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Advisory Committee on Reactor Safeguards (ACRS) Future Plant Designs Subcommittee

10 CFR Part 53
"Licensing and Regulation of Advanced Nuclear Reactors"

September 23-24, 2021

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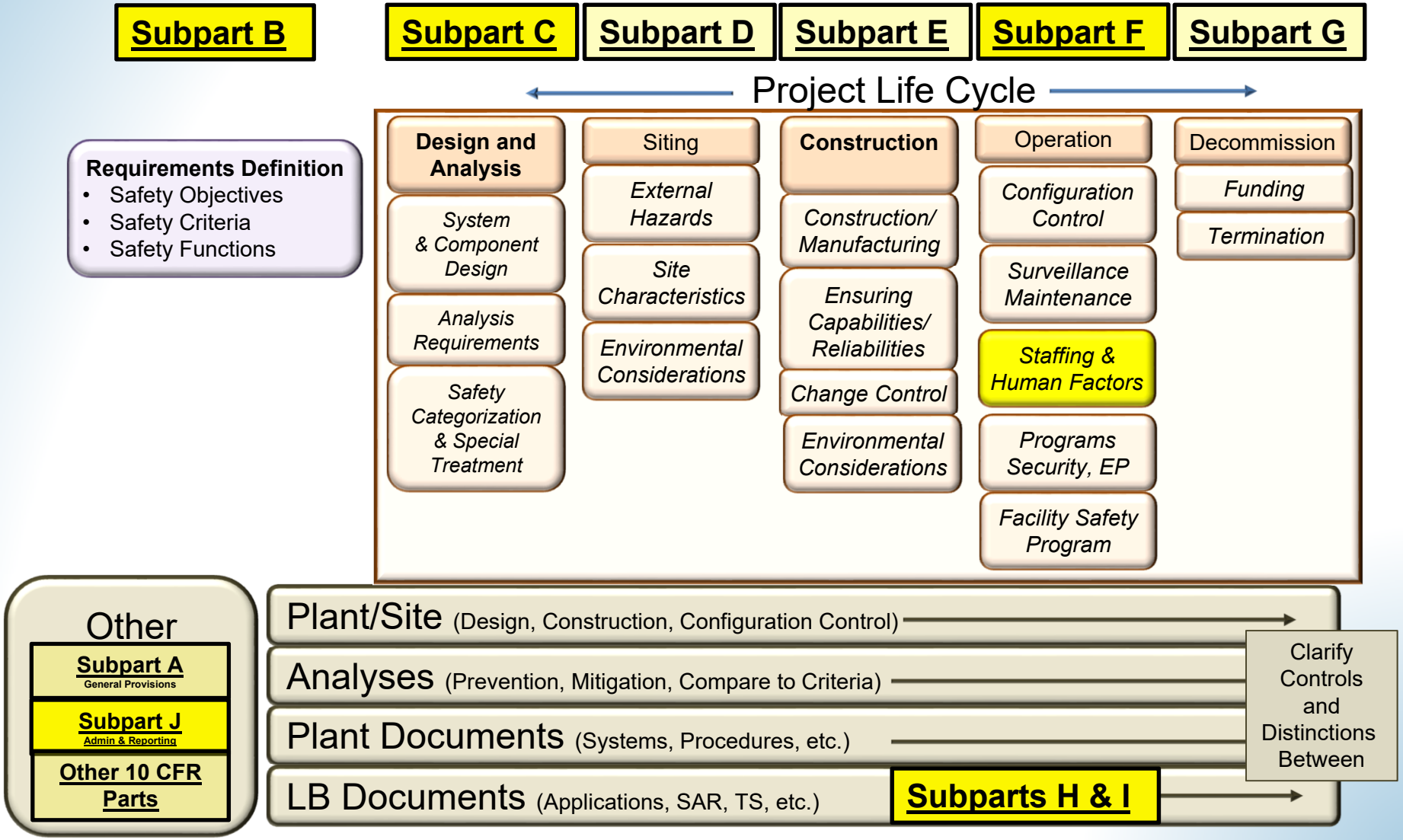
September 23rd Agenda

9:30am – 9:40am	Opening Remarks & Staff Introductions
9:40am – 1:00pm	Subpart B – Technology-Inclusive Safety Requirements; Subpart C – Requirements for Design and Analysis
1:00pm – 2:00pm	Lunch Break
2:00pm – 3:15pm	Subpart H – Licenses, Certifications, and Approvals
3:15pm – 4:30pm	Subpart I – Maintaining and Revising Licensing Basis Information
4:30pm – 4:45pm	Break
4:45pm – 5:50pm	Subpart J - Reporting and Other Administrative Requirements
5:50pm – 6:00pm	Discussion

NRC Staff Plan to Develop Part 53



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NRC Staff Engagement Plan

ACRS Interactions

	Framework	Safety Criteria	Design	Siting	Construction	Operations	Decommissioning	Licensing	General/Admin
Sept 20									
Nov 20									
Dec 20									
Jan 21									
Feb 21									
Mar 21									
Apr 21									
May 21									
Jun 21									
Jul 21									
Aug 21									
Sept 21									
Oct 21									
Nov 21	Consolidated Rulemaking Package								
Dec 21	Consolidated Rulemaking Package								
Jan 22	Consolidated Rulemaking Package								
Feb 22	ACRS Full Committee								
Mar 22									
Apr 22									
May 22	Draft Proposed Rulemaking Package to the Commission								
Jun 22									
Jul 22									
Aug 22									
Sept 22									
Oct 22									

	Concept/Introduction
	Discussion
	Interim Staff Resolution

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Part 53 Licensing Framework and Subpart Structure

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Part 53 Licensing Framework and Subpart Structure

- Subpart A, General Provisions
- Subpart B, Technology-Inclusive Safety Objectives
- Subpart C, Design and Analysis
- Subpart D, Siting Requirements
- Subpart E, Construction and Manufacturing Requirements
- Subpart F, Requirements for Operation
- Subpart G, Decommissioning Requirements
- Subpart H, Applications for Licenses, Certifications and Approvals
- Subpart I, Maintaining and Revising Licensing Basis Information
- Subpart J, Reporting and Administrative Requirements

Part 53 Licensing Framework and Subpart Structure

Requirements for both normal operations and licensing basis events (LBEs)	
Safety objective	Limit the possibility of an immediate threat to the public health and safety **(§ 53.200)**
Safety functions	Primary safety function: limit release of radioactive material during normal operations and LBEs. Additional safety functions (e.g., controlling heat generation, heat removal, and chemical interactions) must be defined. Both primary and additional safety functions are required to meet the safety criteria and are fulfilled by design features and programmatic controls. **(§ 53.230)**
Requirements for normal operations (i.e., "routine operations" or "planned events")	
Safety criteria	Comply with public dose limits in Part 20. Meet ALARA. **(§ 53.260)**
Design features	Design features must be defined for each advanced nuclear plant such that the plant will satisfy § 53.260 **(§ 53.425)**
Functional design criteria	Functional design criteria must be provided to show that § 53.260 dose limit is met **(§ 53.425)**

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Part 53 Licensing Framework and Subpart Structure

Requirements for LBEs (i.e., "unplanned events" and including AOOs, "DBEs," DBAs, and "BDBEs") **(§ 53.240)**		
	DBAs	**LBEs that are not DBAs**
LBE classifications **(§ 53.020)**	Design basis accidents (DBAs) DBAs are derived from design basis events (DBEs) but assume that only safety related SSCs remain functional to respond to accidents. **(§ 53.020, § 53.450(f))**	Anticipated operational occurrences (AOOs) Unlikely event sequences (known in the Licensing Modernization Project (LMP) as DBEs) Very unlikely event sequences (known in the LMP as beyond design basis events (BDBEs))
Safety criteria	25 rem total effective dose equivalent [*i.e., 10 CFR 50.34 dose limit*] for events with an upper bound frequency greater than 1x10-4 at exclusion area boundary (EAB) **(§ 53.210)**	Ensure that LBEs are addressed and provide DID, and maintain overall cumulative risk from LBEs such that potential for immediate health effects remains below 5 x 10-7 and latent health effects remains below 2 x 10-7 [*i.e., Quantitative Health Objectives (QHOs)*] **(§ 53.220)** Alternative criteria may be used. (**§ 53.470)**
Structures, systems, and components (SSCs) responding to the LBE	Safety related SSCs **(§ 53.020)**	Take into account the expected responses (successes and failures) of all SSCs within the plant, regardless of safety classification **(§ 53.020)**
Design features	Design features must be defined for each advanced nuclear plant such that the plant will satisfy §§ 53.210 and 53.220. Design features ensure safety functions (§ 53.230) are fulfilled during LBEs. **(§ 53.400)**	
Functional design criteria	Functional design criteria must be defined per § 53.400 to show § 53.210 is met **(§ 53.410)**	Functional design criteria must be defined to show § 53.220 is met (**§ 53.420)**
Analysis	Use a probabilistic risk assessment (PRA) to identify the DBEs and then use deterministic methods to analyze DBAs and demonstrate compliance with safety criteria in § 53.210 **(§ 53.450(f))**	All LBEs must be analyzed in PRA. Analysis must demonstrate compliance with safety criteria in § 53.220 and "evaluation criteria" per § 53.450(e). **(§§ 53.450(a) and (e))**
Defense in depth (DID)	N/A -- not directly considered in establishing DBAs (DID for DBAs is provided for by addressing the other LBEs)	DID is necessary for SSCs relied upon to meet safety criteria in § 53.220 or safety functions in § 53.230 **(§ 53.250)**
Special treatment **(§ 53.020)**	Tech specs, quality assurance (QA) programs, etc.	Licensee programs

