THIS PRELIMINARY 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 CONCEPTS AND DETAILS PROVIDED IN THIS PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES. THE STAFF IS PRIMARILY SEEKING INSIGHTS REGARDING THE CONCEPTS IN THIS PRELIMINARY LANGUAGE AND SECONDARILY SEEKING INSIGHTS RELATED TO DETAILS SUCH AS NUMERICAL VALUES FOR VARIOUS CRITERIA.

Preliminary proposed rule language is provided for selected sections related to the safety and risk criteria that would provide the foundations of the regulatory framework, whether using this outline or an alternative structure. Short summaries of other possible subparts and sections are provided for context. This revision includes revisions to previously released language for Subpart B (Technology-Inclusive Safety Requirements) and Subpart C (Design and Analysis Requirements). This revision also includes previously released proposed rule language for Subpart D (Siting Requirements), Subpart E (Construction and Manufacturing Requirements), and a portion of Subpart F (Requirements for Operations) related to Facility Safety Programs.

PRELIMINARY PROPOSED RULE LANGUAGE March 31, 2021
10 CFR PART 53, "LICENSING AND REGULATION OF ADVANCED NUCLEAR REACTORS"

Subpart A - General Provisions

This subpart is envisioned to include sections related to topics such as scope, definitions, interpretations, relationships to other parts, communications, misconduct, employee protections, and exemptions. Most sections will be developed based on similar requirements in existing parts of NRC regulations.

Subpart B - Technology-Inclusive Safety Requirements

Preliminary rule language for Subpart B was previously released to support interactions with stakeholders, including a public meeting on November 18, 2020 (ADAMS Accession No. ML20289A591). This iteration reflects revisions to the preliminary proposed rule language in response to those interactions and other comments received. The staff will continue to interact with stakeholders and iterate on the preliminary rule language during its development of the proposed rulemaking.

Please note that the section numbers in Subpart B have been expanded to allow for future additions compared to the version made public to support the November 18, 2020, Part 53 public meeting.

§ 53.200 Safety Objectives.

Each advanced nuclear plant must be designed, constructed, operated, and decommissioned ~~such that there is reasonable assurance of adequate protection of~~ to limit the possibility of an immediate threat to the public health and safety ~~and the common defense and security.~~. In addition, each advanced nuclear plant must take such additional measures ~~to protect public health and minimize danger to life or property~~ as may be ~~reasonable~~appropriate when considering ~~technology changes, economic costs, operating experience, or other factors~~potential risks to public health and safety. These safety objectives shall be carried out by meeting the safety criteria identified in ~~the assessments performed under the facility safety program required by § 53.800~~this subpart.

§ 53.210 ~~Safety Functions.~~

~~(a) The primary safety function is limiting the release of radioactive materials from the facility and must be maintained during routine operation and for licensing basis events over the life of the plant.~~

~~(b) Additional safety functions supporting the retention of radioactive materials during routine operation and licensing basis events—such as controlling heat generation, heat removal, and chemical interactions—must be defined.~~

~~(c) Design features and programmatic controls serve to fulfill the primary safety function and additional safety functions and must be maintained over the life of the plant.~~

~~§ 53.220~~ First Tier Safety Criteria.

(a) *Normal operations.* Design features and programmatic controls must be provided for each advanced nuclear plant to ensure the contribution to total effective dose equivalent to individual members of the public from normal plant operation does not exceed ~~0.1 rem (1 mSv) in a year and the contribution to dose in any unrestricted area does not exceed 0.002 rem (0.02 millisievert) in any one hour.~~the public dose limits provided in Subpart D to 10 CFR part 20.

(b) *Unplanned events.* Design features and programmatic controls must be provided for each advanced nuclear plant such that analyses of licensing basis events in accordance with § 53.240, including treatment of uncertainties, demonstrate ~~with high confidence~~ that events with an upper bound frequency greater than approximately once per 10,000 years meet the following:

(1) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release would not receive a radiation dose in excess of 25 rem (250 mSv) total effective dose equivalent; and

(2) An individual located at any point on the outer boundary of the low population zone who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (250 mSv) total effective dose equivalent.[1]

~~(c) Design features and programmatic controls beyond those needed for paragraphs (a) and (b) of this section must be provided for each advanced nuclear plant to satisfy additional~~

[1] A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP [National Council on Radiation Protection and Measurements] recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

~~requirements established by the NRC for ensuring reasonable assurance of adequate protection of the public health and safety and maintaining common defense and security.~~

§ 53.~~230~~220 Second Tier Safety Criteria.

a) *Normal operations.* Design features and programmatic controls must be provided for each advanced nuclear plant to ensure the estimated total effective dose equivalent to individual members of the public from effluents resulting from normal plant operation are as low as is reasonably achievable taking into account the state of technology, the economics of improvements in relation to the state of technology, operating experience, ~~the economics of improvements in relation to~~and the benefits to the public health and safety ~~and other factors included in the assessments performed under the facility safety program required by § 53.800. Performance objectives for design~~. Design features and programmatic controls must be established such that~~:~~ [to be reworded for consistency with 10 CFR part 20 and 40 CFR part 190].

~~(1) The calculated annual total quantity of all radioactive material above background to be released from each advanced nuclear plant to unrestricted areas will not result in an estimated annual dose or dose commitment from liquid effluents for any individual in an unrestricted area from all pathways of exposure in excess of 3 millirems to the total body or 10 millirems to any organ.~~

~~(2) The calculated annual total quantity of all radioactive material above background to be released from each advanced nuclear plant to the atmosphere will not result in an estimated annual air dose from gaseous effluents at any location near ground level which could be occupied by individuals in unrestricted areas in excess of 10 millirads for gamma radiation or 20 millirads for beta radiation.~~

(b) *Unplanned events.* Design features and programmatic controls must be provided to:

(1) Ensure plant SSCs, personnel, and programs provide the necessary capabilities and maintain the necessary reliability to address licensing basis events in accordance with § 53.240 and provide measures for defense-in-depth in accordance with § 53.250; and

(2) Maintain overall cumulative plant risk from licensing basis events such that the risk to an average individual within the vicinity of the plant receiving a radiation dose with the potential for immediate health effects remains below five in 10 million years, and ~~below two in one million years for~~the risk to such an individual receiving a radiation dose with the potential to cause latent health effects remains below two in one million years.

§ 53.230 Safety Functions.

(a) The primary safety function is limiting the release of radioactive materials from the facility and must be maintained during routine operation and for licensing basis events over the life of the plant.

(b) Additional safety functions supporting the retention of radioactive materials during routine operation and licensing basis events—such as controlling heat generation, heat removal, and chemical interactions--must be defined.

~~(c)Design features and programmatic controls serve to fulfill the primary safety function and additional safety functions and must be maintained over the life of the plant~~. The primary and additional safety functions are required to meet the first and second tier safety criteria and are fulfilled by the design features and programmatic controls specified throughout this part.

§ 53.240 Licensing Basis Events.

Licensing basis events must be identified for each advanced nuclear plant and analyzed in accordance with § 53~~.[3x]~~.450 to support assessments of the safety requirements ~~of~~in this

subpart B. The licensing basis events must address combinations of malfunctions of plant SSCs, human errors, and the effects of external hazards ranging from anticipated operational occurrences to highlyvery unlikely event sequences that are notwith estimated frequencies well below the frequency of events expected to occur in the life of the advanced nuclear plant. The evaluation of licensing basis events must be used to confirm the adequacy of design features and programmatic controls needed to satisfy first and second tier safety criteria of this subpart and to establish related functional requirements for plant SSCs, personnel, and programs.

§ 53.250 Defense in Depth.

