020 and using a surety method, insurance, or other guarantee method to provide financial assurance shall provide that the trust established for decommissioning costs to which the surety or insurance is payable contains in its terms the requirements in § 53.4645(b)(1), (2), (3), and (4).

§ 53.4650 NRC oversight.

The NRC reserves the right to take the following steps in order to ensure a licensee's adequate accumulation of decommissioning funds: review, as needed, the

rate of accumulation of decommissioning funds; and, either independently or in cooperation with the FERC and the licensee's State PUC, take additional actions as appropriate on a case-by-case basis, including modification of a licensee's schedule for the accumulation of decommissioning funds.

§ 53.4660 Reporting and recordkeeping requirements.

(a) Each holder of an operating license under Framework B of this part or holder of a combined license under Framework B of this part after the date that the Commission has made the finding under § 53.5052(g) must report, at least once every 2 years, by March 31, on the status of its certification of decommissioning funding for each reactor or part of a reactor that it owns. The information in this report must include, at a minimum, the amount of decommissioning funds estimated to be required pursuant to §§ 53.4620 and 53.4630; the amount of decommissioning funds accumulated to the end of the calendar year preceding the date of the report; a schedule of the annual amounts remaining to be collected; the assumptions used regarding rates of escalation in decommissioning costs, rates of earnings on decommissioning funds, and rates of other factors used in funding projections; any contracts upon which the licensee is relying pursuant to § 53.4640(e); any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and any material changes to trust agreements. If any of the preceding items is not applicable, the licensee should so state in its report. Any licensee for a plant that is within 5 years of the projected end of its operation, or where conditions have changed such that it will close within 5 years (before the end of its licensed life), or that has already closed (before the end of its licensed life), or that is involved in a merger or an acquisition shall submit this report annually.

(b) Each holder of a combined license under Framework B of this part shall, 2 years before and 1 year before the scheduled date for initial loading of fuel, submit a report to the NRC containing a certification updating the decommissioning cost estimates and a copy of the financial instrument to be used to satisfy § 53.4640. No later than 30 days after the Commission publishes notice in the Federal Register under § 53.5052(a), the licensee shall submit a report containing a certification that financial assurance for decommissioning is being provided in an amount specified in the licensee's most recent updated certification, including a copy of the financial instrument obtained to satisfy § 53.4640.

(c) Each licensee shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Commission. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of—

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when significant contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed

individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(4) Records of:

(i) The licensed site area, as originally licensed and any revisions, which must include a site map and any acquisition or use of property outside the originally licensed site area for the purpose of receiving, possessing, or using licensed materials;

(ii) The licensed activities carried out on the acquired or used property; and

(iii) The release and final disposition of any property recorded in paragraph (c)(4)(i) of this section, the historical site assessment performed for the release, radiation surveys performed to support release of the property, submittals to the NRC made in accordance with § 53.6075, and the methods employed to ensure that the property met the radiological criteria of 10 CFR part 20, subpart E, at the time the property was released.

(d) Each holder of an operating license or combined license under Framework B of this part shall at or about 5 years prior to the projected end of operations submit a preliminary decommissioning cost estimate which includes an up-to-date assessment of the major factors that could affect the cost to decommission.

(e) Prior to or within 2 years following permanent cessation of operations, the licensee shall submit a PSDAR to the NRC, and a copy to the affected State(s). The PSDAR must contain a description of the planned decommissioning activities along with a schedule for their accomplishment, a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued

environmental impact statements, and a site-specific decommissioning cost estimate (DCE), including the projected cost of managing irradiated fuel.

(f) For decommissioning activities that delay completion of decommissioning by including a period of storage or surveillance, the licensee shall provide a means of adjusting cost estimates and associated funding levels over the storage or surveillance period.

(g) After submitting its site-specific DCE required by paragraph (e) of this section, and until the licensee has completed its final radiation survey and demonstrated that residual radioactivity has been reduced to a level that permits termination of its license, the licensee must annually submit to the NRC, by March 31, a financial assurance status report. The report must include the following information, current through the end of the previous calendar year:

(1) The amount spent on decommissioning, both cumulative and over the previous calendar year, the remaining balance of any decommissioning funds, and the amount provided by other financial assurance methods being relied upon;

(2) An estimate of the costs to complete decommissioning, reflecting any difference between actual and estimated costs for work performed during the year, and the decommissioning criteria upon which the estimate is based;

(3) Any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and

(4) Any material changes to trust agreements or financial assurance contracts.

(5) If the sum of the balance of any remaining decommissioning funds, plus earnings on such funds calculated at not greater than a 2 percent real rate of return, together with the amount provided by other financial assurance methods being relied upon, does not cover the estimated cost to complete the decommissioning, the financial

assurance status report must include additional financial assurance to cover the estimated cost of completion.

(h) After submitting its site-specific DCE required by paragraph (e) of this section, the licensee must annually submit to the NRC, by March 31, a report on the status of its funding for managing irradiated fuel. The report must include the following information, current through the end of the previous calendar year:

(1) The amount of funds accumulated to cover the cost of managing the irradiated fuel;

(2) The projected cost of managing irradiated fuel until title to the fuel and possession of the fuel is transferred to the Secretary of Energy; and

(3) If the funds accumulated do not cover the projected cost, a plan to obtain additional funds to cover the cost.

§ 53.4670 Termination of license.

For each holder of an operating license or combined license under Framework B of this part—

(a)(1) When the licensee has determined to permanently cease operations the licensee shall, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 53.040(b)(8);

(2) When appropriate to support decommissioning activities and the eventual permanent removal of fuel from the reactor vessel, the licensee must review the operational technical specifications and determine which specifications no longer apply during decommissioning and which ones should remain applicable. The licensee must make the appropriate submittals to the NRC in accordance with § 53.6010 to request changes to the technical specifications; and

(3)(i) Once fuel has been permanently removed from the reactor vessel, the licensee shall submit a written certification to the NRC that meets the requirements of § 53.040(b)(9).

(ii) The licensee may establish and maintain staffing consisting of certified fuel handlers, as defined under § 53.020, and other non-licensed personnel with appropriate qualifications, and in sufficient numbers, to ensure support for facility operations and radiological control activities, as required by the facility defueled technical specifications. These personnel shall be subject to the training requirements of §§ 53.4280 through 53.4282.

(b) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, or when a final legally effective order to permanently cease operations has come into effect, the license issued under Framework B of this part no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel.

(c) Decommissioning will be completed within 60 years of permanent cessation of operations. Completion of decommissioning beyond 60 years will be approved by the Commission only when necessary to protect public health and safety. Factors that will be considered by the Commission in evaluating an alternative that provides for completion of decommissioning beyond 60 years of permanent cessation of operations include unavailability of waste disposal capacity and other site-specific factors affecting the licensee's capability to carry out decommissioning, including presence of other nuclear facilities at the site.

(d)(1) Prior to or within 2 years following permanent cessation of operations, the licensee shall submit a PSDAR and site-specific DCE in accordance with § 53.4660(e).

(2) The NRC shall notice receipt of the PSDAR and make the PSDAR available for public comment. The NRC shall also schedule a public meeting readily accessible to

individuals in the vicinity of the licensee's facility upon receipt of the PSDAR. The NRC shall publish a notice in the Federal Register and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

(e) Licensees shall not perform any major decommissioning activities, as defined in § 53.020, until 90 days after the NRC has received the licensee's PSDAR submittal and until certifications of permanent cessation of operations and permanent removal of fuel from the reactor vessel, as required under § 53.6075, have been submitted.

(f) Licensees shall not perform any decommissioning activities, as defined in § 53.020, that—

- (1) Foreclose release of the site for possible unrestricted use;
- (2) Result in significant environmental impacts not previously reviewed; or
- (3) Result in there no longer being reasonable assurance that adequate funds will be available for decommissioning.

(g) In taking actions permitted under § 53.6040 following submittal of the PSDAR, the licensee shall notify the NRC, in writing and send a copy to the affected State(s), before performing any decommissioning activity inconsistent with, or making any significant schedule change from, those actions and schedules described in the PSDAR, including changes that increase the decommissioning cost by more than 20 percent from the previously provided DCE.

(h) Licensees may use decommissioning trust funds consistent with the limitations of § 53.4645(a). Licensees must report on the status of decommissioning trust funds consistent with the requirements of § 53.4660(g).

(i) Licensees must submit an application for termination of license in accordance with § 53.6075. The application for termination of license must be accompanied or preceded by a license termination plan to be submitted for NRC approval.

(1) The license termination plan must be a supplement to the FSAR or equivalent and must be submitted at least 2 years before termination of the license date.

(2) The license termination plan must include—

(i) A site characterization;

(ii) Identification of remaining dismantlement activities;

(iii) Plans for site remediation;

(iv) Detailed plans for the final radiation survey;

(v) A description of the end use of the site, if restricted;

(vi) An updated site-specific estimate of remaining decommissioning costs;

(vii) A supplement to the environmental report, pursuant to § 51.53, describing any new information or significant environmental change associated with the licensee's proposed termination activities; and

(viii) Identification of parts, if any, of the facility or site that were released for use before approval of the license termination plan.

(3) The NRC shall notice receipt of the license termination plan and make the license termination plan available for public comment. The NRC shall also schedule a public meeting readily accessible to individuals in the vicinity of the licensee's facility upon receipt of the license termination plan. The NRC shall publish a notice in the Federal Register and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

(j) If the license termination plan demonstrates that the remainder of decommissioning activities will be performed in accordance with the regulations in this

chapter, will not be inimical to the common defense and security or to the health and safety of the public, and will not have a significant effect on the quality of the environment and after notice to interested persons, the Commission shall approve the plan, by license amendment, subject to such conditions and limitations as it deems appropriate and necessary and authorize implementation of the license termination plan.

(k) The Commission shall terminate the license if it determines that—

(1) The remaining dismantlement has been performed in accordance with the approved license termination plan, and

(2) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in 10 CFR part 20, subpart E.

§ 53.4680 Release of part of a commercial nuclear plant or site for unrestricted use.

(a) Prior written NRC approval is required to release part of a commercial nuclear plant or site for unrestricted use at any time before receiving approval of a license termination plan. Section 53.4660 specifies recordkeeping requirements associated with partial release. Holders of an operating license or combined license under Framework B of this part seeking NRC review and approval shall—

(1) Evaluate the effect of releasing the property to ensure that—

(i) The dose to individual members of the public does not exceed the limits and standards of 10 CFR part 20, subpart D;

(ii) There is no reduction in the effectiveness of emergency planning or physical security;

(iii) Effluent releases remain within license conditions;

(iv) The environmental monitoring program and offsite dose calculation manual are revised to account for the changes;

(v) The siting criteria of 10 CFR part 100 continue to be met; and

(vi) All other applicable statutory and regulatory requirements continue to be met.

(2) Perform a historical site assessment of the part of the commercial nuclear plant or site to be released; and

(3) Perform surveys adequate to demonstrate compliance with the radiological criteria for unrestricted use specified in § 20.1402 for impacted areas.

(b) For release of non-impacted areas, the licensee may submit a written request for NRC review and approval of the release if a license amendment is not otherwise required. The request submittal must include—

(1) The results of the evaluations performed in accordance with paragraphs (a)(1) and (a)(2) of this section;

(2) A description of the part of the commercial nuclear plant or site to be released;

(3) The schedule for release of the property;

(4) The results of the evaluations performed in accordance with § 53.6040; and

(5) A discussion that provides the reasons for concluding that the environmental impacts associated with the licensee's proposed release of the property will be bounded by appropriate previously issued environmental impact statements.

(c) After receiving a request from the licensee for NRC approval of the release of a non-impacted area, the NRC shall—

(1) Determine whether the licensee has adequately evaluated the effect of releasing the property as required by paragraph (a)(1) of this section;

(2) Determine whether the licensee's classification of any release areas as non-impacted is adequately justified; and

(3) If determining that the licensee's submittal is adequate, inform the licensee in writing that the release is approved.

(d) For release of impacted areas, the licensee shall submit an application for amendment of its license for the release of the property. The application must include--

(1) The information specified in paragraphs (b)(1) through (b)(3) of this section;

(2) The methods used for and results obtained from the radiation surveys required to demonstrate compliance with the radiological criteria for unrestricted use specified in § 20.1402; and

(3) A supplement to the environmental report, under § 51.53, describing any new information or significant environmental change associated with the licensee's proposed release of the property.

(e) After receiving a license amendment application from the licensee for the release of an impacted area, the NRC shall--

(1) Determine whether the licensee has adequately evaluated the effect of releasing the property as required by paragraph (a)(1) of this section;

(2) Determine whether the licensee's classification of any release areas as non-impacted is adequately justified;

(3) Determine whether the licensee's radiation survey for an impacted area is adequate; and

(4) If determining that the licensee's submittal is adequate, approve the licensee's amendment application.

(f) The NRC shall notice receipt of the release approval request or license amendment application and make the approval request or license amendment application available for public comment. Before acting on an approval request or license

amendment application submitted in accordance with this section, the NRC shall conduct a public meeting readily accessible to individuals in the vicinity of the licensee's facility for the purpose of obtaining public comments on the proposed release of part of the commercial nuclear plant or site. The NRC shall publish a document in the Federal Register and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

Subpart R – Licenses, Certifications, and Approvals

§ 53.4700 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 under Framework B of this part, and any amendments to the applications, must be submitted to the U.S. Nuclear Regulatory Commission under § 53.040.

(2) Each applicant for a construction permit, early site permit, combined license, or manufacturing license under Framework B of this part must, 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, 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 that 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, 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 approval, standard design certification, 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.

(c) [Reserved]

(d) [Reserved]

(e) *Filing fees.* Each application for a standard design approval, standard design certification, or commercial nuclear plant license under Framework B of 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.

(f) *Environmental report.* An application for a construction permit, operating license, early site permit, design certification, combined license, or manufacturing license for a commercial nuclear plant shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

§ 53.4701 Requirement for license.

Except as provided in § 53.4720, no person within the United States shall transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use any utilization facility except as authorized by a license issued by the Commission.

§ 53.4703 Combining applications and licenses.

(a) An applicant may combine in one its several applications for different kinds of licenses under the regulations in this chapter.

(b) The Commission may combine in a single license the activities of an applicant which would otherwise be licensed separately.

§ 53.4706 Elimination of repetition.

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.

§ 53.4709 Contents of applications; general information.

Each application must include, unless otherwise indicated in this subpart:

(a) Name of applicant;

(b) Address of applicant;

(c) Description of business or occupation of applicant;

(d)(1) If applicant is an individual, the citizenship of the applicant;

(2) If applicant is a partnership, the name, citizenship and address of each partner and the principal location where the partnership does business;

(3) If applicant is a corporation or an unincorporated association, the following information:

(i) The State where it is incorporated or organized and the principal location where it does business;

(ii) The names, addresses and citizenship of its directors and of its principal officers;

(iii) Whether it is owned, controlled, or dominated by an alien, a foreign corporation, or foreign government, and if so, give details;

(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 paragraph (d) of this section with respect to the principal;

(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 operators' licenses, issued or applied for in connection with the proposed facility;

(f) [Reserved]

(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 § 53.4756(b)(2)(ii) of this chapter, the applicant shall submit radiological emergency response plans of State, local, and participating Tribal governmental entities in the United States that are wholly or partially within the plume exposure pathway emergency planning zone (EPZ),¹ and, for applicants choosing to comply with 10 CFR 50.47 and Appendix E, the plans of State governments wholly or partially within the ingestion pathway EPZ.² Except as provided in paragraph (g)(2) of this section, if the application is for an early site permit that, under § 53.4756(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, for applicants choosing to follow 10 CFR 50.47 and Appendix E, 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.

(2) [To be added when EP for SMR and ONT final rule is published.]

(h) [Reserved]

(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.

(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.

(k) [Reserved]

* * * * *

¹ 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.

² If the State, local and participating Tribal 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.

§ 53.4712 Environmental conditions.

(a) Each construction permit, early site permit, and combined license under Framework B of this part may include conditions to address environmental issues during construction. 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 submitted pursuant to § 53.4700(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.

(b) Each license authorizing operation of a commercial nuclear plant, including a combined license, under Framework B of this part, and each license for a commercial nuclear plant for which the certification of permanent cessation of operations required under § 53.4670(a)(1) of this part has been submitted 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 under §§ 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.

§ 53.4715 Agreement limiting access to classified information.

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 or standard design approval under Framework B of this part, or before the Commission has adopted a final standard design certification rule under Framework B of this part, 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 or standard design approval.

§ 53.4718 Ineligibility of certain applicants.

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.

§ 53.4720 Exceptions and exemptions from licensing requirements.

Nothing in this part shall be deemed to require a license for:

(a) The manufacture, production, or acquisition by the Department of Defense of any utilization facility authorized pursuant to section 91 of the Act, or the use of such facility by the Department of Defense or by a person under contract with and for the account of the Department of Defense;

(b) Except to the extent that Administration facilities of the types subject to licensing pursuant to section 202 of the Energy Reorganization Act of 1974 are involved;

(1)(i) The processing, fabrication or refining of special nuclear material or the separation of special nuclear material, or the separation of special nuclear material from other substances by a prime contractor of the Department of Energy under a prime contract for:

(A) The performance of work for the Department of Energy at a United States government-owned or controlled site;

(B) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or

(C) The use or operation of a utilization facility in a United States owned vehicle or vessel; or

(ii) By a prime contractor or subcontractor of the Commission or the Department of Energy under a prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that,

under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety;

(2)(i) The construction or operation of a utilization facility for the Department of Energy at a United States government-owned or controlled site, including the transportation of the utilization facility to or from such site and the performance of contract services during temporary interruptions of such transportation; or the construction or operation of a utilization facility for the Department of Energy in the performance of research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof; or the use or operation of a utilization facility for the Department of Energy in a United States government-owned vehicle or vessel: Provided, That such activities are conducted by a prime contractor of the Department under a prime contract with the Department of Energy.

(ii) The construction or operation of a utilization facility by a prime contractor or subcontractor of the Commission or the Department of Energy under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

(c) The transportation or possession of any utilization facility by a common or contract carrier or warehousemen in the regular course of carriage for another or storage incident thereto.

§ 53.4721 Public inspection of applications.

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.

§ 53.4724 Relationship between sections.

(a) *Limited work authorization.* (1) An application for a limited work authorization under Framework B of this part may be submitted as part of an application for a construction permit or combined license under Framework B of this part as required in § 53.4740(a)(2).

(2) A holder of an early site permit may request a limited work authorization.

(b) *Early site permit.* (1) An application for a construction permit or combined license under Framework B of this part may, but need not, reference an early site permit.

(2) An application for an early site permit under Framework B of this part may be submitted prior to an application for a construction permit or a combined license under Framework B of this part in connection with the site for which the early site permit is sought.

(c) *Standard design approval.* An application for a standard design approval under Framework B of this part may, but need not, reference an operating license or custom combined license under Framework B of this part that is essentially the same as the standard design for which approval is being requested.

(d) *Standard design certification.* An application for a standard design certification under Framework B of this part may, but need not, reference an operating license or custom combined license under Framework B of this part that is essentially the same as the standard design for which certification is being requested.

(e) *Manufacturing license.* (1) A manufactured reactor or manufactured reactor module manufactured under a manufacturing license (ML) issued under Framework B of this part may only be transported to and installed at a site for which a combined license (COL) under Framework B of this part has been issued. Manufactured reactor modules licensed for factory installation of fuel can only be shipped to sites for which an appropriate license, including for the possession of special nuclear material, has been issued.

(2) A manufacturing license applicant under Framework B of this part may reference a standard design certification or a standard design approval under Framework B of this part in its application.

(3) If licensed under Framework B of this part for factory installation of fuel, a license for receipt, possession, handling, and storage of special nuclear material under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," must be obtained prior to receipt of the fuel at the manufacturer's facility.

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

(g) *Operating license.* (1) An application for an operating license under Framework B of this part may, but need not, reference an early site permit, standard design certification, or standard design approval issued under Framework B of this part.

In the absence of a demonstration that an entity other than the one originally sponsoring and obtaining a standard design certification is qualified to supply a design, the Commission will entertain an application for an operating license that references a standard design certification issued under Framework B of this part only if the entity that sponsored and obtained the certification supplies the design for the applicant's use.

(2) The holder of a construction permit issued under Framework B of this part must, at the time of submission of the final safety analysis report (FSAR), file an application for an operating license.

(h) *Combined licenses.* An application for a combined license under Framework B of this part may, but need not, reference an early site permit, standard design certification, standard design approval, or manufacturing license issued under Framework B of this part. In the absence of a demonstration that an entity other than the one originally sponsoring and obtaining a standard 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 Framework B of this part only if the entity that sponsored and obtained the certification supplies the design for the applicant's use.

§ 53.4725 Standards for review.

(a) *Common standards.* In determining that a construction permit, operating license, early site permit, combined license, or manufacturing license under Framework B of this part will be issued to an applicant, the Commission will be guided by the following considerations:

(1) Except for an early site permit or manufacturing license, the processes to be performed, the operating procedures, the facility and equipment, the use of the facility,

and other technical specifications, or the proposals, in regard to any of the foregoing collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in part 20 of this chapter, and that the health and safety of the public will not be endangered.

(2) The applicant for a construction permit, operating license, combined license, or manufacturing license is technically and financially qualified to engage in the proposed activities in accordance with the regulations in this chapter. However, no consideration of financial qualification is necessary for an electric utility applicant for an operating license or combined license or for an applicant for a manufacturing license.

(3) The issuance of a construction permit, operating license, early site permit, combined license, or manufacturing license to the applicant will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public.

(4) Any applicable requirements of subpart A of 10 CFR part 51 have been satisfied.

(b) *Additional standards for class 103 licenses.* In determining whether a class 103 license will be issued to an applicant, the Commission will, in addition to applying the standards set forth in paragraph (a) of this section, consider whether the proposed activities will serve a useful purpose proportionate to the quantities of special nuclear material or source material to be utilized.

(c) *Additional standards and provisions affecting class 103 licenses and certifications for commercial power.* In addition to applying the standards set forth in paragraphs (a) and (b) of this section, paragraphs (c)(1) through (c)(5) of this section apply in the case of a class 103 license for a facility for the generation of commercial power. For a design certification under Framework B of this part, only paragraph (c)(5) of this section applies.

(1) The NRC will:

(i) Give notice in writing of each application to the regulatory agency or State as may have jurisdiction over the rates and services incident to the proposed activity;

(ii) Publish notice of the application in trade or news publications as it deems appropriate to give reasonable notice to municipalities, private utilities, public bodies, and cooperatives which might have a potential interest in the utilization or production facility; and

(iii) Publish notice of the application once each week for 4 consecutive weeks in the *Federal Register*. No license will be issued by the NRC prior to the giving of these notices and until 4 weeks after the last notice is published in the *Federal Register*.

(2) If there are conflicting applications for a limited opportunity for such license, the Commission will give preferred consideration in the following order: First, to applications submitted by public or cooperative bodies for facilities to be located in high cost power areas in the United States; second, to applications submitted by others for facilities to be located in such areas; third, to applications submitted by public or cooperative bodies for facilities to be located in other than high cost power areas; and, fourth, to all other applicants.

(3) The licensee who transmits electric energy in interstate commerce, or sells it at wholesale in interstate commerce, shall be subject to the regulatory provisions of the Federal Power Act.

(4) Nothing shall preclude any government agency, now or hereafter authorized by law to engage in the production, marketing, or distribution of electric energy, if otherwise qualified, from obtaining a construction permit, operating license, or combined license under Framework B of this part for a utilization facility for the primary purpose of producing electric energy for disposition for ultimate public consumption.

(5) Applications for a design certification, combined license, manufacturing license, operating license or standard design approval that propose nuclear reactor designs which differ 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 will be approved only if:

(i)(A) The performance of each safety feature of the design has been demonstrated through either analysis, appropriate test programs, experience, or a combination thereof;

(B) Interdependent effects among the safety features of the design are acceptable, as demonstrated by analysis, appropriate test programs, experience, or a combination thereof; and

(C) Sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions; or

(ii) There has been acceptable testing of a prototype plant over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions. If a prototype plant is used to comply with the testing requirements, then the NRC may impose additional requirements on siting, safety features, or operational conditions for the prototype plant to protect the public and the plant staff from the possible consequences of accidents during the testing period.

§ 53.4730 General technical requirements.

