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

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

Revisions to Previously Released Preliminary Proposed Rule Language & Subpart E Preliminary Proposed Rule Language

April 22, 2021

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Agenda

9:30 am – 9:35 am	Opening Remarks
9:35 am – 9:40 am	Staff Introduction
9:40 am – 11:30 am	Subpart B – Technology-Inclusive Safety Requirements – 2nd Iteration
11:30 am – 1:00 pm	Subpart C – Design and Analysis Requirements – 2nd Iteration
1:00 pm – 2:00 pm	Lunch
2:00 pm – 3:00 pm	Subpart C – Design and Analysis Requirements – 2nd Iteration (continued)
3:00 pm – 5:30 pm	Subpart E – Construction and Manufacturing Requirements
5:30 pm – 6:00 pm	Discussion

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NRC Staff Engagement Plan

ACRS Interactions

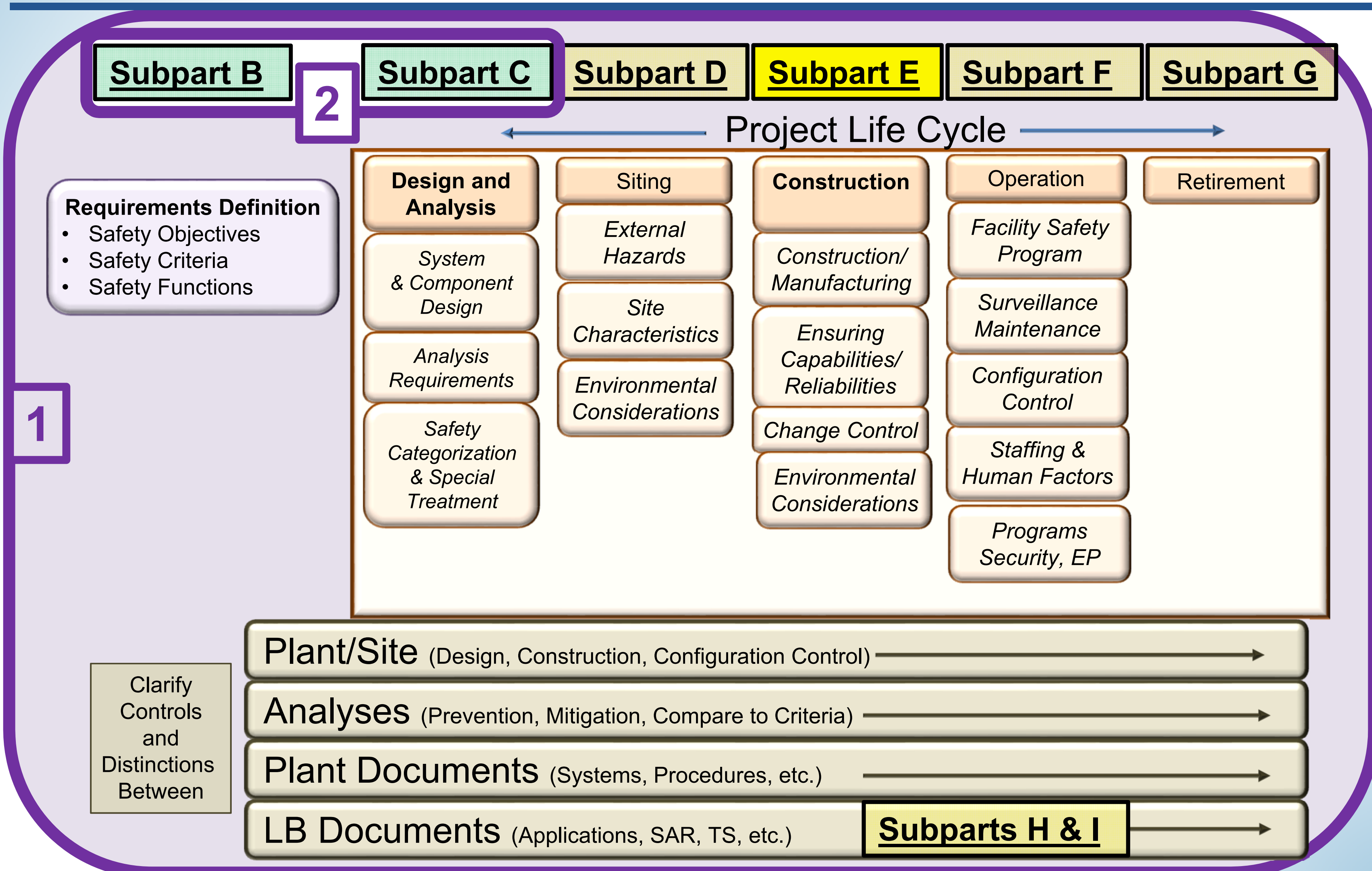
	Framework	Safety Criteria	Design	Siting	Construction	Operations	Decommissioning	Licensing	General/Admin
Sept 20									
Nov 20									
Dec 20									
Jan 21									
Feb 21									
Mar 21	✓	✓	✓		✓				
Apr 21									
May 21									
Jun 21									
Jul 21	Consolidated Technical Sections								
Aug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