Measures must be taken for each advanced nuclear plant to ensure appropriate defense in depth is provided to compensate for epistemic and aleatory uncertainties such that there is high confidence that the safety criteria in this subpart B are met over the life of the plant. The epistemic and aleatory uncertainties to be considered include those related to the state of knowledge and modeling capabilities, the ability of barriers to limit the release of radioactive materials from the facility during routine operation and for licensing basis events, and those related to the reliability and performance of plant SSCs and personnel, and programmatic controls. Measures to compensate for these uncertainties can include increased safety margins in the design of SSCs and providing alternate means to accomplish safety functions. No single engineered design or operational feature, human action, and or programmatic control, no matter how robust, should be exclusively relied upon to meet the safety criteria of 10 CFR part§ 53.220(b) or the safety functions defined in accordance with § 53.230.

§ 53.260 Protection of Plant Workers.

(a) Design features and programmatic controls must exist for each advanced nuclear plant to ensure that radiological dose to plant workers does not exceed the occupational dose limits provided in subpart C to 10 CFR part 20.

(b) The licensee As required by Subpart B to 10 CFR part 20, design features and programmatic controls must use, to the extent practical, procedures and engineering controls be based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable.

Subpart C - Design and Analysis Requirements

Preliminary rule language for Subpart C was previously released to support interactions with stakeholders, including a public meeting on January 7, 2021 (ADAMS Accession No. ML ML20337A432). This iteration reflects revisions to the preliminary proposed rule language in response to those interactions and other comments received. The staff will continue to interact with stakeholders and iterate on the preliminary rule language during its development of the proposed rulemaking.
Discussions are needed on the potential inclusion of requirements to address non-radiological hazards (e.g., chemical hazards) and on the potential role of an analyses of unmitigated event consequences (e.g., crediting inherent characteristics but not engineered design features).

§ 53.400 Design Objectives and Design Features.

Design features must be provided for each advanced nuclear plant such that, when combined with associated programmatic controls and human actions, the plant will satisfy the first and second tier safety criteria defined in §§ 53.220210 and 53.230220. Design features must ensure that the safety functions identified in § 53.210230, of limiting the release of

radioactive materials from the facility, is maintained during routine operations and licensing basis events by controlling the release of radioactive materials and by supporting other safety functions.

§ 53.410 Functional Design Criteria for First Tier Safety Criteria.

(a) *Normal operations.* Functional design criteria must be defined for each design feature required by § 53.400 to demonstrate compliance with the first tier safety criteria defined in § 53.220210(a). Corresponding programmatic controls, including monitoring programs, must be established to confirm that the established functional design criteria and the first tier safety criteria required in § 53.220210(a) are not exceeded during normal operations.

(b) *Unplanned events.* Functional design criteria must be defined for each design feature required by § 53.400 relied upon to demonstrate compliance with the first tier safety criteria defined in § 53.220210(b). Corresponding programmatic controls and interfaces must be established in accordance with this and [other subparts to achieve and maintain the reliability and capability of SSCs relied upon to meet the established functional design criteria and the first tier safety criteria required in § 53.220210(b), and to maintain consistency with analyses required by § 53.450.

§ 53.420 Functional Design Criteria for Second Tier Safety Criteria.

~~(a) Design features must be provided for each advanced nuclear plant such that, when combined with associated programmatic controls and human actions, the total effective dose equivalent to individual members of the public from effluents resulting from normal plant operation are as low as is reasonably achievable taking into account the state of technology, the economics of improvements in relation to the state of technology, operating experience, and benefits to the public health and safety, and other factors included in the assessments performed under the facility safety program required by § 53.800, and the safety criteria and performance objectives in § 53.230(a).~~ (a) *Normal operations.* Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with the second tier safety criteria in § 53.230220(a). Corresponding programmatic controls, including monitoring programs, must be established to confirm that the established functional design criteria and the safety criteria and performance objectives in § 53.230220(a) are not exceeded during normal operations.

~~(b) Design features must be provided for each advanced nuclear plant such that, when combined with associated programmatic controls and human actions, the analyses required by § 53.450 provide reasonable assurance that the estimated risks from unplanned events will be below the second tier safety criteria in § 53.230(b).~~ (b) *Unplanned events.* Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with the second tier safety criteria in § 53.~~230(b).~~220(b) considering licensing basis events ranging from anticipated operational occurrences to very unlikely event sequences with estimated frequencies well below the frequency of events expected to occur in the life of the advanced nuclear plant. Corresponding programmatic controls and interfaces must be established in accordance with this and other subparts to achieve and maintain the reliability and capability of SSCs relied upon to meet the second tier safety criteria in § 53.230220(b) and to maintain consistency with analyses required by § 53.450.

§ 53.430 Functional Design Criteria for Protection of Plant Workers.

Design features must be provided for each advanced nuclear plant such that, when combined with associated programmatic controls and human actions, there is reasonable assurance the requirements for the protection of plant workers in § 53.260 will be met. Functional design criteria must be defined for each design feature relied upon to demonstrate

compliance with § 53.260. Corresponding programmatic controls, including monitoring programs, must be established to confirm that the worker protection criteria in § 53.260(a) are not exceeded. In addition, functional design criteria must be defined for each design feature to ensure that plant SSCs and associated programmatic controls, including monitoring programs, achieve occupational doses as low as is reasonably achievable as required by § 53.260(b).

§ 53.440 Design Requirements.

(a) The design features required to meet the first and second tier safety criteria defined in §§ 53.220210 and 53.230220 shall be designed using generally accepted consensus codes and standards wherever applicable.

(b) The materials used for safety related and non-safety related but safety significant SSCs ([as will be defined in § 53.460)subpart A] must be qualified for their service conditions over the plant lifetime.

(c) Safety and security must be considered together in the design process such that, where possible, security issues are effectively resolved through design and engineered security features.

(d) Design features must be demonstrated capable of accomplishing the safety functions defined in § 53.210 without adversely affecting other design features. The demonstration must be through analysis consistent with § 53.450fulfilling functional design criteria considering interdependent effects through analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof for the range of conditions under which the analysis required in § 53.450 assumes these features will function throughout the plant's lifetime.

§ 53.450 Analysis Requirements.

(a) *Requirement to have a probabilistic risk assessment.* A probabilistic risk assessment (PRA) of each advanced nuclear plant [reminder – plant definition to include multi-module and multi-source] must be performed to identify potential failures, degradation mechanisms, susceptibility to internal and external hazards, and other contributing factors to unplanned events that might challenge the safety functions identified in § 53.210.230 and to support demonstrating that each advanced nuclear plant meets the second tier safety criteria of § 53.220(b).

(b) The probabilistic risk assessment (PRA) must:

(1) Be used in(b) *Specific uses of analyses*. The PRA, other generally accepted risk-informed approach for systematically evaluating engineered systems, or combination thereof must be used:

(1) In determining the licensing basis events, as described in § 53.240, which must be considered in the design to determine compliance with the safety criteria in Subpart B of this part.

(2) Be used forFor classifying SSCs and human actions according to their safety significance in accordance with § 53.460 and for identifying the environmental conditions under which the SSCs and operating staff must perform their safety functions.

(3) Be used inIn evaluating the adequacy of defense-in-depth measures required in accordance with § 53.250.

(4) AssessTo identify and assess all plant operating states where there is the potential for the uncontrolled release of radioactive material to the environment.

(5) ConsiderTo identify and assess events that challenge plant control and safety systems whose failure could lead to the uncontrolled release of radioactive material to the environment. These include internal events, such as human errors and equipment failures, and external events, such as earthquakes, identified in accordance with Subpart D of this part.

~~(6) Conform~~(c) *Maintenance and upgrade of analyses*. The PRA, other generally accepted risk-informed approach for systematically evaluating engineered systems, or combination thereof must be maintained and upgraded in conformance with generally accepted methods, standards, and practices.

~~(7) Be maintained and upgraded to cover initiating events and modes of operation contained in generally accepted methods, standards, and practices in effect one year prior to each required PRA upgrade. The PRA must be upgraded every two years until the permanent cessation~~(d) *Qualification of ~~operations under Subpart G of this part.~~*(c)*analytical codes*. The analytical codes used in modeling plant behavior ~~during~~in analyses of licensing basis events (e.g. thermodynamics, reactor physics, fuel performance, mechanistic source term) must be qualified for the range of conditions for which they are to be used.