(a) *Purpose and applicability.* The Safety Analysis Report in an application for a construction permit, operating license, early site permit, combined license, standard

design approval, standard design certification, or manufacturing license must include, to the extent required by §§ 53.4909, 53.4969, 53.4756, 53.5016, 53.4809, 53.4839, and 53.4879, respectively, the information specified below:

(1) *Site safety analysis*. A description of the site that includes:

(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 commercial nuclear plant that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in paragraphs (a)(1)(vi)(A), (a)(1)(vi)(B), and (a)(1)(vi)(C) of this section. In performing this assessment, an applicant must consider circumstances involving fuel or core damage or potential for large radiological releases from sources other than the reactor system. The applicant must perform an evaluation of the postulated fission product release, using the expected demonstrable barrier leak rate(s) and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with site characteristics or postulated site parameters for the license,

certification, or approval being sought, including site meteorology, to evaluate the offsite radiological consequences. For applications based on a mechanistic source term that is derived from physically representative models of the facility response or a bounding assessment assuming severe plant conditions (similar to those assessed as required by § 53.4730(a)(5)(iv)), a design-specific fission product release must be developed and provided. The assessment must specify how any additional barrier(s) are relied upon. Site characteristics must comply with Part 100 of this chapter. The analysis and 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 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

(C) The design demonstrates acceptable dose consequence criteria.

(2) *Facility description.* 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. All structures, systems, and components and facility design features shall be discussed insofar as they are pertinent to the safety of the facility. These may

include, but are not limited to: the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, and engineered safety features. 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 performing this assessment, an applicant shall assume a fission product release as described in paragraph (a)(1)(vi) of this section assuming that the facility is operated at the ultimate power level contemplated;

(3) Kinds and quantities of radioactive materials.

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. As required by Subpart B to 10 CFR part 20, a combination of design features and programmatic controls must, to the extent practical, be based upon sound radiation protection principles to achieve occupational doses that are as low as is reasonably achievable;

(4) *Design bases and principal design criteria.* The design of the facility must include:

(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 commercial nuclear reactors. Applicants for reactors that are not water cooled must provide PDC that must establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety;

(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) *Initiating events and accident analysis.* A description identifying postulated initiating events for anticipated operational occurrences and design basis accidents using a risk-informed approach for systematically evaluating engineered systems. These events must be categorized and analyzed at a minimum to meet the following requirements:

(i) Applicants must provide an analysis and evaluation of the design and performance of SSCs 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

commercial nuclear reactor, and the adequacy of SSCs provided for the prevention of accidents and the mitigation of the consequences of accidents.

(ii) For design basis accidents (DBAs):

(A) Applicants are required to identify acceptance criteria for safety-related SSCs to demonstrate that their performance during design basis accidents adequately mitigates the consequences of such events. Acceptance criteria must be associated with the performance of a safety function(s) for the design such that meeting the acceptance criteria can be shown to satisfy the safety function(s) in order to meet the requirements in paragraphs (a)(5)(i) and (ii).

(B) The analyses and evaluations required in paragraph (a)(5)(i) must demonstrate that fission products are retained within specified barriers for each analyzed design basis accident (e.g., there should not be substantial fuel damage for these events) or otherwise that the dose to an individual located at the exclusion area boundary or low population zone outer boundary remains below the reference values specified in paragraph (a)(1)(vi).

(C) SSCs credited to mitigate design basis accidents must be classified as safety-related. Safety-related SSCs must be designed and located with due consideration to the environments and conditions associated with the internal and external hazards associated with design basis events, including design basis accidents.

(D) Applicants may elect to perform a single or multiple bounding analyses and evaluations to demonstrate the design appropriately mitigates the consequences of accidents; in doing so, applicants must demonstrate that the bounding analyses or evaluations adequately envelope conditions for the full range of anticipated operational occurrences and design basis accidents with sufficient margin. The analyses or evaluations need not be realistic in order to demonstrate the conditions selected envelope those associated with the operation of the commercial nuclear plant.

(E) Applicants must identify limiting parameters that serve as acceptance criteria for the analyses of design basis events and provide the values associated with these parameters as part of the application. These acceptance criteria must demonstrate that the commercial nuclear plant meets appropriate design-specific conditions and safety functions for design basis accidents (e.g., a fuel temperature limit below which radiological releases can be shown to be acceptable or a barrier can be shown to remain intact). For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects these acceptance criteria, the applicant or holder of a construction permit, operating license, combined license, or manufacturing license must report the nature of the change or error and its estimated effect on the safety analysis to the Commission at least annually as specified in § 53.040 of this chapter, as applicable. If the change or error is significant, the applicant or licensee must provide this report within 30 days of identification and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with other requirements in this section.

(F) An evaluation model is the calculational framework used to evaluate the behavior of the reactor system and calculated acceptance criteria for demonstrating safety during design basis accident conditions. It includes one or more computer programs and all other information necessary for application of the calculational framework, such as mathematical models used, assumptions included in the programs, procedure for treating the program input and output information, specification of those portions of analysis not included in computer programs, values of parameters, and all other information necessary to specify the calculational procedure.

(iii) For anticipated operational occurrences:

(A) Applicants must provide analyses that demonstrate that the radiological consequences remain below the values specified in 10 CFR part 20 Subpart D. SSCs

required to mitigate the effects resulting from anticipated operational occurrences must be identified and acceptance criteria for these SSCs specified for continued operation.

(B) Event sequences initiated from events identified as anticipated operational occurrences must not result in a more severe event (e.g., a design basis event).

(C) Event sequences initiated from events identified as anticipated operational occurrences must not result in damage to an SSC that impairs the capability to perform other safety functions as identified in § 53.4730(a)(36), such as cooling to maintain the integrity of required systems and barriers.

(iv) For beyond design basis events (BDBEs),

(A) Applicants must perform assessments to identify design features or programmatic controls for enhancing the plant's capabilities to withstand, without undue risk, credible events that are either more severe than design basis accidents or that involve additional failures. Events include unlikely but credible events that could lead to situations beyond those considered for DBAs, multiple credible failures (e.g., common cause failures in redundant SSCs) that prevent safety systems from performing their intended function, or credible failure sequences that are not assessed within the scope of DBAs but are mitigated by other plant SSCs outside the scope of the credited safety function of those SSCs.

(B) For recognized BDBE initiators applicable to the design (e.g., reduction of risk from anticipated transients without scram, loss of all alternating current power) or complex accident sequences that may have substantial uncertainty associated and are of similar consequence to a recognized BDBE initiator, applicants are required to provide design features or programmatic controls to establish supplementary protections to mitigate against these events.

(C) SSCs required to mitigate beyond design basis events need not be classified as safety related but should have appropriate treatments identified to ensure these

SSCs function as specified in the analyses required in paragraph (a)(5)(iv)(A) to mitigate these events. If an applicant elects to provide a bounding evaluation as described in paragraph (a)(5)(i) of this section, that evaluation may be used to address any or all of the event(s) required as part this section provided the bounding evaluation is demonstrated to envelope these beyond design basis events.

(D) For other BDBE conditions specific to the design derived on the basis of engineering judgement, deterministic assessments, or risk evaluations, designers must establish performance, reliability, and availability targets for safety functions and ensure they are met. If non-safety-related SSCs are used to meet these targets, augmented design standards and a corresponding regulatory treatment for these standards must be identified for those SSCs in order to demonstrate that the SSCs will perform when relevant demands occur.

(v) For severe accidents,

(A) Applicants must provide a description and analysis of design features that prevent or mitigate accidents that could progress beyond the conditions addressed in paragraph (a)(5)(i) of this section. These accidents include those that would require analysis of how the design as a whole addresses the prevention and mitigation of severe accidents, including potential vulnerabilities to these events.

(B) Severe accidents are those events that progress beyond the design basis accidents, as described in paragraph (a)(5)(ii) of this section, in which substantial damage is done to the reactor core whether or not there are serious offsite consequences.

(C) A light water reactor applicant must address how the design prevents and mitigates severe accidents based on conditions derived from operating experience and input from risk evaluations (those required in 53.4730(a)(34)).

(D) An applicant with a non-light-water reactor design must use engineering judgement and input from risk evaluations required by paragraph (a)(34) to identify what constitutes severe accident conditions for their specific design and describe the measures provided in the design for preventing or mitigating such accidents.

(E) The applicant must provide information regarding safety features that will be engineered in the facility and any barriers that must be protected during various accidents to limit the release of radioactive material released to the environment.

(F) The applicant must perform an assessment of the severe accidents that could lead to fission product release, using the expected barrier leak rate(s) 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.

(vi) For chemical hazards, design features and related design criteria must be defined such that analyses demonstrate a low risk of permanent injury to the public due to the health effects of the chemical hazards of licensed material.

(6) *Fire protection.* A description and analysis of the fire protection design features and fire protection program, including its implementation, for the commercial nuclear plant necessary to comply with § 53.4350;

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

(8) *Environmental qualification of electric equipment important to safety.*

(i) A description of the program, and its implementation, required by § 53.4380(a) of this chapter for the environmental qualification of electric equipment important to safety

(ii) The list of electric equipment important to safety that is required by § 53.4380(d)

(9) *Role of personnel.*

(i) A description of the completed assessments related to the role of personnel in ensuring safe operations considering the analyses required by § 53.4226. These assessments must include:

(A) Human Factors Engineering Design Requirements

(B) Human System Interface Design Requirements

(C) Concept of Operations

(D) Functional Requirements Analysis and Function Allocation

(E) Programmatic Requirements

(F) Staffing Plan

(G) Training and Examination Programs

(ii) Initial estimates of staffing plans and the anticipated operations staffing using the criteria in § 53.4230.

(10) *Maintenance rule.* A description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of § 53.4210, as applicable;

(11) *Effluent control.* 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 § 53.4310, the design objectives, and the means to be employed for keeping levels of radioactive material in effluents to unrestricted areas as low as is reasonably achievable. A guide for meeting the criterion as low as is reasonably achievable is that the dose to the maximally exposed member of the public does not exceed 10 mrem total effective dose equivalent per year. The 10 mrem/year dose criteria should not be construed as a dose limit;

(12) *Post-accident radiation monitoring and protection.* The information necessary to demonstrate compliance with the technically relevant portions of the following requirements:

(i) Perform radiation and shielding design reviews of spaces around systems that may, as a result of an accident, contain accident source term⁴ radioactive materials, and design as necessary to permit adequate access to important areas and to protect safety equipment from the radiation environment;

(ii) Provide a capability to promptly obtain and analyze samples from the reactor coolant system and containment that may contain accident source term⁴ radioactive materials without radiation exposures to any individual exceeding 5 rems to the whole body or 50 rems to the extremities. Materials to be analyzed and quantified include certain radionuclides that are indicators of the degree of core damage (e.g., noble gases, radioiodines and cesiums, and nonvolatile isotopes), hydrogen in the containment atmosphere, dissolved gases, chloride, and boron concentrations;

(iii) Provide a capability for containment purging/venting designed to minimize the purging time consistent with ALARA principles for occupational exposure. Provide and demonstrate high assurance that the purge system will reliably isolate under accident conditions;

(13) Reserved.

(14) *Earthquake engineering criteria.* The information necessary to demonstrate that the plant complies with the earthquake engineering criteria of appendix S to part 50 of this chapter in order to implement the principal design criterion corresponding to criterion 2 of appendix A to part 50. In implementing appendix S to part 50 under Framework B of this part, structures, systems, and components required to withstand the effects of the safe-shutdown earthquake ground motion or surface deformation must include all safety-related structures, systems, and components as defined in § 53.3010.

(15) *Emergency plans.* Emergency plans complying with the requirements of § 53.4320.

(16) *State and local government cooperation in emergency planning.*

(i) All emergency plan certifications that have been obtained from the State, participating Tribal, 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.

(17) *Safety feature testing, analyses, operating experience, and prototypes.*

Applications for a design certification, combined license, manufacturing license, operating license or standard design approval that propose nuclear reactor designs which differ 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 will be approved only if the requirements in § 53.4725(d)(5) are met.

(18) *Quality assurance program.*

(i) Establish a quality assurance (QA) program based on consideration of: (A) Ensuring independence of the organization performing checking functions from the organization responsible for performing the functions; (B) performing quality assurance/quality control functions at construction sites to the maximum feasible extent;

(C) including QA personnel in the documented review of and concurrence in quality related procedures associated with design, construction and installation; (D) establishing criteria for determining QA programmatic requirements; (E) establishing qualification requirements for QA and QC personnel; (F) sizing the QA staff commensurate with its duties and responsibilities; (G) establishing procedures for maintenance of “as-built” documentation; and (H) providing a QA role in design and analysis activities.

(ii) Ensure that the quality assurance (QA) program required by Subpart U includes all structures, systems, and components important to safety.

(iii) Provide 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. Subpart U under Framework B of Part 53 sets forth the requirements for quality assurance programs for commercial nuclear plants licensed under Framework B of Part 53. The description of the quality assurance program for a nuclear power plant must include a discussion of how the applicable requirements of Subpart U under Framework B of Part 53 have been and will be satisfied, including a discussion of how the quality assurance program will be implemented;

(19) *Organizational structure.* The applicant's organizational structure, allocations of responsibilities and authorities, and personnel qualifications requirements for operation;

(20) *Managerial and administrative controls.*

(i) Managerial and administrative controls to be used to assure safe operation. Subpart U under Framework B in Part 53 sets forth the requirements for these controls for commercial nuclear plants. The information on the controls to be used for a nuclear power plant must include a discussion of how the applicable requirements of Subpart U under Framework B in Part 53 will be satisfied;

(ii) As applicable, provide a description of the management plan for design and construction activities, to include: (A) The organizational and management structure singularly responsible for direction of design and construction of the proposed plant; (B) technical resources director by the applicant; (C) details of the interaction of design and construction 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; (D) proposed procedures for handling the transition to operation; and (E) the degree of top level management oversight and technical control to be exercised by the applicant during design and construction, including the preparation and implementation of procedures necessary to guide the effort;

(21) *Preoperational testing and initial startup.* Plans for preoperational testing and initial operations;

(22) Normal operations and maintenance.

(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 § 53.4730(a)(15);

(23) *Technical specifications.*

(i) Each applicant for an operating license or combined license under Framework B of this part shall include in its application proposed technical specifications in accordance with the requirements of § 53.4213. A summary statement of the bases or reasons for such specifications, other than those covering administrative controls, shall also be included in the application, but shall not become part of the technical specifications.

(ii) Each applicant for a design certification under § 53.4839 of this chapter or manufacturing license under § 53.4879 this chapter shall include in its application

proposed generic technical specifications in accordance with the requirements of § 53.4213 for the portion of the plant that is within the scope of the design certification or manufacturing license application.

(24) *Fitness-for-duty program.* A description of the fitness-for-duty program required by part 26 of this chapter and its implementation;

(25) *Multi-unit sites.* 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;

(26) *Technical qualifications.* The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter;

(27) *Training program.* A description of the training program required to meet § 53.4280 and its implementation;

(28) *Physical security plan.*

(i) A physical security plan that describes how the applicant will meet the requirements of § 53.4330 of this part (and 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 program must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of § 53.4330, and 10 CFR parts 11 and 73, if applicable;

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

(29) *Safeguards, security, and related training and qualifications.*

(i) A safeguards contingency plan meeting 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.¹ (Implementing procedures required for this plan need not be submitted for approval);

(ii) A training and qualification plan that describes how the applicant will meet the criteria set forth in § 73.100 or appendix B to part 73 of this chapter;

(iii) A cyber security plan in accordance with the criteria set forth in § 73.110 of this chapter;

(iv) A description of the implementation of the physical security program, safeguards contingency plan, security training and qualification plan, and cyber security plan. Each applicant who prepares a physical security program, a safeguards contingency plan, a security training and qualification plan, or a cyber security plan shall protect the plans and other related Safeguards Information against unauthorized disclosure under the requirements of §§ 73.21 and 73.22 of this chapter

(30) *Operating experience.* The information necessary to demonstrate how operating experience insights have been incorporated into the plant design, as applicable;

(31) *Radiation protection program.* A description of the radiation protection program required by § 53.4310 of this chapter and its implementation.

(32) *Criticality accident requirements.* Information demonstrating how the applicant will comply with requirements for criticality accidents in [§ 53.xxxx];

(33) *Minimization of contamination.* The information required by § 20.1406 of this chapter.

(34) *Description of risk evaluation.* A description of the risk evaluation developed for the commercial nuclear plant and its results. The risk evaluation must be based on:

(i) A probabilistic risk assessment (PRA), or

(ii) An alternative evaluation for risk insights (AERI), provided that the dose from a postulated bounding event to an individual located 100 meters (328 feet) away from the commercial nuclear plant does not exceed 1 rem total effective dose equivalent (TEDE) over the first four days following a release, an additional 2 rem TEDE in the first year, and 0.5 rem TEDE per year in the second and subsequent years.

(35) *Aircraft impact assessment.*

(i) *Assessment requirements.* (A) *Assessment.* Applicants shall perform a design-specific assessment of the effects on the facility of the impact of a large, commercial aircraft. Using realistic analyses, the applicant shall identify and incorporate into the design those design features and functional capabilities to show that, with reduced use of operator actions:

(1) The capability to remove heat from the reactor fuel is retained, or the structures, systems, and components associated with the confinement of radionuclides remains functional; and

(2) For facilities that rely on active cooling or submergence of spent reactor fuel to protect public health and safety, spent fuel cooling or spent fuel pool integrity is maintained.

(B) *Aircraft impact characteristics.* The assessment must be based on the beyond-design-basis impact of a large, commercial aircraft used for long distance flights in the United States, with aviation fuel loading typically used in such flights, and an impact speed and angle of impact considering the ability of both experienced and inexperienced pilots to control large, commercial aircraft at the low altitude representative of a nuclear power plant's low profile.

(ii) *Content of application.* The preliminary or final safety analysis report, as applicable, must include a description of:

(A) The design features and functional capabilities identified in paragraph (i)(A) of this section; and

(B) How the design features and functional capabilities identified in paragraph (i)(A) of this section meet the assessment requirements in paragraph (i)(A) of this section.

(36) *Functional containment.* A description of the barriers to radionuclide release credited for the facility.

(i) Non-LWR applicants may elect to provide a functional containment; that is, may designate a set of barriers taken together that effectively limit the physical transport and release of radionuclides to the environment for events that meet analysis requirements in 53.4730(a)(1)(vi), (a)(5)(ii), and (a)(5)(iii). SSCs designated as part of the functional containment (and those that support these SSCs) used in the analyses of DBAs must be classified as safety-related. These safety-related SSCs should be qualified to demonstrate they perform as assumed in the analyses (e.g., leakage testing if leakage is an assumption related to mitigating radionuclide release).

(ii) Water-cooled reactor applicants must have a primary containment to in part fulfill the function of barriers to radionuclide release, and this containment must:

(A) Meet the requirements set forth in appendix J to 10 CFR part 50, including providing a description of the primary containment leakage rate testing program, and its implementation.

(B) If technically relevant, provide containment isolation systems that:

(1) Ensure all non-essential systems are isolated automatically by the containment isolation system,

(2) For each non-essential penetration (except instrument lines) have two isolation barriers in series,

(3) Do not result in reopening of the containment isolation valves on resetting of the isolation signal,

(4) Utilize a containment set point pressure for initiating containment isolation as low as is compatible with normal operation,

(5) Include automatic closing on a high radiation signal for all systems that provide a path to the environs.

(C) Provide a capability for containment purging/venting designed to minimize the purging time consistent with ALARA principles for occupational exposure. Provide and demonstrate high assurance that the purge system will reliably isolate under accident conditions;

(D) If technically relevant, provide one or more dedicated containment penetrations, equivalent in size to a single 3-foot diameter opening, in order not to preclude future installation of systems to prevent containment failure, such as a filtered vented containment system.

(37) *Water-cooled reactor requirements.* For applications for water-cooled nuclear power plants:

(i) *Emergency core cooling systems.* Analysis and evaluation of emergency core cooling system 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, as applicable;

(ii) *Codes and standards.* 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;

(iii) *Pressurized thermal shock and fracture toughness requirements.* 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, as applicable;

(iv) *Anticipated transients without scram.* 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;

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

(vi) *Reactor vessel material surveillance.* A description of the reactor vessel material surveillance program required by appendix H to part 50 of this chapter and its implementation;

(vii) *Containment leakage testing.* 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 part 50 of this chapter;

(viii) *Standard review plan evaluation.* 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 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;

(ix) *Resolution of generic issues.* Proposed technical resolutions of all generic issues identified since July 21,1999, unresolved safety issues, and medium- and high-priority generic safety issues identified before July 21,1999, that are relevant to the design. These issues are based upon the applicant's review of publicly available information published up to 6 months before the docket date of the application (for example, the issues listed in NRC's NUREG-0933, "Resolution of Generic Safety Issues.");

(x) *Requirements from light-water-reactor operating experience.* The information with respect to compliance with technically relevant portions of the following requirements:

(A) Provide pressurizer heater power supply and associated motive and control power interfaces sufficient to establish and maintain natural circulation in hot standby conditions with only onsite power available. (Applicable to PWR's only)

(B) Provide power supplies for pressurizer relief valves, block valves, and level indicators such that: (1) Level indicators are powered from vital buses; (2) motive and control power connections to the emergency power sources are through devices qualified in accordance with requirements applicable to systems important to safety and (3) electric power is provided from emergency power sources. (Applicable to PWR's only).

(C) Provide a test program and associated model development and conduct tests to qualify reactor coolant system relief and safety valves and, for PWR's, PORV block valves, for all fluid conditions expected under operating conditions, transients, and accidents. Consideration of anticipated transients without scram (ATWS) conditions shall be included in the test program. Actual testing under ATWS conditions need not be carried out until subsequent phases of the test program are developed.

* * * * *

¹ 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.

§ 53.4731 Risk-informed classification of structures, systems, and components.

(a) Definitions.

Risk-Informed Safety Class (RISC)–1 structures, systems, and components (SSCs) means safety-related SSCs that perform safety significant functions.

Risk-Informed Safety Class (RISC)–2 structures, systems and components (SSCs) means non-safety-related SSCs that perform safety significant functions.

Risk-Informed Safety Class (RISC)–3 structures, systems and components (SSCs) means safety-related SSCs that perform low safety significant functions.

Risk-Informed Safety Class (RISC)–4 structures, systems and components (SSCs) means non-safety-related SSCs that perform low safety significant functions.

Safety significant function means a function whose degradation or loss could result in a significant adverse effect on defense-in-depth, safety margin, or risk.

(b) Applicability and scope of risk-informed treatment of SSCs and submittal/approval process.

(1) This section describes alternative requirements for the SSCs of a commercial nuclear plant. Holders of a construction permit, or an operating, combined, or manufacturing license under Framework B of this part that develop a PRA in accordance with the requirements of § 53.4730(a)(34)(i) may voluntarily comply with the requirements in this section. Compliance with the requirements in this section may be proposed when applying for a standard design certification or approval, construction permit, or an operating, combined operating, or manufacturing license under Framework B of this part. For RISC–3 and RISC–4 SSCs, the requirements in this section are an alternative to compliance with the following:

(i) 10 CFR part 21.

(ii) For licensees of facilities with high point vents under § 53.4730(a)(37)(i), that portion of § 50.46a(b) that imposes requirements to conform Subpart U under Framework B of Part 53.

(iii) § 53.4380.

(iv) § 53.6355

(v) For licensees of LWR facilities, the inservice testing requirements in 10 CFR 50.55a(f); the inservice inspection, and repair and replacement (with the exception of fracture toughness), requirements for ASME Class 2 and Class 3 SSCs in 10 CFR 50.55a(g); and the electrical component quality and qualification requirements in Section 4.3 and 4.4 of IEEE 279, and Sections 5.3 and 5.4 of IEEE 603-1991, as incorporated by reference in 10 CFR 50.55a(h).

(vi) § 53.4210, except for paragraph (a)(4).

(vii) § 53.6330.

(viii) § 53.6340.

(ix) Subpart U under Framework B of Part 53

(x) For licensees of water-cooled reactors, the Type B and Type C leakage testing requirements in both Options A and B of Appendix J to 10 CFR part 50, for penetrations and valves meeting the following criteria:

(A) Containment penetrations that are either 1-inch nominal size or less, or continuously pressurized.

(B) Containment isolation valves that meet one or more of the following criteria:

(1) The valve is required to be open under accident conditions to prevent or mitigate core damage events;

(2) The valve is normally closed and in a physically closed, water- filled system;

(3) The valve is in a physically closed system whose piping pressure rating exceeds the containment design pressure rating and is not connected to the reactor coolant pressure boundary; or

(4) The valve is 1-inch nominal size or less.

(2) A licensee voluntarily choosing to implement this section shall submit the following as part of its application for a construction permit, or an operating, combined, or manufacturing license under Framework B of this part or as an application for license amendment under § 53.6010:

(i) A description of the process for categorization of RISC–1, RISC–2, RISC–3 and RISC–4 SSCs.

(ii) A description of the measures taken to assure that the quality and level of detail of the systematic processes that evaluate the plant for internal and external events during normal operation, low power, and shutdown (including the plant-specific probabilistic risk assessment (PRA), margins-type approaches, or other systematic evaluation techniques used to evaluate severe accident vulnerabilities) are adequate for the categorization of SSCs.