(yellow)	Concept/Introduction
(blue)	Discussion
(green)	Interim Staff Resolution

Proposed Focus (Full Committee/Letter)

- Overall Structure (Framework)
- 2nd Iteration Preliminary Proposed Rule Language – Subpart B (Safety Criteria)
- 2nd Iteration Preliminary Proposed Rule Language – Subpart C (Design and Analysis)
- Challenges and Recommendations

NRC Staff Plan to Develop Part 53

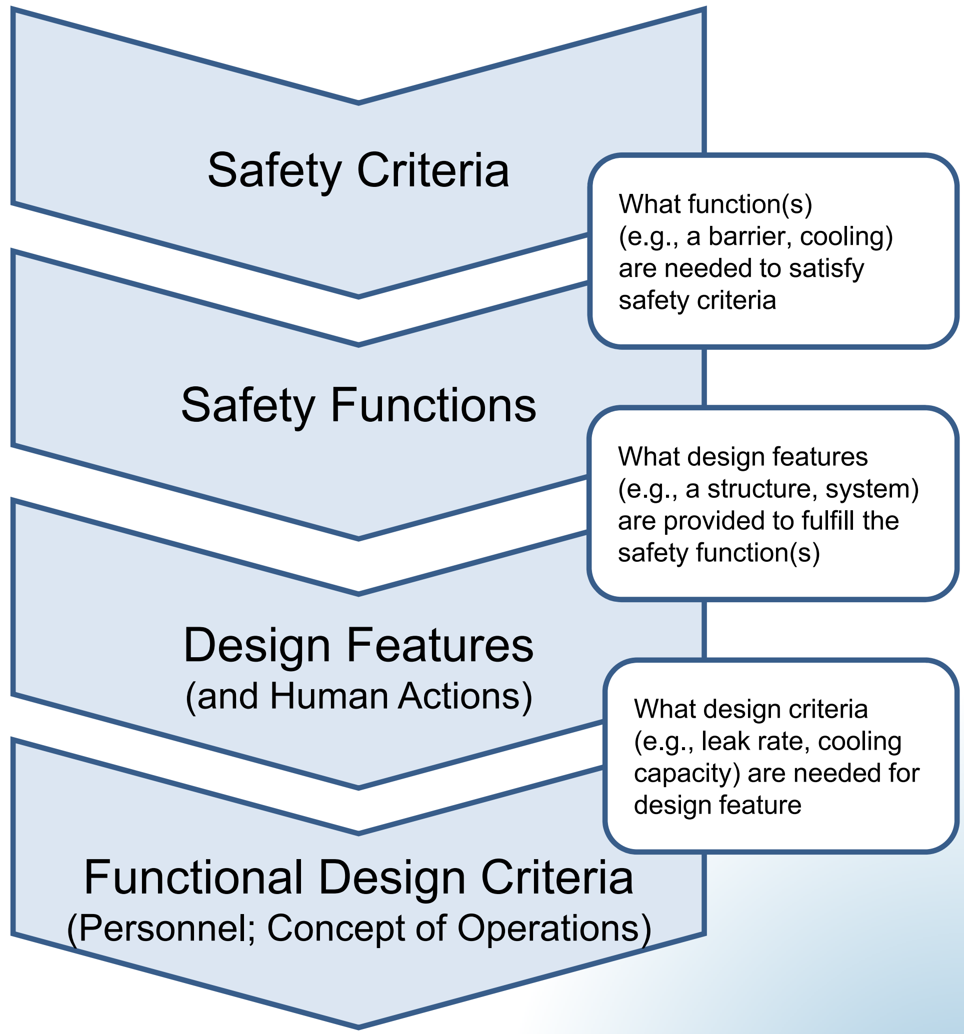


Subpart A – General Provisions

- Scope
- **Definitions**
- Interpretations
- Written Communications
- Employee Protection
- Completeness and Accuracy of Information
- Specific Exemptions
- Deliberate Misconduct
- Combining licenses; elimination of repetition
- Jurisdictional Limits
- Attacks and Destructive Acts
- Information Collection Requirements: Office of Management and Budget Approval

Subpart B – Safety Criteria

- Safety Objectives
- First Tier Safety Criteria
- Second Tier Safety Criteria
- Safety Functions
- Licensing Basis Events (LBEs)
- Defense in Depth
- Protection of Plant Workers



Subpart C – Design and Analysis

- Design Features
- Functional Design Criteria for First Tier Safety Criteria
- Functional Design Criteria for Second Tier Safety Criteria
- Functional Design Criteria for Protection of Plant Workers
- Design Requirements
- Analysis Requirements
- Safety Categorization and Special Treatment
- Application of Analytical Safety Margins to Operational Flexibilities
- Design Control Quality Assurance
- Design and Analyses Interfaces

Subpart D – Siting

- General Siting
- External Hazards
- Site Characteristics
- Population-Related Considerations
- Siting Interfaces
- Environmental Considerations