~~(d) If not addressed within the PRA under paragraph (b), analyses must be performed to assess:~~

~~(1) measures provided to protect against, detect and suppress fires that could impact the ability of equipment to perform its safety function and challenge the safety criteria contained in §§ 53.220 and 53.230.~~

~~(2) measures provided to protect against aircraft impacts as required by 10 CFR 50.150, and~~

~~(3) measures to mitigate specific beyond design basis events as required by 10 CFR 50.155.~~

~~(e)~~(e) *Analyses of licensing basis events*. Analyses must be performed for licensing basis events ranging from anticipated operational occurrences to very unlikely event sequences with estimated frequencies well below the frequency of events expected to occur in the life of the advanced nuclear plant. The licensing basis events must be identified using insights from a PRA, other generally accepted risk-informed approach for systematically evaluating engineered systems, or combination thereof to systematically identify and analyze equipment failures and human errors. The analyses must address event sequences from initiation to a defined end state and demonstrate that the functional design criteria required by § 53.420 provide sufficient barriers to the unplanned release of radionuclides to satisfy the second tier safety criteria of § 53.220(b) and provide defense in depth as required by § 53.250.

(f) *Analysis of design basis accidents*. The analysis of licensing basis events required by § 53.240 and § 53.450(e) must include analysis of a set of design basis accidents that address possible challenges to the safety functions identified in accordance with § 53.~~210~~230. Design basis accidents must be selected from those unanticipated event sequences with an upper bound frequency of less than one in 10,000 years as identified using insights from a ~~design-specific probabilistic~~PRA, other generally accepted risk~~ assessment that~~-informed approach for systematically ~~identifies~~evaluating engineered systems, or combination thereof to systematically identify and ~~analyzes~~analyze equipment failures and human errors. The events selected as design basis accidents should be those that, if not terminated, have the potential for exceeding the safety criteria in § 53.~~220~~210(b). The design-basis accidents selected must be analyzed using deterministic methods ~~assuming~~that address event sequences from initiation to a safe stable end state and assume only the safety~~-~~-related SSCs identified in § 53.460 and human actions addressed by § 53.8xx (reference to concept of operations sections of Subpart F) are available to perform the safety functions identified in accordance with § 53.~~210~~230. The analysis must conservatively demonstrate compliance with the safety criteria in § 53.~~220~~210(b).

(g) *Other required analyses*. If not addressed within the PRA, other generally accepted risk-informed approach for systematically evaluating engineered systems, or combination thereof under paragraph (b), analyses must be performed to assess:

(1) measures provided to protect against, detect and suppress fires that could impact the ability of equipment to perform its safety function and challenge the safety criteria contained in §§ 53.210 and 53.220.

(2) measures provided to protect against aircraft impacts as required by 10 CFR 50.150, and

(3) measures to mitigate specific beyond design basis events as required by 10 CFR 50.155.

§ 53.460 Safety Categorization and Special Treatment.

(a) SSCs and human actions must be classified according to their safety significance. The categories must include "Safety Related" (SR), ~~which are those SSCs and human actions relied upon to function in response to design basis accidents to meet the safety criteria in § 53.220(b); "Non-Safety Related but Safety Significant" (NSRSS), which are those SSCs and human actions that perform a function that is necessary to achieve adequate defense-in-depth or are classified as risk significant (i.e., whose failure contributes 1% or more to cumulative plant risk, as defined in § 53.230, or would cause a licensing basis event to exceed the safety criteria in § 53.220(b)); and "Non-Safety Significant" (NSS), which are those SSCs not warranting special treatment~~"Non-Safety Related but Safety Significant" (NSRSS), and "Non-Safety Significant" (NSS), as defined in subpart A of this part.

(b) For SR and NSRSS SSCs and human actions, the conditions under which they must perform their safety function in § 53.~~210~~230 must be identified. Special Treatment (e.g., functional design criteria and programmatic controls) must be established in accordance with this and ~~[~~other Subparts to provide appropriate confidence that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in §§ 53.~~220~~210(b) and 53.~~230~~220(b).

(c) Human actions to prevent or mitigate licensing basis events must be capable of being reliably performed under the postulated environmental conditions present and be addressed by programs established in accordance with Subpart F of this part to provide confidence that those actions will be performed as assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in §§ 53.~~220~~210(b) and 53.~~230~~220(b).

§ 53.470 Application of Analytical Safety Margins to Operational Flexibilities.

Where an applicant or licensee so chooses, design criteria more restrictive than those defined in § 53.~~230~~220(b) may be adopted to support operational flexibilities (e.g., emergency planning requirements under Subpart F of this part). In such cases, applicants and licensees must ensure that the functional design criteria of § 53.420(b), the analysis requirements of § 53.450, and identification of special treatment of SSCs and human actions under § 53.460 reflect and support the use of alternative design criteria to obtain additional analytical safety margins. Licensees must ensure that measures taken to provide the analytical margins supporting operational flexibilities are incorporated into design features and programmatic controls and are maintained within programs required in other Subparts.

§ 53.480 Design Control Quality Assurance.

(a) Measures must be established to assure that the design criteria, analysis, categorization and special treatment of SSCs as required by § 53.460 are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures must also be established for the selection and review for suitability of application of materials, parts, equipment, and processes needed to meet the safety criteria identified per §§ 53.~~220~~210 and

53.~~230~~220 in accordance with ~~§ 53.xxx (construction and procurement subpart).~~Subpart E of this part. The QA program must conform with generally accepted consensus codes and standards.

(b) Measures must be established for the identification and control of design interfaces in accordance with § 53.490.

(c) The design control measures must provide for verifying or checking the adequacy of design in a manner commensurate with its safety significance, 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 must be performed in accordance with appropriate quality standards. Design changes, including field changes, must 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 qualified organization.

§ 53.490 Design and Analyses Interfaces.

Measures must be established for the identification and control of interfaces between (a) the plant design and supporting analyses required by this Subpart and (b) the activities addressed by other Subparts over the life of each advanced nuclear plant. These measures must include procedures for the review, approval, release, distribution, and revision of documents involving design interfaces such that design decisions are made in an integrated fashion considering all aspects of the facility impacted by the design or operational change prior to its implementation. Changes to design features and related programmatic controls over the lifetime of an advanced nuclear plant must be considered along with the state of technology, the economics of improvements in relation to the state of technology, operating experience, and benefits to the public health and safety, and other factors included in the assessments performed under the facility safety program required by § 53.800.

Subpart D - Siting Requirements

§ 53.500 General Siting.

Considerations must be given to the siting of each advanced nuclear plant such that, when combined with associated design features and programmatic controls, the plant will satisfy the first and second tier safety criteria defined in §§ 53.~~220~~210 and 53.~~230~~220. A siting assessment for each advanced nuclear ~~plants~~plant must be performed and must ensure that external hazards and site characteristics that might contribute to the initiation, progression, or consequences of licensing basis events analyzed in accordance with § 53.240 are identified and addressed by design features or programmatic controls. The siting assessments must address the potential adverse impacts that an advanced nuclear plant may have on nearby environs as a result of normal operations or radiological accidents as required by Part 51, “Environmental protection regulations for domestic licensing and related regulatory functions,” of this chapter.

§ 53.510 External Hazards.

(a) Structures, systems, and components needed to ensure the first tier safety criteria defined in § 53.~~220~~210(b) are met must be designed to withstand the effects of natural phenomena (e.g., earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches) and man-related hazards (e.g., dams, transportation routes, military and industrial facilities) of magnitudes up to the design basis external hazard levels without losing the capability to perform

the safety functions defined in § 53.~~210~~230. The design bases external hazard level for the relevant external hazards for a site must be identified and must address a range of estimated external hazard frequencies from routine to once in one hundred thousand years, with sufficient margin for the limited accuracy, quantity, and period of time used to estimate the hazard.