ACRS Interim Letter (May 30, 2021)

CONCLUSIONS AND RECOMMENDATIONS

1. The overall structure of Subparts A through I provides a logical framework for the rule. It is complete with respect to topics that must be covered and addresses the lifetime of a power reactor. It will be helpful to all applicants and to the NRC staff. *(maintained structure)*
2. A coherent and detailed explanation of the integrated intent of the rule and its associated design-specific guidance should be developed as soon as possible and enshrined in the rule itself. *(working)*
3. Subpart B, "Technology-Inclusive Safety Requirements," is coming together, but we would like to offer a few specific comments and see some further improvements:
    a. To this point in the development, we find no value in the two-tiered approach to safety requirements. Alternative integral risk criteria to the quantitative health objectives (QHOs) should be investigated. *(Subpart B, revised)*
    b. Desired flexibility to address the broad range of technologies and power levels is provided by establishing high-level safety criteria that must be assured in top-down fashion as the applicant identifies needed lower-level safety functions. This allows novel technologies to make their safety case specific to their designs, while still precluding release of radioactive materials from the facility. *(Subpart B)*
    c. The rule should include a set of over-arching general principles in one place (Subpart B) *(working, largely related to quality assurance requirements)*

ACRS Interim Letter (continued)

d. The rule should state that safety analyses must demonstrate that for normal operation and anticipated operational occurrences (AOOs) all safety related barriers to release are maintained. *(Subpart C, revised)*

e. The rule should state that safety analyses must demonstrate that Design Basis Accidents (DBAs) achieve and maintain a safe, stable, and subcritical condition. *(Subparts C & D, revised)*

4. Subpart C, "Design and Analysis Requirements," is generally in good shape.

   a. The requirement for risk-informed analysis is appropriate if the use of probabilistic risk assessment (PRA) is approached in a graded fashion commensurate with the potential consequences and the simplicity of the design. *(Subpart C and working on changes to support more deterministic alternative)*

   b. The requirements for selection and analysis of DBAs must be clarified. *(Subpart C, revised)*

   c. The rule eliminates single failure criteria but needs to define the process that replaces it. *(working)*

5. The two recommendations in our first letter report on 10 CFR Part 53 of October 21, 2020, still apply: for novel designs with uncertainties due to incompleteness in the knowledge base, systematic searches for hazards, initiating events, and accident scenarios should be required; and a licensing pathway including additional testing and monitoring akin to prototype testing should be available. *(Subpart C and Subpart H)*

Part 53 General Layout

- Subpart A, General Provisions
- Subpart B, Technology-Inclusive Safety Objectives
- Subpart C, Design and Analysis
- Subpart D, Siting Requirements
- Subpart E, Construction and Manufacturing Requirements
- Subpart F, Requirements for Operation
- Subpart G, Decommissioning Requirements
- Subpart H, Applications for Licenses, Certifications and Approvals
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Subpart B – Technology-Inclusive Safety Requirements 3rd Iteration

Third Iteration of Subparts B & C

- An important note for this iteration is that the staff is actively assessing various alternative design/licensing approaches to address comments that the rulemaking should support methodologies that are less reliant on PRA.
- The development of recent subparts (including this iteration of Subparts B and C) primarily reflects a risk-informed, PRA-centered approach.
- The staff is developing alternative approaches and related preliminary rule sections for a future iteration that can be considered by and discussed with the ACRS

Subpart B – Technology-Inclusive Safety Requirements

§ 53.200, “Safety Objectives”

Each commercial nuclear plant must be designed, constructed, operated, and decommissioned to limit the possibility of an immediate threat to the public health and safety. In addition, each commercial nuclear plant must take such additional measures as may be appropriate when considering potential risks to public health and safety. These safety objectives shall be carried out by meeting the safety criteria identified in this subpart.

- No changes from the previously released preliminary language other than a conforming change related to referring to “commercial nuclear plant” licensed under this part versus “advanced nuclear plant.”

Subpart B – Technology-Inclusive Safety Requirements

§ 53.210, "Safety Criteria for Design Basis Accidents"

Design features and programmatic controls must be provided for each commercial nuclear plant such that analyses of design basis accidents in accordance with § 53.240 demonstrate the following:

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

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

- Section titles changed to "Safety Criteria for Design Basis Accidents" to address numerous comments related to the use of "first tier" and "second tier" safety criteria.
- Intended to better describe the role of the two categories of safety criteria, the relationship between these safety criteria and the different types of LBEs, and the relationship to later sections in Subpart B and C.
- Normal operations moved to dedicated section (also for § 53.220)

Subpart B – Technology-Inclusive Safety Requirements

§ 53.220, "Safety Criteria for Licensing Basis Events Other than Design Basis Accidents"

Design features and programmatic controls must be provided to:

(a) Ensure plant structures, systems and components (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

(b) 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 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

- Section titles changed to "Safety Criteria for Licensing Basis Events Other Than Design Basis Accidents" to address numerous comments related to the use of "first tier" and "second tier" safety criteria.
- Intended to better describe the role of the two categories of safety criteria, the relationship between these safety criteria and the different types of LBEs, and the relationship to later sections in Subpart B and C.

Subpart B – Technology-Inclusive Safety Requirements

§ 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 licensing basis events—such as controlling heat generation, heat removal, and chemical interactions--must be defined.

(c) The primary and additional safety functions are required to meet the safety criteria defined in §§ 53.210 and 53.220 and are fulfilled by the design features and programmatic controls specified throughout this part.

- Conforming changes to reflect changes to §§ 53.210 and 53.220.
- Reactivity included within heat generation at this level and addressed more specifically within Subpart C for those functions related to the reactor core

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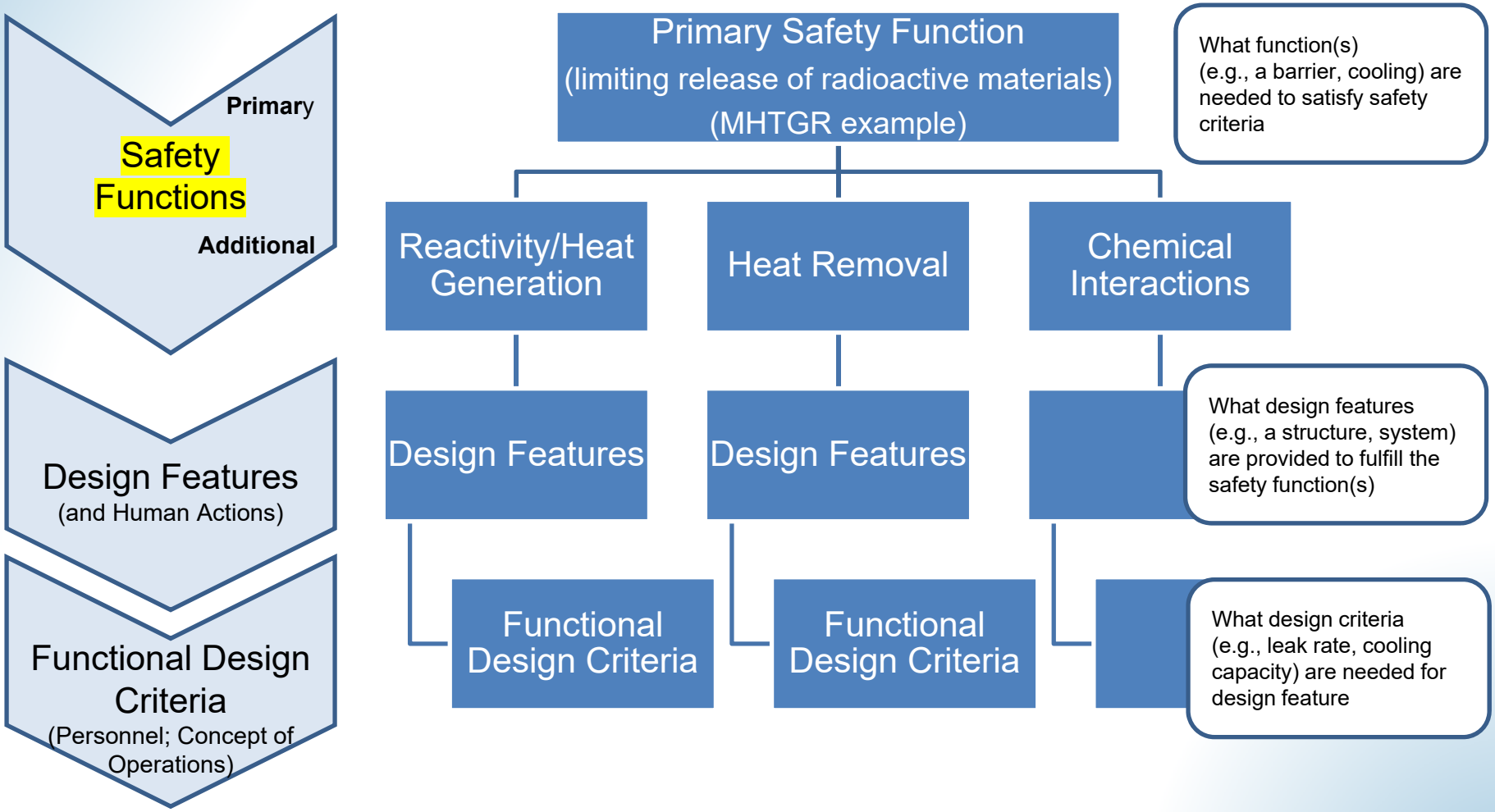
Technology-Inclusive Methodology



Subpart B – Technology-Inclusive Safety Requirements

§ 53.240, “Licensing Basis Events”

Licensing basis events must be identified for each commercial nuclear plant and analyzed in accordance with § 53.450 to support assessments of the safety requirements in this subpart. 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 very unlikely event sequences with estimated frequencies well below the frequency of events expected to occur in the life of the commercial nuclear plant. The analysis of licensing basis events must include analysis of one or more design basis accidents in accordance with § 53.450(f). The analysis of licensing basis events must be used to confirm the adequacy of design features and programmatic controls needed to satisfy safety criteria defined in §§ 53.210 and 53.220 and to establish related functional requirements for plant SSCs, personnel, and programs.