(iii) Results of the PRA review process conducted to meet paragraph (c)(1)(i) of this section.

(iv) A description of, and basis for acceptability of, the evaluations to be conducted to satisfy paragraph (c)(1)(iv) of this section. The evaluations must include the effects of common cause interaction susceptibility, and the potential impacts from known degradation mechanisms for both active and passive functions, and address internally and externally initiated events and plant operating modes (e.g., full power and shutdown conditions).

(3) The Commission will approve a licensee's implementation of this section if it determines that the process for categorization of RISC–1, RISC–2, RISC–3, and RISC–

4 SSCs satisfies the requirements of paragraph (c) of this section by issuing a license amendment approving the licensee's use of this section.

(4) An applicant choosing to implement this section shall include the information in paragraph (b)(2) of this section as part of application. The Commission will approve an applicant's implementation of this section if it determines that the process for categorization of RISC-1, RISC-2, RISC-3, and RISC-4 SSCs satisfies the requirements of paragraph (c) of this section.

(c) SSC Categorization Process. (1) SSCs must be categorized as RISC-1, RISC-2, RISC-3, or RISC-4 SSCs using a categorization process that determines if an SSC performs one or more safety significant functions and identifies those functions.

The process must:

(i) Consider results and insights from the plant-specific PRA. This PRA must at a minimum model severe accident scenarios resulting from internal initiating events occurring at full power operation. The PRA must be of sufficient quality and level of detail to support the categorization process and must be subjected to a peer review process assessed against a standard or set of acceptance criteria that is endorsed by the NRC.

(ii) Determine SSC functional importance using an integrated, systematic process for addressing initiating events (internal and external), SSCs, and plant operating modes, including those not modeled in the plant-specific PRA. The functions to be identified and considered include design bases functions and functions credited for mitigation and prevention of severe accidents. All aspects of the integrated, systematic process used to characterize SSC importance must reasonably reflect the current plant configuration and operating practices, and applicable plant and industry operational experience.

(iii) Maintain defense-in-depth.

(iv) Include evaluations that provide reasonable confidence that for SSCs categorized as RISC-3, sufficient safety margins are maintained and that any potential increases in risk resulting from changes in treatment permitted by implementation of paragraphs (b)(1) and (d)(2) of this section are small.

(v) Be performed for entire structures and systems, not for selected components within a structure or system.

(2) The SSCs must be categorized by an Integrated Decisionmaking Panel (IDP) staffed with expert, plant-knowledgeable members whose expertise includes, at a minimum, PRA, safety analysis, plant operation, design engineering, and system engineering.

(d) Alternative treatment requirements—(1) RISC-1 and RISC 2 SSCs. The licensee or applicant shall ensure that RISC-1 and RISC-2 SSCs perform their functions consistent with the categorization process assumptions by evaluating treatment being applied to these SSCs to ensure that it supports the key assumptions in the categorization process that relate to their assumed performance.

(2) RISC-3 SSCs. The licensee or applicant shall ensure, with reasonable confidence, that RISC-3 SSCs remain capable of performing their safety-related functions under design basis conditions, including seismic conditions and environmental conditions and effects throughout their service life. The treatment of RISC-3 SSCs must be consistent with the categorization process. Inspection and testing, and corrective action shall be provided for RISC-3 SSCs.

(i) Inspection and testing. Periodic inspection and testing activities must be conducted to determine that RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions; and

(ii) Corrective action. Conditions that would prevent a RISC-3 SSC from performing its safety-related functions under design basis conditions must be corrected

in a timely manner. For significant conditions adverse to quality, measures must be taken to provide reasonable confidence that the cause of the condition is determined and corrective action taken to preclude repetition.

(e) Feedback and process adjustment—(1) RISC–1, RISC–2, RISC–3 and RISC–4 SSCs. The licensee shall review changes to the plant, operational practices, applicable plant and industry operational experience, and, as appropriate, update the PRA and SSC categorization and treatment processes. The licensee shall perform this review in a timely manner but no longer than once every 48 months.

(2) RISC–1 and RISC–2 SSCs. The licensee shall monitor the performance of RISC–1 and RISC–2 SSCs. The licensee shall make adjustments as necessary to either the categorization or treatment processes so that the categorization process and results are maintained valid.

(3) RISC–3 SSCs. The licensee shall consider data collected in paragraph (d)(2)(i) of this section for RISC–3 SSCs to determine if there are any adverse changes in performance such that the SSC unreliability values approach or exceed the values used in the evaluations conducted to satisfy paragraph (c)(1)(iv) of this section. The licensee shall make adjustments as necessary to the categorization or treatment processes so that the categorization process and results are maintained valid.

(f) Program documentation, change control and records. (1) The licensee or applicant shall document the basis for its categorization of any SSC under paragraph (c) of this section before removing any requirements under paragraph (b)(1) of this section for those SSCs.

(2) Following implementation of this section, licensees and applicants shall update their final safety analysis report (FSAR) to reflect which systems have been categorized, in accordance with § 53.6045.

(3) When a licensee first implements this section for an SSC, changes to the FSAR for the implementation of the changes in accordance with paragraph (d) of this section need not include a supporting § 53.6050 evaluation of the changes directly related to implementation. Thereafter, changes to the programs and procedures for implementation of paragraph (d), as described in the FSAR, may be made if the requirements of this section and § 53.6050 continue to be met.

(4) When a licensee first implements this section for an SSC, changes to the quality assurance plan for the implementation of the changes under paragraph (d) of this section need not include a supporting § 53.6065(d) review of the changes directly related to implementation. Thereafter, changes to the programs and procedures for implementation of paragraph (d), as described in the quality assurance plan may be made if the requirements of this section and § 53.6065(d) continue to be met.

(g) Reporting. The licensee shall submit a licensee event report under § 53.6340 for any event or condition that prevented, or would have prevented, a RISC-1 or RISC-2 SSC from performing a safety significant function.

§ 53.4740 Limited work authorizations.

(a) *Request for limited work authorization.* (1) Any person to whom the Commission may otherwise issue either a license or permit related to a 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, 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 § 53.4110 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 53.4909, or 10 CFR 53.5016 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 under Framework B 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.

(b) *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;

(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.

(c) *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 (b)(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).

(d) *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 application or the underlying combined license application, as applicable.

§ 53.4750 Early site permits.

Sections §§ 53.4750 through 53.4798 set out the requirements and procedures applicable to Commission issuance of an early site permit for approval of a site for a commercial nuclear plant, which may consist of one or more reactor modules separate from the filing of an application for a construction permit or combined license for the facility.

§ 53.4753 Filing of applications.

Any person who may apply for a construction permit or for a combined license under Framework B of 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.

§ 53.4754 Contents of applications for early site permits; general information.

The application must contain all of the information required by 10 CFR 53.4709 (a) through (d) and (j).

§ 53.4756 Contents of applications for early site permits; technical information.

(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 information required by §§ 53.4730(a)(1)(i) through (v);

(v) A facility description that satisfies the requirements associated with §§ 53.4730(a)(2) and the assessment required in §§ 53.4730(a)(1)(vi);

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

(vii) A description of the quality assurance program required by Subpart U 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.

(xii) For water-cooled reactor applicants, the information necessary to address the requirements associated with § 53.4730(a)(37)(viii).

(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 § 53.4320 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 § 53.4320 of this chapter. To the extent approval of emergency plans is sought, the application must contain the information required by § 53.4709(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 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, participating Tribal 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 § 53.4740 be issued in conjunction with the early site permit. The application must include the information otherwise required by § 53.4740.

(d) Each applicant for an early site permit under Framework B of 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.

§ 53.4759 Review of applications.

(a) *Standards for review of applications.* Applications filed under this subpart will be reviewed according to the applicable standards set out in Framework B. 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 § 53.4756(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 § 53.4756(b)(2)(i) are acceptable in accordance with the applicable standards of § 53.4320 of this chapter, and whether any emergency plans submitted by the applicant under § 53.4756(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

(b) *Administrative review of applications; hearings.* An early site permit application 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 Framework B of this part are governed by the procedures contained in subparts C, G, L, and N of 10 CFR Part 2, as applicable.

§ 53.4765 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

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 application which concern safety.

§ 53.4768 Issuance of early site permit.

(a) After conducting a hearing under § 53.5759(b) and receiving the report to be submitted by the ACRS under § 53.4765, the Commission may issue an early site permit, in the form the Commission deems appropriate, if the Commission finds that:

(1) An application for an early site permit meets the applicable standards and requirements of the Act and the Commission's regulations;

(2) Notifications, if any, to other agencies or bodies have been duly made;

(3) There is reasonable assurance that the site is in conformity with the provisions of the Act, and the Commission's regulations;

(4) The applicant is technically qualified to engage in any activities authorized;

(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;

(6) Issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public;

(7) Any significant adverse environmental impact resulting from activities requested under § 53.4756(c) can be redressed; and

(8) The findings required by subpart A of 10 CFR Part 51 have been made.

(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.

(c) The early site permit shall specify those 10 CFR 53.4740(b) activities requested under § 53.4756(c) that the permit holder is authorized to perform.

§ 53.4771 Extent of activities permitted.

If the activities authorized by § 53.4768(c) are performed and the site is not referenced in an application for a construction permit or a combined license issued under Framework B of 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 under the terms of the site redress plan required by § 53.4756(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.

§ 53.4774 Duration of permit.

(a) Except as provided in paragraph (b) of this section, an early site permit issued under this subpart may be valid for not less than 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.

§ 53.4777 Limited work authorization after issuance of early site permit.

A holder of an early site permit may request a limited work authorization under § 53.4756(c) of this part.

§ 53.4780 Transfer of early site permit.

An application to transfer an early site permit will be processed under 10 CFR 53.6070.

§ 53.4783 Application for renewal.

(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.

(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.

(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 § 53.4774(b).

(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 § 53.4786.

§ 53.4786 Criteria for renewal.

(a) The Commission shall grant the renewal if it determines that:

(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

(2) Any new requirements the Commission may wish to impose:(i) Are necessary for adequate protection to public health and safety or common defense and security;

(ii) Are necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the site permit was originally issued; or

(iii) Will provide 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 implementation of those requirements are justified in view of this increased protection.

(b) A denial of renewal for failure to comply with the provisions of § 53.4786(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.

§ 53.4789 Duration of renewal.

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.

§ 53.4792 Use of site for other purposes.

A site for which an early site permit has been issued under this subpart may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder 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, under the provisions of § 53.4798. If the permit holder informs the Director that the holder no longer intends to use the site for a commercial nuclear power plant, the Director may terminate the permit.

§ 53.4795 Reporting of defects and noncompliance; revocation, suspension, modification of permits for cause.

For purposes of part 21 of this chapter and § 53.6085, an early site permit is a construction permit.

§ 53.4798 Finality of early site permit determinations.

(a) *Commission finality.*

(1) While an early site permit is in effect under §§ 53.4774 or 53.4789, the Commission may not change or impose new site 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 § 53.5052, 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 commercial 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 § 53.6065 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 commercial nuclear power plant, the Commission shall treat as resolved changes that are equivalent to those that could be made under § 53.6065 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 shall update the emergency preparedness information that was provided under § 53.4756(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 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 response to the petition shall meet the requirements of paragraph (a)(1) of this section.

(d) *Variances*. 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.

(e) *Early site permit amendment.* 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 53.6010 and 53.6020.

§ 53.4800 Standard design approvals.

Sections 53.4800 through 53.4821 set out procedures for the filing, NRC staff review, and referral to the Advisory Committee on Reactor Safeguards of standard designs, or major portions thereof, for a commercial nuclear plant under Framework B of this part.

§ 53.4803 Filing of applications.

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 final design for the entire facility or the final design for major portions thereof.

§ 53.4806 Contents of applications for standard design approvals; general information.

The application must contain all of the information required by 10 CFR 53.4709 (a) through (c) and (j).

§ 53.4809 Contents of applications for standard design approvals; technical information.

If the applicant seeks review of a major portion of a standard design, the application need only contain the information required by this section to the extent the requirements are applicable to the major portion of the standard design for which NRC staff approval is sought.

(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, 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 facility description that satisfies the requirements in § 53.4730(a)(2) and the assessment required in § 53.4730(a)(1)(vi);

(3) The information pertaining to design features that affect plans for coping with emergencies in the operation of the reactor facility or a major portion thereof;

(4) For applicants subject to the risk evaluation requirements in § 53.4730(a)(34)(i), the list of electric equipment important to safety that is required by 10 CFR 53.4380(d);

(5) Information demonstrating how the applicant will comply with the relevant requirements for criticality accidents in § 53.4730(a)(32);

(6) A description and analysis of the fire protection design features for the standard plant necessary to comply with the principal design criterion corresponding to criterion 3 of appendix A to part 50 of this chapter and § 53.4350;

(7) A description of the quality assurance program, applied to the design of the structures, systems, and components of the facility. Subpart U under Framework B of Part 53 sets forth the requirements for quality assurance programs for commercial nuclear plants licensed under Framework B of Part 53. The description of the quality assurance program for a commercial nuclear plant must include a discussion of how the applicable requirements of Subpart U under Framework B of Part 53 will be satisfied;

(8) A description, analysis, and evaluation of the interfaces between the standard design and the balance of the nuclear power plant; and

(9) The information required by:

(i) Paragraph (a)(3) of § 53.4730 – kinds and quantities of radioactive materials;

(ii) Paragraph (a)(4) of § 53.4730 – design bases and principal design criteria;

(iii) Paragraph (a)(5) of § 53.4730 – initiating events and accident analysis;

(iv) Paragraph (a)(7) of § 53.4730 – combustible gas control;

(v) Paragraph (a)(8)(ii) of § 53.4730 – environmental qualification of electric equipment important to safety;

(vi) Paragraph (a)(11) of § 53.4730 – effluent control;

(vii) Paragraph (a)(12) of § 53.4730 – post-accident radiation monitoring and protection;

(viii) Paragraph (a)(14) of § 53.4730 – earthquake engineering criteria;

(ix) Paragraph (a)(17) of § 53.4730 – safety feature testing, analyses, operating experience, and prototypes;

(x) Paragraph (a)(26) of § 53.4730 – technical qualifications;

(xi) Paragraph (a)(30) of § 53.4730 – operating experience;

(xii) Paragraph (a)(33) of § 53.4730 – minimization of contamination;

- (xiii) Paragraph (a)(34) of § 53.4730 – description of risk evaluation;
- (xiv) Paragraph (a)(35) of § 53.4730 – aircraft impact assessment;
- (xv) Paragraph (a)(36) of § 53.4730 – functional containment;
- (10) For water-cooled reactor applicants, the information required by:
 - (i) Paragraph (a)(37)(i) of § 53.4730– emergency core cooling systems;
 - (ii) Paragraph (a)(37)(iii) of § 53.4730 – pressurized thermal shock and fracture toughness requirements;
 - (iii) Paragraph (a)(37)(iv) of § 53.4730 – anticipated transients without scram;
 - (iv) Paragraph (a)(37)(v) of § 53.4730 – station blackout;
 - (v) Paragraph (a)(37)(viii) of § 53.4730 –standard review plan evaluation;
 - (vi) Paragraph (a)(37)(ix) of § 53.4730 – resolution of generic issues; and
 - (vii) Paragraph (a)(37)(x) of § 53.4730 – Requirements from light-water-reactor operating experience.
- (b) Reserved.

§ 53.4812 Review of applications.

Applications filed under this section will be reviewed for compliance with the standards set out in 10 CFR parts 20, 53, 73, and 100.

§ 53.4815 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.

§ 53.4818 Staff approval of design.

(a) Upon completion of its review of a submittal under §§ 53.4800 through 53.4821 and receipt of a report by the Advisory Committee on Reactor Safeguards under § 53.4815 of this section, the NRC staff shall publish a determination in the *Federal Register* 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, <http://www.nrc.gov>.

(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, an operating license, a combined license, or a manufacturing license under Framework B of this part that references the design approval and is docketed before the date of expiration of the design approval.

§ 53.4821 Finality of standard design approvals; information requests.

(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 certification or individual facility license application under Framework B of this part that incorporates by reference a standard design approved under Framework B of this part 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 § 53.6080 and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

(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.

§ 53.4830 Standard design certifications.

Sections 53.4830 through 53.4863 set forth the requirements and procedures applicable to Commission issuance of rules granting standard design certifications for commercial nuclear plants under Framework B of this part separate from the filing of an application for a construction permit or combined license for such a facility.

§ 53.4833 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 § 53.040 and §§ 2.811 and 2.813 of this chapter.

§ 53.4836 Contents of applications for standard design certifications; general information.

The application must contain all of the information required by 10 CFR 53.4709 (a) through (c) and (j).

§ 53.4839 Contents of applications for standard design certifications; 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) *Final safety analysis report.* Each application for a design certification shall include 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 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 facility description that satisfies the requirements associated with § 53.4730(a)(2) and the assessment required in § 53.4730(a)(1)(vi);

(3) 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)(4) of this section;

(4) 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;

(5) Justification that compliance with the interface requirements of paragraph (a)(4) 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 § 53.4841(a)(1);

(6) A description and analysis of the fire protection design features for the standard plant necessary to comply with the principal design criterion corresponding to criterion 3 of appendix A to part 50 of this chapter and § 53.4350;

(7) A description of a design integrity assessment program that addresses the elements described in § 53.4400(d).

(8) A description of the quality assurance program, applied to the design of the structures, systems, and components of the facility. Subpart U under Framework B of Part 53 sets forth the requirements for quality assurance programs for commercial nuclear plants licensed under Framework B of Part 53. The description of the quality assurance program for a commercial nuclear plant must include a discussion of how the applicable requirements of Subpart U under Framework B of Part 53 were satisfied;

(9) The information required by:

(i) Paragraph (a)(3) of § 53.4730 – kinds and quantities of radioactive materials;

(ii) Paragraph (a)(4) of § 53.4730 – design bases and principal design criteria;

(iii) Paragraph (a)(5) of § 53.4730 – initiating events and accident analysis;

(iv) Paragraph (a)(7) of § 53.4730 – combustible gas control;

(v) Paragraph (a)(8)(ii) of § 53.4730 – environmental qualification of electric equipment important to safety;

(vi) Paragraph (a)(11) of § 53.4730 – effluent control;

(vii) Paragraph (a)(12) of § 53.4730 – post-accident radiation monitoring and protection;

(viii) Paragraph (a)(14) of § 53.4730 – earthquake engineering criteria;

(ix) Paragraph (a)(17) of § 53.4730 – safety feature testing, analyses, operating experience, and prototypes;

(x) Paragraph (a)(23)(ii) of § 53.4730 – technical specifications;

(xi) Paragraph (a)(26) of § 53.4730 – technical qualifications;

(xii) Paragraph (a)(30) of § 53.4730 – operating experience;

(xiii) Paragraph (a)(32) of § 53.4730 – criticality accident requirements;

(xiv) Paragraph (a)(33) of § 53.4730 – minimization of contamination;

(xv) Paragraph (a)(34) of § 53.4730 – description of risk evaluation;

- (xvi) Paragraph (a)(35) of § 53.4730 – aircraft impact assessment;
- (xvii) Paragraph (a)(36) of § 53.4730 – functional containment;
- (9) For water-cooled reactor applicants, the information required by:
 - (i) Paragraph (a)(37)(i) of § 53.4730 – emergency core cooling systems;
 - (ii) Paragraph (a)(37)(iii) of § 53.4730 – pressurized thermal shock and fracture toughness requirements;
 - (iii) Paragraph (a)(37)(iv) of § 53.4730 – anticipated transients without scram;
 - (iv) Paragraph (a)(37)(v) of § 53.4730 – station blackout;
 - (v) Paragraph (a)(37)(ix) of § 53.4730 – resolution of generic issues; and
 - (vi) Paragraph (a)(37)(x) of § 53.4730 – Requirements from light-water-reactor operating experience.
- (b) Reserved.

§ 53.4841 Contents of applications for standard design certifications; other application content.

- (a) In addition to the FSAR, the application must also include the following:
 - (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.
- (b) 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.

(c) Each applicant for a standard design certification under Framework B of 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.

§ 53.4842 Review of applications.

(a) *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, 51, 53, and 73.

(b) *Administrative review of applications; hearings.* (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 § 53.4833 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, the Commission decides that a legislative hearing should be held, the information required by § 2.1502(c) must be included in the *Federal Register* document for the proposed design certification.

(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 *Federal Register* of its decision to hold a legislative hearing. The document shall contain the information specified in § 2.1502(c) and specify whether the Commission or a presiding officer will conduct the legislative hearing.

(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.

(c) *Reference to an issued operating license or combined license.* 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 NRC review will follow the processes for referencing a standard design approval in § 53.4821, to the extent practicable.

§ 53.4845 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.

§ 53.4848 Issuance of standard design certification.

(a) After conducting a rulemaking proceeding under § 53.4842 on an application for a standard design certification and receiving the report to be submitted by the Advisory Committee on Reactor Safeguards under § 53.4845, the Commission may

issue a standard design certification in the form of a rule for the design, which is the subject of the application, if the Commission determines that:

(1) The application meets the applicable standards and requirements of the Atomic Energy Act and the Commission's regulations;

(2) Notifications, if any, to other agencies or bodies have been duly made;

(3) There is reasonable assurance that the standard design conforms with the provisions of the Act, and the Commission's regulations;

(4) The applicant is technically qualified;

(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;

(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;

(7) The findings required by subpart A of part 51 of this chapter have been made;

and

(8) The applicant has implemented the quality assurance program described or referenced in the safety analysis report.

(b) The design certification rule must specify the site parameters, design characteristics, and any additional requirements and restrictions of the design certification rule.

(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.

§ 53.4851 Duration of certification.

(a) Except as provided in paragraph (b) of this section, a standard design certification issued under this subpart is valid for 15 years from the effective date of the rule.

(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 under Framework B of this part 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 § 53.5052 before operation begins under a combined license that references the design certification.

(c) An applicant for a construction permit, operating license, combined license, or a manufacturing license under framework B of this part may, at its own risk, reference in its application a design for which a design certification application has been docketed but not granted.

§ 53.4854 Application for renewal.

(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.

(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, under § 53.4851.

(c) The Commission shall refer a copy of the application for renewal to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 53.4857.

§ 53.4857 Criteria for renewal.

(a) The Commission shall issue a rule granting the renewal if the design, either as originally certified or as modified during the rulemaking on the renewal, complies with the Atomic Energy Act and the Commission's regulations applicable and in effect at the time the certification was issued.

(b) The Commission may impose other requirements if it determines that:

(1) They are necessary for adequate protection to public health and safety or common defense and security;

(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

(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.

(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.

(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.

§ 53.4860 Duration of renewal.

Each renewal of certification for a standard design will be for not less than 10, nor more than 15 years.

§ 53.4863 Finality of standard design certifications.

(a)(1) While a standard design certification rule is in effect under § 53.4851, the Commission may not modify, rescind, or impose new requirements on the certification

information, whether on its own motion or in response to a petition from any person, unless the Commission determines in a rulemaking that the change:

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

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

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

(iv) Is necessary to correct material errors in the certification information; or

(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.

(2)(i) In a rulemaking under § 53.4848, 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.

(ii) The rulemaking procedures for changes under § 53.4863(a)(1) must provide for notice and opportunity for public comment.

(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.

(4) The Commission may not impose new requirements by plant-specific order on any part of the design of a specific plant referencing the design certification rule if that part was approved in the design certification while a design certification rule is in effect under § 53.4851, 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 § 53.5052, the Commission shall treat as resolved those matters resolved in connection with the issuance or renewal of a design certification rule.

(b)(1) An applicant or licensee who references a design certification rule may request an exemption from one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080. In addition to the factors listed in § 53.080, the Commission shall consider whether the special circumstances that § 53.080 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. The granting of an exemption on request of an applicant is subject to litigation in the same manner as other issues in the operating license or combined license hearing.

(2) Subject to § 53.6050, a licensee who references a design certification rule may make departures from the design of the commercial nuclear plant, without prior Commission approval, unless the proposed departure involves a change to the design as described in the rule certifying the design. The licensee shall maintain records of all

departures from the commercial nuclear plant and these records must be maintained and available for audit until the date of termination of the license.

(c) The Commission will require, before granting a construction permit, combined license, operating license, or manufacturing license that references a design certification rule, 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. This information may be acquired by appropriate arrangements with the design certification applicant.

§ 53.4870 Manufacturing licenses.

Sections 53.4870 through 53.4895 set out the requirements and procedures applicable to Commission issuance of a license under 10 CFR Part 53 authorizing manufacture of multiple manufactured reactors or manufactured reactor module(s) to be installed at sites not identified in the manufacturing license application.

§ 53.4873 Filing of applications.

(a) Any person, except one excluded by § 53.4718, may file an application for a manufacturing license under this section with the Director, Office of Nuclear Reactor Regulation.