(b) *Safe Shutdown Earthquake Ground Motion*. The geologic and seismic siting factors considered for design must include a determination of the Safe Shutdown Earthquake Ground Motion for the site. The Safe Shutdown Earthquake Ground Motion is the vibratory ground motion for which certain structures, systems, and components must be designed to remain functional. The Safe Shutdown Earthquake Motion for the site is characterized by both horizontal and vertical free-field ground motion response spectra at the free ground surface. The Safe Shutdown Earthquake Ground Motion for the site is determined considering the results of the geological, seismological, and engineering characteristics of a site and its environs. The size of the region to be investigated and the type of data pertinent to the investigations must be determined based on the nature of the region surrounding the proposed site. Data on vibratory ground motion, earthquake recurrence rates, fault geometry and slip rates, and site subsurface material properties must be obtained by reviewing pertinent literature and carrying out field investigations. Uncertainties are inherent in the parameters and models used to estimate the Safe Shutdown Earthquake Ground Motion for the site. These uncertainties must be addressed through an appropriate analysis, such as a probabilistic seismic hazard analysis or suitable sensitivity analyses. The horizontal component of the Safe Shutdown Earthquake Ground Motion in the free-field at the foundation level of the structures must be an appropriate response spectrum with a peak ground acceleration of at least 0.1g.

(c) The analyses required by § 53.450 must address external hazard frequencies and related SSC fragilities in determining reasonable assurance that the second tier safety criteria defined in § 53.~~230~~220(b) will be met. Corresponding functional design criteria, programmatic controls and interfaces must be established to achieve and maintain the performance of SSCs relied upon to meet the safety criteria in § 53.~~230~~220(b) and to maintain consistency with analyses required by § 53.450.

§ 53.520 Site Characteristics.

Meteorological, geological, seismological, topographical, hydrological, and other characteristics of the site and surrounding area that may have a bearing on the consequences of radioactive material escaping from the subject advanced nuclear plant should be identified, estimated, and considered in the design and analyses required by Subpart C of this part.

§ 53.530 Population-related Considerations.

Every site must have an exclusion area, low population zone, and provide a population center distance as defined in § 53.120. [Note proposed definitions currently provided in 10 CFR 100.3] The offsite radiological consequences estimated by the supporting analyses required by § 53.~~430~~450 to ensure meeting the second tier safety criteria of § 53.~~230~~220(b) are used to define:

(a) An exclusion area of such size that an individual located at any point on its boundary for any two-hour period following onset of the postulated fission product release would not receive in excess of 25 rem (250 mSv) total effective dose equivalent (TEDE).

(b) A low population zone of such size that an individual located at any point on its outer boundary who is exposed to the radioactive cloud resulting from the postulated fission product

release (during the entire period of its passage) would not receive in excess of 25 rem (250 mSv) TEDE.

(c) The population center distance must be at least one and one-third times the distance from the reactor to the outer boundary of the low population zone. The boundary of the population center shall be determined upon consideration of population distribution. Political boundaries are not controlling in the calculation of population center distance.

(d) Reactor sites should be located away from very densely populated centers. Areas of low population density are, generally, preferred. However, in determining the acceptability of a particular site located away from a very densely populated center but not in an area of low population density, consideration will be given to safety, environmental, economic, or other factors, which may result in the site being found acceptable.

§ 53.540 Siting Interfaces.

External hazards and site characteristics must be incorporated into, confirmed to be consistent with, or otherwise addressed by the design features, programmatic controls, and supporting analyses used to demonstrate that the first and second tier safety criteria in §§ 53.~~220~~210 and 53.~~230~~220 are met for each advanced nuclear plant. Site characteristics must be such that adequate emergency plans and security plans can be developed and maintained. Changes to external hazards or site characteristics over the lifetime of an advanced nuclear plant should be considered in the assessments performed under the facility safety program required by § 53.~~800~~8xx.

§ 53.550 Environmental Considerations.

Requirements to address environmental protection regulations must be addressed in accordance with 10 CFR part 51.

Subpart E - Construction and Manufacturing Requirements

This subpart is envisioned to address areas such as construction, manufacturing, and procurement. Specific sections are likely to address areas such as quality assurance, testing, and interfaces with design (change control).

§ 53.600 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 a Limited Work Authorization (LWA) under subpart H of this regulation. The term construction, as defined in § 53.xyz, refers to those activities contributing to meeting the first and second tier safety criteria defined in §§ 53.210 and 53.220, respectively, that are conducted on-site to build the nuclear facility in support of subsequent operations. [Note - Definition of construction to exclude items currently excluded by § 50.10(a)(2)]. The term manufacturing, as defined in § 53.xyz, refers to those activities conducted at one or more facilities under a ML for transport to a licensed location for installation and operation.

These requirements are intended to provide assurance that construction and manufacturing activities are managed and conducted such that when combined with associated design

features and programmatic controls, the plant will satisfy the first and second tier safety criteria required in §§ 53.210 and 53.220 throughout the plant's lifecycle.

§ 53.610 Construction.

(a) Management and Control. Before starting construction activities, the licensee or permit holder must ensure that the following plans, programs, and organizational units are in place to manage and control the construction activities:

(1) Design and analyses that are sufficiently complete to provide assurance that construction will conform with associated requirements in subpart C of this part.

(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 or permit holder's management and control organization and the organizational responsibilities, authority and interfaces with other parts of the licensee's or permit holder'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 preliminary plan for coping with emergencies that includes an on-site emergency organization capable of providing first aid, transporting individuals to off-site treatment facilities, decontaminating any radiological hazard and establishing and maintaining arrangements with local off-site organizations that can provide support services, if needed.

(6) A fitness-for-duty program, in accordance with 10 CFR part 26, applicable to the licensee's or permit holder's construction management and control personnel and to the construction work force.

(7) A Quality Assurance (QA) Program conforming with generally accepted consensus codes and standards, applicable to construction activities, describing the policies, procedures and instructions to be used to ensure the facility is constructed in accordance with the design. The QA Program must provide control over the activities affecting quality and performance of the safety-related (SR) SSCs and the special treatment of SSCs determined to be safety-significant (SS). As a minimum, the QA Program must include the following:

I. Organization: A description of the personnel and organizational units within the licensee's or permit holder's organization responsible for QA, including their qualifications, authority and duties. The personnel and organizational units responsible for QA must have sufficient authority and freedom to identify quality problems, initiate or recommend corrective actions and verify satisfactory resolution. The personnel and organizational units performing the QA functions must report to the construction management and control organization at a high enough level to be independent from other competing interests.

II. Scope: The licensee or permit holder must identify the SR and SS SSCs and other activities covered by the QA program. The planned QA to be performed should be

identified in consideration of (1) the requirements contained in the codes and standards used in the design and construction, (2) the specifications and instructions from the design organization, and (3) the potential for other activities to affect the quality or performance of the SR and SS SSCs.

III. Use of Procedures: Construction, fabrication and test activities that could affect the quality or performance of SR and SS SSCs must be conducted using approved procedures, instructions or drawings, where appropriate. The procedures, instructions and drawings must contain qualitative or quantitative acceptance criteria that can be used to determine if the work is satisfactorily completed.

IV. Use of Qualified Personnel: The SR and SS construction activities must be conducted by personnel qualified for the work assigned. The required qualification and associated training must be documented along with records that show the personnel performing the work have been appropriately qualified.

V. Document Control: Measures must be in place to control the issuance of documents such as procedures, instructions and drawings, including any subsequent changes. These measures must assure that the documents, including any subsequent changes, are reviewed and approved for use by authorized and qualified personnel. Any document changes must be reviewed and approved by the same organization that approved the original document, unless there is a justified reason for changing the approval process. The measures must also assure that the documents are distributed to and used at the place where the construction activity takes place.