- Conforming changes to reflect changes to §§ 53.210 and 53.220.

Subpart B – Technology-Inclusive Safety Requirements

§ 53.250, “Defense in Depth”

Measures must be taken for each commercial nuclear plant to ensure appropriate defense in depth is provided to compensate for uncertainties such that there is high confidence that the safety criteria in this subpart are met over the life of the plant. The 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. No single engineered design feature, human action, and or programmatic control, no matter how robust, should be exclusively relied upon to meet the safety criteria of § 53.220 or the safety functions defined in accordance with § 53.230.

- Only conforming changes

Subpart B – Technology-Inclusive Safety Requirements

§ 53.260, "Normal Operations"

(a) Maximum public dose. Licensees under this part must ensure that the contribution to total effective dose equivalent to individual members of the public from normal plant operation does not exceed the public dose limits provided in Subpart D to 10 CFR part 20.

(b) As low as reasonably achievable. Design features and programmatic controls must be established such that 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 in accordance with 10 CFR part 20 [consider also possible updates for consistency with requirements in 10 CFR 50.34a, Appendix I to part 50, and 40 CFR part 190].

- Added as a result of the removal of normal operations from §§ 53.210 and 53.220.
- The reorganization of the preliminary rule language does not change the technical requirements from those included in the previously released preliminary rule language.
- Paragraph (a) refers to licensees in recognition that requirement is actual plant performance measure

Subpart B – Technology-Inclusive Safety Requirements

§ 53.270, “Protection of Plant Workers”

(a) Maximum occupational dose. Licensees under this part must ensure that radiological dose to plant workers does not exceed the occupational dose limits provided in subpart C to 10 CFR part 20.

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

- Renumbered and includes conforming changes to reflect the proposed revisions in previous sections.
- Section 53.270(a) is revised to require “licensees under this part” to ensure that the dose to plant workers does not exceed limits in 10 CFR Part 20 and in recognition that only a combination of design features and programmatic controls can ensure actual worker doses remain below Part 20 limits.

Subpart B – Technology-Inclusive Safety Requirements

Discussion

Part 53 General Layout

- Subpart A, General Provisions
- Subpart B, Technology-Inclusive Safety Objectives
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Subpart C – Requirements for Design and Analysis 3rd Iteration

Subpart C – Requirements for Design and Analysis

- § 53.400, "Design Features for Licensing Basis Events"
  - Conforming changes to reflect changes to §§ 53.210 and 53.220 and to better align design features under § 53.400 to those needed to prevent or mitigate LBEs (i.e., unplanned events).
- § 53.410, "Functional Design Criteria for Design Basis Accidents"
  - Conforming changes to reflect changes to § 53.210 (Safety Criteria for Design Basis Accidents), which include relocating requirements for normal operations and emphasizing the tie to DBAs.
- § 53.420, "Functional Design Criteria for Licensing Basis Events Other than Design Basis Accidents"
  - Conforming changes to reflect changes to § 53.220 (Safety Criteria for Licensing Basis Events Other Than Design Basis Accidents), which include relocating requirements for normal operations and emphasizing the tie to LBEs such as anticipated operational occurrences, unlikely event sequences, and highly unlikely event sequences.

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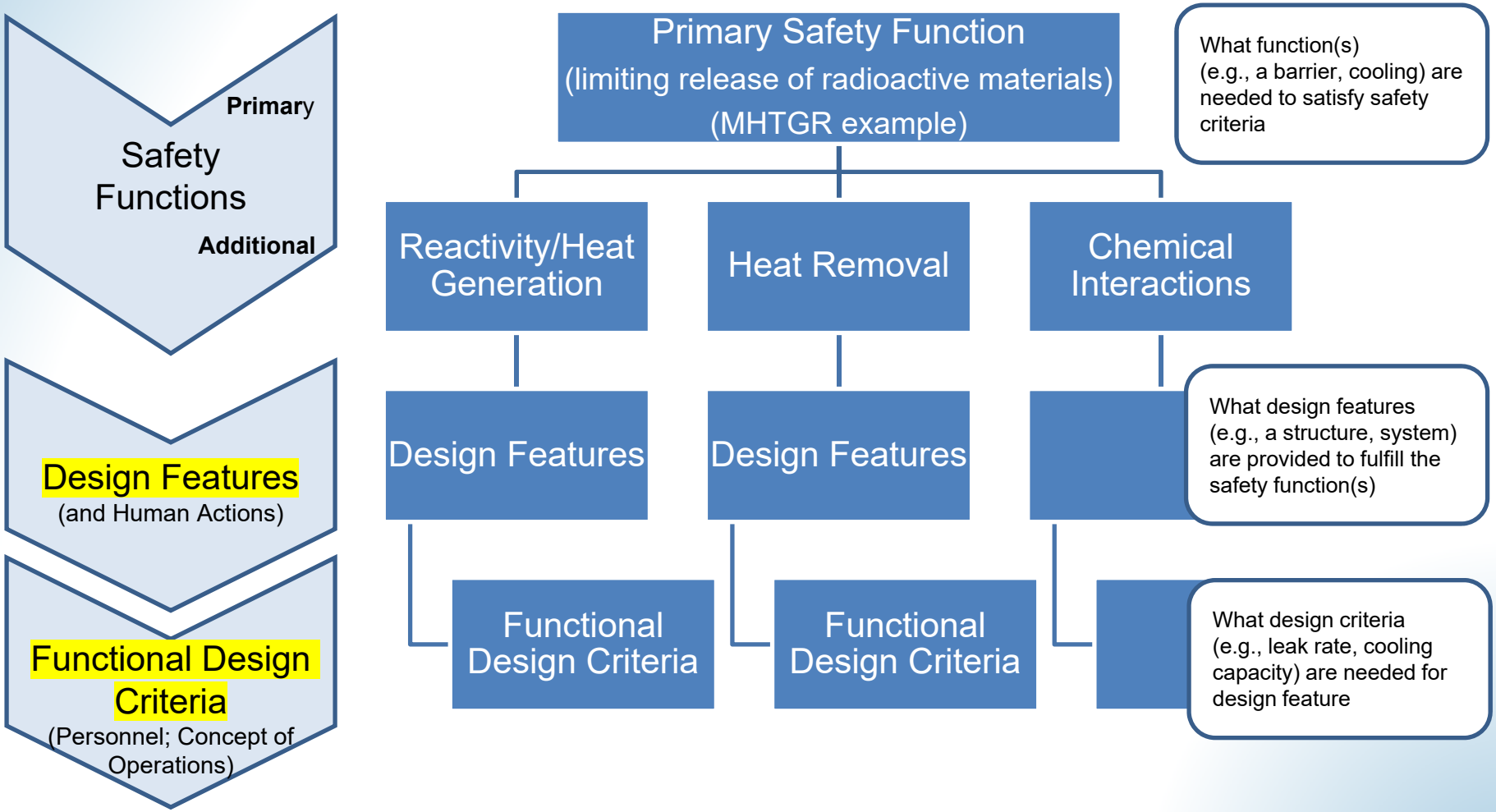
Technology-Inclusive Methodology



Subpart C – Requirements for Design and Analysis

- § 53.425, "Design Features and Functional Design Criteria for Normal Operations"
  - Addition of this section results from the removal of normal operations from §§ 53.210 and 53.220 and the movement of normal operations in Subpart B to § 53.260.
  - This section and the following presents a challenge in terms of implementing a performance-based approach that recognizes the roles of design features and programmatic controls. Staff is seeking suggestions on how an integrated framework can be best incorporated into the subparts of lifecycle stages.
- § 53.430, "Design Features and Functional Design Criteria for Protection of Plant Workers"
  - Conforming changes to reflect renumbering of § 53.270.