(b) Applicants for manufactured reactor module(s) for which fuel is to be installed at the manufacturer's facility and the manufactured reactor modules are to be

transported to a licensed site must also possess, apply for, or reference licenses and certifications required by 10 CFR parts 70 and 71.

§ 53.4876 Contents of applications for manufacturing licenses; general information.

Each application for a manufacturing license must include the information contained in § 53.4709 (a) through (e), and (j).

§ 53.4879 Contents of applications for manufacturing licenses; technical information.

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

(a) The principal design criteria and design bases of the manufactured reactor or manufactured reactor module(s) required by § 53.4730(a)(4);

(b) 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. All structures, systems, and components and manufactured reactor design features shall be discussed insofar as they are pertinent to the safety of the manufactured reactor or manufactured reactor module. These may include, but are not limited to: the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, and engineered safety features. The following power reactor design characteristics will be taken into consideration by the Commission:

(1) Intended use of the manufactured reactor or manufactured reactor module 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 manufactured reactor or manufactured reactor module; and

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

(c) The safety features that are to be engineered into the manufactured reactor or manufactured reactor module 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 as described in § 53.4730(a)(1)(vi) and that the manufactured reactor or manufactured reactor module is operated at the ultimate power level contemplated;

(d) 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) A description and analysis of the fire protection design features for the manufactured reactor or manufactured reactor module necessary to comply with the principal design criterion corresponding to criterion 3 of appendix A to part 50 of this chapter and § 53.4350;

(2) The list of electric equipment important to safety that is required by 10 CFR 53.4380(d);

(3) Information demonstrating how the applicant will comply with requirements for criticality accidents in § 53.4730(a)(32);

(4) For applicants that seek to use risk-informed treatment of SSCs in accordance with § 53.4731, the information required by § 53.4731(b)(2);

(5) 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 manufactured reactor or manufactured reactor module(s). Subpart U under Framework B of Part 53 sets forth the requirements for quality assurance programs for commercial nuclear plants licensed under Framework B of part 53. The description of the quality assurance program must include a discussion of how the applicable requirements of subpart U under Framework B of part 53 have been and will be satisfied;

(6) Proposed technical specifications applicable to the reactor being manufactured, prepared in accordance with the requirements of § 53.4730(a)(23);

(7) The site parameters postulated for the design, and an analysis and evaluation of the manufactured reactor or manufactured reactor module(s) design in terms of those site parameters;

(8) The interface requirements between the manufactured reactor or manufactured reactor module(s) and the remaining portions of the nuclear power plant.

These requirements must be sufficiently detailed to allow for completion of the final safety analysis;

(9) Justification that compliance with the interface requirements of paragraph (d)(8) 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 § 53.4882(a)(1);

(10) A representative conceptual design for a commercial nuclear plant using the manufactured reactor or manufactured reactor module, 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 (d)(8) of this section;

(11) If the manufactured reactor or manufactured reactor module is to be used in modular plant design, a description of the possible operating configurations of the manufactured 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;

(12) 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 or manufactured reactor module(s);

(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;

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

(14) The information required by:

(i) Paragraph (a)(3) of § 53.4730 – kinds and quantities of radioactive materials;

(ii) Paragraph (a)(5) of § 53.4730 – initiating events and accident analysis;

(iii) Paragraph (a)(7) of § 53.4730 – combustible gas control;

(iv) Paragraph (a)(8)(ii) of § 53.4730 – environmental qualification of electric equipment important to safety;

(v) Paragraph (a)(11) of § 53.4730 – effluent control;

(vi) Paragraph (a)(12) of § 53.4730 – post-accident radiation monitoring and protection ;

(vii) Paragraph (a)(14) of § 53.4730 – earthquake engineering criteria;

(viii) Paragraph (a)(17) of § 53.4730 – safety feature testing, analyses, operating experience, and prototypes;

(ix) Paragraph (a)(26) of § 53.4730 – technical qualifications;

(x) Paragraph (a)(30) of § 53.4730 – operating experience;

(xi) Paragraph (a)(33) of § 53.4730 – minimization of contamination;

(xii) Paragraph (a)(34) of § 53.4730 – description of risk evaluation;

(xiii) For applicants that do not reference a standard design certification or standard design approval, paragraph (a)(35) of § 53.4730 – aircraft impact assessment;

(xiv) Paragraph (a)(36) of § 53.4730 – functional containment;

(15) For water-cooled reactor applicants, the information required by:

(i) Paragraph (a)(37)(i) of § 53.4730 – emergency core cooling systems;

(ii) Paragraph (a)(37)(iii) of § 53.4730 – pressurized thermal shock and fracture toughness requirements;

(iii) Paragraph (a)(37)(iv) of § 53.4730 – anticipated transients without scram;

(iv) Paragraph (a)(37)(v) of § 53.4730 –station blackout;

(v) Paragraph (a)(37)(viii) of § 53.4730 –standard review plan evaluation;

(vi) Paragraph (a)(37)(ix) of § 53.4730 – resolution of generic issues; and

(vii) Paragraph (a)(37)(x) of § 53.4730 – Requirements from light-water-reactor operating experience.

(e) *Deployment of the completed manufactured reactor or manufactured reactor module.* The application must include the following information related to the deployment of a manufactured reactor or manufactured reactor module:

(1) Procedures governing the preparation of the manufactured reactor, portions of the manufactured reactor, or manufactured reactor module for shipping to the site where it is to be operated, the conduct of shipping, and verifying the condition of the shipped items upon receipt at the site;

(2) Details of the interaction of the design, manufacture, and installation of a manufactured reactor or manufactured reactor module within the applicant's organization and the manner by which the applicant will ensure close integration between the designer, contractors, and any facility in which the manufactured reactor or manufactured reactor module is to be installed;

(3) A description of the measures used for the control of interfaces, including the consideration of key site parameters, between the holder of the manufacturing license and the holder of the combined license for the commercial nuclear plant at which the manufactured reactor or manufactured reactor module is to be installed;

(f) *Special considerations for factory fueling.* In addition to the above paragraphs, an application for a manufacturing license for a manufactured reactor module that includes the installation of fuel at the factory must include the following information related to the fueling operations and the needed precautions to prevent inadvertent criticality and to otherwise ensure the safety of workers and the public during the manufacture, storage, and transport of each manufactured reactor module:

(1) A description of the safety program and integrated safety analysis required by subpart H of part 70 of this Chapter. The description shall include the procedures to be used for receipt, storage and loading of the fuel into the manufactured reactor module. The description may be in the form of a reference to the applicable Part 70 application and license, if issued, or within the safety analysis report supporting the manufacturing license if a combined application is used for the manufacturing license and Part 70 license.

(i) The application should specifically address the measures taken for fuel loading, in-factory inspections and testing, including precautions to be taken to prevent inadvertent criticality, and an analysis of the safety and security of the manufactured reactor module within the factory, during possible periods of storage, and during transportation to the licensed site. The storage and transport of a fueled manufactured reactor module must comply with applicable regulations in Parts 70, 71, and 73 of this chapter.

(ii) The application should specifically address the principal design criteria and design features included in the manufactured reactor module or physical or

programmatic controls implemented, during manufacturing, storage, or transport to prevent inadvertent criticality during various conditions, including when subject to potential hazards and human errors.

(2) A description of the procedures governing the transfer of authorities and responsibilities for the manufactured reactor module from the holder of the manufacturing license to the holder of the combined license for the installation site.

(3) A description of the controls needed to meet the requirements of § 53.4120 to address the receipt, storage, and loading of special nuclear material into a manufactured reactor module, including:

(i) The fitness for duty program, in accordance with § 53.4120(a)(5) and 10 CFR part 26.

(ii) A Radiation Protection Program in accordance with § 53.4120(a)(7).

(iii) An information security program in accordance with § 53.4120(a)(8).

(iv) A physical security program in accordance with § 53.4120(c)(5).

(v) A fire protection program in accordance with § 53.4120(c)(2).

(vi) An emergency plan in accordance with § 53.4120(c)(3).

(vii) A description of the plant staff training program in accordance with § 53.4120(d).

§ 53.4882 Contents of applications for manufacturing licenses; other application content.

In addition to the FSAR, the application must also include the following:

(a)(1) *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 § 53.4885(b) must indicate that the application includes this notification.

(b) *Environmental report.* (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 module as used in a commercial nuclear plant. Nonetheless, an application for a manufacturing license that references a standard design certification that includes the installation of fuel at the factory must discuss severe accident mitigation design alternatives for the reactor module while at the factory and must also discuss severe accident mitigation alternatives for the factory itself.

§ 53.4885 Review of applications.

(a) *Standards for review of applications.* Applications for manufacturing licenses under Framework B of this part will be reviewed according to the applicable standards set out in this subpart as well as applicable standards in 10 CFR parts 20, 25, 26, 51, 53, 70, 71, 73, and 75.

(b) *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 module 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.

§ 53.4886 Referral to 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 and shall apply the standards referenced in § 53.4885(a), in accordance with the finality provisions in § 53.4888.

§ 53.4887 Issuance of manufacturing license.

(a) After completing any hearing under § 53.4885(b) and receiving the report submitted by the ACRS, the Commission may issue a manufacturing license if the Commission finds that:

(1) Applicable standards and requirements of the Act and the Commission's regulations have been met;

(2) There is reasonable assurance that the manufactured reactor or manufactured reactor module(s) will be manufactured, and can be transported, incorporated into a commercial nuclear plant, and operated in conformity with the manufacturing license, the provision of the Act, and the Commission's regulations;

(3) The proposed manufactured reactor or manufactured reactor module(s) can be incorporated into a commercial nuclear plant and operated at sites having characteristics that fall within the site parameters postulated for the design of the manufactured reactor or manufactured reactor module(s) without undue risk to the health and safety of the public;

(4) The applicant is technically qualified to design and manufacture the proposed manufactured reactor or manufactured reactor module(s);

(5) The proposed inspections, tests, analyses and acceptance criteria are necessary and sufficient, within the scope of the manufacturing license, to provide reasonable assurance that the manufactured reactor or manufactured reactor module has been manufactured and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(6) The issuance of a license to the applicant will not be inimical to the common defense and security or to the health and safety of the public; and

(7) The findings required by subpart A of part 51 of this chapter have been made.

(b) Each manufacturing license issued under this subpart shall specify:

(1) Terms and conditions as the Commission deems necessary and appropriate;

(2) Technical specifications for operation of the manufactured reactor or manufactured reactor module, as the Commission deems necessary and appropriate;

(3) Site parameters and design characteristics for the manufactured reactor or manufactured reactor module(s); and

(4) The interface requirements to be met by the site-specific elements of the facility, such as the energy conversions systems and ultimate heat sink, not within the scope of the manufactured reactor or manufactured reactor module(s).

(c)(1) A holder of a manufacturing license may not transport or allow to be removed from the place of manufacture the manufactured reactor or manufactured reactor module except to the site for which the Commission has issued a combined license under Framework B of this part. The combined license must authorize the construction and operation of a nuclear power facility using the manufactured reactor or manufactured reactor module(s).

(2) A manufacturing license shall contain terms and conditions as the Commission deems necessary and appropriate, including the following:

(i) A holder of a manufacturing license shall include, in any contract governing the transport of a manufactured reactor, segments of the manufactured reactor, or manufactured reactor module(s) from the place of manufacture to any other location, a provision requiring that the person or entity transporting the items to comply with all NRC-approved shipping requirements in the manufacturing license or the NRC-issued license, certificate of compliance or other NRC approval for transporting a manufactured reactor module(s).

§ 53.4888 Finality of manufacturing licenses; information requests.

(a)(1) Notwithstanding any provision in § 53.6090, during the term of a manufacturing license issued under Framework B of this part the Commission may not modify, rescind, or impose new requirements on the design of the manufactured reactor or manufactured reactor module, or the requirements for the manufacture of the nuclear reactor manufactured reactor or manufactured reactor module, unless the Commission determines that a modification is necessary to bring the design of the reactor module or its manufacture into compliance with the Commission's requirements applicable and in effect at the time the manufacturing license was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.

(2) Any modification to the design of a manufactured reactor or manufactured reactor module(s) which is imposed by the Commission under paragraph (a)(1) of this section will be applied to all reactors manufactured under the license, including those that have already been transported and sited, except those reactor modules to which the modification has been rendered technically irrelevant by action taken under paragraph (b) of this section.

(3) In making the findings required under Framework B of this part for issuance of a combined license, in any hearing under § 53.5052, or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, for which a manufactured reactor or manufactured reactor module under this subpart is referenced or used, the Commission shall treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the manufacturing license, including the adequacy of design of the manufactured reactor or manufactured reactor module, the costs and benefits of severe accident mitigation design alternatives, and the bases for not incorporating severe accident mitigation design alternatives into the design of the manufactured reactor or manufactured reactor module to be manufactured.

(b) An applicant who references or uses a manufactured reactor or manufactured reactor module under a manufacturing license under Framework B of this part may include in the application a request for a departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor module.

§ 53.4891 Duration of manufacturing licenses.

A manufacturing license issued under Framework B of this part is valid for not less than 5, nor more than 15 years from the date of issuance. A holder of a manufacturing license under Framework B of this part may not initiate the manufacture of a reactor less than 3 years before the expiration of the license even though a timely application for renewal has been docketed with the NRC. Upon expiration of the manufacturing license, the manufacture of any uncompleted manufactured reactors or manufactured reactor modules must cease unless a timely application for renewal has been docketed with the NRC.

§ 53.4893 Transfer of manufacturing licenses.

A manufacturing license may be transferred under § 53.6070.

§ 53.4895 Renewal of manufacturing licenses.

(a)(1) Not less than 12 months, nor more than 5 years before the expiration of the manufacturing license, or any later renewal period, the holder of the manufacturing license issued under Framework B of this part may apply for a renewal of the license. An

application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(2) The filing of an application for a renewed license must be in accordance with subpart A of 10 CFR part 2 and § 53.4700.

(3) A manufacturing license issued under Framework B of this part, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has made a final determination on the renewal application, *provided, however*, that under § 53.4891, the holder of a manufacturing license may not begin manufacture of a manufactured reactor or manufactured reactor module(s) less than 3 years before the expiration of the license.

(4) Any person whose interest may be affected by renewal of the license 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 2.104.

(5) The Commission shall refer a copy of the application for renewal to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 53.4885.

(b) The Commission may grant the renewal if the Commission determines:

(1) The manufacturing license complies with the Atomic Energy Act, as amended, and the Commission's regulations and orders applicable and in effect at the time the manufacturing license was originally issued; and

(2) Any new requirements the Commission may wish to impose are:

(i) Necessary for adequate protection to public health and safety or common defense and security;

(ii) Necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the manufacturing license was originally issued; or

(iii) 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 implementation of those requirements are justified in view of this increased protection.

(c) A renewed manufacturing license may be issued for a term of not less than 5, nor more than 15 years, plus any remaining years on the manufacturing license then in effect before renewal. The renewed license shall be subject to the requirements of §§ 53.4888 and 53.4893.

§ 53.4900 Construction permits.

Sections 53.4900 through 53.4948 set out the requirements and procedures applicable to Commission issuance of a construction permit for commercial nuclear plants. A construction permit for the construction of a commercial nuclear plant under Framework B of this part will be issued before the issuance of an operating license if the application is otherwise acceptable and will be converted upon completion of the facility and Commission action, into an operating license as provided under §§ 53.4960 through 53.5005.

§ 53.4906 Contents of applications for construction permits; general information.

An application for a construction permit must include the information required by § 53.4709 and the following information:

(a) Except for an application submitted by an electric utility applicant, information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, under the regulations in this chapter, the activities for which the permit is sought. As applicable, the following should be provided:

(1) The information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs, including estimates of the total construction costs and related fuel cycle costs of the facility and shall indicate the source(s) of funds to cover these costs.

(2) Each application for a construction permit submitted by a newly-formed entity organized for the primary purpose of constructing and operating a facility must also include information showing:

(i) The legal and financial relationships the entity has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to meet any contractual obligation to the entity which they have incurred or proposed to incur; and

(iii) Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification.

(3) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding an applicant's ability to continue the conduct of the activities authorized by the construction permit and to decommission the facility.

(b) If the applicant proposes to construct or alter a facility, the application must state the earliest and latest dates for completion of the construction or alteration.

§ 53.4909 Contents of applications for construction permits; technical information.

(a) *Preliminary safety analysis report.* Each application for a construction permit shall include a preliminary safety analysis report. The PSAR shall include the following information, at a level of detail sufficient to enable the Commission to reach a conclusion on safety matters that must be resolved by the Commission before issuance of a construction permit:

(1) A summary description and discussion of the facility, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations.

(2) A facility description that satisfies the requirements associated with § 53.4730(a)(2). The assessment must contain an analysis and evaluation of the major structures, systems and components of the facility which bear significantly on the acceptability of the site under the site evaluation factors identified in part 100 of this chapter, assuming that the facility will be operated at the ultimate power level which is contemplated by the applicant. With respect to operation at the projected initial power level, the applicant is required to submit information prescribed in paragraphs (a)(4) through (a)(8) of this section, as well as the information required by § 53.4909(a)(2), in support of the application for a construction permit, or a design approval;

(3) the description and assessment of the site required in § 53.4730(a)(1);

(4) An identification and justification for the selection of those variables, conditions, or other items which are determined as the result of preliminary safety analysis and evaluation to be probable subjects of technical specifications for the facility, with special attention given to those items which may significantly influence the final design

(5) A preliminary plan for the applicant's organization, training of personnel, and conduct of operations.

(6) An identification of those structures, systems, or components of the facility, if any, which require research and development to confirm the adequacy of their design; and identification and description of the research and development program which will be conducted to resolve any safety questions associated with such structures, systems or components; and a schedule of the research and development program showing that such safety questions will be resolved at or before the latest date stated in the application for completion of construction of the facility.

(7) The information required by:

(i) Paragraph (a)(4) of § 53.4730 - design bases and principal design criteria;

(ii) Paragraph (a)(5) of § 53.4730 – initiating events and accident analysis;

(iii) Paragraph (a)(7) of § 53.4730 – combustible gas control;

(iv) Paragraph (a)(12) of § 53.4730 – post-accident radiation monitoring and protection;

(v) Paragraph (a)(14) of § 53.4730 – earthquake engineering criteria;

(vi) Paragraph (a)(15) of § 53.4730 – emergency plans;

(vii) Paragraph (a)(18) of § 53.4730 – quality assurance program;

(viii) Paragraph (a)(25) of § 53.4730 – multi-unit sites. In addition, the applicant shall provide information on potential hazards to safety of operating nuclear facilities from construction activities, as well as any managerial and administrative controls that will be used during construction to assure the safety of the operating unit(s);

(ix) Paragraph (a)(26) of § 53.4730 – technical qualifications;

(x) Paragraph (a)(32) of § 53.4730 – criticality accident requirements;

(xi) Paragraph (a)(34) of § 53.4730 – description of risk evaluation;

(xii) For applicants that do not reference a standard design certification, standard design approval, or manufactured reactor, paragraph (a)(35) of § 53.4730 – aircraft impact assessment;

(8) For water-cooled reactor applicants, the information required by:

(i) Paragraph (a)(37)(i) of § 53.4730– emergency core cooling systems;

(ii) Paragraph (a)(37)(ii) of § 53.4730 – codes and standards; and

(iii) Paragraph (a)(37)(x) of § 53.4730 – Requirements from light-water-reactor operating experience.

(b) Reserved.

§ 53.4912 Contents of applications for construction permits; other application content.

(a) In addition to the PSAR, the application must include the following:

(1) *Environmental report.*

(i) An environmental report either under 10 CFR 51.50(a) if a limited work authorization under § 53.4740 is not requested in conjunction with the construction permit application, or under §§ 51.49 and 51.50(a) of this chapter if a limited work authorization is requested in conjunction with the construction permit application.

(ii) If the applicant wishes to request that a limited work authorization under § 53.4740 be issued before issuance of the construction permit, the application must include the information otherwise required by § 53.4740, in accordance with either 10 CFR 2.101(a)(1) through (a)(4), or 10 CFR 2.101(a)(9).

(2) Reserved.

(b) If the construction permit application references an early site permit, standard design approval, manufacturing license, or standard design certification issued under Framework B, then the following requirements apply:

(1) The PSAR need not contain information or analyses submitted to the Commission in connection with the referenced NRC approval, license or certification, provided, however, that the PSAR incorporates the material by reference and where appropriate confirms that the site and design of the facility falls within parameter limits established in the approved standard design, license, or certification.

(2) The PSAR must provide a means to demonstrate that all terms and conditions that have been included in the referenced NRC approval, license, or certification will be satisfied by the date of issuance of the operating license, as appropriate. If the PSAR does not demonstrate that the site or design of the facility falls within the site characteristics and design parameters, the application shall include appropriate requests for a departure, variance, or exemption from the referenced NRC approval, license, or certification that complies with the requirements of Framework B of this part.

(3) If a referenced early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the PSAR must include any new or additional information that updates and corrects the information that was provided under § 53.4756(b)(2) and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements.

§ 53.4915 Review of applications.

(a) *Standards for review of applications.* Applications filed under this subpart will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53, 73, and 140.

(b) *Administrative review of applications; hearings.* A proceeding on a construction permit application is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). All hearings on construction permit applications are governed by the procedures contained in 10 CFR part 2.

§ 53.4924 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 that concern safety and shall apply the standards referenced in § 53.4915(a).

§ 53.4927 Authorization to conduct limited work authorization activities.

(a) If the application does not reference an early site permit which authorizes the holder to perform the activities under § 53.4740, the applicant may not perform those activities without obtaining the separate authorization required by § 53.4740. Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by § 53.4740(c)(1)(ii) and (iv), and the Director of the Office of Nuclear Reactor Regulation makes the determination required by §§ 53.4740(c)(1)(iii).

(b) If, after an applicant has performed the activities permitted by paragraph (a) of this section, the application for the construction permit is withdrawn or denied, then the applicant shall implement an approved site redress plan.

§ 53.4930 Exemptions, departures, and variances.

(a) Applicants for a construction permit under this subpart, or any amendment to a construction permit, may include in the application a request for an exemption from one or more of the Commission's regulations. The Commission may grant a request if it determines that the exemption complies with § 53.080.

(b) An applicant for a construction permit who has filed an application referencing an NRC approval, license, or certification issued under Framework B of this part may include in the application a request for departures, variances, or exemptions related to the subject referenced NRC approval, license, or certification. In determining whether to grant the departure, variance, or exemption, the Commission shall apply the same technically relevant criteria as were applicable to the application for the original or renewed approval, license, or certification.

§ 53.4933 Issuance of construction permits.

(a) After conducting a hearing in accordance with § 53.4915(b) and receiving the report submitted by the ACRS, the Commission may issue a construction permit. For applications that do not supply initially all of the technical information required to complete the application and support the issuance of a construction permit approving all proposed design features, the Commission may issue a construction permit only if the Commission finds that:

(1) the applicant has described the proposed design of the facility, including, but not limited to the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(2) such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;

(3) safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and

(4) on the basis of the foregoing, there is reasonable assurance that,

(i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and

(ii) taking into consideration the site criteria contained in part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(b) A construction permit shall contain the terms and conditions for the permit, as the Commission deems necessary and appropriate. The Commission may, in its discretion, incorporate in any construction permit provisions requiring the applicant to furnish periodic reports of the progress and results of research and development programs designed to resolve safety questions.

§ 53.4936 Finality of construction permits.

A construction permit constitutes an authorization to proceed with construction but does not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such approval is incorporated in the permit. The applicant, at its option, may request such approvals in the construction permit or by amendment to the construction permit. If approved by the

NRC and included in the permit, the NRC will consider modifications to the approved design features or specifications in accordance with § 53.6090.

§ 53.4939 Construction activities.

A construction permit holder must meet the requirements in § 53.4110 prior to beginning construction activities. The permit holder must notify NRC at least 30 days prior to the start of construction that all requirements described in § 53.4110 have been or will be met.

§ 53.4942 Duration of construction permit.

(a) A construction permit will state the earliest and latest dates for completion of construction or alteration of the facility, not to exceed 40 years from date of issuance;

(b) If the proposed construction or alteration of the facility is not completed by the latest completion date, the construction permit shall expire, and all rights forfeited.

However, upon good cause shown, the Commission will extend the completion date for a reasonable period of time. The Commission will recognize, among other things, developmental problems attributed to the experimental nature of the facility or fire, flood explosion, strike, sabotage, domestic violence, enemy action, an act of the elements and other acts beyond the control of the permit holder, as a basis for extending the completion date.

§ 53.4945 Transfer of construction permits.

A construction permit may be transferred under § 53.6070.

§ 53.4948 Termination of construction permits.

When a permit holder has determined to permanently cease construction, the holder shall, within 30 days, submit a written certification to the NRC.