Subpart E – Construction and Manufacturing

- Scope and Purpose
- Part 1 – Construction
  - (a) Management and Control
  - (b) Construction Activities
  - (c) Inspection and Acceptance
  - (d) Communication
- Part 2 – Manufacturing
  - (a) Management and Control
  - (b) Manufacturing Activities
  - (c) Fuel Loading
  - (d) Communication
  - (e) Transportation
  - (f) Acceptance and Installation at the Site

Subpart F – Operations

- (1) Maintaining Capabilities/Reliabilities of Safety Related and Safety Significant Equipment
  - Operational Objectives
  - Transition from Construction/Manufacturing to Operation
  - Configuration Management for Safety-Related Design Functions
    - Technical Specifications
  - Configuration Management for Safety-Significant Design Functions
    - Special Treatment (e.g., Reliability Assurance)
  - Maintenance, Repair and Inspection Programs
  - Quality Assurance (QA)
  - Design Control

Subpart F – Operations, Cont'd.

- (2) Establishing and Maintaining Appropriate Staffing
  - Concept for Operations
    - Identifying Role of Personnel in Meeting First Tier Safety Criteria
    - Identifying Role of Personnel in Meeting Second Tier Safety Criteria
  - Requirements for Licensed Personnel
    - Staffing
    - Training
    - Medical Requirements
    - Licensing (Applications, Examinations, Licenses)
  - Requirements for Non-Licensed Personnel (Graded based on roles)
    - Staffing
    - Training
    - Other Requirements

- See NRC staff white paper "Risk-Informed and Performance-Based Human-System Considerations for Advanced Reactors," (ADAMS accession no. ML21069A003; March 2021) for background information on this topic.

Subpart F – Operations, Cont'd.

- (3) Programs
  - General Requirement to Develop Needed Programs
  - Radiation Protection
  - Emergency Preparedness
  - Security (Physical, Cyber, etc.)
  - QA
  - Integrity Assessment (Aging, Fatigue, Environmental)
  - Fire Protection
  - Inservice Inspection/Inservice Testing
  - Criticality Safety
  - Facility Safety Program
  - Procedures and Guidelines

Subpart G – Decommissioning

- Termination of power reactor licenses
  - Transition from operation to possession-only license
- Financial assurance for decommissioning
- Transition to unrestricted use

Subpart H – Licensing

- General
- Siting
  - Site Suitability Reviews
  - Limited Work Authorizations
  - Early Site Permits
- Design
  - Conceptual Design Reviews?
  - Standard Design Approvals
  - Design Certifications
  - Manufacturing Licenses (MLs)
    - Manufacturing, Transportation, Deployment
- Site & Design
  - Construction Permit (CP)
  - Operating License
  - Combined Licenses (COL)
- Appendix A (Content Table)

Subpart I – Maintaining Licensing Basis

- Amendments to a license
  - Application (review?)
  - Public notice and consultations
  - Issuance
- Updating Final Safety Analysis Report
  - Including probabilistic risk assessment (PRA)
- Revocation, suspension, modification of license for cause
- Retaking special nuclear material (SNM)
- Commission order for operation after revocation
- Suspension and operation in war or national emergency, (§ 50.54(d))
- Backfitting and Issue Finality
- Information requests (§ 50.54(f))

Subpart J – Administrative and Reporting

- Common standards
- Selective implementation (relationship to Parts 50, 52)
- Reporting
- Notifications (§§ 50.72, 50.73)
- Financial Qualifications
- Creditor Regulations
- Enforcement
- US/International Atomic Energy Agency (IAEA)
- Bankruptcy (§ 50.54(cc))
- Property insurance (§ 50.54(w))
- Liability / Price Anderson
- Water pollution control act (§ 50.54(aa))
- National emergency, can deviate from technical specifications (TS) (§ 50.54(dd))
- Share SNM and byproduct material between units (§ 50.54(ee))
- Need to address Federal Emergency Management Agency deficiencies (§ 50.54(gg))
- Receipt of aircraft threat (§ 50.54(hh))
- American Society of Mechanical Engineers (§ 50.55(a)) & quality standards (§ 50.54(jj))
- SNM (§ 50.54(b)-(d))
- Antitrust (§ 50.54(g))
- Subject to laws & regulations – (§ 50.54(h))

NRC Staff Plan to Develop Part 53

Subpart B | **Subpart C** | **Subpart D** | **Subpart E** | **Subpart F** | **Subpart G**

2

← Project Life Cycle →

Requirements Definition
- Safety Objectives
- Safety Criteria
- Safety Functions

1

Design and Analysis
- *System & Component Design*
- *Analysis Requirements*
- *Safety Categorization & Special Treatment*

Siting
- *External Hazards*
- *Site Characteristics*
- *Environmental Considerations*

Construction
- *Construction/ Manufacturing*
- *Ensuring Capabilities/ Reliabilities*
- *Change Control*
- *Environmental Considerations*

Operation
- *Facility Safety Program*
- *Surveillance Maintenance*
- *Configuration Control*
- *Staffing & Human Factors*
- *Programs Security, EP*