Subpart C – Requirements for Design and Analysis

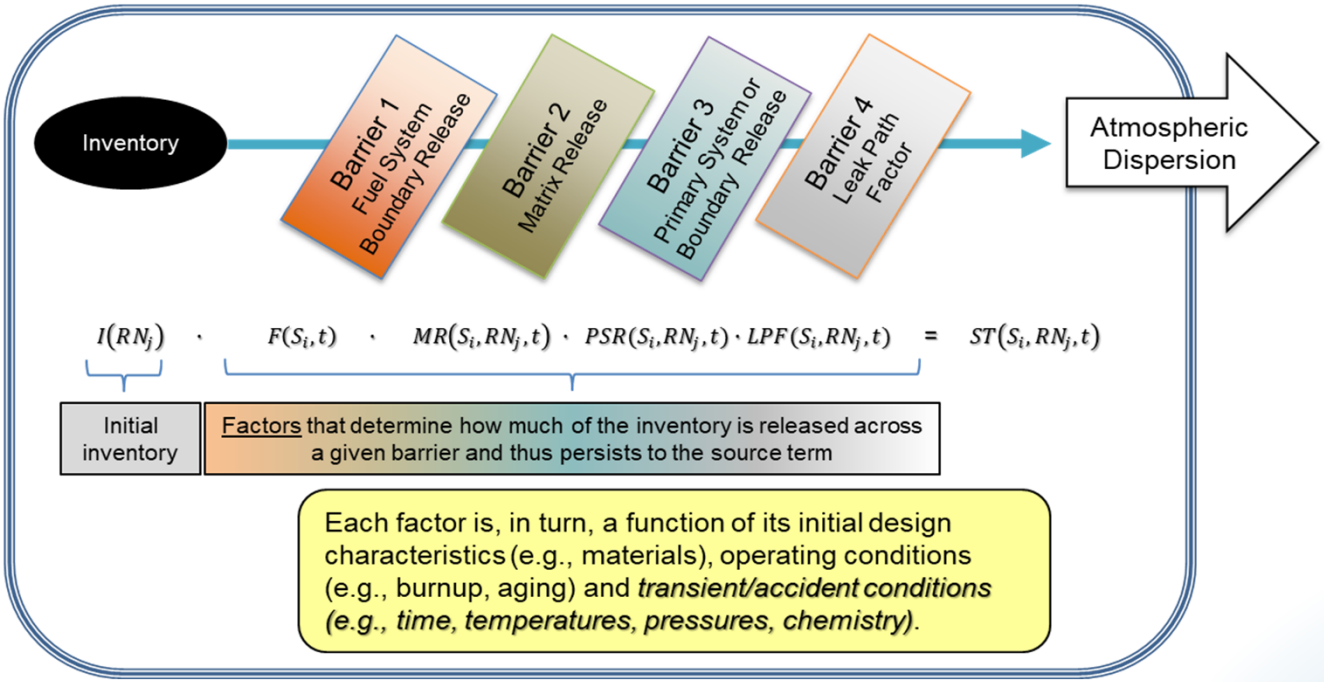
- § 53.440, “Design Requirements”
  - Conforming changes to reflect changes to §§ 53.210 and 53.220.
  - Addition of paragraph (c) results from the need for designers to evaluate and consider, in both the design and integrity assessment programs, possible degradation mechanisms such as aging, fatigue, and chemical interactions.
  - Paragraph (f) added to provide additional discussion for fire protection.
  - Paragraphs (g) & (h) add requirements for longer term capabilities to ensure reactor and waste stores can achieve and maintain subcritical conditions and cooling. (note that longer term may refer to after achieving a safe stable end state in the LBE analysis)
  - Paragraph (i) added to reinforce that the design and analyses activities under Part 53 are based on the concept of a “nuclear plant” and need to consider the number of units and radioactive sources and possible interactions between them.

Subpart C – Requirements for Design and Analysis

- § 53.450, “Analysis Requirements”
  - Paragraph (a) adds conforming changes to reflect changes to § 53.220 (Safety Criteria for Licensing Basis Events Other Than Design Basis Accidents) and removes “degradation mechanisms,” which are better addressed through the design and programmatic requirements defined elsewhere in Part 53.
  - Paragraph (e) revised to include requirements to define evaluation criteria for specific event categories and a means to identify event sequences deemed significant for controlling risks posed to public health and safety.
  - Paragraph (f) is revised to clarify the selection of DBAs.
  - Paragraph (g) updated for fire protection analysis.

First Principles

Recent NRC activities related to advanced reactors (e.g., functional containment performance criteria, possible changes to emergency planning & security, and DG-1353) recognize the limitations of existing LWR-related guidance, which requires a return to first principles such as fundamental safety functions supporting the retention of radionuclides



See: **SECY-18-0096**, "Functional Containment Performance Criteria for Non-Light-Water-Reactors," INL/EXT-20-58717, "Technology-Inclusive Determination of Mechanistic Source Terms for Offsite Dose-Related Assessments for Advanced Nuclear Reactor Facilities," and **SECY-19-0117**, "Technology-Inclusive, Risk-Informed, and Performance-Based Methodology.."

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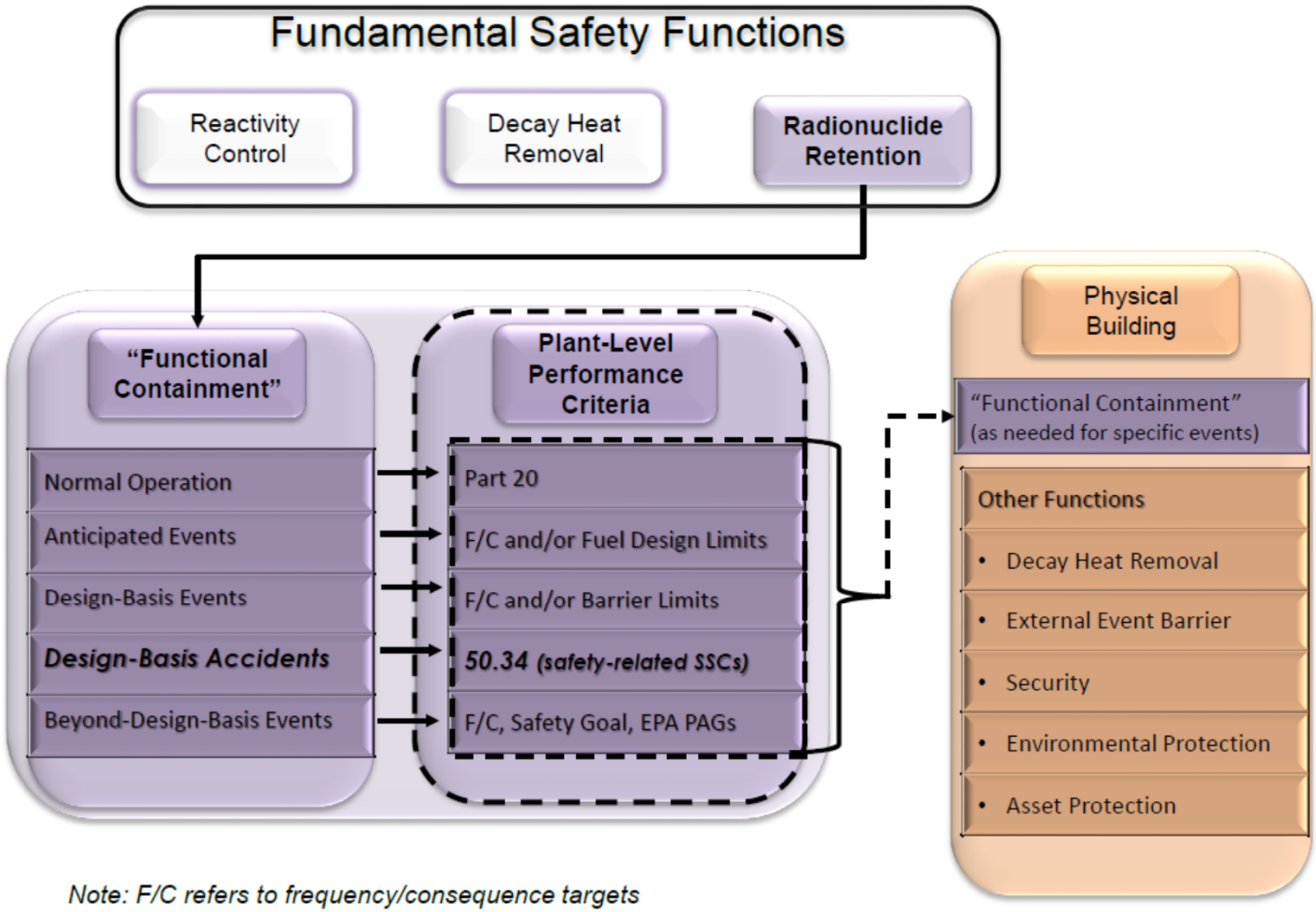
Functional Containment
(SECY-18-0096)



Note: F/C refers to frequency/consequence targets

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Risk-significant LBEs (example)