§ 53.4960 Operating licenses.

Sections 53.4960 through 53.5005 set out the requirements and procedures applicable to Commission issuance of an operating license for a nuclear power facility.

§ 53.4966 Contents of applications for operating licenses; general information.

An application for an operating license must include the information required by § 53.4709 and the following information:

(a) Except for an electric utility applicant, information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with regulations in this chapter, the activities for which the license is sought. As applicable, the following should be provided:

(1) The applicant shall submit information that demonstrates the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant shall submit estimates for total annual operating costs for each of the first five years of operation of the facility. The applicant shall also indicate the source(s) of funds to cover these costs.

(2) Each application for an operating license submitted by a newly-formed entity organized for the primary purpose of operating the facility must also include information showing:

(i) The legal and financial relationships the entity has or proposes to have with its stockholders or owners; and

(ii) The stockholders' or owners' financial ability to meet any contractual obligation to the entity which they have incurred or proposed to incur.

(3) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(b) Information in the form of a report, as described in Subpart Q, indicating how reasonable assurance will be provided that funds will be available to decommission the facility.

§ 53.4969 Contents of applications for operating licenses; technical information.

(a) *Final safety analysis report.* Each application for an operating license shall include a final safety analysis report. The final safety analysis report shall include information 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 shall include the following:

(1) *Current information relating to site evaluation.* All current information, such as the results of environmental and meteorological monitoring programs, which has been developed since issuance of the construction permit, relating to site evaluation factors identified in part 100 of this chapter.

(2) *Facility description.* A final description and analysis of the structures, systems, and components of the facility in accordance with § 53.4730(a)(2).

(3) *Kinds and quantities of radioactive materials.* The information necessary to address the requirements in accordance with § 53.4730(a)(3) of this subpart.

(4) *Initiating events and accident analysis.* A final analysis and evaluation of the design and performance of structures, systems, and components with the objective stated in §§ 53.4730(a)(2) and (5) and taking into account any pertinent information developed since the submittal of the preliminary safety analysis report.

(5) *Research and development.* A description and evaluation of the results of the applicant's programs, including research and development, if any, to demonstrate that any safety questions identified at the construction permit stage have been resolved.

(6) The following information concerning facility operation:

(i) *Role of personnel.* The information necessary to address the requirements for personnel in § 53.4730(a)(9) of this subpart.

(ii) *Integrity assessment program.* A description of an Integrity Assessment Program that addresses the elements described in § 53.4400.

(iii) *Emergency plans.* The information necessary to address the requirements for emergency plans in § 53.4730(a)(15) of this subpart.

(iv) *State and local government cooperation.* The information necessary to address the requirements for state and local government cooperation in § 53.4730(a)(16) of this subpart.

(v) *Organizational structure.* The information necessary to address the requirements for organizational structure in § 53.4730(a)(19) of this subpart.

(vi) The information necessary to address the requirements for managerial and administrative controls in § 53.4730(a)(20) of this subpart.

(vii) *Preoperational testing and initial startup*. The information necessary to address the requirements for preoperational testing and initial startup in § 53.4730(a)(21) of this subpart.

(viii) *Normal operations and maintenance*. The information necessary to address the requirements for normal operations and maintenance in § 53.4730(a)(22)(i) of this subpart.

(ix) *Plans for coping with emergencies*. The information necessary to address the requirements for plans for coping with emergencies in § 53.4730(a)(22)(ii) of this subpart.

(x) *Quality assurance*. The information necessary to address the requirements for the applicant's quality assurance program in § 53.4730(a)(18);

(xi) *Technical specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.4730(a)(23).

(xii) *Fitness for duty*. The information necessary to address the requirements for fitness for duty programs in § 53.4730(a)(24) of this subpart.

(xiii) *Training program*. The information necessary to address the requirements for training programs in accordance with § 53.4730(a)(27) of this subpart.

(xiv) *Radiation protection*. A description of the radiation protection program in accordance with § 53.4730(a)(31);

(xv) *Maintenance rule*. A description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of § 53.4730(a)(10).

(xvi) *Risk-informed SSC classification*. For applicants that seek to use risk-informed treatment of SSCs in accordance with § 53.4731 of this chapter, the information required by § 50.4731(b)(2) of this chapter.

(7) The information required by:

(i) Paragraph (a)(4) of § 53.4730 – design bases and principal design criteria;

(ii) Paragraph (a)(6) of § 53.4730 – fire protection;

(iii) Paragraph (a)(7) of § 53.4730 – combustible gas control;

(iv) Paragraph (a)(8) of § 53.4730 – environmental qualification of electric equipment important to safety;

(v) Paragraph (a)(11) of § 53.4730 – effluent control;

(vi) Paragraph (a)(12) of § 53.4730 – post-accident radiation monitoring and protection;

(vii) Paragraph (a)(14) of § 53.4730 – earthquake engineering criteria;

(viii) Paragraph (a)(17) of § 53.4730 – safety feature testing, analyses, operating experience, and prototypes;

(ix) Paragraph (a)(25) of § 53.4730 – multi-unit sites;

(x) Paragraph (a)(26) of § 53.4730 – technical qualifications;

(xi) Paragraph (a)(33) of § 53.4730 – minimization of contamination;

(xii) Paragraph (a)(34) of § 53.4730 – description of risk evaluation;

(xiii) Paragraph (a)(35) of § 53.4730 – aircraft impact assessment;

(xiv) Paragraph (a)(36) of § 53.4730 – functional containment;

(8) For water-cooled reactor applicants, the information required by:

- (i) Paragraph (a)(37)(i) of § 53.4730– emergency core cooling systems;
 - (ii) Paragraph (a)(37)(ii) of § 53.4730 – codes and standards;
 - (iii) Paragraph (a)(37)(iii) of § 53.4730 – pressurized thermal shock and fracture toughness requirements;
 - (iv) Paragraph (a)(37)(iv) of § 53.4730 – anticipated transients without scram;
 - (v) Paragraph (a)(37)(v) of § 53.4730 – station blackout;
 - (vi) Paragraph (a)(37)(vi) of § 53.4730 – reactor vessel material surveillance;
 - (vii) Paragraph (a)(37)(vii) of § 53.4730 – containment leakage testing;
 - (viii) Paragraph (a)(37)(ix) of § 53.4730 – resolution of generic issues; and
 - (ix) Paragraph (a)(37)(x) of § 53.4730 – Requirements from light-water-reactor operating experience.
- (b) Reserved.

§ 53.4972 Contents of applications for operating licenses; other application content.

- (a) In addition to the FSAR, the application must also include the following:
- (1) *Environmental report.* An environmental report in accordance with 10 CFR 51.53(b).
 - (2) *Physical security plan.* A description of the physical security plan and associated requirements in accordance with § 53.4730(a)(28);
 - (3) *Safeguards, security, and related training and qualifications.* A description of the safeguards contingency plan and associated requirements in accordance with § 53.4730(a)(29);

(4) *Protection against unauthorized disclosure.* Each applicant for an operating license for a production or utilization facility, 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.

(5) *Mitigation of beyond-design-basis events.* Each application for a commercial nuclear plant operating license under Framework B of this part that does not meet the criteria in § 53.4730(a)(34)(ii) must include the applicant's plans for implementing the requirements of § 50.155, including a schedule for achieving full compliance with these requirements and a description of the equipment upon which the strategies and guidelines required by § 50.155(b)(1) rely, including the planned locations of the equipment and how the equipment meets the requirements of § 50.155(c).

(b) Reserved.

§ 53.4975 Review of applications.

(a) *Standards for review of applications.* Applications filed under this subpart will be reviewed according to the standards set out in 10 CFR parts 20, 26, 51, 53, 73, and 140. Upon receipt of an application, the NRC will:

(1) Give notice in writing to the regulatory agency or State as may have jurisdiction over the rates and services incident to the proposed activity;

(2) Publish notice of the application in trade or news publications as appropriate to give reasonable notice to municipalities, private utilities, public bodies and cooperatives which might have a potential interest in the facility;

(3) Publish notice of the application once each week for 4 consecutive weeks in the *Federal Register*.

(b) *Administrative review of applications; hearings.* A proceeding on an operating license is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). All hearings on operating licenses are governed by the procedures contained in 10 CFR part 2.

§ 53.4981 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 that concern safety and shall apply the standards referenced in § 53.4975(a).

§ 53.4984 Exemptions, departures, and variances.

(a) Applicants for an operating license under this subpart, or any amendment to an operating license, may include in the application a request for an exemption from one or more of the Commission's regulations. The Commission may grant an exemption request if it determines that the exemption complies with § 53.080.

(b) An applicant for an operating license who has filed an application referencing a NRC approval, permit, license, or certification issued under Framework B of this part may include in the application a request for departures, variances, or exemptions related to the subject referenced NRC approval, permit, license, or certification. In determining whether to grant the departure, variance, or exemption, the Commission shall apply the same technically relevant criteria as were applicable to the application for the original or renewed approval, license, or certification.

§ 53.4987 Issuance of operating licenses.

(a)(1) After receiving the report submitted by the ACRS, the Commission may issue an operating license if the Commission finds that:

(i) Construction of the facility has been substantially completed, in conformity with the construction permit and the application as amended, the provisions of the Act, and the rules and regulations of the Commission;;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) The facility will operate in conformity with the application as amended, the provisions of the Act, and the rules and regulations of the Commission;

(iv) There is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the regulations in this chapter;

(v) The applicant is technically and financially qualified to engage in the activities authorized, however, no finding of financial qualification is necessary for an electric utility applicant for an operating license;

(vi) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public;

(vii) The applicable provisions of Part 140 of this chapter have been satisfied;
and

(viii) The findings required by subpart A of part 51 of this chapter have been made.

(2) [Reserve]

(b) Fuel loading may not begin until the operating license is issued.

(c) The operating license may include appropriate provisions with respect to any uncompleted items of construction and such limitations or conditions as are required to assure that operation during the period of the completion of such items will not endanger public health and safety.

(d) The Commission will issue a license in such form and containing such conditions and limitations, including technical specifications, as it deems appropriate and necessary.

§ 53.4990 Finality of operating licenses.

After issuance of an operating license, the Commission may not modify, add, or delete any term or condition of the operating license, the design of the facility, except in accordance with the provisions of § 53.6090(c) of this part.

§ 53.4996 Duration of operating license.

The Commission will issue an operating license under Framework B of this part for the term requested by the applicant, not to exceed 40 years from the date of issuance, or for the estimated useful life of the facility if the Commission determines that the estimated useful life is less than the term requested.

§ 53.4999 Transfer of an operating license.

An operating license may be transferred in accordance with § 53.6070.

§ 53.5002 Application for renewal.

The filing of an application for a renewed license must be in accordance with § 53.6095.

§ 53.5005 Continuation of an operating license.

Each operating license for a facility that has permanently ceased operations, continues in effect beyond the expiration date to authorize ownership and possession of the facility, until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness, the licensee shall:

(a) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control and maintenance of the spent fuel, in a safe condition; and

(b) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the operating license for the facility.

§ 53.5010 Combined licenses.

Sections 53.5010 through 53.5061 set out the requirements and procedures applicable to Commission issuance of combined licenses for commercial nuclear plants under Framework B of this part.

§ 53.5013 Contents of applications for combined licenses; general information.

An application for a combined license must include the information required by § 53.4709 and the following information:

(a) Except for an electric utility applicant, information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with the regulations in this chapter, the activities for which the permit or license is sought. As applicable, the following should be provided:

(1) The applicant must submit information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs. The applicant must submit estimates of the total construction costs of the facility and related fuel cycle costs and must indicate the source(s) of funds to cover these costs.

(2) The applicant must submit information that demonstrates the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant must submit estimates for total annual operating costs for each of the first five years of operation of the facility. The applicant must also indicate the source(s) of funds to cover these costs.

(3) Each application for a combined license submitted by a newly-formed entity organized for the primary purpose of constructing and operating a facility must also include information showing:

(i) The legal and financial relationships the entity has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to meet any contractual obligation to the entity which they have incurred or proposed to incur.

(4) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(b) Information in the form of a report, as described in Subpart Q of this part, indicating how reasonable assurance will be provided that funds will be available to decommission the facility.

§ 53.5016 Contents of applications for combined licenses; technical information.

(a) The application must contain a 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 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) The information related to site characteristics necessary to address requirements in § 53.4730(a)(1) of this subpart.

(2) The information for the facility necessary to address requirements in § 53.4730(a)(2) of this subpart.

(3) The following information concerning facility operation:

(i) *Role of personnel.* The information necessary to address the requirements associated with personnel in § 53.4730(a)(9) of this subpart.

(ii) *Integrity assessment program.* A description of an Integrity Assessment Program that addresses the elements described in § 53.4400.

(iii) *Emergency plans.* The information necessary to address the requirements for emergency plans in § 53.4730(a)(15) of this subpart.

(iv) *State and local government cooperation.* The information necessary to address the requirements for state and local government cooperation in § 53.4730(a)(16) of this subpart.

(v) *Quality assurance.* The information necessary to address the requirements for the applicant's quality assurance program in § 53.4730(a)(18);

(vi) *Organizational structure.* The information necessary to address the requirements for organizational structure in § 53.4730(a)(19) of this subpart.

(vii) The information necessary to address the requirements for managerial and administrative controls in § 53.4730(a)(20) of this subpart.

(viii) *Preoperational testing and initial startup.* The information necessary to address the requirements for preoperational testing and initial startup in § 53.4730(a)(21) of this subpart.

(ix) *Normal operations and maintenance.* The information necessary to address the requirements for normal operations and maintenance in § 53.4730(a)(22)(i) of this subpart.

(x) *Plans for coping with emergencies.* The information necessary to address the requirements for plans for coping with emergencies in § 53.4730(a)(22)(ii) of this subpart.

(xi) *Technical specifications.* Proposed technical specifications prepared in accordance with the requirements of § 53.4730(a)(23).

(xii) *Fitness for duty.* The information necessary to address the requirements for fitness for duty programs in § 53.4730(a)(24) of this subpart.

(xiii) *Training program.* The information necessary to address the requirements for training programs in § 53.4730(a)(27) of this subpart.

(xiv) *Radiation protection.* Radiation protection program in § 53.4730(a)(31)

(xv) *Maintenance rule.* A description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of § 53.4730(a)(10).

(xvi) *Risk-informed SSC classification*. For applicants that seek to use risk-informed treatment of SSCs in accordance with § 53.4731 of this chapter, the information required by § 50.4731(b)(2).

(4) The information required by:

(i) Paragraph (a)(3) of § 53.4730 – kinds and quantities of radioactive materials;

(ii) Paragraph (a)(4) of § 53.4730 – design bases and principal design criteria;

(iii) Paragraph (a)(5) of § 53.4730 – initiating events and accident analysis;

(iv) Paragraph (a)(6) of § 53.4730 – fire protection;

(v) Paragraph (a)(7) of § 53.4730 – combustible gas control;

(vi) Paragraph (a)(8) of § 53.4730 – environmental qualification of electric equipment important to safety;

(vii) Paragraph (a)(11) of § 53.4730 – effluent control;

(viii) Paragraph (a)(12) of § 53.4730 – post-accident radiation monitoring and protection;

(ix) Paragraph (a)(14) of § 53.4730 – earthquake engineering criteria;

(x) Paragraph (a)(17) of § 53.4730 – safety feature testing, analyses, operating experience, and prototypes;

(xi) Paragraph (a)(25) of § 53.4730 – multi-unit sites;

(xii) Paragraph (a)(26) of § 53.4730 – technical qualifications;

(xiii) Paragraph (a)(30) of § 53.4730 – operating experience;

(xiv) Paragraph (a)(32) of § 53.4730 – criticality accident requirements;

(xv) Paragraph (a)(33) of § 53.4730 – minimization of contamination;

(xvi) Paragraph (a)(34) of § 53.4730 – description of risk evaluation;

(xvii) For applicants that do not reference a standard design certification, standard design approval, or manufacturing license, paragraph (a)(35) of § 53.4730 – aircraft impact assessment;

(xviii) Paragraph (a)(36) of § 53.4730 – functional containment;

(5) For water-cooled reactor applicants, the information required by:

(i) Paragraph (a)(37)(i) of § 53.4730 – emergency core cooling systems;

(ii) Paragraph (a)(37)(ii) of § 53.4730 – codes and standards;

(iii) Paragraph (a)(37)(iii) of § 53.4730 – pressurized thermal shock and fracture toughness requirements;

(iv) Paragraph (a)(37)(iv) of § 53.4730 – anticipated transients without scram;

(v) Paragraph (a)(37)(v) of § 53.4730 – station blackout;

(vi) Paragraph (a)(37)(vi) of § 53.4730 – reactor vessel material surveillance;

(vii) Paragraph (a)(37)(vii) of § 53.4730 – containment leakage testing;

(viii) Paragraph (a)(37)(ix) of § 53.4730 – resolution of generic issues; and

(ix) Paragraph (a)(37)(x) of § 53.4730 – Requirements from light-water-reactor operating experience.

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

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the early site permit provided that the FSAR either include or incorporate by reference the early site permit site safety analysis report and 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 FSAR does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application must include a request for a variance that complies with the requirements of §§ 53.4798(d) and 53.5037.

(3) The FSAR must demonstrate that all terms and conditions that have been included in the early site permit 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 FSAR must include any new or additional information that updates and corrects the information that was provided under § 53.4756(b)(2) 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 change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.

(5) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(3)(iii) of this section are not required.

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

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the design approval, provided, however, that the FSAR

must either include or incorporate by reference the standard design approval FSAR 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 risk evaluation information must use the risk evaluation information for the design approval and must be updated to account for site specific design information and any design changes or departures.

(2) The FSAR must demonstrate that all terms and conditions that have been included in the 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 FSAR need not contain information or analyses submitted to the Commission in connection with the standard design certification, provided, however, that the FSAR must either include or incorporate by reference the standard design certification FSAR 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 standard design certification. In addition, the plant specific risk evaluation information must use the risk evaluation information for the standard design certification and must be updated to account for site-specific design information and any design changes or departures.

(2) The FSAR must demonstrate that the interface requirements established for the design under § 53.4839(a)(4) have been met.

(3) The FSAR must demonstrate that all requirements and restrictions set forth in the referenced standard design certification rule must be satisfied by the date of

issuance of the combined license. Any requirements and restrictions set forth in the referenced standard 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 § 53.4870 of this part, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the manufacturing license, provided, however, that the FSAR must either include or incorporate by reference the manufacturing license FSAR 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 risk evaluation information must use the risk evaluation information for the manufactured reactor and must be updated to account for site-specific design information and any design changes or departures.

(2) The FSAR must demonstrate that the interface requirements established for the design have been met.

(3) The FSAR must demonstrate that all terms and conditions that have been included in the manufacturing license 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 part must protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

§ 53.5019 Contents of applications for combined licenses; other application content.

(a) In addition to the FSAR, the application must also include the following:

(1) *Environmental report.* (i) An environmental report either in accordance with 10 CFR 51.50(c) if a limited work authorization under § 53.4740 is not requested in conjunction with the combined license application, or in accordance with §§ 51.49 and 51.50(c) of this chapter if a limited work authorization is requested in conjunction with the combined license application.

(ii) If the applicant wishes to request that a limited work authorization under § 53.4740 be issued before issuance of the combined license, the application must include the information otherwise required by § 53.4740, in accordance with either 10 CFR 2.101(a)(1) through (a)(4), or 10 CFR 2.101(a)(9).

(2) *Physical security plan.* A description of the physical security plan and associated requirements in accordance with § 53.4730(a)(28);

(3) *Safeguards, security, and related training and qualifications.* A description of the safeguards contingency plan and associated requirements in accordance with § 53.4730(a)(29);

(4) *ITAAC.* 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, the provisions of the Act, and the Commission's rules and regulations.

(i) If the application references an early site permit with ITAAC, the early site permit ITAAC must apply to those aspects of the combined license which are approved in the early site permit.

(ii) 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 approved in the standard design certification.

(iii) If the application references an early site permit with ITAAC or a standard design certification or both, the application may include a notification that a required inspection, test, or analysis in the ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The Federal Register notification required by § 52.85 must indicate that the application includes this notification.

(5) *Mitigation of beyond-design-basis events.* Each application under Framework B of this part that does not meet the criteria in § 53.4730(a)(34)(ii) must include the applicant's plans for implementing the requirements of § 50.155, including a schedule for achieving full compliance with these requirements and a description of the equipment upon which the strategies and guidelines required by § 50.155(b)(1) rely, including the planned locations of the equipment and how the equipment meets the requirements of § 50.155(c).

§ 53.5022 Review of applications.

(a) *Standards for review of applications.* Applications filed under this subpart will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53, 73, and 140.

(b) *Administrative review of applications; hearings.* A proceeding on a combined license is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (10 CFR 2.101) and issuance of a notice of hearing (10 CFR 2.104). If an applicant requests a Commission finding on certain ITAAC with the issuance of the combined license, then those ITAAC will be identified in the notice of hearing. All hearings on combined licenses are governed by the procedures contained in 10 CFR part 2.

§ 53.5025 Finality of referenced NRC approvals.

If the application for a combined license under Framework B of this part references an early site permit, standard design certification rule, standard design approval, or manufacturing license, issued under Framework B of this part, the scope and nature of matters resolved for the application and any combined license issued are governed by the relevant provisions addressing finality, including §§ 53.4798, 53.4863, 53.4821, and 53.4888.

§ 53.5031 Referral to the Advisory Committee on Reactor Safeguards.

The Commission shall refer a copy of the application to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS must report on those portions of the application that concern safety and shall apply the standards referenced in § 53.5022(a), in accordance with the finality provisions in § 53.5025.

§ 53.5034 Authorization to conduct limited work authorization activities.

(a) If the application for a combined license under Framework B of this part does not reference an early site permit which authorizes the holder to perform the activities under § 53.4740(b), the applicant may not perform those activities without obtaining the separate authorization required by § 53.4740(a). Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by § 53.4740(c)(1)(ii) and (c)(1)(iv), and the Director of the Office of Nuclear Reactor Regulation makes the determination required by § 53.4740(c)(1)(iii).

(b) If, after an applicant has performed the activities permitted by paragraph (a) of this section, the application for the combined license is withdrawn or denied, then the applicant must implement the approved site redress plan.

§ 53.5037 Exemptions, departures, and variances.

(a) Applicants for a combined license under this subpart, or any amendment to a combined license, may include in the application a request for an exemption from one or more of the Commission's regulations.

(1) If the request is for an exemption from any part of a referenced standard design certification rule, the Commission may grant the request if it determines that the exemption complies with any exemption provisions of the referenced standard design certification rule, or with § 53.4863 if there are no applicable exemption provisions in the referenced standard design certification rule.

(2) For all other requests for exemptions, the Commission may grant a request if it determines that the exemption complies with § 53.080.

(b) An applicant for a combined license who has filed an application referencing an early site permit issued under § 53.4768 of this part may include in the application a request for a variance from one or more site characteristics, design parameters, or terms

and conditions of the permit, or from the site safety analysis report. In determining whether to grant the variance, the Commission shall apply the same technically relevant criteria as were applicable to the application for the original or renewed site permit. Once a 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.

(c) An applicant for a combined license who has filed an application referencing a nuclear power reactor manufactured under a manufacturing license issued under § 53.4870 of this part may include in the application a request for a departure from one or more design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant a request only if it determines that the departure will comply with the requirements of § 53.080, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure.

(d) Issuance of a variance under paragraph (b) or a departure under paragraph (c) of this section is subject to litigation during the combined license proceeding in the same manner as other issues material to that proceeding.

§ 53.5040 Issuance of combined licenses.

(a)(1) After conducting a hearing in accordance with § 53.5022(b) and receiving the report submitted by the ACRS, the Commission may issue a combined license if the Commission finds that:

(i) The applicable standards and requirements of the Act and the Commission's regulations have been met;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) There is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission's regulations;

(iv) The applicant is technically and financially qualified to engage in the activities authorized, however, no finding of financial qualification is necessary for an electric utility applicant for a combined license;

(v) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public; and

(vi) The findings required by subpart A of part 51 of this chapter have been made.

(2) The Commission may also find, at the time it issues the combined license, that certain acceptance criteria in one or more of the ITAAC in a referenced early site permit or standard design certification have been met. This finding will finally resolve that those acceptance criteria have been met, those acceptance criteria will be deemed to be excluded from the combined license, and findings under § 53.5052(g) with respect to those acceptance criteria are unnecessary.

(b) The Commission shall identify within the combined license the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee must perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's rules and regulations.

(c) A combined license must contain the terms and conditions, including technical specifications, as the Commission deems necessary and appropriate.

§ 53.5043 Finality of combined licenses.

(a) After issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license which are not derived from a referenced standard design certification or manufacturing license, except in accordance with the provisions of §§ 53.5052 or 53.6090.