Retirement

Clarify Controls and Distinctions Between

- Plant/Site (Design, Construction, Configuration Control) →
- Analyses (Prevention, Mitigation, Compare to Criteria) →
- Plant Documents (Systems, Procedures, etc.) →
- LB Documents (Applications, SAR, TS, etc.) **Subparts H & I** →

2nd Iteration on Previously Released Preliminary Proposed Rule Language – Subpart B

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Feedback & Iterations

- This iterative rulemaking approach is novel and unprecedented at NRC.
- The Part 53 working group has received numerous internal and external comments on preliminary proposed rule text.
- We are continuing to assess those comments and may reflect assessment in future iterations of rule text.
- The NRC staff has developed internal management review processes for iterations of rule text.
- The preliminary proposed rule language will remain open for discussion as the staff works toward providing the Commission with the draft proposed rule package.
- The NRC staff may discuss some comments not reflected in rule text in the Commission paper transmitting draft proposed rule or in questions for comment in draft proposed rule Federal Register Notice.

Part 50 and Part 53
Comparing Licensing Frameworks

- Safety criteria
  - Same safety criteria in Parts 50 and 53
  - Quantitative health objectives (QHOs) used in guidance under Part 50
- Design and Analyses
  - Design Basis Accidents (DBAs)
    - Part 50: Assessed using prescriptive, highly conservative analyses
    - Part 53: Assessed methodically considering event frequencies and assuming only safety-related structures, systems, and components (SSCs) are available
  - Beyond Design Basis Events (BDBEs)
    - Part 50: Identified & assessed by largely ad-hoc, prescriptive approach with uncertainties addressed through conservatisms
    - Part 53: Derived methodically using event frequencies with explicit consideration for uncertainties
- Special Treatment for Non-Safety-Related but Risk-Significant SSCs
  - Part 50: Ad-hoc (e.g., § 50.69 programs, Reliability Assurance Programs)
  - Part 53: Systematic approach to control frequencies and consequences of the LBEs in relation to safety criteria

Additional Discussion – First Tier

- Possible Applications of First Tier Safety Criteria
  - Minimally acceptable level of safety
  - Met by satisfying the safety functions needed for dose < 25 rem
  - Provides basis for safety classification of SSCs
  - Demonstration of meeting the first tier safety criteria supported by analyses (DBA)
  - Provides basis for identifying SSCs needing protection against external events up to the design basis external hazard levels
  - Provides basis for identifying appropriate content of TS
    - Reserved for the most significant safety requirements
    - Necessary to obviate the possibility of an abnormal situation or event giving rise to an immediate threat to the public health and safety
  - May provide basis for staffing and operator licensing decisions
  - Greatest level of detail for information in licensing documents

Additional Discussion – Second Tier

- Possible Applications of Second Tier Safety Criteria
  - With first tier, ensures appropriate level of safety for long-term, risk-informed operations
  - Met by satisfying the safety functions for meeting QHOs
  - Demonstration of meeting the second tier safety criteria supported by systematic analyses
  - Provides basis for identifying additional risk-informed requirements
  - Provides basis for identifying appropriate special treatment for non-safety related SSCs
  - Provides basis for enabling risk management approach to operations
  - May provide basis for staffing and operator licensing decisions
  - Enables appropriate level of detail in licensing basis documentation based on a risk-informed, function-oriented and performance-based approach

Feedback – Safety Objectives

FIRST ITERATION
§ 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 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 when considering technology changes, economic costs, operating experience, or other factors identified in the assessments performed under the facility safety program required by § 53.800.

- Questions/comments on Safety Objectives
  - Need for and wording of objective to minimize danger
  - Alignment of objectives with first and second tier safety criteria
  - Incorporation of wording from Atomic Energy Act (AEA)

Second Iteration - Objectives

§ 53.200 Safety Objectives.
Each advanced 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 advanced 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.

- Discussion
  - Generally aligns with requirements for content of technical specifications and regulatory treatment of non-safety systems
  - Addresses concerns related to tying tiers to authorities provided in the AEA

Feedback – First Tier

FIRST ITERATION

§ 53.210 First Tier Safety Objectives.

(a) Public dose does not exceed 0.1 rem from normal plant operation

(b) Provide design features and programmatic controls such that events with frequencies greater than once per 10,000 years meet the following

(1) 2-hour dose below 25 rem at exclusion area boundary (EAB)

(2) Duration dose below 25 rem at low population zone (LPZ) boundary

(c) Additional requirements established by NRC to ensure reasonable assurance of adequate protection

- Questions/comments on First Tier Safety Criteria
  - Inclusion of normal operations
  - Open-endedness of Paragraph (c)
  - Concerns that connection to adequate protection standard was leading to perception that additional requirements not needed

Second Iteration – First Tier

§ 53.210 First Tier Safety Criteria.