VI. Quality of Purchased Items: Purchase documents for materials, components and services must contain information on quality, such as regulatory requirements, applicable codes and standards, cleanliness requirements and other relevant controls. When appropriate, suppliers should be required to submit to the licensee or permit holder a copy of their QA program that will be used to ensure quality. Measures must be established to assure that purchased material, components and services for SR and SS SSCs conform to the purchase documents. This applies to material, components and services purchased directly by the licensee or permit holder or indirectly through contractors or subcontractors. These measures must consider objective evidence of quality, such as previous satisfactory performance by the supplier, relevant information submitted by the supplier demonstrating quality, inspections of the supplier carried out by the licensee or permit holder and receipt inspection of the finished product. Documentation that the products conform to the purchase specifications must be maintained by the licensee or permit holder. Periodic assessments of contractor and subcontractor performance in controlling quality must be conducted by the licensee or permit holder to determine if a degradation in quality has occurred over time and what corrective action is appropriate.

VII. Identification: Measures must be established for the identification and control of materials, parts and components used in the construction of SR SSCs. This must include identification of each item by part number, serial number or other means of identification such that the origin and acceptability of the item can be determined. Appropriate special treatment associated with construction must be defined and implemented to ensure SSCs determined to be SS satisfy the requirements of § 53.460.

VIII. Handling, Shipping and Storage: Measures must be established for the handling, cleaning, storage and shipping of purchased materials and components. These measures must address protection of purchased material and components from damage or contamination during shipping, protection from damage, deterioration, theft or tampering during storage and, if required, providing a special protective environment (e. g. inert atmosphere) for certain items, as specified in the purchase documents.

IX. Control of Items Released for Use in Construction: Measures must be established to control the release of materials, components and other items used in construction (e.g. weld rod, NDE materials) to ensure the released items are consistent with the procedures, instructions or drawings used for construction.

X. Special Conditions and Processes: Measures must be established to ensure that the construction activities and processes (e.g. welding, NDE, testing) are conducted under controlled conditions. These measures include using qualified personnel and procedures in accordance with applicable codes, standards, specifications or other special requirements and establishing a controlled environment, when necessary.

XI. Inspection: An inspection program to verify construction activities are conducted in conformance with approved procedures, instructions or drawings must be established. An inspection plan and schedule must be developed and maintained up to date, in coordination with the construction schedule, identifying the planned inspections. Risk insights should be used to focus the inspection program on the most risk significant components, subcomponents, construction activities and processes. The inspections must be conducted by personnel independent from those who performed the work. Hold points must be established where there is a critical activity or milestone requiring witnessing or inspection by the licensee's or permit holder's designated representative. The hold points must be included in the inspection plan and described in the procedures or instructions for conducting the construction activity. Where field changes are proposed or made to the design, the inspection must confirm that the design organization has approved the change, that the change was made using approved procedures, instructions or drawings, including acceptance criteria, and that the change is acceptable.

XII. Testing: All testing required to demonstrate that the SR and SS SSCs perform satisfactorily must be identified in the inspection plan and in the construction procedures and instructions. The testing must be performed using approved written procedures which also contain the acceptance criteria and identify any prerequisites, special test instrumentation, and environmental conditions needed for the test. The test program may include proof tests conducted prior to installation and proof of performance tests conducted after installation to demonstrate satisfactory completion of construction. All instrumentation, tools or other devices used to verify the acceptance criteria have been met must be properly calibrated and controlled to maintain accuracy.

XIII. Inspection and Test Status: Measures must be established to indicate the status of each SR and SS SSC with respect to inspection, testing and acceptance. In addition, the operating status of equipment such as valves, switches, pumps, etc. should be clearly indicated to prevent inadvertent operation or a change in power status.

XIV. Corrective Action: Measures must be established to ensure that defective material, components or other non-conforming items are identified and corrected. The cause of the non-conformance must be identified and, along with the corrective action, reported to management. Where repetitive non-conformances are identified, management should be notified and action taken to correct any systemic cause.

XV. Record Keeping: Measures must be established for the retention of records related to procurement, receipt inspection, inspections, tests and test logs, procedures, instructions, and drawings used for construction, personnel qualification, corrective actions, and audits. The licensee or permit holder is responsible for determining the duration, location, and responsibility for the record keeping.

XVI. Audits of the QA Program: Planned and periodic audits shall be carried out to verify compliance with all aspects of the QA Program and to determine the effectiveness of the program. Audits shall be conducted using written procedures or checklists using trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the areas audited.

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

(9) An information security program must be established in accordance with 10 CFR 73.21, 73.22 and 73.23, as applicable.

(10) Construction activities must conform to a cyber security program established in accordance with 10 CFR 73.54, as applicable.

(11) Posting of Requirements.

(i) Signs and labels, in accordance with subpart J of 10 CFR part 20, must be posted where there is a potential radiation hazard.
(ii) Each individual, licensee, permit holder, partnership, corporation, dedicating entity, or other entity subject to the regulations in this subpart must post current copies of the regulations in this subpart; Section 206 of the Energy Reorganization Act of 1974 (ERA); and procedures adopted under the regulations in this subpart.
(iii) If posting of the regulations in this subpart or the procedures adopted under the regulations in this subpart is not practical, the licensee, permit holder or firm subject to the regulations in this subpart must, 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 the regulation, procedures, and reports may be examined.

(b) Construction Activities

(1) Licensees or permit holders must meet the following requirements:

I. As appropriate, considering the types and quantities of radioactive materials being brought onto the site.

i. The licensee or permit holder 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 permit holder (or licensee) shall implement a SNM MC&A Program in accordance with 10 CFR part 74.

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

iii. 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 nuclear power plants to be operated on multi-unit sites, plans and procedures must be in place prior to the start of construction activities to prevent and/or mitigate potential hazards to the SSCs of operating units resulting from construction activities, including the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation of the operating units are not exceeded as a result of construction activities at the multi-unit sites. [The term "site" refers to the contiguous real estate on which nuclear units are located and for which one or more licensees has the legal right to control access by individuals and to restrict and use for purposes of limiting the potential doses from radiation or radioactive material during normal operation of the units.]

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. A plan must be developed for redress of activities performed under the CP or LWA should one of the following situations arise:

(a) CP or LWA work activities are terminated by the holder of the CP or LWA

(b) the CP or LWA is revoked by the NRC

(c) the Commission denies the associated operating license application.

(2) On-site fresh fuel storage must be in compliance with 10 CFR 73.67 or within a protected area in compliance with 10 CFR 73.55. Before fuel is brought within a protected area, a cyber security program that meets the requirements of 10 CFR 73.54, a physical security program that meets the requirements of 10 CFR 73.55 and an access authorization program that meets the requirements of 10 CFR 73.56 must be established.

(3) 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 or permit holder 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 consider the results of the inspections, pre-operational tests, and analyses that have been performed and the acceptance criteria that are necessary and sufficient to conclude that there is reasonable assurance the facility has been constructed and will be operated in conformity with the operating license, the provisions of the Atomic Energy Act, and the Commission's rules and regulations.

(d) Communication

Procedures for communication among elements of the construction program must be established that require:

(1) Interfacing among construction activities, inspections and other ongoing work.

(2) Coordination with operating units on the site.

(3) Coordination with site preparation activities for other units being built on the site to ensure site characteristics (e.g. drainage) remain acceptable.

(4) Coordination with NRC on planned inspections.

§ 53.620 Manufacturing

(a) Management and Control

Before starting manufacturing activities, the licensee must ensure that the following plans, programs and organizational units are in place to manage and control the manufacturing activities:

(1) Design and analysis performed in accordance with subpart C.

(2) An organizational and management structure responsible for the 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, applicable to the licensee's management and control organization personnel and the manufacturing work force.