(b) If the combined license does not reference a standard design certification or a reactor manufactured under § 53.4870 of this part, then a licensee may make changes in the facility as described in the FSAR (as updated), make changes in the procedures as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated) under the applicable change processes in Subpart S of this part.

(c) If the combined license references a certified design, then—

(1) Changes to or departures from information within the scope of the referenced design certification rule are subject to the applicable change processes in that rule; and

(2) Changes that are not within the scope of the referenced design certification rule are subject to the applicable change processes in Subpart S of this part, unless they also involve changes to or noncompliance with information within the scope of the referenced design certification rule. In these cases, the applicable provisions of this section and the design certification rule apply.

(d) If the combined license references a reactor manufactured under a manufacturing license under Framework B of this part, then—

(1) Changes to or departures from information within the scope of the manufactured reactor's design are subject to the change processes in § 53.4888; and

(2) Changes that are not within the scope of the manufactured reactor's design are subject to the applicable change processes in Subpart S.

(e) The Commission may issue and make immediately effective any amendment to a combined license upon a determination by the Commission that the amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person. The amendment may be issued and made immediately effective in advance of the holding and completion of any required hearing. The amendment will be processed in accordance with the procedures specified in § 53.6015.

(f) Any modification to, addition to, or deletion from the terms and conditions of a combined license, including any modification to, addition to, or deletion from the inspections, tests, and analyses, or related acceptance criteria contained in the license is a proposed amendment to the license. There must be an opportunity for a hearing on the amendment.

§ 53.5046 Construction activities.

A combined license holder must meet the requirements in § 53.4110 prior to beginning construction activities. The licensee holder must notify the NRC at least 30 days prior to the beginning of construction that all requirements described in § 53.4110 have been addressed.

§ 53.5049 Inspection during construction.

(a) *Licensee schedule for inspections, tests, or analyses.* The licensee must submit to the NRC, no later than 1 year after issuance of the combined license or at the

start of construction as defined at § 53.020, whichever is later, its schedule for completing the inspections, tests, or analyses in the ITAAC. The licensee must submit updates to the ITAAC schedules every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, the licensee must submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under paragraph (c)(1) of this section.

(b) *Licensee and applicant conduct of activities subject to ITAAC.* With respect to activities subject to an ITAAC, an applicant for a combined license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any one of the prescribed acceptance criteria are met.

(c) *Licensee notifications* – (1) *ITAAC closure notification.* The licensee must notify the NRC that prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria are met. The notification must contain sufficient information to demonstrate that the ITAAC activities have been performed and that the prescribed acceptance criteria are met.

(2) *ITAAC post-closure notifications.* Following the licensee's ITAAC closure notifications under paragraph (c)(1) of this section until the Commission makes the finding under § 53.5052(g), the licensee must notify the NRC, in a timely manner, of new information that materially alters the basis for determining that either inspections, tests, and analyses were performed as required, or that acceptance criteria are met. The notification must either contain sufficient information to demonstrate that, notwithstanding the new information, the prescribed inspections, tests, and analyses have been performed as required, and the prescribed acceptance criteria are met or provide a projected date for when such information will be available.

(3) *Uncompleted ITAAC notification.* If the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by paragraph (c)(1) of this section for all ITAAC, then the licensee must notify the NRC that the prescribed inspections, tests, and analyses for all uncompleted ITAAC will be performed and that the prescribed acceptance criteria will be met prior to operation. The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the prescribed inspections, tests, and analyses will be performed and the prescribed acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the prescribed inspections, tests, and analyses and determining that the prescribed acceptance criteria are met.

(4) *All ITAAC complete notification.* The licensee must notify the NRC that all ITAAC activities are complete.

(d) *Licensee determination of noncompliance with ITAAC.* (1) In the event that an activity is subject to a ITAAC derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request an exemption from the standard design certification ITAAC, as applicable. A request for an exemption must also be accompanied by a request for a license amendment under Subpart S of this part.

(2) In the event that an activity is subject to an ITAAC not derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request a license amendment under Subpart S of this part.

(e) *NRC inspection, publication of notices, and availability of licensee notifications.* The NRC shall ensure that the prescribed inspections, tests, and analyses in the ITAAC are performed.

(1) At appropriate intervals until the last date for submission of requests for hearing under § 53.5052(g), the NRC shall publish notices in the *Federal Register* of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

(2) The NRC shall make publicly available the licensee notifications under paragraph (c) of this section. The NRC shall, no later than the date of publication of the notice of intended operation required by § 53.5052(a), make publicly available those licensee notifications under paragraph (c) of this section that have been submitted to the NRC at least seven (7) days before that notice.

§ 53.5052 Operation under a combined license.

(a) The licensee must notify the NRC of its scheduled date for initial loading of fuel no later than 270 days before the scheduled date and must notify the NRC of updates to its schedule every 30 days thereafter. Not less than 180 days before the date scheduled for initial loading of fuel into a plant by a licensee that has been issued a combined license under Framework B of this part, the Commission shall publish notice of intended operation in the *Federal Register*. The notice must provide that any person whose interest may be affected by operation of the plant may, within 60 days, request that the Commission hold a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria in the combined license, except that a hearing shall not be granted for those ITAAC which the Commission found were met under § 53.5040(a)(2).

(b) A request for hearing under paragraph (a) of this section must show, *prima facie*, that—

(1) One or more of the acceptance criteria of the ITAAC in the combined license have not been, or will not be, met; and

(2) The specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety.

(c) The Commission, acting as the presiding officer, shall determine whether to grant or deny the request for hearing in accordance with the applicable requirements of 10 CFR 2.309. If the Commission grants the request, the Commission, acting as the presiding officer, shall determine whether during a period of interim operation there will be reasonable assurance of adequate protection to the public health and safety. The Commission's determination must consider the petitioner's *prima facie* showing and any answers thereto. If the Commission determines there is such reasonable assurance, it shall allow operation during an interim period under the combined license.

(d) The Commission, in its discretion, shall determine appropriate hearing procedures, whether informal or formal adjudicatory, for any hearing under paragraph (a) of this section, and shall state its reasons therefore.

(e) The Commission shall, to the maximum possible extent, render a decision on issues raised by the hearing request within 180 days of the publication of the notice provided by paragraph (a) of this section or by the anticipated date for initial loading of fuel into the reactor, whichever is later.

(f) A petition to modify the terms and conditions of the combined license will be processed as a request for action in accordance with 10 CFR 2.206. The petitioner shall file the petition with the Secretary of the Commission. Before the licensed activity allegedly affected by the petition (fuel loading, low power testing, etc.) commences, the

Commission shall determine whether any immediate action is required. If the petition is granted, then an appropriate order will be issued. Fuel loading and operation under the combined license will not be affected by the granting of the petition unless the order is made immediately effective.

(g) The licensee must not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met, except for those acceptance criteria that the Commission found were met under § 53.5040(a)(2). If the combined license is for a modular design, each reactor module may require a separate finding as construction proceeds.

(h) After the Commission has made the finding in paragraph (g) of this section, the ITAAC do not, by virtue of their inclusion in the combined license, constitute regulatory requirements either for licensees or for renewal of the license; except for the specific ITAAC for which the Commission has granted a hearing under paragraph (a) of this section, all ITAAC expire upon final Commission action in the proceeding. However, subsequent changes to the facility or procedures described in the FSAR (as updated) must comply with the requirements in § 53.5043(e) or (f), as applicable.

§ 53.5055 Duration of combined license.

A combined license is issued for a specified period not to exceed 40 years from the date on which the Commission makes a finding that acceptance criteria are met under § 53.5052(g) or allowing operation during an interim period under the combined license under § 53.5052(c).

§ 53.5056 Transfer of a combined license.

A combined license may be transferred under § 53.6070.

§ 53.5058 Application for renewal.

The filing of an application for a renewed license must be in accordance with § 53.6095.

§ 53.5061 Continuation of combined license.

Each combined license for a facility that has permanently ceased operations, continues in effect beyond the expiration date to authorize ownership and possession of the facility, until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness, the licensee must—

(a) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control and maintenance of the spent fuel, in a safe condition; and

(b) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the combined license for the facility.

§ 53.5070 Standardization of commercial nuclear power plant designs: licenses to construct and operate nuclear power reactors of identical design at multiple sites.

(a) Except as otherwise specified in this section or as the context otherwise indicates, the provisions of this subpart apply to construction permit, operating license, and combined license applications under Framework B of this subpart subject to this section.

(b) Each application for a construction permit, operating license, or combined license submitted pursuant to this section must be submitted as specified in §§ 53.4900, 53.4960, or 53.5010 and 10 CFR 2.101. Each application must state that the applicant wishes to have the application considered under this section and must list each of the applications to be treated together under this section.

(c) Each application must include the information required by the applicable sections of this subpart, *provided however*, that the application must identify the common design, and, if applicable, reference a standard design certification under Framework B of this part, or the use of a reactor manufactured under Framework B of this part. The final safety analysis report for each application must either incorporate by reference or include the final safety analysis of the common design, including, if applicable, the final safety analysis report for the referenced standard design certification or the manufactured reactor.

(d) Each application submitted pursuant to this section must contain an environmental report as required by §§ 53.4912, 53.4972, or 53.5019, as applicable, and which complies with the applicable provisions of 10 CFR part 51, *provided, however*, that the application may incorporate by reference a single environmental report on the environmental impacts of the common design.

(e) Upon a determination that each application is acceptable for docketing under 10 CFR 2.101, each application will be docketed and a notice of docketing for each application will be published in the *Federal Register*, in accordance with 10 CFR 2.104, *provided, however*, that the notice must state that the application will be processed under the provisions of this section and subpart D of 10 CFR part 2. At the discretion of the Commission, a single notice of docketing for multiple applications may be published in the *Federal Register*.

(f) The NRC shall prepare draft and final environmental impact statements for each of the applications under 10 CFR part 51. Scoping under 10 CFR 51.28 and 51.29 for each of the license applications may be conducted simultaneously and joint scoping may be conducted with respect to the environmental issues relevant to the common design.

If the applications reference a standard design certification, then the environmental impact statement for each of the applications must incorporate by reference the standard design certification environmental assessment. If the applications do not reference a standard design certification, then the NRC shall prepare draft and final supplemental environmental impact statements which address severe accident mitigation design alternatives for the common design, which must be incorporated by reference into the environmental impact statement prepared for each application. Scoping under 10 CFR 51.28 and 51.29 for the supplemental environmental impact statement may be conducted simultaneously and may be part of the scoping for each of the applications.

(g) The ACRS shall report on each of the applications as required by the applicable sections of this subpart. Each report must be limited to those safety matters for each application which are not relevant to the common design. In addition, the ACRS shall separately report on the safety of the common design, *provided, however*, that the report need not address the safety of a referenced standard design certification or reactor manufactured under Framework B of this part.

(h) The Commission shall designate a presiding officer to conduct the proceeding with respect to the health and safety, common defense and security, and environmental matters relating to the common design. The hearing will be governed by the applicable provisions of subparts A, C, G, L, N, and O of 10 CFR part 2 relating to applications for

construction permits, operating licenses, and combined licenses. The presiding officer shall issue a partial initial decision on the common design.

(i) If the design for the power reactor(s) proposed in a particular application is not identical to the others, that application may not be processed under this section and subpart D of 10 CFR part 2.

(j) As used in this section, the design of a nuclear power reactor included in a single referenced safety analysis report means the design of those structures, systems, and components important to radiological health and safety and the common defense and security.

Subpart S – Maintaining and Revising Licensing Basis Information

§ 53.6000 Licensing basis information.

Each holder of a license for a commercial nuclear plant under Framework B of this part must maintain licensing basis information; evaluate changes to site characteristics, plant design features, and programmatic controls to determine needed approvals and revisions; and submit appropriate updates to the NRC in accordance with the requirements in this subpart. As used in this subpart, licensing basis information refers to that information contained in regulations, orders, licenses, certifications, or approvals issued by the NRC for a commercial nuclear plant licensed under Framework B of this part and that information submitted to the NRC by an applicant or licensee in a safety analysis report, program description, or other licensing-related information required to be maintained and submitted to the NRC under Framework B of this part.

§ 53.6002 Specific terms and conditions of licenses.

(a) Each license issued under Framework B of this part must be subject to the provisions of the Atomic Energy Act of 1954, as amended, now or hereafter in effect and to all rules, regulations, and orders of the Commission. The terms and conditions of the license must be subject to amendment, revision, or modification, by reason of amendments of the Act or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.

(b) Each license issued under Framework B of this part must be subject to all conditions deemed imposed as a matter of law by sections 401(a)(2) and 401(d) of the Federal Water Pollution Control Act, as amended (33 U.S.C.A. 1341(a)(2) and (d)).

(c) A holder of an operating license or combined license under Framework B of this part may take reasonable action that departs from a license condition or a technical specification (contained in a license issued under Framework B of this part) in a national security emergency:

(1) When this action is immediately needed to implement national security objectives as designated by the national command authority through the Commission, and

(2) No action consistent with license conditions and technical specifications that can meet national security objectives is immediately apparent.

A national security emergency is established by a law enacted by the Congress or by an order or directive issued by the President pursuant to statutes or the Constitution of the United States. The authority under this paragraph must be exercised in accordance with law, including section 57e of the Act, and is in addition to the authority granted under § 53.4230(h), which remains in effect unless otherwise directed by the Commission during a national security emergency.

§ 53.6005 Changes to licensing basis information requiring NRC approval.

(a) Sections 53.6010 through 53.6020 define the process for a licensee to request and the NRC to issue amendments to licenses, including any conditions contained therein, technical specifications or other attachments to a license, and any orders issued by the NRC modifying a license unless the order itself defines another method for controlling revisions to the requirements included in the order or the order is revised or superseded by another order issued by the NRC.

(b) A licensee may propose changing licensing basis information established by NRC regulations by requesting an exemption in accordance with § 53.080.

§ 53.6010 Application for amendment of license.

Whenever a holder of a license under Framework B of this part desires to amend the license, an application for an amendment must be filed with the Commission, as specified in § 53.040 of this part, that fully describes the changes desired, and following as far as applicable, the form prescribed for original applications. At the time a licensee requests an amendment, it must provide to the Commission, in accordance with the distribution requirements specified in § 53.040, its analysis about the issue of no significant hazards consideration using the standards in § 53.6020.

§ 53.6015 Public notices; State consultation.

The Commission will use the following procedures for an application requesting an amendment to a license issued under Framework B of this part.

(a) Public notices.

(1)(i) The Commission may publish in the *Federal Register* under § 2.105 an individual notice of proposed action for an amendment for which it makes a proposed determination that no significant hazards consideration is involved, or, at least once every 30 days, publish a periodic *Federal Register* notice of proposed actions, which identifies each amendment issued and each amendment proposed to be issued since the last such periodic notice, or it may publish both such notices.

(ii) For each amendment proposed to be issued, the notice will (A) contain the staff's proposed determination, under the standards in § 53.6020, (B) provide a brief description of the amendment and of the facility involved, (C) solicit public comments on the proposed determination, and (D) provide for a 30-day comment period.

(iii) The comment period will begin on the day after the date of the publication of the first notice, and, normally, the amendment will not be granted until after this comment period expires.

(2) The Commission may inform the public about the final disposition of an amendment request for which it has made a proposed determination of no significant hazards consideration either by issuing an individual notice of issuance under § 2.106 of this chapter or by publishing such a notice in its periodic system of *Federal Register* notices. In either event, it must not make and must not publish a final determination of no significant hazards consideration, unless it receives a request for a hearing on that amendment request.

(3) Where the Commission makes a final determination that no significant hazards consideration is involved and that the amendment should be issued, the amendment will be effective on issuance, even if adverse public comments have been received and even if an interested person meeting the provisions for intervention called for in § 2.309 of this chapter has filed a request for a hearing. The Commission need hold any required hearing only after it issues an amendment, unless it determines that a

significant hazards consideration is involved, in which case the Commission will provide an opportunity for a prior hearing.

(4) Where the Commission finds that an emergency situation exists, in that failure to act in a timely way would result in derating or shutdown of a commercial nuclear plant, or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, it may issue a license amendment involving no significant hazards consideration without prior notice and opportunity for a hearing or for public comment. In such a situation, the Commission will not publish a notice of proposed determination on no significant hazards consideration, but will publish a notice of issuance under § 2.106 of this chapter, providing for opportunity for a hearing and for public comment after issuance. The Commission expects its licensees to apply for license amendments in timely fashion. It will decline to dispense with notice and comment on the determination of no significant hazards consideration if it determines that the licensee has abused the emergency provision by failing to make timely application for the amendment and thus itself creating the emergency. Whenever an emergency situation exists, a licensee requesting an amendment must explain why this emergency situation occurred and why it could not avoid this situation, and the Commission will assess the licensee's reasons for failing to file an application sufficiently in advance of that event.

(5) Where the Commission finds that exigent circumstances exist, in that a licensee and the Commission must act quickly and that time does not permit the Commission to publish a Federal Register notice allowing 30 days for prior public comment, and it also determines that the amendment involves no significant hazards considerations, it:

(i)(A) Will either issue a Federal Register notice providing notice of an opportunity for hearing and allowing at least two weeks from the date of the notice for prior public comment; or

(B) Will use local media to provide reasonable notice to the public in the area surrounding a licensee's facility of the licensee's amendment and of its proposed determination as described in paragraph (a)(1) of this section, consulting with the licensee on the proposed media release and on the geographical area of its coverage;

(ii) Will provide for a reasonable opportunity for the public to comment, using its best efforts to make available to the public whatever means of communication it can for the public to respond quickly, and, in the case of telephone comments, have these comments recorded or transcribed, as necessary and appropriate;

(iii) When it has issued a local media release, may inform the licensee of the public's comments, as necessary and appropriate;

(iv) Will publish a notice of issuance under § 2.106;

(v) Will provide a hearing after issuance, if one has been requested by a person who satisfies the provisions for intervention specified in § 2.309 of this chapter; and

(vi) Will require the licensee to explain the exigency and why the licensee cannot avoid it and use its normal public notice and comment procedures in paragraph (a)(1) of this section if it determines that the licensee has failed to use its best efforts to make a timely application for the amendment in order to create the exigency and to take advantage of this procedure.

(6) Where the Commission finds that significant hazards considerations are involved, it will issue a Federal Register notice providing an opportunity for a prior hearing even in an emergency situation, unless it finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

(b) State consultation.

(1) At the time a licensee requests an amendment, it must notify the State in which its facility is located of its request by providing that State with a copy of its application and its reasoned analysis about no significant hazards considerations and indicate on the application that it has done so.

(2) The Commission will advise the State of its proposed determination about no significant hazards consideration normally by sending it a copy of the *Federal Register* notice.

(3) The Commission will make available to the State official designated to consult with it about its proposed determination the names of the Project Manager or other NRC personnel it designated to consult with the State. The Commission will consider any comments of that State official. If it does not hear from the State in a timely manner, it will consider that the State has no interest in its determination; nonetheless, to ensure that the State is aware of the application, before it issues the amendment, it will make a good faith effort to communicate directly with that official.

(4) The Commission will make a good faith attempt to consult with the State before it issues a license amendment involving no significant hazards consideration. If, however, it does not have time to use its normal consultation procedures because of an emergency situation, it will attempt to communicate directly with the appropriate State official.

(5) After the Commission issues the requested amendment, it will send a copy of its determination to the State.

(c) Caveats about State consultation.

(1) The State consultation procedures in paragraph (b) of this section do not give the State a right:

(i) To veto the Commission's proposed or final determination;

(ii) To a hearing on the determination before the amendment becomes effective;

or

(iii) To insist upon a postponement of the determination or upon issuance of the amendment.

(2) These procedures do not alter present provisions of law that reserve to the Commission exclusive responsibility for setting and enforcing radiological health and safety requirements for commercial nuclear power plants.

§ 53.6020 Issuance of amendment.

(a) In determining whether an amendment to a license will be issued to the applicant, the Commission will be guided by the considerations which govern the issuance of initial licenses to the extent applicable and appropriate. If the application involves the material alteration of a licensed facility, a construction permit will be issued before the issuance of the amendment to the license, provided however, that if the application involves a material alteration to a manufactured reactor under Framework B of this part before its installation at a site, or a combined license before the date that the Commission makes the finding under § 53.5052(g), no application for a construction permit is required. If the amendment involves a significant hazards consideration, the Commission will give notice of its proposed action:

(1) Under § 2.105 of this chapter before acting thereon; and

(2) As soon as practicable after the application has been docketed.

(b) The Commission will be particularly sensitive to a license amendment request that involves irreversible consequences (such as one that permits a significant increase in the amount of effluents or radiation emitted by a commercial nuclear plant).

(c) The Commission may make a final determination, under the procedures in § 53.6015, that a proposed amendment to an operating license or a combined license for a commercial nuclear plant under Framework B of this part involves no significant hazards consideration, if operation of the plant in accordance with the proposed amendment would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

§ 53.6025 Revising certification information within a design certification rule.

(a) A holder of an operating license or combined license who references a design certification rule issued under Framework B of this part must request an exemption if proposing to change one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080.

(b) The request for an exemption must be included with the associated proposed changes to the license, which must be requested and processed in accordance with §§ 53.6010, 53.6015, and 53.6020.

(c) Licensees must evaluate changes to the facility as described in the final safety analysis report not involving changes to the certification information using the criteria in § 53.6050.

§ 53.6030 Revising design information within a manufacturing license.

(a) The holder of a manufacturing license may not make changes to the design of the manufactured reactor or manufactured reactor module authorized to be manufactured without prior Commission approval. The request for a change to the design must be in the form of an application for a license amendment, and must meet the requirements of §§ 53.6010, 53.6015, and as applicable 53.6020.

(b) The holder of an operating or combined license under Framework B of this part who references or uses a reactor manufactured under Framework B of this part must request approval for any proposed departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The application for such departures must be submitted and processed in accordance with §§ 53.6010, 53.6015, and 53.6020. In those cases where a manufacturing license references a design certification rule, the amendment application must also request an exemption from the design certification rule in accordance with § 53.6025 if one or more elements of the certification information are adversely affected by the proposed change. Licensees must evaluate changes to the facility as described in the final safety analysis report but outside of the scope of the referenced manufacturing license using the criteria in § 53.6050.

§ 53.6035 Amendments during construction.

(a) The holder of a construction permit or limited work authorization under Framework B of this part may request an amendment to the construction permit or limited work authorization in order to gain Commission approval of the safety of selected design features or specifications, including proposed departures from a design certification rule or manufacturing license. Amendments to construction permits or

limited work authorizations under Framework B of this part must be requested and processed in accordance with §§ 53.6010, 53.6015, and 53.6020.

(b) The holder of a combined license under Framework B of this part for which the NRC has not yet made a finding in accordance with § 53.5052(g) must request amendments required by §§ 53.6025 or 53.6050 no later than 45 days from the date the licensee begins the construction of the SSCs to implement the change or departure requiring NRC approval. The licensee proceeds with such changes at its own risk recognizing that there is a possibility that the amendment request will not be granted.

§ 53.6040 Updating licensing basis information and determining the need for NRC approval.

Sections 53.6025 through 53.6065 define the process for a licensee to modify licensing basis information and to evaluate potential changes to their facilities, procedures, programs, and organizations to determine if NRC approval is required.

(a) Definitions for the purposes of Sections 53.6040 through 53.6065:

(1) *Change* means a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) *Departure from a method of evaluation described in the Updated Final Safety Analysis Report (UFSAR) used in establishing the design bases or in the safety analyses* means:

(i) Changing any of the elements of the method described in the UFSAR unless the results of the analysis are conservative or essentially the same; or

(ii) Changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

(3) *Facility as described in the UFSAR* means:

(i) The structures, systems, and components (SSC) that are described in the UFSAR,

(ii) The design and performance requirements for such SSCs described in the UFSAR, and

(iii) The evaluations or methods of evaluation included in the UFSAR for such SSCs which demonstrate that their intended function(s) will be accomplished.

(4) *Final Safety Analysis Report (as updated)* means the Final Safety Analysis Report submitted in accordance with §§ 53.4969 or 53.5016, as amended and supplemented, and as updated per the requirements of § 53.6045, as applicable.

(5) *Procedures as described in the final safety analysis report (as updated)* means those procedures that contain information described in the UFSAR such as how structures, systems, and components are operated and controlled (including assumed operator actions and response times).

(6) *Tests or experiments not described in the final safety analysis report (as updated)* means any activity where any structure, system, or component is utilized or controlled in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the UFSAR
or

(ii) Inconsistent with the analyses or descriptions in the UFSAR.

(b) Sections §§ 53.6040 through 53.6065 apply to each holder of a license issued under Framework B of this part, including the holder of an operating or combined license that has submitted the certification of permanent cessation of operations required under

§§ 53.6075 or a reactor licensee whose license has been amended to allow possession of nuclear fuel but not operation of the facility.