(a) Public dose does not exceed Part 20 limit (0.1 rem) from normal plant operation

(b) Provide design features and programmatic controls such that events with frequencies greater than once per 10,000 years meet the following

(1) 2-hour dose below 25 rem at EAB

(2) Duration dose below 25 rem at LPZ boundary

~~(c) Additional requirements established by NRC to ensure reasonable assurance of adequate protection~~

- Discussion
  - Maintains technical criteria from first iteration
  - Generally aligns with requirements for content of technical specifications and regulatory treatment of non-safety systems
  - Deleted paragraph (c) since the first tier criteria are no longer tied to adequate protection standard
  - Added existing footnote on 25 rem as reference value
  - General note that staff assessing terminology (tiers)

Feedback – Second Tier

FIRST ITERATION

§ 53.220 Second Tier Safety Criteria

a) Normal Operations – Public dose as low as reasonably achievable (ALARA) with performance goals from Appendix I to 10 CFR Part 50

(b) Design features and programmatic controls provided to:

(1) Address LBEs and defense in depth

(2) Maintain overall cumulative plant risks below QHOs

- Questions/comments on Second Tier Safety Criteria
  - Overall need for the second tier
  - Inclusion of normal operations ALARA requirement
  - Use of QHOs as codified safety criteria

Feedback – 2nd Tier, ALARA

- ALARA
  - o Proposal by some stakeholders to eliminate all ALARA requirements under Part 53.
- NRC Iteration: Maintained requirements for normal operations and occupational exposures to be ALARA

Note that concerns related to ALARA and NRC reviews of design-related applications are also being addressed through the Advanced Reactor Content of Application Project with current drafts of Chapter 9 released to support stakeholder interactions:

"... in lieu of providing detailed system descriptions and analysis of estimated effluent releases as required by 10 CFR 50.34, 50.34a, 52.47, and 52.79, an application may demonstrate compliance with the applicable regulations by describing a radiation protection program and an effluent release monitoring program that will ensure that effluent release limits will be met during normal operations for the life of the plant. Information related to physical systems can be limited to general descriptions of layout and technologies used to limit the release of the various inventories of radioactive materials within the plant."

Feedback – 2nd Tier, QHOs

- QHOs
  - Proposal by some stakeholders to maintain QHOs as policy but exclude from rule
    - Some concern over use of QHOs related to inclusion of requirement to perform PRA
  - Proposal by some stakeholders to use a metric other than QHOs as second tier
    - Range of stakeholder views, from use of QHOs to use of cost-benefit assessment for second tier, which in NRC practice includes assessment against QHOs
- NRC Iteration: Maintained QHOs within the second tier safety criteria
  - The QHOs are a well-established measure used in NRC risk-informed decision making and are a logical performance metric to support the risk management approaches to operations that will be reflected in Subpart F, "Operations."
  - Note that using less defined criteria for the second tier would decrease the predictability of the regulations in terms of the desired graded approach (e.g., differentiation between SSCs that are safety related and non-safety related with special treatment)

Second Iteration – Second Tier

- Second Tier Safety Criteria

FIRST ITERATION/SECOND ITERATION

§ 53.220 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, and the benefits to the public health and safety. 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].

(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 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.

Proposed Second Iteration

- Discussion (Second Tier Safety Criteria)
  - Maintains second tier to ensure appropriate level of safety for long-term, risk-informed operations
  - Maintains ALARA for normal operations as longstanding element of NRC regulations
  - Maintains QHOs for unplanned events as well established policy and measure for risk-informed decisionmaking

Feedback – Safety Functions

FIRST ITERATION

§ 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.

- Questions/comments on Safety Functions
  - Proposal by some stakeholders to explicitly cite fundamental safety functions.

Second Iteration – Safety Functions

§ 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.~~ **<u>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.</u>**

- Discussion (Safety Functions)
  - Maintains mention of fundamental safety functions as examples to maintain technology-inclusive framework (with potential use for multiple inventories of radionuclides within plants and possibly technologies such as fusion energy systems)
  - Reinforces general hierarchy of safety criteria, safety function, design feature, and functional design criteria.

Feedback – Licensing Basis Events

FIRST ITERATION

§ 53.240 Licensing Basis Events

Licensing basis events must be identified for each advanced nuclear plant and analyzed in accordance with § 53.[3x] to support assessments of the safety requirements of 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 highly unlikely event sequences that are not 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.

- Questions/comments on LBEs:
  - Comments generally associated with other areas such as the first and second tier safety criteria
  - Some discussion on use of alternative paths such as the use of a maximum hypothetical accident concept

Second Iteration – Licensing Basis Events

§ 53.240 Licensing Basis Events

Licensing basis events must be identified for each advanced nuclear plant and analyzed in accordance with § 53.450 to support assessments of the safety requirements
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 ~~highly~~ very unlikely event sequences**
~~that are not~~ with 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.