NEI 18-04

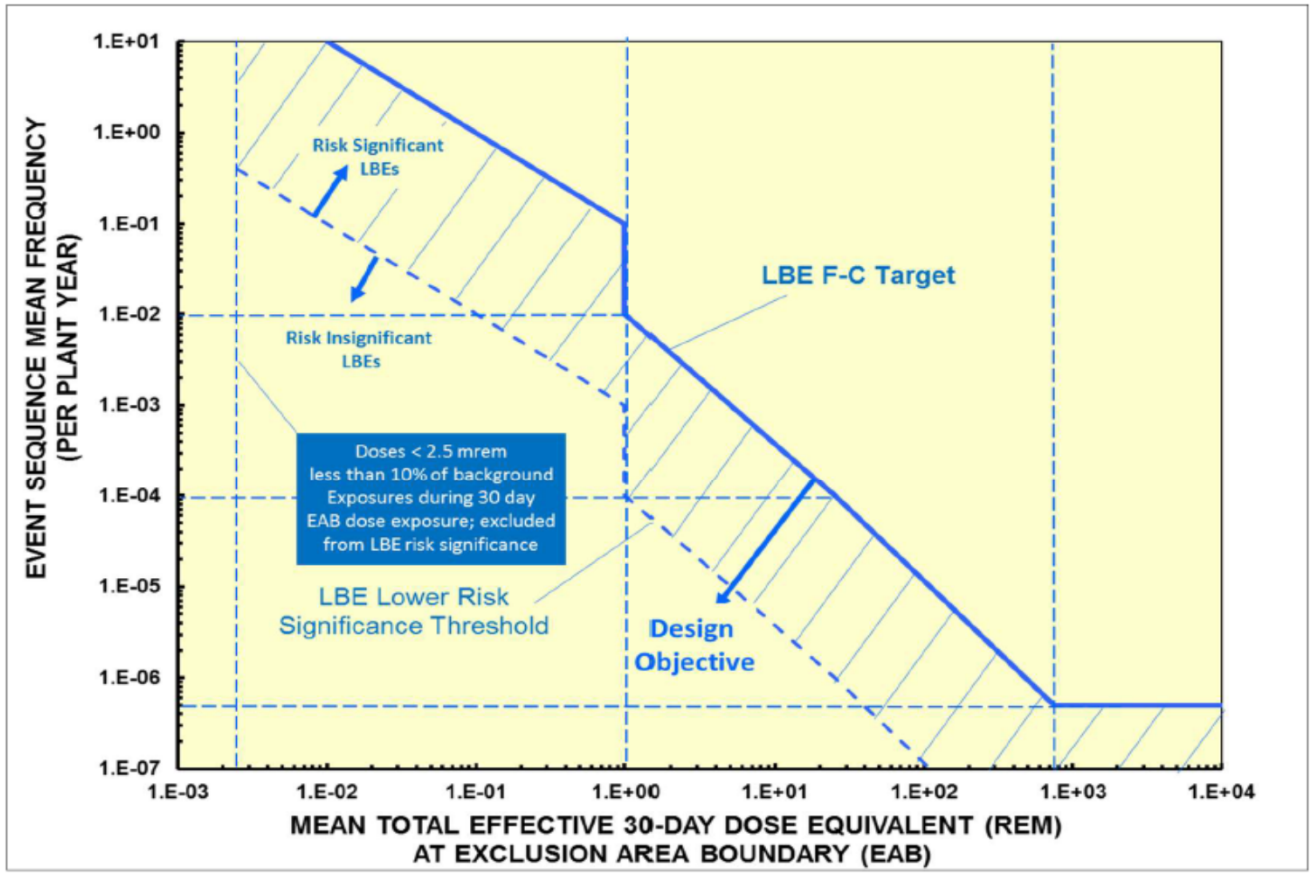

Figure 3-4. Use of the F-C Target to Define Risk-Significant LBEs

Subpart C – Requirements for Design and Analysis

- § 53.460, “Safety Categorization and Special Treatment”
  - No changes
- § 53.470, “Application of Analytical Safety Margins to Operational Flexibilities”
  - Conforming changes to reflect changes to §§ 53.210 and 53.450.
- § 53.480, “Design Control Quality Assurance”
  - No changes
- § 53.490, “Design and Analyses Interfaces”
  - No changes

Subpart C – Requirements for Design and Analysis

Discussion

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MEETING BREAK

Meeting to resume in 1 hour

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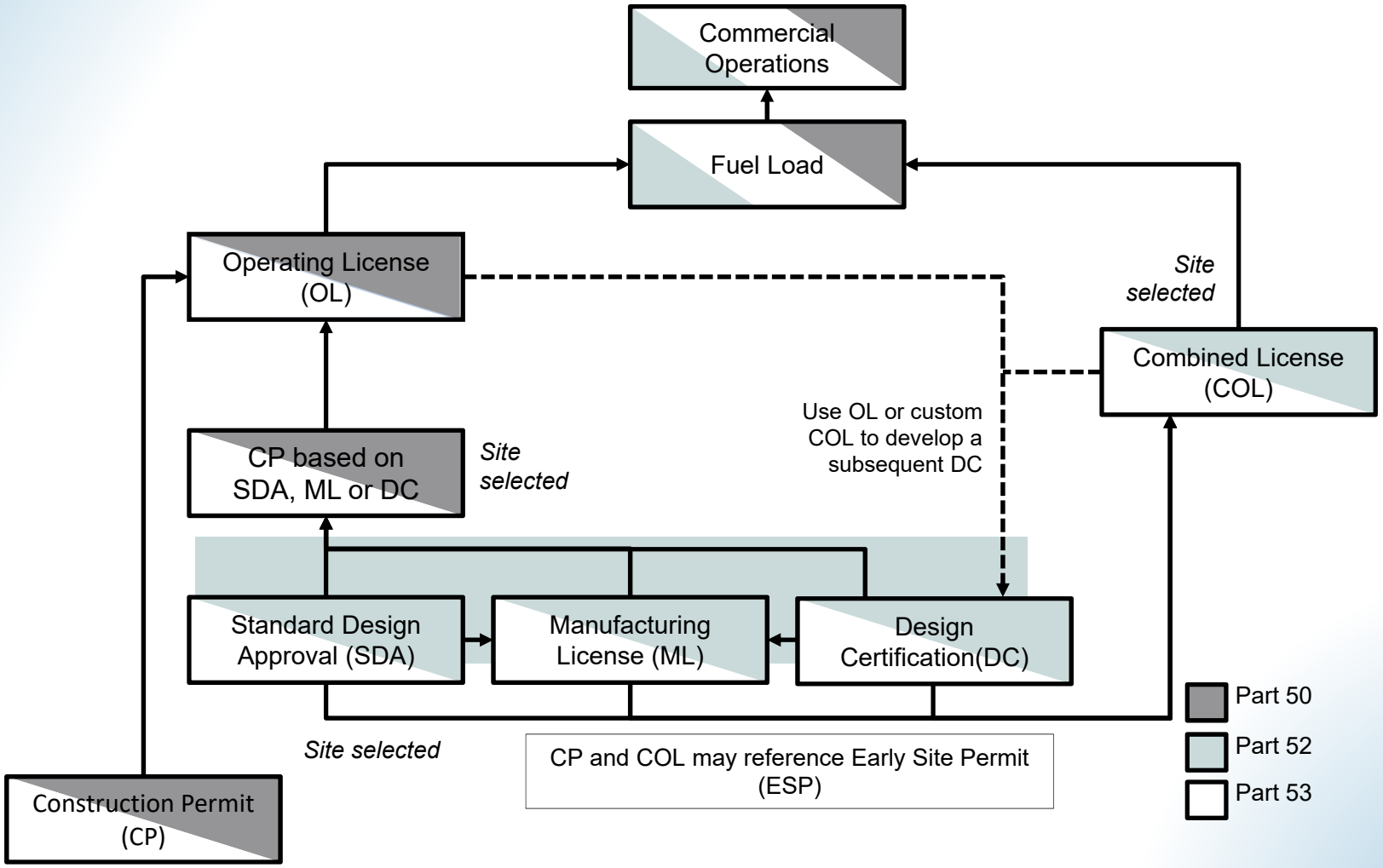
Subpart H – Licenses, Certifications, and Approvals Part 1: LWAs, ESPs, SDAs, DCs

Leveraging and Combining Existing Licensing Processes



Subpart H - Licenses, Certifications, and Approvals

- Several issues relate to items being addressed in the ongoing lessons learned rulemaking for Parts 50 and 52 and reconciliation will occur later.
  - The first iteration of Subpart H largely reflects the current version of Parts 50 and 52.
- Application requirements tailored to match Part 53 technical requirements. TICAP/ARCAP guidance will support Part 53.
- § 53.1100 Filing of application for licenses, certifications or approvals; oath or affirmation.
  - Provides the equivalent of § 50.30 for general administrative requirements for filing applications.
- § 53.1110 Combining applications
  - Provides the equivalent of §§ 50.31 and 52.8 and allows the combining in one application several applications for different kinds of licenses.
- § 53.1120 Elimination of repetition
  - Provides the equivalent of § 50.32 and allows applicants to incorporate by reference information contained in previous applications or reports.

Subpart H - Licenses, Certifications, and Approvals

- § 53.1130 Contents of applications; general information
  - Provides the equivalent of § 50.33 for general content information applicable to all applications or a subset of applications.
  - Paragraphs on emergency plans here and throughout Subpart H will be updated following completion of the rulemaking on “Emergency Preparedness Requirements for Small Modular Reactors and Other New Technologies”
- § 53.1135 Environmental conditions
  - Provides the equivalent of § 50.36(b) noting that certain licenses may include conditions to address environmental issues.
- § 53.1140 Agreement limiting access to Classified Information
  - Provides the equivalent of § 50.37 requirements related to controls over Restricted Data or classified National Security Information.
- § 53.1150 Ineligibility of certain applicants
  - Provides the equivalent of § 50.38 and covers restrictions related to foreign owned, controlled, or dominated applicants.
- § 53.1160 Public inspection of applications
  - Provides the equivalent of § 50.39 provisions for public inspection of applications.

Subpart H - Licenses, Certifications, and Approvals

- § 53.1162 Relationship between sections
  - This is a new section that will be populated later to include text from the Part 52 sections on "Relation to other subparts," as well as explain relationships with Part 50 licensing processes.
- § 53.1165 Site suitability reviews
  - Provides the equivalent of the Part 50, Appendix Q and Part 2, Subpart F site suitability review process.
  - Covers procedures for the filing, staff review, and referral to the ACRS of requests for early review of one or more site suitability issues relating to the construction and operation of facilities separately from and prior to the submittal of applications for CPs for the facilities (predecessor to ESPs).
  - Staff is seeking stakeholder input as to whether the process should be carried forward into Part 53.
- § 53.1170 Limited work authorizations (LWAs)
  - Provides the equivalent of § 50.10 requirements for seeking an LWA.
  - In Part 53, the definition of construction from § 50.10(a) is contained in the Subpart A definitions.

Subpart H - Licenses, Certifications, and Approvals

- §§ 53.1180-53.1199 Early site permits
  - These sections are largely copied from the existing Part 52 equivalent sections.
  - § 53.1185 Contents of applications; technical information
    - (a)(1)(ix) "An analysis of licensing basis events associated with potential designs and their results, as described in § 53.240, considered in the design to determine compliance with the safety criteria in §§ 53.210 and 53.220, or more restrictive alternative evaluation criteria elected under § 53.470 of this part. This analysis description must address the elements in §§ 53.450(e) and 53.450(f), as applicable for the licensing basis events associated with potential designs that the applicant may be considering."
      - The phrase "licensing basis events associated with potential designs" is meant to acknowledge that the applicant may be considering one or more designs in the evaluation of its proposed site, similar to the plant parameter envelope approach that has been used by ESP applicants under Part 52.
    - (a)(1)(xi) "A description of the quality assurance program required by § 53.XX applied to site-related activities for the future design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site."
      - The reference to § 53.XX is to a new QA section that will be added to Subpart D, "Siting Requirements," as the staff inadvertently failed to include such a requirement for siting activities in the first iteration of Subpart D.