§ 53.6045 Updating final safety analysis reports.

(a) Each holder of an operating license or combined license under Framework B of this part for which the Commission has made the finding under § 53.5052(g) must update the final safety analysis report (FSAR) originally submitted as part of the application for the license biennially or more frequently to assure that the information included in the report contains the latest information developed. This submittal must contain all the changes necessary to reflect information and analyses submitted to the Commission by the applicant or licensee or prepared by the applicant or licensee pursuant to Commission requirement since the submittal of the original FSAR, or as appropriate, the last update to the FSAR under this section. The submittal must include the effects on the content of the FSAR of:

(1) Changes made to the facility or procedures as described in the FSAR;

(2) Safety analyses and evaluations performed by the licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 53.6050;

(3) Analyses of new safety issues performed by or on behalf of the licensee at Commission request.

(b)(1) The licensee shall submit revisions containing updated information to the Commission, as specified in § 53.040, identifying the location of revised or new information.

(2) The submittal shall include:

(i) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and

(ii) an identification of changes made under the provisions of § 53.6050 but not previously submitted to the Commission.

(c) During the period from the docketing of an application for a combined license under Framework B of this part until the Commission makes the finding under § 53.5052(g), the update to the FSAR must be submitted annually by combined license applicants who have not requested the NRC to suspend its review of the combined license application, or combined license holders who have not informed the NRC that they do not plan to pursue construction. If a combined license applicant requests that the NRC resume its review, or a combined license holder notifies the NRC that the combined license holder plans to commence or resume construction, then the combined license applicant or holder shall submit to NRC an update to its FSAR within 90 days of the request or notification, as applicable, and annually thereafter.

(d) The updated FSAR must be retained by the licensee until the Commission terminates their license.

(e) Reserved.

(f) Each person licensed to manufacture a nuclear reactor module under Framework B of this part must update the FSAR originally submitted as part of the application to reflect any modification to the design that is directed or approved by the Commission under §§ 53.4888 or 53.6030, and any new analyses of the design performed by or on behalf of the licensee at the NRC's request. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the

Commission by the licensee or prepared by the licensee with respect to the modification approved under § 53.6030 or the analyses requested by the Commission under § 53.4888. The updated information shall be appropriately located within the update to the FSAR.

§ 53.6050 Evaluating changes to facility as described in final safety analysis reports.

(a) A licensee may make changes in the facility as described in the UFSAR, make changes in the procedures as described in the UFSAR, and conduct tests or experiments not described in the UFSAR without obtaining a license amendment pursuant to § 53.6010 only if:

(1) A change to the technical specifications incorporated in the license is not required, and

(2) The change, test, or experiment would not:

(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the UFSAR;

(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the UFSAR;

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the UFSAR;

(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the UFSAR;

(v) Create a possibility for an accident of a different type than any previously evaluated in the UFSAR;

(vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the UFSAR;

(vii) Result in a design basis limit for a fission product barrier as described in the UFSAR being exceeded or altered;

(viii) Result in a departure from a method of evaluation described in the UFSAR used in establishing the design bases or in the safety analyses.

(3) In implementing this paragraph, the UFSAR is considered to include FSAR changes resulting from evaluations performed pursuant to this section and analyses performed pursuant to § 53.6010 since submittal of the last update of the FSAR pursuant to § 53.6045.

(4) The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(b)(1) A licensee who references a design certification rule may make departures from the standard design, without obtaining an amendment, unless the proposed departure involves a change to the design as described in the rule certifying the design, in which case the requirements of § 53.6025 are applicable.

(2) The licensee shall maintain records of all departures from the certified design of the facility and these records must be maintained and available for audit until the date of termination of the license. The licensee must identify the location and nature of departures from licensing basis information within supporting documents for a certified design within the updates to the safety analysis report required by § 53.6045.

(3) Licensees for which the NRC has docketed the certifications required under subpart Q of this part are not required to retain records of departures from the design of

the facility associated with structures, systems, and components that have been permanently removed from service using an NRC-approved change process.

(c)(1) The licensee must maintain records of changes in the facility and procedures made pursuant to paragraph (a) of this section. These records must include a written evaluation which provides the bases for the determination that the change does not require a license amendment pursuant to paragraph (a)(2) of this section.

(2) The licensee shall submit, as specified in § 53.040 of this part, a report containing a brief description of any departures and changes, including a summary of the evaluation of each. A report must be submitted at appropriate times in the facility's operating cycle such that the interval between reports does not exceed 24 months. For combined licenses, the report must be submitted at intervals not to exceed 6 months during the period from the date of application for a combined license to the date the Commission makes its findings under 10 CFR 53.5052(g).

(3) The records of changes in the facility must be maintained until the termination of an operating license or combined license issued under Framework B of this part, or the termination of a renewed license issued under § 53.6095, whichever is later. Records of changes in procedures must be maintained for a period of 5 years.

§ 53.6052 Maintenance of risk evaluations.

Applicants or licensees required to submit a risk evaluation under § 53.4730(a)(34) must meet the following requirements:

(a) No later than the scheduled date for initial loading of fuel, each holder of an operating or combined license for a commercial nuclear plant under Framework B of this part must develop a risk evaluation.

(b) Each licensee required to develop a risk evaluation under paragraph (a) shall maintain the risk evaluation to reflect the as-built, as-operated facility. The risk evaluation must be maintained at least every five years until the permanent cessation of operations under § 53.4670. If a PRA is performed in accordance with § 53.4730(a)(34)(i), the licensee must upgrade the PRA to cover initiating events and modes of operation contained in consensus standards on PRA that are endorsed by the NRC. The upgrade must be completed within five years of NRC endorsement of the standard.

(c) Each licensee required to develop a risk evaluation based on a PRA must, no later than the date on which the licensee submits an application for a renewed license, upgrade the PRA required by paragraph (a) of this section to cover all modes and all initiating events.

(d) Each licensee who developed an alternative evaluation for risk insights per § 53.4730(a)(34)(ii) must, no later than the date on which the licensee submits an application for a renewed license, confirm that the alternative evaluation for risk insights reflects the as-built, as-operated facility.

§ 53.6054 Control of aircraft impact assessments.

(a) For construction permits subject to § 53.4730(a)(35)(i) of this section, if the permit holder changes the information required by § 53.4909(a)(6)(xii) to be included in the preliminary safety analysis report, then the permit holder shall consider the effect of the changed feature or capability on the original assessment required by § 53.4730(a)(35)(i) and amend the information required by § 53.4909(a)(6)(xii) to be included in the preliminary safety analysis report to describe how the modified design

features and functional capabilities continue to meet the assessment requirements in paragraph § 53.4730(a)(35)(i)(1).

(b) For operating licenses subject to § 53.4730(a)(35)(i) of this section, if the licensee changes the information required by § 53.4969(a)(7)(xiv) to be included in the final safety analysis report, then the licensee shall consider the effect of the changed feature or capability on the original assessment required by § 53.4730(a)(35)(i) and amend the information required by § 53.4969(a)(7)(xiv) to be included in the final safety analysis report to describe how the modified design features and functional capabilities continue to meet the assessment requirements in paragraph § 53.4730(a)(35)(i)(1).

(c) For standard design certifications subject to paragraph § 53.4730(a)(35)(i), generic changes to the information required by § 53.4839(a)(7)(xv) to be included in the final safety analysis report are governed by the applicable requirements of § 53.4863.

(d)(1) For combined licenses subject to paragraph § 53.4730(a)(35)(i), if the licensee changes the information required by § 53.5016(d)(17) to be included in the final safety analysis report, then the licensee shall consider the effect of the changed feature or capability on the original assessment required by § 53.4730(a)(35)(i), and amend the information required by § 53.5016(d)(17) to be included in the final safety analysis report to describe how the modified design features and functional capabilities continue to meet the assessment requirements in paragraph § 53.4730(a)(35)(i)(1).

(2) For combined licenses not subject to paragraph § 53.4730(a)(35)(i) but reference a standard design certification subject to § 53.4730(a)(35)(i) of this section, proposed departures from the information required by § 53.4839(a)(37)(xv) to be included in the final safety analysis report for the referenced standard design certification are governed by the change control requirements in the applicable design certification rule and the provisions in § 53.6050(b).

(3) For combined licenses not subject to paragraph § 53.4730(a)(35)(i) but reference a manufactured reactor subject to paragraph § 53.4730(a)(35)(i), proposed departures from the information required by § 53.4879(d)(14)(xii) to be included in the final safety analysis report for the manufacturing license are governed by the applicable requirements in § 53.6030.

(e)(1) For manufacturing licenses subject to § 53.4730(a)(35)(i), generic changes to the information required by § 53.4879(d)(14)(xii) to be included in the final safety analysis report are governed by the applicable requirements of § 53.4888.

(2) For manufacturing licenses not subject to paragraph § 53.4730(a)(35)(i) but reference a standard design certification subject to paragraph § 53.4730(a)(35)(i), proposed departures from the information required by § 53.4839(a)(37)(xv) to be included in the final safety analysis report for the referenced standard design certification are governed by the change control requirements in the applicable design certification rule.

§ 53.6055 Control of licensing basis information in program descriptions.

Program documents must be included in licensing basis information to describe measures taken to ensure compliance with specific NRC regulations. §§ 53.6060 through 53.6065 define the process for a licensee to evaluate changes to the program documents included in the licensing basis information submitted to the NRC and to modify such programs without NRC prior approval.

§ 53.6060 Updating program documents included in licensing basis information.

(a) Each licensee under Framework B of this part must biennially or more frequently update the program documents submitted as part of an application to obtain or maintain the license to assure that the information included in the documents contains the latest information developed. The submittals shall include the effects on the content of the program documents of:

(1) changes made in the facility, procedures, licensee's organization, or site environs;

(2) safety analyses and evaluations performed by the applicant or licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 53.6050;

(3) analyses of new safety issues performed by or on behalf of the licensee at Commission request; and

(4) changes to the programs as a result of operating experience, corrective actions, or other reasons deemed appropriate to ensure the programs serve their underlying purpose to meet applicable NRC regulations.

(b)(1) The licensee shall submit revisions containing updated information to the Commission, as specified in § 53.040, identifying the location of revised or new information.

(2) The submittal shall include (i) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittals, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and (ii) an identification of changes made under the provisions of § 53.6045 but not previously submitted to the Commission.

(c) The updated program documents shall be retained by the licensee until the Commission terminates their license.

§ 53.6065 Evaluating changes to programs included in licensing basis information.

(a) A licensee may make changes to the facility, procedures, or organizations or to address changes to site environs as described in the program documents included in licensing basis information without obtaining prior NRC approval only if:

(1) A change to the technical specifications incorporated in the license is not required,

(2) An exemption from an NRC regulation is not required,

(3) The change conforms to program-specific requirements included in regulations in Framework B of this part, technical specifications, or the NRC-approved program document included and reviewed as part of a license application under Subpart R or an amendment under this subpart.

(b) In implementing this paragraph, the program documents (as updated) are considered to include changes since submittal of the last updates of the program documents pursuant to § 53.6060.

(c) The provisions in this section do not apply to changes to the program documents when the applicable regulations establish more specific criteria for accomplishing such changes.

(d) To make changes to the facility, procedures, or organizations or to address changes to site environs as described in the program documents included in licensing basis information for individual programs, the following requirements must be satisfied:

(1) *Quality assurance program—operation.* (i) Each holder of an operating license or combined license, after the Commission makes the finding under § 53.5052(g), under Framework B of this part may make a change to a previously

accepted quality assurance program description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce the commitments in the program description as accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted to the NRC in accordance with the requirements of § 53.6045. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

(A) The use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's QA program at the time of the change;

(B) The use of a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility;

(C) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(D) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;

(E) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

(F) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(ii) Changes to the quality assurance program description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation, as follows:

(A) Changes made to the quality assurance program description as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 53.040.

(B) The submittal of a change to the Safety Analysis Report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of Subpart U of this part and the Safety Analysis Report quality assurance program description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(C) A copy of the forwarding letter identifying the change must be maintained as a facility record for three years.

(D) Changes to the quality assurance program description included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(2) *Quality assurance program—siting, construction, and manufacturing.* Each holder of a limited work authorization, early site permit, construction permit, manufacturing license, or combined license, before the Commission makes the finding under § 53.5052(g) of this chapter, under Framework B of this part may make a change to a previously accepted quality assurance program description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not

reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted to NRC within 90 days. Changes to the quality assurance program description that reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:

(i) Changes to the safety analysis report must be submitted for review as specified in § 53.040. Changes made to NRC-accepted quality assurance topical report descriptions must be submitted as specified in § 53.040.

(ii) The submittal of a change to the safety analysis report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of Subpart U of this part and the safety analysis report quality assurance program description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(iii) A copy of the forwarding letter identifying the changes must be maintained as a facility record for three years.

(iv) Changes to the quality assurance program description included or referenced in the safety analysis report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(3) *Emergency preparedness program.*

(i) The licensee may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the plan and the plan, as changed, continues to meet the

requirements in § 53.4320. A change reduces the effectiveness of the plan if it results in reducing the licensee's capability to perform an emergency planning function required by § 53.4320 in the event of a radiological emergency.

(ii) The licensee shall retain a record of each change to the emergency plan made without prior NRC approval for a period of three years from the date of the change and shall submit, as specified in § 53.040, a report of each such change, including a summary of its analysis, within 30 days after the change is put in effect.

(iii) The changes to a licensee's emergency plan that reduce the effectiveness of the plan may not be implemented without prior approval by the NRC. A licensee desiring to make such a change must submit an application for an amendment to its license. In addition to the filing requirements of §§ 53.6010, 53.6015, and 53.6020, the request must include all emergency plan pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the licensee's emergency plan, as revised, will continue to meet the requirements of § 53.4320.

(4) *Security programs.*

(i) The licensee shall prepare and maintain safeguards contingency plan procedures in accordance with appendix C of part 73 of this chapter for affecting the actions and decisions contained in the Responsibility Matrix of the safeguards contingency plan. The licensee may not make a change which would decrease the effectiveness of a physical security plan, or guard training and qualification plan, or cyber security plan submitted under subpart R or part 73 of this chapter, or of the first four categories of information (Background, Generic Planning Base, Licensee Planning Base, Responsibility Matrix) contained in a licensee safeguards contingency plan submitted under subpart R or part 73 of this chapter, as applicable, without prior approval of the

Commission. A licensee desiring to make such a change shall submit an application for amendment to the licensee's license under §§ 53.6010, 53.6015, and 53.6020.

(ii) The licensee may make changes to the safeguards contingency plan without prior Commission approval if the changes do not decrease the safeguards effectiveness of the plan. The licensee shall maintain records of changes to the plans made without prior Commission approval for a period of 3 years from the date of the change, and shall submit, as specified in § 53.040, a report containing a description of each change within 2 months after the change is made. Prior to the safeguards contingency plan being put into effect, the licensee shall have:

(A) All safeguards capabilities specified in the safeguards contingency plan available and functional;

(B) Detailed procedures developed according to appendix C to part 73 of this chapter available at the licensee's site; and

(C) All appropriate personnel trained to respond to safeguards incidents as outlined in the plan and specified in the detailed procedures.

(iii) The licensee shall provide for the development, revision, implementation, and maintenance of its safeguards contingency plan. The licensee shall ensure that all program elements are reviewed by individuals independent of both security program management and personnel who have direct responsibility for implementation of the security program either:

(A) At intervals not to exceed 12 months; or

(B) As necessary, based on an assessment by the licensee against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect security, but no longer than 12 months after the change. In any case, all elements of the safeguards contingency plan must be reviewed at least once every 24 months.

(iv) The review must include a review and audit of safeguards contingency procedures and practices, an audit of the security system testing and maintenance program, and a test of the safeguards systems along with commitments established for response by local law enforcement authorities. The results of the review and audit, along with recommendations for improvements, must be documented, reported to the licensee's corporate and plant management, and kept available at the plant for inspection for a period of 3 years.

§ 53.6070 Transfer of licenses.

(a) No commercial nuclear plant license issued under Framework B of this part, or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing.

(b)(1) An application for transfer of a license shall include:

(i) As much of the information described in §§ 53.4709, 53.4906, 53.4966, and 53.5013 with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. The Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards.

(ii) A statement of the purposes for which the transfer of the license is requested, the nature of the transaction necessitating or making desirable the transfer of the license, and an agreement by the proposed transferee to limit access to Restricted Data pursuant to § 53.4715. The Commission may require any person who submits an application for license pursuant to the provisions of this section to file a written consent

from the existing licensee or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act and these regulations) to possession of the facility or site involved.

(c) After appropriate notice to interested persons, including the existing licensee, and observance of such procedures as may be required by the Act or regulations or orders of the Commission, the Commission will approve an application for the transfer of a license, if the Commission determines:

(1) That the proposed transferee is qualified to be the holder of the license; and

(2) That transfer of the license is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

§ 53.6075 Termination of license.

(a) When the holder of an operating license or combined license under Framework B of this part has determined to permanently cease operations the licensee shall, within 30 days, submit a written certification to the NRC, consistent with the requirements of Subpart Q.

(b) Once fuel has been permanently removed from the reactor system, the licensee shall submit a written certification to the NRC that meets the requirements of Subpart Q.

(c)(1) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor system, or when a final legally effective order to permanently cease operations has come into effect, the license no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor system.

(2) Activities associated with decommissioning will be carried out in accordance with the requirements and procedures in Subpart Q.

(3) The Commission shall terminate the license if it determines that—

(i) The remaining dismantlement has been performed in accordance with the approved license termination plan required in Subpart Q, and

(ii) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in 10 CFR part 20, subpart E.

(d) A holder of a construction permit or combined license under Framework B of this part may request the termination of the license as well as licenses issued by the NRC under Parts 30, 40, 70 of this Chapter prior to plant operations. Such requests may support an immediate NRC approval of the site for unrestricted use.

§ 53.6080 Information requests.

Any licensee under Framework B of this part shall at any time before expiration of the license, upon request of the Commission, submit, as specified in § 53.040 written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended, or revoked. Except for information sought to verify licensee compliance with the current licensing basis for that facility, the NRC must prepare the reason or reasons for each information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such justification provided for an evaluation performed by the NRC

staff must be approved by the Executive Director for Operations or his or her designee prior to issuance of the request.

§ 53.6085 Revocation, suspension, modification of licenses and approvals for cause.

A license or standard design approval issued under Framework B of this part may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in the supplemental or other statement of fact required of the applicant; or because of conditions revealed by the application or statement of fact of any report, record, inspection, or other means which would warrant the Commission to refuse to grant a license or approval on an original application; or for failure to manufacture a reactor, or construct or operate a facility in accordance with the terms of the license, provided, however, that failure to make timely completion of the proposed construction or alteration of a facility under a construction permit under Framework B of this part shall be governed by the provisions of § 53.4942(b); or for violation of, or failure to observe, any of the terms and provisions of the act, regulations, license, approval, or order of the Commission.

§ 53.6090 Backfitting.

(a)(1) Backfitting is defined as the modification of or addition to systems, structures, components, or design of a facility; or the design approval for a facility or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position

interpreting the Commission's regulations that is either new or different from a previously applicable staff position after the date of the nuclear plant license issued under Framework B of this part.

(2) Except as provided in paragraph (a)(4) of this section, the Commission shall require a systematic and documented analysis pursuant to paragraph (b) of this section for backfits which it seeks to impose.

(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission or staff, as appropriate, finds and declares, with appropriated documented evaluation for its finding, either:

(i) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or

(ii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or

(iii) That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

(5) The Commission shall always require the backfitting of a facility if it determines that such regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

(6) The documented evaluation required by paragraph (a)(4) of this section shall include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediately effective regulatory action is required, then the documented evaluation may follow rather than precede the regulatory action.

(7) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there are two or more ways to reach a level of protection which is adequate, then ordinarily the applicant or licensee is free to choose the way which best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(b) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) Statement of the specific objectives that the proposed backfit is designed to achieve;

(2) General description of the activity that would be required by the licensee or applicant in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental off-site release of radioactive material;

(4) Potential impact on radiological exposure of facility employees;

(5) Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit;

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(c) No licensing action will be withheld during the pendency of backfit analyses required by the Commission's rules.

(d) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his designee.

§ 53.6095 Renewal.

Licenses may be renewed by the Commission upon expiration of the period of the license.

Subpart T – Reporting and Other Administrative Requirements

§ 53.6300 General information.

Each applicant and licensee under Framework B of this part must ensure that NRC inspectors have unfettered access to sites and facilities licensed or proposed to be licensed in § 53.6310, must maintain records and make reports to the NRC in accordance with requirements in §§ 53.6320 through 53.6350, must meet financial qualification and reporting requirements in §§ 53.6370 through 53.6400, and must obtain and maintain required financial protections in case of an accident in §§ 53.6420 and 53.6430.

§ 53.6310 Unfettered access for inspections.

(a) Each applicant for or holder of a manufacturing license, operating license, combined license, construction permit or an early site permit, must permit inspection by duly authorized representatives of the Commission, of its records, premises, activities, and of licensed materials in possession or use, related to the license or construction permit or early site permit as may be necessary to effectuate the purposes of the Act, as amended, and the Energy Reorganization Act of 1974, as amended.

(b)(1) Each holder of a manufacturing license, operating license, combined license, or construction permit must, upon request by the Director, Office of Nuclear Reactor Regulation, provide rent-free office space for the exclusive use of the Commission inspection personnel. Heat, air conditioning, light, electrical outlets, and janitorial services must be furnished by each licensee and each holder of a construction permit. The office must be convenient to and have full access to the facility and shall provide the inspectors both visual and acoustic privacy.

(2) For a site or facility with an assigned resident inspector, the space provided must be adequate to accommodate a full-time inspector, a part-time secretary, and

transient NRC personnel and must be generally commensurate with other office facilities at the site. A space of 250 square feet either within the site's office complex or in an office trailer or other onsite space is suggested as a guide. For sites or facilities assigned multiple resident inspectors, additional space may be requested. The office space that is provided must be subject to the approval of the Director, Office of Nuclear Reactor Regulation. All furniture, supplies, and communication equipment will be furnished by the Commission.

(3) For a site or facility without an assigned resident inspector, temporary space to accommodate periodic or special inspections must be provided. The office space must be generally commensurate with other office accommodations at the site.

(4) The licensee or permit holder must afford any NRC resident inspector assigned to that site, or other NRC inspectors identified by the Regional Administrator as likely to inspect the facility, immediate unfettered access, equivalent to access provided regular plant employees, following proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

(5) The licensee or permit holder must ensure that the arrival and presence of an NRC inspector, who has been properly authorized facility access as described in paragraph (b)(4) of this section, is not announced or otherwise communicated by its employees or contractors to other persons at the facility unless specifically requested by the NRC inspector.

§ 53.6320 Maintenance of records, making of reports.

(a) Each holder of a manufacturing license, operating license, combined license, construction permit or early site permit, must maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license or

permit or by the regulations and orders of the Commission in effectuating the purposes of the Act, and the Energy Reorganization Act of 1974, as amended. Reports must be submitted in accordance with § 53.040.

(b) Reserved

(c) Records that are required by the regulations in Framework B of this part, by license condition, or by technical specifications must be retained for the period specified by the appropriate regulation, license condition, or technical specification. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility license or, in the case of an early site permit, until the permit expires.

(d)(1) Records which must be retained under Framework B of this part may be the original or a reproduced copy or a microform if the reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with, and loss of records.

(2) If there is a conflict between the Commission's regulations in Framework B of this part, license condition, or technical specification, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in Framework B of this part for such records shall apply unless the Commission, pursuant to § 53.080 of this part, has granted a specific exemption from the record retention requirements in the regulations in Framework B of this part.

(e) Each licensee shall notify the Commission as specified in § 53.040 of this chapter, of successfully completing power ascension testing or startup testing as applicable within 30 calendar days of completing the testing.

§ 53.6330 Immediate notification requirements for operating commercial nuclear plants.

(a) *General requirements.** (1) Each holder of an operating license under Framework B of this part or a combined license under Framework B of this part after the Commission makes the finding under § 53.5052(g), must notify the NRC Operations Center via the Emergency Notification System of:

(i) The declaration of any of the Emergency Classes specified in the licensee's approved Emergency Plan; or

(ii) Those non-emergency events specified in paragraph (b) of this section that occurred within three years of the date of discovery.

(2) If the Emergency Notification System is inoperative, the licensee must make the required notifications via commercial telephone service, other dedicated telephone system, or any other method which will ensure that a report is made as soon as practical to the NRC Headquarters Operations Center at the numbers specified in appendix A to part 73 of this chapter.

(3) The licensee must notify the NRC immediately after notification of the appropriate State or local agencies and not later than one hour after the time the licensee declares one of the Emergency Classes.