(6) A QA program conforming with generally accepted consensus codes and standards, applicable to design and manufacturing activities, describing the policies, procedures and instructions to be used to ensure that the reactor is designed and manufactured must be established. The QA Program must provide control over the activities affecting quality and performance of the SR SSCs and the special treatment of SSCs determined to be SS

consistent with their risk significance. As a minimum, the QA Program must include the following:

I. Organization: A description of the personnel and organizational units within the licensee's organization responsible for QA, including their qualifications, authority and duties. The personnel and organizational units responsible for QA must have sufficient authority and freedom to identify quality problems, initiate or recommend corrective actions and verify satisfactory resolution. The personnel and organizational units performing the QA functions must report to the design and manufacturing management and control organization at a high enough level to be independent from other competing interests.

II. Scope: The licensee must identify the SR and SS SSCs and activities covered by the QA program. The planned QA activities to be performed should be identified in consideration of (1) the requirements contained in the codes and standards used in the design and manufacturing, (2) the specifications and instructions from the design organization, (3) best industry practices and (4) the potential for other activities to affect the quality or performance of the SR and SS SSCs.

III. Use of Procedures: Design, manufacturing, fabrication and test activities that could affect the quality or performance of SR and SS SSCs must be conducted using approved procedures, instructions or drawings, where appropriate. The procedures, instructions and drawings must contain qualitative or quantitative acceptance criteria that can be used to determine if the work is satisfactory.

IV. Use of Qualified Personnel: The SR and SS design and manufacturing activities must be conducted using personnel qualified for the work assigned. The required qualification and associated training must be documented along with records that show the personnel performing the work have been appropriately qualified.

V. Document Control: Measures must be in place to control the issuance of documents such as procedures, instructions and drawings, including any subsequent changes. These measures must assure that the documents, including any subsequent changes, are reviewed and approved for use by authorized and qualified personnel. Any document changes must be reviewed and approved by the same organization that approved the original document, unless there is a justified reason for changing the approval process. The measures must also assure that the documents are distributed to and used at the place where the manufacturing activity takes place.

VI. Quality of Purchased Items: Purchase documents for materials, components and services must contain information on quality, such as regulatory requirements, applicable codes and standards, cleanliness requirements and other relevant controls. When appropriate, suppliers should be required to submit to the licensee a copy of their QA program that will be used to ensure quality. Measures must be established to assure that purchased material, components and services for SR and SS SSCs conform to the purchase documents. This applies to material, components and services purchased directly by the licensee or indirectly through contractors or subcontractors. These measures must consider objective evidence of quality, such as previous satisfactory performance by the supplier, relevant information submitted by the supplier demonstrating quality, inspections of the supplier carried out by the licensee and receipt inspection of the finished product. Documentation that the products conform to the purchase specifications must be maintained by the licensee.

Periodic assessments of contractor and subcontractor performance in controlling quality must be conducted by the licensee to determine if a degradation in quality has occurred over time and what corrective action is appropriate.

VII. Identification: Measures must be established for the identification and control of materials, parts and components used in the manufacturing of SR SSCs. This must include identification of each item by part number, serial number or other means of identification such that the origin and acceptability of the item can be determined. Appropriate special treatment must be defined and implemented to ensure SSCs determined to be SS satisfy the requirements of § 53.460

VIII. Handling, Shipping and Storage: Measures must be established for the handling, cleaning, storage and shipping of purchased materials and components. These measures must address protection of purchased material and components from damage or contamination during shipping, protection from damage, deterioration, theft or tampering during storage and, if required, providing a special protective environment (e. g. inert atmosphere) for certain items, as specified in the purchase documents.

IX. Control of Items Released for Use in Manufacturing: Measures must be established to control the release of materials, components and other items used in manufacturing (e. g. weld rod, NDE materials) to ensure the released items are consistent with the manufacturing license.

X. Special Conditions and Processes: Measures must be established to ensure that the manufacturing activities and processes (e.g. welding, NDE and testing) are conducted under controlled conditions. These measures include using qualified personnel and procedures in accordance with applicable codes, standards, specifications, manufacturing license, or other special requirements and establishing a controlled environment, when necessary.

XI. Inspection: An inspection program to verify manufacturing activities are conducted in conformance with approved procedures, instructions or drawings must be established. An inspection plan and schedule must be developed and maintained up to date, in coordination with the manufacturing schedule, identifying the planned inspections. Risk insights should be used to focus the inspection program on the most risk significant components, subcomponents, manufacturing activities and processes. The inspections must be conducted by personnel independent from those who performed the work. Hold points must be established where there is a critical activity or milestone requiring witnessing or inspection by the licensee's designated representative. The hold points must be described in the inspection plan and included in the procedures or instructions for conducting the manufacturing activity. Where field changes are proposed or made to the design, the inspection must confirm that the design organization has approved the change, that the change was made using approved procedures, instructions or drawings, including acceptance criteria, and that the change was satisfactorily made.

XII. Testing: All testing required to demonstrate that the SR and SS SSCs will perform satisfactorily must be identified in the inspection plan and in the manufacturing procedures or instructions. The testing must be performed using approved written procedures which also contain the acceptance criteria and identify any prerequisites, special test instrumentation and environmental conditions needed for the test. The test program may include proof tests conducted prior to installation and proof of

performance tests conducted after installation to demonstrate satisfactory completion of manufacturing. All instrumentation, tools or other devices used in the testing must be properly calibrated and controlled to maintain accuracy.

XIII. Inspection and Test Status: Measures must be established to indicate the status of each SR and SS SSC with respect to inspection, testing and acceptance. In addition, the operating status of equipment such as valves, switches, pumps, etc. should be clearly indicated to prevent inadvertent operation or a change in power status.

XIV. Corrective Action: Measures must be established to ensure that defective material, components or other non-conforming items are identified and corrected. The cause of the non-conformance must be identified and, along with the corrective action, reported to management. Where repetitive non-conformances are identified, management should be notified and action taken to correct any systemic cause. If the non-conformance could represent a substantial safety hazard, reporting in compliance with 10 CFR part 21 should also made.

XV. Record Keeping: Measures must be established for the retention of records related to design, procurement, receipt inspection, inspections and inspection records, tests and test logs, procedures, instructions and drawings used in manufacturing, personnel qualification, corrective actions and audits. The licensee is responsible for determining the duration, location and responsibility for the record keeping.

XVI. Audits of the QA Program: Planned and Periodic audits shall be carried out to verify compliance with all aspects of the QA Program and to determine the effectiveness of the program. Audits shall be conducted using written procedures or checklists using trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the areas audited

(7) A Radiation Protection Program that includes measures for monitoring the dose to individuals working with radioactive materials must be established in accordance with 10 CFR part 20.

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

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

(10) Posting of Requirements

(i) Signs and labels, in accordance with subpart J of 10 CFR part 20, must be posted where there is a potential radiation hazard.

(ii) Each individual, licensee, partnership, corporation, dedicating entity, or other entity subject to the regulations in this subpart must post current copies of the regulations in this part, Section 206 of the Energy Reorganization Act of 1974 (ERA) and procedures adopted under the regulations in this subpart.

(iii) If the posting of the regulations in this subpart or the procedures adopted under the regulations in this subpart is not practical, the licensee or firm subject to the regulations in this subpart must, 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 the regulation, procedures and reports may be examined.

(b) Manufacturing Activities

(1) Licensees must meet the following requirements:

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

II. Manufacturing processes must be performed in accordance with the ML and the referenced generally accepted consensus codes and standards

III. Quality control of the manufacturing process and key steps within the process must be ensured by appropriate verifications, inspections, and tests as required by paragraph (a) of this section.

IV. As appropriate considering the types and quantities of radioactive materials being brought into the manufacturing facility;

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

ii. A fire protection program must be approved and implemented before the 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 fresh fuel (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.

iii. An emergency plan for responding to the radiological hazards of an accidental release of special nuclear material and to any associated chemical hazards directly incident thereto must be approved and implemented prior to the receipt of byproduct, source, or SNM (excluding exempt quantities as described in 10 CFR 30.18).