Subpart H - Licenses, Certifications, and Approvals

- §§ 53.1220-53.1229 Standard design approvals
  - These sections are largely copied from the existing Part 52 equivalent sections.
  - § 53.1225 Contents of applications; technical information
    - "If the applicant seeks review of a major portion of a standard design, the application need only contain the information required by this section to the extent the requirements are applicable to the major portion of the standard design for which NRC staff approval is sought. If an applicant seeks approval of a major portion of the design, the scope of the application for which approval is sought must include all functional design criteria as can be identified at that stage of design. Such applicants must identify conditions related to interfaces with systems outside the scope of the major portion of the standard design for which NRC staff approval is sought, and functional or physical boundary conditions between the major portion of the standard design for which NRC staff approval is sought and the remainder of the standard design. These conditions must be demonstrated when the standard design approval is incorporated into a subsequent construction permit, design certification, manufacturing license, or combined license application."
    - Additional discussion regarding SDAs for a major portion of a standard design can be found in the NRC's "A Regulatory Review Roadmap for Non-Light Water Reactors," and the Nuclear Innovation Alliance report "Clarifying 'Major Portions' of a Reactor Design in Support of a Standard Design Approval" (ML17128A507)

Subpart H - Licenses, Certifications, and Approvals

- §§ 53.1230-53.1239 Standard design certifications
  - These sections are largely copied from the existing Part 52 equivalent sections.
  - § 53.1235 Contents of applications; technical information
  - (a) FSAR (Final safety analysis report)

(1) Site Parameters	(6) Programmatic Controls and Interfaces	(11) Safety and Security	(16) Analytical Margins
(2) General Plant Description	(7) Design Features and Functional Design Criteria for the Protection of Plant Workers	(12) Probabilistic Risk Assessment	(17) Design and Analyses Quality Assurance
(3) Design Features – Licensing Basis Events	(8) Programmatic Controls for Protection of Plant Workers	(13) Analyses	(18) Design and Analyses Interfaces
(4) Design Features and Functional Design Criteria – Normal Operations	(9) Codes and Standards	(14) PRA Maintenance	(19) Design Features and Controls to Address the Minimization of Contamination
(5) Functional Design Criteria – Licensing Basis Events	(10) Materials	(15) Special Treatments	(20) Interface Requirements

  - (b) Other application content

(1) Environmental Report	(3) Availability Controls (if not included in the FSAR)	(5) Inspections, Tests, Analyses, and Acceptance Criteria	(7) Safeguards Information
(2) Technical Specifications	(4) Technical Qualifications	(6) Integrity Assessment Program	

Subpart H - Licenses, Certifications, and Approvals

- § 53.1236, Review of applications, contains a new proposal for a DC applicant to reference an issued OL or custom COL with finality provisions like those for a DC applicant referencing an SDA
- Remainder of Subpart H addressing MLs, CPs, OLs, and COLs will be covered in October Subcommittee meeting

Subpart H - Licenses, Certifications, and Approvals

Discussion

Part 53 General Layout

- Subpart A, General Provisions
- Subpart B, Technology-Inclusive Safety Objectives
- Subpart C, Design and Analysis
- Subpart D, Siting Requirements
- Subpart E, Construction and Manufacturing Requirements
- Subpart F, Requirements for Operation
- Subpart G, Decommissioning Requirements
- Subpart H, Applications for Licenses, Certifications and Approvals
- Subpart I, Maintaining and Revising Licensing Basis Information
- Subpart J, Reporting and Administrative Requirements

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Subpart I – Maintaining and Revising Licensing Basis Information

Subpart I – Maintaining and Revising Licensing Basis Information

- § 53.1300, "Licensing Basis Information"
- § 53.1310, "Changes to Licensing Basis Information Requiring Prior NRC Approval"
  - Introduces the requirements for proposing changes to the licensing basis information defined by licenses, orders, and regulations.
- § 53.1311, "Application for Amendment of License"
  - Provides the equivalent of § 50.90 for applications to amend an ESP, CP, OL, or COL issued under Part 53.
- § 53.1312, "Public Notices; State Consultation"
  - Provides the equivalent of § 50.91 for the NRC's processes related to applications to amend an ESP, CP, OL, or COL issued under Part 53.
- 53.1313, "Issuance of Amendment"
  - Provides the equivalent of § 50.92 for the NRC's processes related to applications to amend an ESP, CP, OL, or COL issued under Part 53.

Subpart I – Maintaining and Revising Licensing Basis Information

- § 53.1315, "Revising Certification Information Within a Design Certification Rule"
  - Provides the requirements for the holder of an OL or COL issued under Part 53 that references a design certification rule to propose an exemption from the specified characteristics of the certified design.
  - Other requirements related to design certification and changes to the DC by parties other than the holder of an OL or COL included in Subpart H.
- § 53.1316, "Revising Design Information Within a Manufacturing License"
  - From Subpart F of Part 52, provides the requirements for the holder of an OL or COL issued under Part 53 that references a ML to propose a departure from the specified characteristics of the manufactured reactor.

Subpart I – Maintaining and Revising Licensing Basis Information

- § 53.1317, "Amendments During Construction"
  - Provides the requirements for amending the permit or license the holder of a CP or COL issued under Part 53.
  - Paragraph (a) reflects the same requirements in § 50.35(b), while paragraph (b) reflects the process for Part 52 changes during construction.
- § 53.1320, "Evaluating Changes and Updating Licensing Basis Information Without NRC Prior Approval"
  - This section introduces the requirements for licensees to pursue changes to the licensing basis information in licensee controlled documents such as FSARs and program documents.
- § 53.1321, "Updating Final Safety Analysis Reports"
  - This section provides the equivalent of § 50.71 for the updating of FSARs.
  - Assuming a risk-informed approach in Subpart C results in PRA information being in the FSAR and therefore a separate PRA update requirement (§ 50.71(h)) is not included in this iteration of Subpart I.

Subpart I – Maintaining and Revising Licensing Basis Information

- § 53.1322, “Evaluating Changes to Facility as Described in Final Safety Analysis Reports”
  - Provides the equivalent of § 50.59 for evaluating changes to updated final safety analysis reports (UFSAR) and determining if a license amendment is required.
  - Include a risk-informed approach for assessing the results of changes on LBEs and using criteria related to the impact on margins to acceptance criteria.

§ 53.1322(a)(2)(i)

(i) Does not result in a change to the frequency or consequences of an event sequence such that an event sequence previously deemed not risk significant becomes risk significant by the analyses performed in accordance with § 53.450(e).

§ 53.450(e)

… 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 evaluation criteria defined for licensing basis events, to satisfy the safety criteria of § 53.220, and provide defense in depth as required by § 53.250. The methodology used to identify, categorize, and analyze licensing basis events must include a means to identify event sequences deemed significant for controlling the risks posed to public health and safety.

NEI 18-04

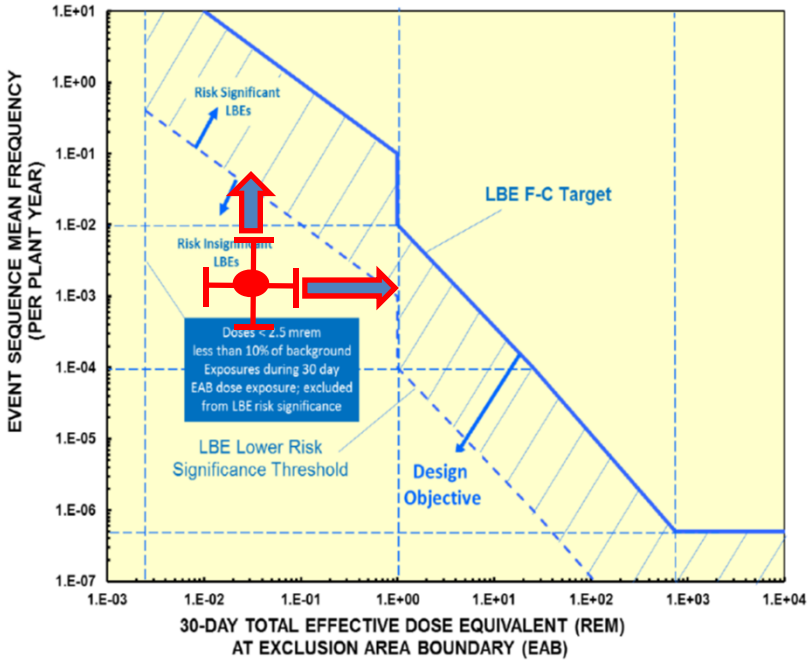

Figure 3-4. Use of the F-C Target to Define Risk-Significant LBEs

§ 53.1322(a)(2)(ii)

(ii) Does not result in a change to the frequency or consequences of an event sequence such that an event sequence deemed risk significant in accordance with § 53.450(e) has a decrease of 10 percent or more in the calculated margins to the LBE evaluation criteria required to be established in accordance with § 53.450(e).

