

THIS PRELIMINARY PROPOSED RULE LANGUAGE AND ACCOMPANYING DISCUSSION 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 DOCUMENT 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.

STAFF DISCUSSION OF SUBPART F (Facility Safety Program) - PRELIMINARY RULE LANGUAGE, DECEMBER 2020

Preliminary Language	Discussion
Subpart F – Requirements for Operation Section 53.8XX Only – Facility Safety Program	<p>Subpart F addresses ongoing requirements for the operations phase of the life cycle of advanced nuclear plants. This subpart is envisioned to address operational areas such as configuration control; maintaining availability and capabilities of SSCs; maintenance, repair and inspection programs; quality assurance; staffing (including operator licensing); emergency preparedness; security; radiation protection; and facility safety program.</p> <p>The preliminary rule language and discussion points within this document address a proposal for requiring an ongoing facility safety program (FSP). The FSP concept is being considered, in part, to address expected changes to advanced reactors over the course of such a facility’s lifecycle, and a move from regulating a relatively small number of large facilities to possible a larger number of smaller facilities. The staff looked at models in other U.S. agencies (e.g., Department of Transportation, Environmental Protection Agency) and identified an approach as reflected in the following sections for a facility safety program as a way to support this new regulatory program in Part 53 (i.e., licensing and inspection/oversight). The Federal Railroad Administration Part 270 under Title 49, “Transportation” of the CFR was used as a model.</p>

§ 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, 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.

This section establishes the general requirement for an FSP and it and the following sections are used to supplement expected requirements in Subpart C, “Design and Analysis Requirements,” which will include provisions to perform and periodically update probabilistic risk assessments (PRAs), and other requirements within this subpart related to configuration control and maintaining the capabilities and reliabilities of SSCs and programmatic controls consistent with underlying analyses.

The staff is interested in stakeholder views on whether the desire to assess and, as appropriate, address new or revised information on potential hazards could be better addressed by embedding sections within other expected requirements (e.g., requirements to update PRAs).

§ 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 when considering 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

Requirements from other sections (e.g., design & analysis, operations) address compliance with the first and second tier safety criteria.

This section provides the criteria for considering risk-reduction measures when performing the periodic assessments per the process in the following section (§ 53.820). The actual numerical values are expected to be a topic of discussion and may change. However, the concept is to provide an entry condition for considering risk reduction – with the actual decision on whether to implement a change being decided by a cost-benefit process. It is expected that guidance will be prepared to define appropriate factors such as dollars per person-rem and be able to use existing guidance (e.g., regulatory analysis guidelines, severe accident mitigation alternatives). The goal for establishing criteria for considering risk-reduction measures is that they are low enough to

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

initiate the process when appropriate but not so low as to initiate unnecessary analyses.

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.

This section provides the mechanics for the facility safety programs. The scope of the program includes assessments of new or revised information related to SSCs, personnel, and programs; natural or manmade hazards, and operating experience. A guidance document (perhaps template) would be useful for implementing this requirement.

(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 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 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 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 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 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 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)

This section provides the connection between the facility safety program and NRC approval/change control processes that will be in Subparts H, "Licenses, Certifications, and Approvals," and I, "Maintaining and Revising Licensing Basis Information."