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

v. Prior to the receipt of fresh fuel at the manufacturer's facility, the following measures must be in place:

a. A physical security program for the storage of fresh fuel in accordance with 10 CFR 73.67 or 10 CFR 73.54, 10 CFR 73.55, and 10 CFR 73.56.
b. An access authorization program in accordance with 10 CFR 73.56.
c. A Material Control and Accounting Program in accordance with 10 CFR part 74.
d. Measures to prevent criticality accidents in accordance with 10 CFR 70.24.

vi. 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, in accordance with the approved radiation protection program.

vii. A post manufacturing inspection and acceptance process must be established and implemented prior to fuel loading or shipping. The process must consider the results of inspections, pre-operational tests and analyses that have been performed and the acceptance criteria that are necessary and sufficient to conclude that there is reasonable assurance the reactor has been manufactured in accordance with the ML.

(c) Fuel Loading [to be more fully developed if pursued]

(1) If the ML authorizes fuel loading 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, conduct any low power physics tests necessary for acceptance and secure the fuel and reactor assembly for shipment.
(IV) A physical security program that meets the requirements of 10 CFR 73.55.
(V) An access control program that meets the requirements of 10 CFR 73.56.
(VI) A cyber security program must be established in accordance with 10 CFR 73.54, as applicable.

(2) If the ML authorizes criticality testing or other nuclear-related testing at the manufacturing facility, design features and programmatic controls must be developed, implemented, and maintained to achieve the following:

(I) Criticality Control
(II) Radiation Protection
(III) Safety Protocols
(IV) Other ?

(d) Communication

The applicant must coordinate with NRC on planned manufacturing activities, inspections, and nuclear-related testing.

(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 either a construction permit or a combined license. The construction permit or 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 prepared 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) If the reactor contains fuel, the packaging and shipping 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 §53.610 of this subpart.

(2) Upon arrival at the site, the manufactured reactor must be certified to be in compliance with the ML and inspected, using approved procedures, to verify it is in acceptable condition. These procedures must also include confirming appropriate interfaces between the manufactured reactor and the remaining portions of the nuclear power plant. Upon completion of the inspections, but prior to installation at the site, it must be concluded that:

(i) The reactor has arrived with no damage or contamination that could affect its safe operation.

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

(iii) The manufactured reactor can be operated safely in conformity with the approved design.

For Information; Current Definitions

[10 CFR 50.10] (a) *Definitions*. As used in this section, *construction* means the activities in paragraph (a)(1) of this section, and does not mean the activities in paragraph (a)(2) of this section.

(1) Activities constituting construction are the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations, or in-place assembly, erection, fabrication, or testing, which are for:

(i) Safety-related structures, systems, or components (SSCs) of a facility, as defined in 10 CFR 50.2;

(ii) SSCs relied upon to mitigate accidents or transients or used in plant emergency operating procedures;

(iii) SSCs whose failure could prevent safety-related SSCs from fulfilling their safety-related function;

(iv) SSCs whose failure could cause a reactor scram or actuation of a safety-related system;

(v) SSCs necessary to comply with 10 CFR part 73;

(vi) SSCs necessary to comply with 10 CFR 50.48 and criterion 3 of 10 CFR part 50, appendix A; and

(vii) Onsite emergency facilities, that is, technical support and operations support centers, necessary to comply with 10 CFR 50.47 and 10 CFR part 50, appendix E.

(2) Construction does not include:

(i) Changes for temporary use of the land for public recreational purposes;

(ii) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(iii) Preparation of a site for construction of a facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(iv) Erection of fences and other access control measures;

(v) Excavation;

(vi) Erection of support buildings (such as, construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(vii) Building of service facilities, such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines;

(viii) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility;

(ix) Manufacture of a nuclear power reactor under a manufacturing license under subpart F of part 52 of this chapter to be installed at the proposed site and to be part of the proposed facility; or

(x) With respect to production or utilization facilities, other than testing facilities and nuclear power plants, required to be licensed under Section 104.a or Section 104.c of the Atomic Energy Act of 1954, as amended, the erection of buildings which will be used for activities other than operation of a facility and which may also be used to house a facility (*e.g.*, the construction of a college laboratory building with space for installation of a training reactor).

Subpart F - Requirements for Operation

Preliminary rule language for Subpart F was previously released to support interactions with stakeholders, including a public meeting on January 7, 2021 (ADAMS Accession No. ML20337A432). This version does not reflect possible revisions in response to those interactions but is being provided to provide context for preliminary versions of other Subparts.

*****

§ 53.800 Facility Safety Program.

Each licensee must establish and implement a facility safety program (FSP) that routinely and systematically **evaluates** potential hazards, operating experience related to plant SSCs, human actions, and programmatic controls affecting the safety functions required by § 53.~~210~~230, and the resulting changes in risks to the public from operation of the facility over its operating lifetime. An FSP must include a risk-informed, performance-based process to proactively identify new or revised internal or external hazards to the facility and performance issues related to plant SSCs, human actions, and programmatic controls and must consider measures to mitigate or eliminate the resulting risks using the criteria defined in § 53.810. The FSP must be implemented and supported by a written FSP as required in § 53.820.

§ 53.810 Facility Safety Program Performance Criteria.

(a) Each licensee for an advanced nuclear plant must take measures ~~to protect public health and minimize danger to life or property~~ as may be ~~reasonably achieved~~appropriate when considering potential risks to public health and safety, technology changes, economic costs, operating experience, new or revised hazard assessments, or other factors included in the FSP plan required by § 53.820. Performance objectives for design features and programmatic controls must be established such that the risks to public health and safety from an advanced nuclear plant due to normal operation or licensing basis events must not be a significant addition to other societal risks.

(1) Each licensee must assess risk reduction measures related to the release or potential release of radioactive materials in plant effluents during normal operation whenever such a release could result in a member of the public receiving an annual radiation dose in excess of 0.3 millirems from liquid effluents or 1 millirem from gaseous effluents. The assessment and risk reduction measures must maintain doses to members of the public as low as is reasonably achievable taking into account the state of technology, the economics of improvements in relation to the state of technology, operating experience, and the economics of improvements in relation to benefits to the public health and safety.

(2) Each licensee must assess potential risk reduction measures related to licensing basis events, identified hazards, or other specific contributors to the overall cumulative risk from unplanned events as follows:

(i) For new or revised hazards, plant features, or other contributors to licensing basis events with an estimated upper bound frequency above one in one thousand years, licensees must consider risk reduction measures whenever the estimated radiation dose to a member of the public exceeds 2.5 millirem and the estimated frequency weighted cumulative dose to nearby populations increases by [5 person-rem].

(ii) For new or revised hazards, plant features, or other contributors to licensing basis events with an estimated lower bound frequency below one in one thousand years, licensees must consider risk reduction measures whenever the estimated frequency weighted cumulative dose to nearby populations increases by [5 person-rem] and either the frequency of a member of the public receiving a radiation dose with the potential for immediate health effects approaches five in one hundred million years or a radiation dose with the potential to cause latent health effects approaches two in ten million years.

(iii) For new or revised hazards, plant features, or other contributors to licensing basis events with an estimated dose to a member of the public less than or equal to a threshold value used for operational flexibilities in accordance with § 53.470, licensees must consider risk reduction measures whenever changes to the estimated consequences reduce the margin to the subject threshold value by more than ten percent and the estimated frequency weighted cumulative dose to nearby populations increases by [5 person-rem].

(iv) The assessment and risk reduction measures must maintain doses to members of the public as low as is reasonably achievable taking into account the state of technology, the economics of improvements in relation to the state of technology, information available on

potential hazards, operating experience, and the economics of improvements in relation to benefits to the public health and safety.

(b) Risk reduction measures taken at advanced nuclear plants whose licenses refer to certified designs or manufacturing licenses must also follow the change control and reporting provisions of 10 CFR part 52 or subpart H of this part related to changes to standardized designs.