NEI 18-04

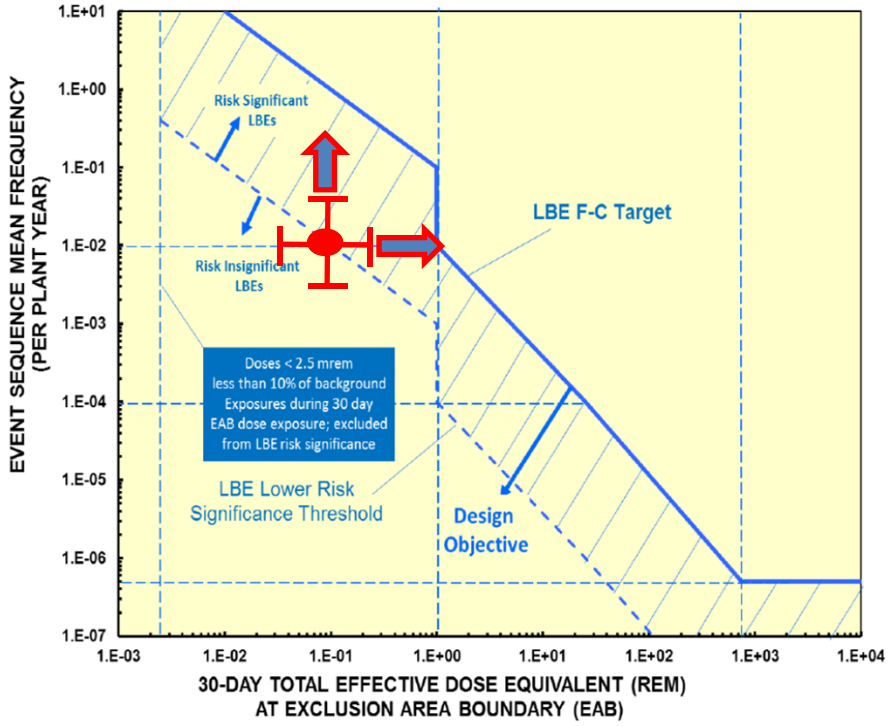

Figure 3-4. Use of the F-C Target to Define Risk-Significant LBEs

§ 53.1322(a)(2)(iii)

(iii) Does not result in a change to the frequency or consequences of one or more event sequences such that the margin between the calculated cumulative risks posed by the commercial nuclear plant and the safety criteria of § 53.220 decreases by 10 percent or more.

§ 53.220 Safety Criteria for Licensing Basis Events Other Than Design Basis Accidents

(b) 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 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.

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§ 53.1322(a)(2)(iv)

(iv) Does not involve a departure from a method of evaluation described in the UFSAR used in assessing margins in accordance with § 53.450(e) unless the results of the analysis are conservative or essentially the same, the revised method of evaluation has been previously approved by the NRC for the intended application, or the revised method of evaluation can be used in accordance with an NRC endorsed consensus code or standard.

§ 50.59(c)(1)(viii)

(viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

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§ 53.1322(a)(2)(v)

(v) For commercial nuclear plants licensed under this part for which alternative evaluation criteria are applicable in accordance with § 53.470, does not result in a change to the frequency or consequences of event sequences such that the calculated margins between the results for event sequences evaluated in accordance with § 53.450(e) and the alternative evaluation criteria decreases by 25 percent or more.

§ 53.470 Application of Analytical Safety Margins to Operational Flexibilities.

Where an applicant or licensee so chooses, alternative criteria more restrictive than those defined in §§ 53.220 and 53.450(e) 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, the analysis requirements of § 53.450(e), and identification of special treatment of SSCs and human actions under § 53.460 reflect and support the use of alternative 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.

NEI 18-04 (w/ 1 rem goal)

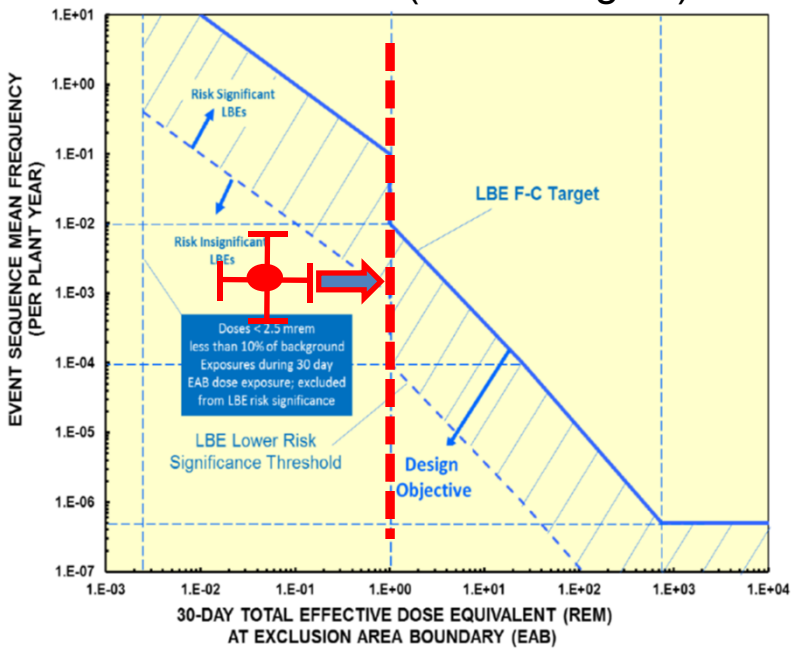

Figure 3-4. Use of the F-C Target to Define Risk-Significant LBEs

Subpart I – Maintaining and Revising Licensing Basis Information

- § 53.1330, “Control of Licensing Basis Information in Program Descriptions”
- § 53.1332, “Updating program documents included in licensing basis information”
  - Provides the equivalent of UFSAR updates for key program documents
  - This iteration provides a uniform approach for program documents, which correspond to the programs required under Subpart F. The staff is interested in stakeholder views on the benefits of a common approach versus the current practice of establishing program-specific requirements for reporting and change control.

Subpart I – Maintaining and Revising Licensing Basis Information

- § 53.1333, "Evaluating Changes to Programs Included in Licensing Basis Information"
  - Provides a uniform approach for program documents, which correspond to the programs required under Subpart F.
  - The staff is interested in stakeholder views on the benefits of a possibly developing a common approach versus the current practice of establishing program-specific requirements for reporting and change control.
- § 53.1340, "Transfer of Licenses or Permits"
  - Provides the equivalent of § 50.80 for the possible transfer of an ESP, CP, OL, or COL.
- § 53.1350, "Termination of License"
  - Provides the equivalent of § 50.82 for the possible termination of an OL or COL.

Subpart I – Maintaining and Revising Licensing Basis Information

- § 53.1360, "Information Requests"
  - Provides the equivalent of § 50.54(f) for a possible request for information that the NRC would issue to holders of an ESP, CP, OL, or COL.
- § 53.1370, "Revocation, suspension, modification of licenses, permits, and approvals for cause"
  - Provides the equivalent of § 50.100 for the possible revocation, suspension, or modification of a license or permit.
- § 53.1380, "Backfitting"
  - Provides the equivalent of § 50.109 for the possible backfitting of requirements to holders of licenses or permits.
  - First iteration may require additional measures to fully capture all of the finality provisions within Subpart H and the staff expects to update and clarify as additional sections of Subpart H are developed.
- § 53.1390, "Renewal"
  - A section may be added to more fully describe or reference the processes related to requesting and processing applications to renew ESPs, CPs, OLs, and COLs.

Subpart I – Maintaining and Revising Licensing Basis Information

Discussion

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MEETING BREAK

Meeting to resume in 15 minutes

Part 53 General Layout

- Subpart A, General Provisions
- Subpart B, Technology-Inclusive Safety Objectives
- Subpart C, Design and Analysis
- Subpart D, Siting Requirements
- Subpart E, Construction and Manufacturing Requirements
- Subpart F, Requirements for Operation
- Subpart G, Decommissioning Requirements
- Subpart H, Applications for Licenses, Certifications and Approvals
- Subpart I, Maintaining and Revising Licensing Basis Information
- Subpart J, Reporting and Administrative Requirements

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Subpart J – Reporting and Other Administrative Requirements

Subpart J – Reporting and Other Administrative Requirements

- § 53.1500, “General Information”
- § 53.1510, “Unfettered Access for Inspection”
  - Requirements taken from 10 CFR 50.70 with minor changes proposed to address possible differences related to advanced reactors. Changes to address possible changes to criteria for assignment of resident inspectors and need to address possible power reactor facilities without resident inspectors.
- § 53.1520, “Maintenance of Records, Making of Reports”
  - Requirements derived from 10 CFR 50.71.
- § 53.1521, “Immediate Notification Requirements for Operating Commercial Nuclear Plants”
  - Requirements derived from 10 CFR 50.72 with minor changes proposed to address possible differences related to advanced reactors.
  - Preliminary language does not take into account a recently initiated rulemaking activity related to possible changes in immediate notification requirements.

Subpart J – Reporting and Other Administrative Requirements

- § 53.1530, “Licensee Event Report System”
  - Requirements derived from 10 CFR 50.73 with minor changes proposed to address possible differences related to advanced reactors and references to Part 53 sections.
- § 53.1535, “Facility Information and Verification”
  - Requirements taken from 10 CFR 50.78.
- § 53.1560, “Financial Requirements”
- § 53.1561, “Financial Qualifications”
  - Requirements taken from 10 CFR 50.33(f) for contents of applications.
  - Note that details on the required contents of applications to show an applicant is financially qualified for a license or permit will be in Subpart H.
- § 53.1562, “Annual Financial Reports”
  - Reporting requirement taken from 10 CFR 50.71(b).

Subpart J – Reporting and Other Administrative Requirements

- § 53.1563, "Licensee's Change of Status; Financial Qualifications"
  - Reporting requirement taken from 10 CFR 50.76.
- § 53.1564, "Creditor Regulations"
  - Requirements taken from 10 CFR 50.81.
- § 53.1570, "Financial Protection"
- § 53.1571, "Insurance Required to Stabilize and Decontaminate Plant Following an Accident"
  - Requirements taken from 10 CFR 50.54(w).
  - Added provision for design-specific estimate
- § 53.1572, "Financial Protection Requirements"
  - Requirements taken from 10 CFR 50.57 and 10 CFR Part 140.