(4) The licensee must activate the data links with the NRC as specified in their emergency plans after declaring an Emergency Class for events of actual or potential substantial degradation of plant safety or security, probable risk to site personnel life or,

site equipment damage caused by hostile action. The data links may also be activated by the licensee during emergency drills or exercises if the licensee's computer system has the capability to transmit the exercise data.

(5) When making a report under paragraph (a)(1) of this section, the licensee must identify:

(i) The Emergency Class declared; or

(ii) Paragraph (b)(1), "One-hour reports," paragraph (b)(2), "Four-hour reports," or paragraph (b)(3), "Eight-hour reports," as the paragraph of this section requiring notification of the non-emergency event.

(b) *Non-emergency events* – (1) *One-hour reports*. If not reported as a declaration of an Emergency Class under paragraph (a) of this section, the licensee must notify the NRC as soon as practical and in all cases within one hour of the occurrence of any deviation from the plant's Technical Specifications authorized pursuant to § 53.4230(h) of this part.

(2) *Four-hour reports*. If not reported under paragraphs (a) or (b)(1) of this section, the licensee must notify the NRC as soon as practical, and in all cases, within four hours of the occurrence of any of the following:

(i) The initiation of any commercial nuclear plant shutdown required by the plant's Technical Specifications.

(ii) Any event or condition that results in actuation of the reactor protection system (RPS) when the reactor is critical except when the actuation results from and is part of a pre-planned sequence during testing or reactor operation.

(iii) Any event or condition that results in an unplanned actuation of a safety-related standby cooling system or the unplanned sole reliance on a safety-related standby cooling system for those systems that are in constant operation.

(iv) Any event or condition that results in an unplanned movement of, change of state in, or chemical interaction involving a significant amount of radioactive material within the commercial nuclear plant.

(v) Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made. Such an event may include an onsite fatality or inadvertent release of radioactively contaminated materials.

(3) *Eight-hour reports.* If not reported under paragraphs (a), (b)(1) or (b)(2) of this section, the licensee must notify the NRC as soon as practical and in all cases within eight hours of the occurrence of any of the following:

(i) Any event or condition that results in:

(A) The condition of the commercial nuclear plant, including its principal safety barriers, being seriously degraded; or

(B) The commercial nuclear plant being in an unanalyzed condition that significantly degrades plant safety.

(ii) Any event or condition that results in valid actuation of a safety-related system, except when the actuation results from and is part of a pre-planned sequence during testing or reactor operation.

(iii) Any event or condition that at the time of discovery could have prevented the fulfillment of the safety function of structures or systems that are needed to:

(A) Shut down the reactor and maintain it in a safe shutdown condition;

(B) Remove residual heat;

(C) Control the release of radioactive material; or

(D) Mitigate the consequences of an accident.

(iv) Events covered in paragraph (b)(3)(iii) of this section may include one or more procedural errors, equipment failures, and/or discovery of design, analysis,

fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to paragraph (b)(3)(iii) of this section if redundant equipment in the same system was operable and available to perform the required safety function.

(v) Any event requiring the transport of a radioactively contaminated person to an offsite medical facility for treatment.

(vi) Any event that results in a major loss of emergency assessment capability, offsite response capability, or offsite communications capability (e.g., significant portion of control room indication, Emergency Notification System, or offsite notification system).

(c) *Followup Notification:* With respect to the notifications made under paragraphs (a) and (b) of this section, in addition to making the required initial notification, each licensee, must during the course of the event:

(1) Immediately Report: (i) any further degradation in the level of safety of the plant or other worsening plant conditions, including those that require the declaration of any of the Emergency Classes, if such a declaration has not been previously made, or

(ii) any change from one Emergency Class to another, or

(iii) a termination of the Emergency Class.

(2) Immediately Report: (i) the results of ensuing evaluations or assessments of plant conditions,

(ii) the effectiveness of response or protective measures taken, and

(iii) important information related to plant behavior that is not understood.

(3) Maintain an open, continuous communication channel with the NRC Operation Center upon request by the NRC.

*Other requirements for immediate notification of the NRC by licensed operating commercial nuclear plants are contained elsewhere in this chapter, in particular §§ 20.1906, 20.2202, 72.216, 73.71, and 73.77.

§ 53.6340 Licensee event report system.

(a) *Reportable events.* (1) Each commercial nuclear plant licensee holding an operating license under § 53.4969 in Framework B of this part or a combined license under § 53.5016 in Framework B of this part after the Commission makes the finding under § 53.5052(g), must submit a Licensee Event Report (LER) for any event of the type described in this section within 60 days after discovery of the event. In the case of an invalid actuation reported under § 53.6340(a)(2), other than automatic reactor shutdown when the reactor is critical, the licensee may, at its option, provide a telephone notification to the NRC Operations Center within 60 days after discovery of the event instead of submitting a written LER. Unless otherwise specified in this section, the licensee must report an event if it occurred within 3 years of the date of discovery regardless of the plant mode or power level, and regardless of the significance of the structure, system, or component that initiated the event.

(2) The licensee must report:

(i)(A) The completion of any commercial nuclear plant shutdown required by the plant's Technical Specifications.

(B) Any operation or condition which was prohibited by the plant's Technical Specifications except when:

(1) The Technical Specification is administrative in nature;

(2) The event consisted solely of a case of a late surveillance test where the oversight was corrected, the test was performed, and the equipment was found to be capable of performing its specified safety functions; or

(3) The Technical Specification was revised prior to discovery of the event such that the operation or condition was no longer prohibited at the time of the event.

(C) Any deviation from the plant's Technical Specifications authorized pursuant to § 53.4230(h) of this part.

(ii) Any event or condition that resulted in:

(A) The condition of the commercial nuclear plant, including its principal safety barriers, being seriously degraded; or

(B) The commercial nuclear plant being in an unanalyzed condition that significantly degraded plant safety.

(iii) Any natural phenomena or other external condition that posed an actual threat to the safety of the commercial nuclear plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the commercial nuclear plant.

(iv) Any event or condition that resulted in manual or automatic actuation of a safety-related system, except when:

(A) The actuation resulted from and was part of a pre-planned sequence during testing; or

(B) The actuation was invalid and;

(1) Occurred while the system was properly removed from service; or

(2) Occurred after the safety function had been already completed.

(v) Any event or condition that could have prevented the fulfillment of the safety function of structures or systems that are needed to:

(A) Shut down the reactor and maintain it in a safe shutdown condition;

- (B) Remove residual heat;
- (C) Control the release of radioactive material; or
- (D) Mitigate the consequences of an accident.

(vi) Events covered in paragraph (a)(2)(v) of this section may include one or more procedural errors, equipment failures, and/or discovery of design, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to paragraph (a)(2)(v) of this section if any other equipment was operable and available to perform the required safety function.

(vii) Any event where a single cause or condition caused at least one independent train or channel to become inoperable in multiple systems or two independent trains or channels to become inoperable in a single system designed to:

- (A) Shut down the reactor and maintain it in a safe shutdown condition;
- (B) Remove residual heat;
- (C) Control the release of radioactive material; or
- (D) Mitigate the consequences of an accident.

(viii)(A) Any airborne radioactive release that, when averaged over a time period of 1-hour, resulted in airborne radionuclide concentrations in an unrestricted area that exceeds 20 times the applicable concentration limits specified in appendix B to part 20, table 2, column 1.

(B) Any liquid effluent release that, when averaged over a time period of 1-hour, exceeds 20 times the applicable concentrations specified in appendix B to part 20, table 2, column 2, at the point of entry into the receiving waters (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases.

(ix)(A) Any event or condition that as a result of a single cause could have prevented the fulfillment of a safety function for two or more trains or channels in different systems that are needed to:

- (1) Shut down the reactor and maintain it in a safe shutdown condition;
- (2) Remove residual heat;
- (3) Control the release of radioactive material; or
- (4) Mitigate the consequences of an accident.

(B) Events covered in paragraph (a)(2)(ix)(A) of this section may include cases of procedural error, equipment failure, and/or discovery of a design, analysis, fabrication, construction, and/or procedural inadequacy. However, licensees are not required to report an event pursuant to paragraph (a)(2)(ix)(A) of this section if the event results from:

(1) A shared dependency among trains or channels that is a natural or expected consequence of the approved plant design; or

(2) Normal and expected wear or degradation.

(x) Any event that posed an actual threat to the safety of the commercial nuclear plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the plant, including fires, toxic gas releases, or radioactive releases.

(b) *Contents.* The Licensee Event Report shall contain:

(1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

(2)(i) A clear, specific narrative description of what occurred so that knowledgeable readers conversant with the design of commercial nuclear plants, but not familiar with the details of a particular plant, can understand the complete event.

(ii) The narrative description must include the following specific information as appropriate for the particular event:

(A) Plant operating conditions before the event.

(B) Status of structures, components, or systems that were inoperable at the start of the event and that contributed to the event.

(C) Dates and approximate time of the occurrences.

(D) The cause of each component or system failure or personnel error, if known.

(E) The failure mode, mechanism, and effect of each failed component, if known.

[(F) Reserved]

(G) For failures of components with multiple functions, include a list of systems or secondary functions that were also affected.

(H) For failure that rendered a train of a safety system inoperable, an estimate of the elapsed time from the discovery of the failure until the train was returned to service.

(I) The method of discovery of each component or system failure or procedural error.

(J) For each human performance related root cause, the licensee must discuss the cause(s) and circumstances.

(K) Automatically and manually initiated safety system responses.

(L) The manufacturer and model number (or other identification) of each component that failed during the event.

(3) An assessment of the safety consequences and implications of the event.

This assessment must include:

(i) The availability of systems or components that could have performed the same function as the components and systems that failed during the event, and

(ii) For events that occurred when the reactor was shut down, the availability of systems or components that are needed to shut down the reactor and maintain safe shutdown conditions, remove residual heat, control the release of radioactive material, or mitigate the consequences of an accident.

(4) A description of any corrective actions planned as a result of the event, including those to reduce the probability of similar events occurring in the future.

(5) Reference to any previous similar events at the same plant that are known to the licensee.

(6) The name and contact information of a person within the licensee's organization who is knowledgeable about the event and can provide additional information concerning the event and the plant's characteristics.

(c) *Supplemental Information:* The Commission may require the licensee to submit specific additional information beyond that required by paragraph (b) of this section if the Commission finds that supplemental material is necessary for complete understanding of an unusually complex or significant event. These requests for supplemental information will be made in writing and the licensee shall submit, as specified in § 53.040, the requested information as a supplement to the initial LER.

(d) *Submission of Reports:* Licensee event reports must be prepared on Form NRC 366 and submitted to the U.S. Nuclear Regulatory Commission, as specified in § 53.040.

(e) *Report Legibility:* The reports and copies that licensees are required to submit to the Commission under the provisions of this section must be of sufficient quality to permit legible reproduction and micrographic processing.

(f) [Reserved]

(g) *Reportable Occurrences:* The requirements contained in this section replace all existing requirements for licensees to report "Reportable Occurrences" as defined in individual plant Technical Specifications.

§ 53.6345 Periodic reports.

(a) *Effluents.* Each holder of an operating license, and each holder of a combined license after the Commission has made the finding under § 53.5052(g), shall submit a report to the Commission annually that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents during the previous 12 months, including any other information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases. The report must be submitted as specified in § 53.040, and the time between submission of the reports must be no longer than 12 months. If quantities of radioactive materials released during the reporting period are significantly above design objectives, the report must cover this specifically. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may require the licensee to take action as the Commission deems appropriate.

(b) [Reserved.]

§ 53.6350 Facility information and verification.

(a) In response to a written request by the Commission, each applicant for a construction permit or license and each recipient of a construction permit or a license must submit facility information, as described in § 75.10 of this chapter, on International Atomic Energy Agency (IAEA) Design Information Questionnaire forms and site information on DOC/NRC Form AP-A and associated forms;

(b) As required by the Additional Protocol, must submit location information described in § 75.11 of this chapter on DOC/NRC Form AP-1 and associated forms; and

(c) Must permit verification thereof by the IAEA and take other action as necessary to implement the US/IAEA Safeguards Agreement, as described in Part 75 of this chapter.

§ 53.6360 Financial requirements.

Sections 53.6370 through 53.6400 set out the requirements and procedures related to financial qualifications and related reporting requirements.

§ 53.6370 Financial qualifications.

Except for an electric utility applicant for a license to operate a commercial nuclear plant, an applicants for a construction permit, operating license, or combined license under Framework B of this part must possess or have reasonable assurance of obtaining the funds necessary for the activities for which the permit or license is sought.

§ 53.6380 Annual financial reports.

With respect to any commercial nuclear plant of a type described in § 53.020, each licensee and each holder of a construction permit must submit its annual financial report, including the certified financial statements, to the Commission, as specified in § 53.040, upon issuance of the report. However, licensees and holders of a construction permit who submit a Form 10-Q with the Securities and Exchange Commission or a Form 1 with the Federal Energy Regulatory Commission, need not submit the annual financial report or the certified financial statement under this paragraph.

§ 53.6390 Licensee's change of status; financial qualifications.

(a) An electric utility licensee holding an operating license or combined license (including a renewed license) for a commercial nuclear plant, no later than seventy-five (75) days prior to ceasing to be an electric utility in any manner not involving a license transfer under § 53.4999, must provide the NRC with the financial qualifications information that would be required for obtaining an initial operating license as specified in § 53.4966. The financial qualifications information must address the first full five years of operation after the date the licensee ceases to be an electric utility.

(b)(1) Any holder of a license issued under Framework B of this part shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee;

(ii) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(2) This notification must indicate:

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

§ 53.6400 Creditor regulations.

(a) Pursuant to section 184 of the Atomic Energy Act of 1954, as amended (AEA), the Commission consents, without individual application, to the creation of any mortgage, pledge, or other lien upon any commercial nuclear plant not owned by the

United States which is the subject of a license or upon any leasehold or other interest in such facility; *provided*:

(1) That the rights of any creditor so secured may be exercised only in compliance with and subject to the same requirements and restrictions as would apply to the licensee pursuant to the provisions of the license, the AEA, and regulations issued by the Commission pursuant to the AEA; and

(2) That no creditor so secured may take possession of the facility pursuant to the provisions of this section prior to either the issuance of a license from the Commission authorizing such possession or the transfer of the license.

(b) Any creditor so secured may apply for transfer of the license covering such facility by filing an application for transfer of the license pursuant to § 53.6070. The Commission will act upon such application pursuant to Subpart S of this part.

(c) Nothing contained in this regulation shall be deemed to affect the means of acquiring, or the priority of, any tax lien or other lien provided by law.

(d) As used in this section: (1) "*License*" includes any license under Framework B of this part, which may be issued by the Commission with regard to a facility;

(2) "*Creditor*" includes, without implied limitation, the trustee under any mortgage, pledge or lien on a facility made to secure any creditor, any trustee or receiver of the facility appointed by a court of competent jurisdiction in any action brought for the benefit of any creditor secured by such mortgage, pledge or lien, any purchaser of such facility at the sale thereof upon foreclosure of such mortgage, pledge, or lien or upon exercise of any power of sale contained therein, or any assignee of any such purchaser.

(3) "*Facility*" includes but is not limited to, a site which is the subject of an early site permit under § 53.4750, and a reactor manufactured under a manufacturing license under § 53.4870 of this part.

§ 53.6410 Financial protection.

Sections 53.6420 and 53.6430 set out the requirements and procedures related to licensees obtaining and maintaining insurance to cover stabilization and decontamination activities in the event of an accident and financial protection in accordance with Part 140, "Financial Protection Requirements and Indemnity Agreements," of this chapter.

§ 53.6420 Insurance required to stabilize and decontaminate plant following an accident.

Each commercial nuclear plant licensee under Framework B of this part shall take reasonable steps to obtain insurance available at reasonable costs and on reasonable terms from private sources or to demonstrate to the satisfaction of the NRC that it possesses an equivalent amount of protection covering the licensee's obligation, in the event of an accident at the licensee's reactor, to stabilize and decontaminate the plant and the plant site at which such an accident may occur, provided that:

(a) The insurance required by this section must have a minimum coverage limit for each reactor station site of \$1.06 billion, an amount based on plant-specific estimates of costs to stabilize and decontaminate a plant, or whatever amount of insurance is generally available from private sources, whichever is less. The required insurance must clearly state that, as and to the extent provided in paragraph (4) of this section, any proceeds must be payable first for stabilization of the plant and next for decontamination of the plant and the plant site. If a licensee's coverage falls below the required minimum, the licensee shall within 60 days take all reasonable steps to restore its coverage to the required minimum. The required insurance may, at the option of the licensee, be

included within policies that also provide coverage for other risks, including, but not limited to, the risk of direct physical damage.

(b)(1) With respect to policies issued or annually renewed, the proceeds of such required insurance must be dedicated, as and to the extent provided in this paragraph, to reimbursement or payment on behalf of the insured of reasonable expenses incurred or estimated to be incurred by the licensee in taking action to fulfill the licensee's obligation, in the event of an accident at the licensee's plant, to ensure that the plant is in, or is returned to, and maintained in, a safe and stable condition and that radioactive contamination is removed or controlled such that personnel exposures are consistent with the occupational exposure limits in 10 CFR part 20. These actions must be consistent with any other obligation the licensee may have under this chapter and must be subject to paragraph (d) of this section. As used in this section, an "accident" means an event that involves the release of radioactive material from its intended place of confinement within the commercial nuclear plant such that there is a present danger of release off site in amounts that would pose a threat to the public health and safety.

(2) The stabilization and decontamination requirements set forth in paragraph (d) of this section must apply uniformly to all insurance policies required under this section.

(c) The licensee shall report to the NRC on April 1 of each year the current levels of this insurance or financial security it maintains and the sources of this insurance or financial security.

(d)(1) In the event of an accident at the licensee's plant, whenever the estimated costs of stabilizing the licensed plant and of decontaminating the plant and the plant site exceed one tenth of the minimum insurance under paragraph (a), the proceeds of the insurance required by this section must be dedicated to and used, first, to ensure that the licensed plant is in, or is returned to, and can be maintained in, a safe and stable condition so as to prevent any significant risk to the public health and safety and,

second, to decontaminate the plant and the plant site in accordance with the licensee's cleanup plan as approved by order of the Director of the Office of Nuclear Reactor Regulation. This priority on insurance proceeds must remain in effect for 60 days or, upon order of the Director, for such longer periods, in increments not to exceed 60 days except as provided for activities under the cleanup plan required in paragraphs (d)(3) and (d)(4) of this section, as the Director may find necessary to protect the public health and safety. Actions needed to bring the plant to and maintain the plant in a safe and stable condition may include one or more of the following, as appropriate:

- (i) Shutdown of the reactor(s) and other processes at the plant;
- (ii) Establishment and maintenance of long-term cooling with stable decay heat removal;
- (iii) Maintenance of sub-criticality;
- (iv) Control of radioactive releases; and
- (v) Securing of structures, systems, or components to minimize radiation exposure to onsite personnel or to the offsite public or to facilitate later decontamination or both.

(2) The licensee shall inform the Director of the Office of Nuclear Reactor Regulation in writing when the plant is and can be maintained in a safe and stable condition so as to prevent any significant risk to the public health and safety. Within 30 days after the licensee informs the Director that the plant is in this condition, or at such earlier time as the licensee may elect or the Director may for good cause direct, the licensee shall prepare and submit a cleanup plan for the Director's approval. The cleanup plan must identify and contain an estimate of the cost of each cleanup operation that will be required to decontaminate the reactor sufficiently to permit the licensee either to resume operation of the reactor or to apply to the Commission under Subpart G for

authority to decommission the reactor and to surrender the license voluntarily. Cleanup operations may include one or more of the following, as appropriate:

(i) Processing any contaminated materials generated by the accident and by decontamination operations to remove radioactive materials;

(ii) Decontamination of surfaces inside the plant buildings to levels consistent with the Commission's occupational exposure limits in 10 CFR part 20, and decontamination or disposal of equipment;

(iii) Decontamination or removal and disposal of internal parts, damaged fuel from the reactor coolant or fuel systems, or related process or waste systems; and

(iv) Cleanup of the reactor coolant or fuel systems or related process or waste systems.

(3) Following review of the licensee's cleanup plan, the Director will order the licensee to complete all operations that the Director finds are necessary to decontaminate the reactor sufficiently to permit the licensee either to resume operation of the reactor or to apply to the Commission under Subpart Q for authority to decommission the reactor and to surrender the license voluntarily. The Director shall approve or disapprove, in whole or in part for stated reasons, the licensee's estimate of cleanup costs for such operations. Such order may not be effective for more than one year, at which time it may be renewed. Each subsequent renewal order, if imposed, may be effective for not more than 6 months.

(4) Of the balance of the proceeds of the required insurance not already expended to place the plant in a safe and stable condition pursuant to paragraph (b)(1) of this section, an amount sufficient to cover the expenses of completion of those decontamination operations that are the subject of the Director's order shall be dedicated to such use, provided that, upon certification to the Director of the amounts expended previously and from time to time for stabilization and decontamination and upon further

certification to the Director as to the sufficiency of the dedicated amount remaining, policies of insurance may provide for payment to the licensee or other loss payees of amounts not so dedicated, and the licensee may proceed to use in parallel (and not in preference thereto) any insurance proceeds not so dedicated for other purposes.

§ 53.6430 Financial protection requirements.

Commercial nuclear plant licensees must satisfy the applicable provisions of Part 140, "Financial Protection Requirements and Indemnity Agreements," of this chapter.

Subpart U – Quality Assurance

§ 53.6600 General provisions.

Commercial nuclear power plants and manufactured reactors include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This subpart establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components classified as safety related. The pertinent requirements of this subpart apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

As used in this subpart, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical

characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

§ 53.6605 Organization.

The applicant³ must establish and execute the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program. The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of (1) assuring that an appropriate quality assurance program is established and effectively executed; and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient

³ While the term “applicant” is used in these criteria, the requirements are applicable after such a person has received a license to construct and operate a commercial nuclear power plant or manufacturing facility or has received an early site permit, design approval, design certification, or manufacturing license, as applicable. These criteria will also be used for guidance in evaluating the adequacy of quality assurance programs in use by holders of construction permits, operating licenses, early site permits, design approvals, combined licenses, and manufacturing licenses.

independence from cost and schedule when opposed to safety considerations, are provided. Because many of the variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to this subpart are being performed, shall have direct access to the levels of management necessary to perform this function.

§ 53.6610 Quality assurance program.

The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this Subpart. The program shall be documented by written policies, procedures, or instructions and shall be carried out throughout the plant life in accordance with those policies, procedures, or instructions. The applicant shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety. Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all

prerequisites for the given activity have been satisfied. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

§ 53.6615 Design control.

Measures shall be established to assure that applicable regulatory requirements and the design basis, as specified in the license application, for those structures, systems, and components to which this subpart applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components.

Measures shall be established for the identification and control of design interfaces and for the coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program.

The verifying or checking process shall be performed by individuals or groups other than those who performed the original design but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions.

Design control measures shall be applied to items such as the following: reactor physics, stress, thermal hydraulic, and accident analysis; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests.

Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

§ 53.6620 Procurement document control.

Measures shall be established to assure that applicable regulatory requirements, design basis, and other requirements which are necessary to assure adequate quality, are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this subpart.

§ 53.6625 Instructions, procedures, and drawings.

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

§ 53.6630 Document control.

Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

§ 53.6635 Control of purchased material, equipment, and services.

Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished

by the contactor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the commercial nuclear plant site or manufacturing facility prior to installation or use of such material and equipment. This documentary evidence shall be retained at the commercial nuclear power plant site or manufacturing facility and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

§ 53.6640 Identification and control of materials, parts, and components.

Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.

§ 53.6645 Control of special processes.

Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by

qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

§ 53.6650 Inspection.

A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspection shall be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific hold points shall be designated in appropriate documents.

§ 53.6655 Test control.

A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program shall include, as appropriate, proof tests prior to

installation, preoperational tests, and operational tests during commercial nuclear power plant and manufacturing facility operation, of structures, systems, and components. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied.

§ 53.6660 Control of measuring and test equipment.

Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specific periods to maintain accuracy within necessary limits.

§ 53.6665 Handling, storage and shipping.

Measures shall be established to control the handling, storage, shipping, cleaning, and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided.

§ 53.6670 Inspection, test, and operating status.

Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the commercial nuclear power plant or manufactured reactor module. These measures shall provide for the identification of

items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures shall also be established for including the operating status of structures, systems, and components of the commercial nuclear power plant or manufactured reactor module, such as by tagging valves and switches, to prevent inadvertent operation.

§ 53.6675 Nonconforming materials, parts, or components.

Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

§ 53.6680 Corrective action.

Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material, and equipment and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

§ 53.6685 Quality assurance records.

Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and material analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

§ 53.6690 Audits.

A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.