§ 53.820 Facility Safety Program Plan

(a) General. Each licensee must adopt and implement an FSP using a written FSP plan that, at a minimum, contains the elements in this section. This FSP plan must be approved by NRC under the process required in § 53.830.

(b) Scope. (1) Each licensee must set forth in its FSP plan a statement describing the facility or facilities covered by the plan. The description must include the facility, personnel, programmatic controls, and facility environs that influence the assessments used in assessing potential risks in accordance with subparts B and C of this part and potential reduction measures using the performance criteria in § 53.810. The scope of the program plan must consider new or revised information related to:

(i) The performance of SSCs in terms of their capability and availability to perform the required safety functions required by § 53.~~210~~230 during normal operation and licensing basis events and assessing potential risk reduction measures using the performance criteria in § 53.810;

(ii) The role of personnel in making decisions, operating plant SSCs, or otherwise supporting the safety functions required by § 53.~~210~~230 and assessing potential risk reduction measures using the performance criteria in § 53.810;

(iii) The programmatic controls required within this part or otherwise implemented by a licensee to ensure capabilities and availabilities of SSCs and personnel performing the safety functions required by § 53.~~210~~230 and assessing potential risk reduction measures using the performance criteria in § 53.810;

(iv) Natural and manmade hazards with the potential to affect plant SSCs or personnel supporting the safety functions required by § 53.~~210~~230 and assessing potential risk reduction measures using the performance criteria in § 53.810; and

(v) Operating experience related to plant SSCs, personnel, or programmatic controls supporting the safety functions required by § 53.~~210~~230 and assessing potential risk reduction measures using the performance criteria in § 53.810.

(2) The methods used to analyze the technologies identified under paragraph (f)(1)(i) of this section against the criteria provided in § 53.810.

(3) Each licensee must set forth in its FSP plan a description of its overall safety philosophy and intended safety culture to be practiced by its management, employees and contractors; and

(4) Each licensee must identify the required participants in the FSP plan, which will include managers, employees, and contractors that directly support facility operations; maintain, inspect, or change plant SSCs or programmatic controls; or assess potential risk reduction measures as required by § 53.820.

(c) Implementation. Each licensee must describe in its FSP plan the process the licensee will use to implement and maintain its FSP. As part of the licensee's implementation process, the licensee must describe roles and responsibilities of each position that has significant responsibility for implementing the FSP, including those held by employees and other persons utilizing or providing significant services as identified by the licensee pursuant to paragraph (b)(3) of this section.

(d) Facility safety program training:

(1) Each manager, employee, and contractor identified under paragraph (b)(3) of this section will be trained on the licensee's FSP.

(2) Each licensee must establish and describe in its FSP plan the licensee's facility safety program training plan. An FSP training plan must set forth the procedures by which managers, employees, and contractors identified under paragraph (b)(3) of this section will be trained on the licensee's FSP. An FSP training plan must help ensure that all personnel who are responsible for implementing and supporting the FSP understand the goals of the program, are familiar with the elements of the program, and have the requisite knowledge and skills to fulfill their responsibilities under the program.

(3) For each position identified pursuant to paragraph (b)(3) of this section, the training plan must describe the frequency and content of the FSP training that the position receives.

(4) Training under this subpart F may include, but is not limited to, classroom, computer-based, or correspondence training.

(5) The licensee must keep a record of all training conducted under this part and update that record as necessary. The FSP training plan must set forth the process used to maintain and update the necessary training records required by this part.

(6) The FSP training plan must set forth the process used by the licensee to ensure that it is complying with the training requirements set forth in the training plan.

(e) Risk-informed hazard management program. Each licensee must establish a risk-informed hazard management program as part of the licensee's FSP. The risk-informed hazard management program must be fully described in the FSP plan. The risk-informed hazard management program must establish:

(1) The processes or procedures used in the risk-informed hazard analysis to identify internal and external hazards having the potential to increase the frequency or consequences of radiological releases from normal operation or licensing basis events;

(2) The processes or procedures used in the risk-informed hazard analysis to analyze identified hazards and support assessments against the criteria provided in § 53.810;

(3) The methods used to identify and implement actions that mitigate or eliminate hazards based on assessments against the criteria provided in § 53.810.

(4) The methods used to ensure changes to the facility design or operations do not adversely affect measures in place to mitigate or eliminate hazards or that such changes have been assessed pursuant to the appropriate change control and have been incorporated into models used for assessments against the criteria provided in § 53.810.

(5) The methods used to maintain records of identified hazards and risks and the mitigation or elimination of the identified hazards and risks throughout the life of the facility.

(6) The position title(s) of the individual(s) responsible for administering the risk-informed hazard management program.

(f) Technology assessment program. Each licensee must establish a technology assessment program as part of the licensee's FSP. The technology assessment program must be fully described in the FSP plan. The technology assessment program must establish:

(1) The methods used to identify and analyze current, new, or novel technologies that will mitigate or eliminate internal or external hazards and resulting risks from the release of radioactive materials from a facility during normal operations or licensing basis events;

(2) The methods used to analyze the technologies identified under paragraph (f)(1) of this section against the criteria provided in § 53.810.

(3) The methods used to identify and implement actions related to technologies identified under paragraph (f)(1) of this section based on assessments against the criteria provided in § 53.810.

(4) The methods used to maintain records of technology assessments throughout the life of the facility.

(5) The position title(s) of the individual(s) responsible for administering the technology assessment program.

(g) Internal facility safety program assessment. (1) The licensee must describe in the FSP plan methods to annually confirm:

(i) The FSP is fully implemented and effective;

(ii) The licensee's overall safety philosophy and intended safety culture are being implemented and effective;

(iii) The facility safety program training program is implemented and effective;

(iv) The facility continues to meet the performance criteria set forth in § 53.~~210~~230 and effectively consider risk reduction measures using the performance criteria set forth in § 53.810.

(2) As part of its FSP plan, the licensee must describe the processes used to:

(i) Conduct internal FSP assessments;

(ii) Internally report the findings of the internal FSP assessments to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided;

(iii) Develop, track, and review recommendations as a result of the internal FSP assessments;

(iv) Develop improvement plans based on the internal FSP assessments; and

(v) Manage revisions and updates to the FSP plan based on the internal facility safety program assessments.

§ 53.830 Review, Approval, and Retention of Facility Safety Program Plans

(a) Initial Filing. Each applicant for a license under this part must include its FSP plan as part of the application.

(b) Approval. The NRC will review the FSP plan to determine if the elements prescribed in this part are sufficiently addressed in the applicant's submission. Approval of an FSP plan under this part does not constitute approval of the specific actions the licensee will implement under its FSP plan pursuant to § 53.820 and must not be construed as establishing an NRC standard regarding those specific actions.

(c) Review of amendments. Need to work out nature of reviews, notices, opportunities for hearing, etc. on amendments to the FSP plan. (CRITERIA X OK report w/in x days, NRC respond within y days). CRITERIA Y follow process in § 53.xyz (license amendment)

*****

Subpart G - Decommissioning Requirements

This subpart is envisioned to address transition to decommissioning.

Subpart H - Licenses, Certifications, and Approvals

This subpart is envisioned to address requirements for initial applications for licenses, certifications, or approvals. The subpart will support either licensing under the Part 50 or Part 52 frameworks. Assessment and update of manufacturing licenses is possible. Other improvements could include combining Part 50 process for first of a kind (FOAK) applications and simper transition to Part 52 for subsequent applications.

Subpart I - Maintaining and Revising Licensing Basis Information

This subpart is envisioned to address requirements for maintaining and revising licensing basis information related to licenses, certifications, or approvals. Specific provisions would include maintaining and updating safety analysis reports and amending licenses.

Subpart J - Reporting and Other Administrative Requirements

This subpart is envisioned to address requirements for maintaining records, making reports, and other administrative-type activities