- Discussion (LBEs)
  - Changes to clarify the range of scenarios to be addressed by LBEs

Feedback – Defense in Depth

FIRST ITERATION
§ 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 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 design or operational feature, no matter how robust, should be exclusively relied upon to meet the safety criteria of 10 CFR part 53.**

- Questions/comments on Defense in Depth:
  - Treat as a design philosophy similar to Parts 50 and 52
  - Unnecessary as a requirement and would create unintended consequences
  - Prescriptive “no single feature” requirement is unnecessary and not risk informed
  - Clarify what is required when prevention or mitigation is related to inherent characteristics

Second Iteration – Defense in Depth

§ 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 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, personnel, and programmatic controls. No single **engineered** design feature, human action, or programmatic control, no matter how robust, should be exclusively relied upon to meet the safety criteria of § 53.220(b) or the safety functions defined in accordance with § 53.230.

- Discussion (Defense in Depth)
  - Maintains defense in depth within Subpart B because of historical and continued importance of its role in addressing risk
  - Parts 50/52 do not include a similar section because the defense-in-depth philosophy is incorporated into prescriptive technical requirements for light-water reactors
  - Possibility that this section could be addressed within Subpart C can be considered as part of the later review of the technical requirements
  - Reflects possible crediting of inherent characteristics within the design and analysis for advanced reactors and the reduced uncertainties associated with such characteristics

Feedback – Protection of Plant Workers

FIRST ITERATION

§ 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 must use, to the extent practical, procedures and engineering controls 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.

- Questions/comments on Protection of Plant workers:
  - Exclude occupational dose from Part 53 or confine to reference to Part 20.
  - Some stakeholders favored retaining these requirements in light of relative importance of potential occupational exposures for some advanced reactor technologies

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Second Iteration – Protection of Plant Workers

§ 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.

- Discussion (Protection of Plant Workers)
  - Maintains the protection of plant workers within Subpart B to capture occupational exposures within the high-level safety requirements
  - Changed to refer to part 20, as suggested by stakeholders

Note that ALARA is not only a long-standing requirement by Atomic Energy Commission/NRC (including maintaining in Part 20 rulemaking) but also is addressed in U.S. Environmental Protection Agency Federal Guidance for Radiation Protection

Discussion

2nd Iteration on Previously Released Preliminary Proposed Rule Language – Subpart C

Feedback – Design

§ 53.400 Design ~~Objectives and Design~~ Features
§ 53.410 Functional Design Criteria for First Tier Safety Criteria
§ 53.420 Functional Design Criteria for Second Tier Safety Criteria
§ 53.430 Functional Design Criteria for Protection of Plant Workers
§ 53.440 Design Requirements

- Questions/comments on Design Requirements
  - Comments generally associated with other areas such as the first and second tier safety criteria, occupational exposures, etc.

Second Iteration – Design

§ 53.400 Design ~~Objectives and Design~~ Features
§ 53.410 Functional Design Criteria for First Tier Safety Criteria
§ 53.420 Functional Design Criteria for Second Tier Safety Criteria
§ 53.430 Functional Design Criteria for Protection of Plant Workers
§ 53.440 Design Requirements

- Discussion (Design)
  - Maintains these sections and their role in helping to establish the general hierarchy of safety criteria, safety function, design feature, and functional design criteria.

Feedback – Analysis (PRA)

First Iteration
§ 53.450 Analysis Requirements
(a) 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 § 53.230.

- Questions/comments on Analysis Requirements
  - Don’t require PRA or require a “risk-informed assessment” instead
  - Support more deterministic approaches to design and analysis

Second Iteration – Analysis (PRA)

§ 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 § 53.230 **and to support demonstrating that each advanced nuclear plant meets the second tier safety criteria of § 53.220(b).**

- Discussion (PRA)
  - Maintains requirement in Part 53 for PRA consistent with evolution of risk-informed approaches but provide alternatives to PRA for design and analysis processes (paragraph (b)) and to support the licensing and regulatory programs being developed in subsequent subparts
  - Staff is engaged in ongoing discussions on how to ensure the level of effort required for a PRA is commensurate with the complexity of the subject reactor design while also ensuring possible deployment of advanced reactors poses no undue risk to public health and safety.

Feedback – Analysis (Use of PRA)

First Iteration
§ 53.450 Analysis Requirements
(b) Requirement to use PRA to:

- **Determine licensing basis events**
- **Support safety classification of SSCs**
- **Evaluate defense in depth**

- Questions/comments on Use of PRA
  - o Support more deterministic approaches to design and analysis
  - o Support international regulatory frameworks (e.g., IAEA SSR-2/1)
  - o Extensive PRA with application submittal may not be feasible for all application types, especially for plants in early phases of application
  - o Concerns about connection to PRA standards and capability categories

Second Iteration – Analysis (Use of PRA)

§ 53.450 Analysis Requirements

(b) Requirement to use PRA, <u>other generally accepted risk-informed approach for systematically evaluating engineered systems, or combination thereof</u> to:

- **Determine LBEs**
- **Support safety classification of SSCs**
- **Evaluate defense in depth**

- Discussion (Use of PRA)
  - Change intended to support alternative approaches to a PRA
  - Worded in terms of "generally accepted" to support possible standards or other guidance documents
  - The use of guidance, Part 53 rule language, or revisions to Part 50 are being explored as possible ways to accommodate deterministic approaches for performing design and analysis

Feedback – Analysis (Other)

§ 53.450 Analysis Requirements

- **Maintenance and upgrade of analyses**
- **Qualification of analytical codes**
- **Analysis of DBAs**
- **Other required analyses**

- Questions/comments on Analysis Requirements
  - o How should requirements for analysis of fires, aircraft impact, and specific BDBEs be addressed?