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Subpart J – Reporting and Other Administrative Requirements

Discussion

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Final Discussion and Questions

September 24th Agenda

9:30am – 9:40am	Opening Remarks
9:40am – 12:45pm	Overview of Subpart F – Requirements for Operations, Section 73.750 – General Staffing, Training, Personnel Qualifications, and Human Factors Requirements
	Part 53 Rulemaking – Additional Efforts
12:45pm – 1:00pm	Discussion

Part 53 General Layout

- Subpart A, General Provisions
- Subpart B, Technology-Inclusive Safety Objectives
- Subpart C, Design and Analysis
- Subpart D, Siting Requirements
- Subpart E, Construction and Manufacturing Requirements
- Subpart F, Requirements for Operation
  - General Staffing, Training, Personnel Qualifications, and Human Factors Requirements
- Subpart G, Decommissioning Requirements
- Subpart H, Applications for Licenses, Certifications and Approvals
- Subpart I, Maintaining and Revising Licensing Basis Information
- Subpart J, Reporting and Administrative Requirements

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Subpart F – General Staffing, Training, Personnel Qualifications, and Human Factors Requirements
- Overview -

Subpart F – General Staffing, Training, Personnel Qualifications, and Human Factors Requirements

- The purpose of this discussion is to provide an overview of the human-system integration requirements in the proposed Part 53 rulemaking.
- A more detailed discussion of these requirements will occur during the October 2021 ACRS subcommittee meeting.

- Subpart F Sections related to staffing build from concepts provided in a previously released white paper discussed with ACRS subcommittee in May 2021 (ML21069A003).
- These requirements may fulfil roles similar to that of certain § 50.34(f) post-TMI requirements (including for human factors engineering (HFE)), portions of the § 50.54 conditions of licenses (including for operations staffing), the § 50.120 training rule, and potentially all of Part 55 for operator licensing.

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Subpart F – General Staffing, Training, Personnel Qualifications, and Human Factors Requirements

- One key area addressed will be contents of applications.
- Emphasis will be placed on information needed to enable the application of flexible and scalable evaluations.
- The facility-specific operator safety role will be central.
- Specific areas anticipated to be covered include:
  - HFE design requirements that are performance-based and focused on safety and emergency response functions.
  - Certain specific human-system interface requirements.
  - The Concept of Operations.
  - Functional Requirements Analysis/Function Allocation
  - Operating Experience evaluation.
  - Staffing plan requirements that are flexible in nature.
  - Licensed operator training and examination program requirements that support tailored approaches.

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Subpart F – General Staffing, Training, Personnel Qualifications, and Human Factors Requirements

- Addresses conditions for operations staffing (aspects of § 50.54).
- Emphasis on providing requirements that are consistent with determining whether a reasonable assurance of safety will exist, while also accommodating new technologies to the maximum extent practicable.
- Specific areas anticipated to be covered include:
  - Operator staffing requirements based on HFE analyses (versus prescriptive staff numbers/positions).
  - Load-following.
  - Online refueling at those facilities capable of doing so.
  - Potential for certain facilities to not require licensed operators based upon design-specific safety considerations; a key consideration would likely be the operator role in addressing LBEs.

Subpart F – General Staffing, Training, Personnel Qualifications, and Human Factors Requirements

- Requirements support technology-inclusive and flexible approaches to operator licensing examinations
- In general, this process would be comprised of:
  - Using Job Task Analyses to identify the necessary knowledge, skills, and abilities for the operator role.
  - Selecting training and evaluation methods using a systems approach to training.
  - Determining the composition of the examination, followed by piloting the proposed examination.
  - NRC review, approval, and administration.
- Elements of this approach may also be applied to those staff with important administrative responsibilities at plants that do not require any licensed operator staffing.

Subpart F – General Staffing, Training, Personnel Qualifications, and Human Factors Requirements

- Part 53 training provisions will:
  - Address training requirements for plant staff in general
  - Establish regulations for the training and qualifications of nuclear power plant operators, supervisors, technicians and other operating personnel.
  - Account for the potential of facilities having non-traditional personnel roles within their organizations
  - Include requirements to base training programs upon a systems approach to training
  - Continue to provide distinct requirements for licensed operator training and requalification programs

Subpart F – General Staffing, Training, Personnel Qualifications, and Human Factors Requirements

- Several areas will require the development of new regulatory guidance, including guidance for:
  - Conducting scalable HFE reviews; staff have been working with Brookhaven National Lab.
  - Reviewing staffing plans that are flexible; staff have been working to adapt the tools of NUREG-1791 to meet this need.
  - Reviewing operator licensing examinations that are tailored based on facility needs; staff have begun working with Idaho National Lab.
- Related areas of staff work include guidance for training program reviews and ARCAP guidance input.

Discussion

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Part 50/53 Supplement: Technology-inclusive, Traditional, Deterministic Licensing Framework Option

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Part 50/53 Supplement: Technology-inclusive, Traditional, Deterministic Licensing Framework Option

- The staff have received comments from stakeholders suggesting that PRA should not be required or play a lead role for licensing.
- As a result, the staff have begun to pursue the development of a potential deterministic licensing framework for advanced reactors.
- This framework would be technology-inclusive with PRA used in a supporting role, and leverage Parts 50 and 52 regulations while aligning with IAEA standards.

Part 50/53 Supplement: Technology-inclusive, Traditional, Deterministic Licensing Framework Option

- This traditional, deterministic option for advanced reactors would potentially include Part 50/52 elements such as:
  - Single Failure Criteria
  - Principal design criteria (PDC)
  - Design basis requirements for AOOs/DBAs
    - Traditional safety classification
  - Consideration of BDBEs and severe accidents
  - Confirmatory PRA & QHOs in guidance.

Part 50/53 Supplement: Technology-inclusive, Traditional, Deterministic Licensing Framework Option

- Including a traditional, deterministic option for advanced reactors would potentially include:
  - Leveraged flexibility by considering dose-oriented emergency preparedness/siting/security (similar to ongoing rulemakings and what is being considered in Part 53)
  - Shared Parts 50 and 53 aspects: enable flexibility in meeting codes and standards (including those related to QA requirements); addition of functional containment concept to make technology inclusive

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Part 50/53 Supplement: Technology-inclusive, Traditional, Deterministic Licensing Framework Option

- Possible areas of providing alternatives to address:
  - PDCs
  - AOOs/DBAs
    - Including possible option of bounding analysis for some or all the accident analysis in a fashion similar to NUREG-1537 (maximum hypothetical accident).
  - BDBEs
    - Building upon traditional station blackout, anticipated transients without scram as well as design extension conditions from IAEA specific safety requirements
  - Severe Accidents
    - Consistent with Policy Statement, technology neutral

Part 50/53 Supplement: Technology-inclusive, Traditional, Deterministic Licensing Framework Option

- To move forward with a deterministic option, the staff are currently:
  - Engaging stakeholders, management, and the Commission on the most appropriate approach.
  - Assessing the placement of the traditional, deterministic option within the NRC's regulations.
  - Reviewing the impact of the required work to develop the framework on the NRC's schedule and resources.

Part 50/53 Supplement: Technology-inclusive, Traditional, Deterministic Licensing Framework Option

Discussion

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Final Discussion and Questions

Part 53 Rulemaking Schedule

Milestone Schedule	
Major Rulemaking Activities/Milestones	Schedule
Public Outreach, ACRS Interactions and Generation of Proposed Rule Package	Present to April 2022 (7 months)
Submit Draft Proposed Rule Package to Commission	May 2022
Publish Proposed Rule and Draft Key Guidance	October 2022
Public Comment Period – 60 days	November and December 2022
Public Outreach and Generation of Final Rule Package	January 2023 to February 2024 (14 months)
Submit Draft Final Rule Package to Commission	March 2024
Office of Management and Budget and Office of the Federal Register Processing	July 2024 to September 2024
Publish Final Rule and Key Guidance	October 2024

Acronyms and Abbreviations

ACRS	Advisory Committee on Reactor Safeguards
ALARA	As low as is reasonably achievable
AOO	Anticipated operational occurrence
ARCAP	Advanced reactor content of application project
BDBE	Beyond design basis event
CFR	Code of Federal Regulations
COL	Combined license
CP	Construction permit
DBA	Design basis accident
DBE	Design basis event
DC	Design certification
DID	Defense-in-depth

EAB	Exclusion area boundary
EP	Emergency preparedness
EPA	U.S. Environmental Protection Agency
ESP	Early site permit
F-C	Frequency-consequence
FSAR	Final safety analysis report
HFE	Human factors engineering
IAEA	International Atomic Energy Agency
LB	Licensing basis
LBE	Licensing basis event
LMP	Licensing Modernization Project
LWA	Limited work authorization

Acronyms and Abbreviations

LWR	Light-water reactor
MHTGR	Modular High-Temperature Gas-Cooled Reactor
ML	Manufacturing license
NEI	Nuclear Energy Institute
NRC	U.S. Nuclear Regulatory Commission
NUREG	U.S. Nuclear Regulatory Commission technical report designation
OL	Operating license
PAG	Protective Action Guide
PDC	Principal design criteria

PRA	Probabilistic risk assessment
QA	Quality assurance
QHO	Quantitative health objective
Rem	Roentgen-equivalent man
SAR	Safety analysis report
SDA	Standard design approval
SSC	Structures, systems, and components
TICAP	Technology-inclusive content of application project
TMI	Three Mile Island
TS	Technical specifications
UFSAR	Updated final safety analysis report