Second Iteration – Analysis Requirements (c – g)

§ 53.450 Analysis Requirements
(c) Maintenance and upgrade of analyses
(d) Qualification of analytical codes
(e) Analyses of LBEs (added)
(f) Analysis of DBAs
(g) Other required analyses

- Discussion (Analysis Requirements)
  - Clarification of maintenance and upgrading of analyses (referring to codes and standards)
  - Maintain placeholder for other required analyses to address fire protection, aircraft impact, and specific beyond design basis accidents.

Second Iteration – Analysis Requirements (c – g)

§ 53.450(e) Analyses of licensing basis events [New sub-paragraph]

(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.

- Discussion (Analyses of LBEs)
  - Section added to clarify requirements for LBEs, including analysis from initiation to a defined end state
  - Staff considering further clarification for anticipated operational occurrences in terms of acceptance criteria beyond QHOs and defense in depth

Second Iteration – Analysis Requirements (c – g)

§ 53.450 (f) Analysis of design basis accidents

(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 § 53.230. 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 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 events selected as design basis accidents should be those that, if not terminated, have the potential for exceeding the safety criteria in § 53.210(b). **The design-basis accidents selected must be analyzed using deterministic methods that address event sequences from initiation to a <u>safe stable end state</u> 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 § 53.230.** The analysis must conservatively demonstrate compliance with the safety criteria in § 53.210(b).

- Discussion (DBAs)
  - Revised to clarify that analysis is to address sequences from initiation to a safe stable end state.

Feedback – Safety Classification

First Iteration

§ 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.

- Questions/comments on Safety Classification
- Some proposing more generic/undefined safety classification (possibly supporting international practices)

Second Iteration – Safety Classification

§ 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.**

- Discussion
  - Editorial changes to remove material duplicating preliminary rule language in other sections
  - Maintaining for now the specific categories of safety related, non-safety related but safety significant, and non-safety significant

Feedback – Analytical Margins and Operating Flexibilities

First Iteration

§ 53.470 Application of Safety Margins to Operational Flexibilities

Where an applicant or licensee so chooses, design criteria more restrictive than those defined in § 53.220(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.

- Questions/comments on application of safety margins
  - General questions on how process would work and integrate with operational requirements
  - Many stakeholders reserving comments pending release of requirements for operation (Subpart F)

Second Iteration – Analytical Margins and Operating Flexibilities

§ 53.470 Application of Safety Margins to Operational Flexibilities (No Change) Where an applicant or licensee so chooses, design criteria more restrictive than those defined in § 53.220(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.

- Discussion
  - No change. Release of related requirements in Subpart F expected to support public meeting on May 6th

Feedback – Design Control QA and Design Interfaces

First Iteration
§ 53.480 Design Control Quality Assurance
§ 53.490 Design Interfaces

- Questions/comments on QA and design interfaces
  - Many stakeholders reserving comments pending release of other subparts

- Discussion
  - No change. Release of related requirements in Subpart F expected to support public meeting on May 6th

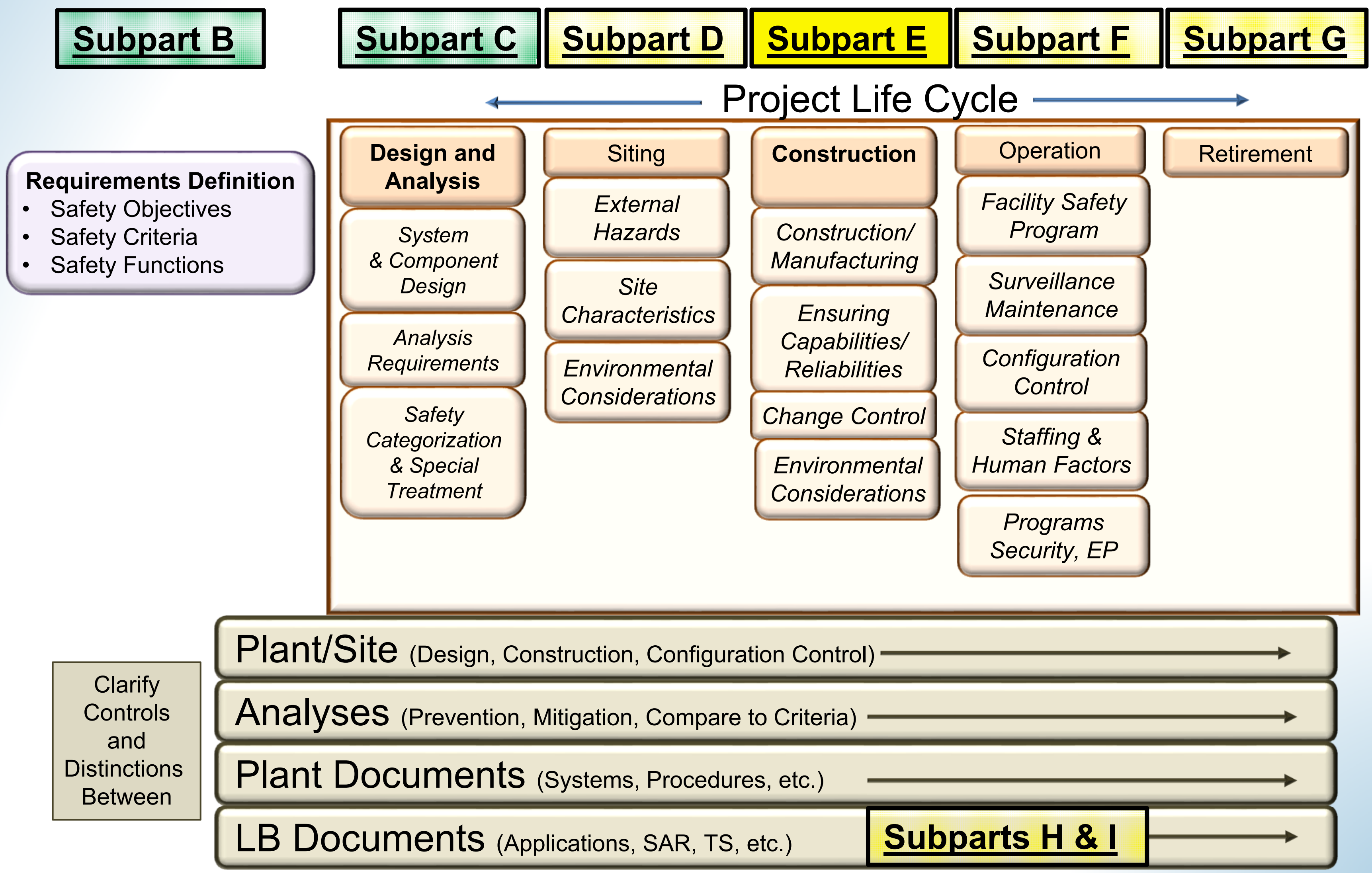
Feedback – Non-Radiological Hazards

- Non-Radiological Hazards
  - Some ACRS members noted inclusion of non-radiological hazards should be considered in Part 53, such as chemical releases.
    - Staff has this issue under consideration and recognizes existing frameworks for addressing this multi-jurisdictional topic
    - Does ACRS have feedback on this topic that could inform the Staff's ongoing considerations?

Discussion

Subpart E – Construction and Manufacturing

NRC Staff Plan to Develop Part 53



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
- Subpart F, Requirements for Operation
  - Facility Safety Program
- 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

Subpart E – Construction and Manufacturing

- Scope and Purpose
- Part 1 – Construction
  - (a) Management and Control
  - (b) Construction Activities
  - (c) Inspection and Acceptance
  - (d) Communication
- Part 2 – Manufacturing
  - (a) Management and Control
  - (b) Manufacturing Activities
  - (c) Fuel Loading
  - (d) Communication
  - (e) Transportation
  - (f) Acceptance and Installation at the Site

§ 53.600 – Scope and Purpose

- Subpart applicable to construction and manufacturing activities authorized by CP, COL, ML, or a Limited Work Authorization

§ 53.610 – Construction

- Management and Control
  - Design and analyses conform with subpart C
  - Organization and procedures describing qualifications, responsibilities, and interfaces
  - Program to evaluate construction experience
  - Preliminary emergency plan for site, fitness-for-duty program
  - QA conforms to generally accepted codes and standards
  - Radiation protection, information security, and cyber security programs, as applicable

§ 53.610 – Construction

- Construction Activities
  - Procedures in place to appropriately handle special nuclear material, multi-unit site hazards, control of design, redress plan
  - Requirements for fresh fuel storage, fire protection
- Inspection and Acceptance
  - Inspect and test SSCs prior to acceptance
- Communication
  - Procedures for coordinating with other units and NRC

§ 53.620 – Manufacturing

- Management and Control
  - Design and analyses conform with subpart C
  - Organization and, procedures describing qualifications, responsibilities, and interfaces
  - Program to evaluate manufacturing experience
  - Fitness-for-duty program
  - QA conforms to generally accepted codes and standards
  - Radiation protection, information security, and cyber security programs, as applicable

§ 53.620 – Manufacturing

- Manufacturing Activities
  - Adhere to manufacturing license, conform to generally accepted codes and standards
  - Procedures in place to appropriately handle SNM, fresh fuel, fire protection, emergency planning (EP), radiation protection, minimizing contamination
- Fuel Loading – Develop further, if pursued

§ 53.620 – Manufacturing

- Communication – Stay in contact with NRC
- Transportation
  - Interface with 10 CFR Part 71
  - Procedures for movement, transfer only to accepted license holders
  - Supports fixed siting of manufactured reactors
  - Not currently planning to address mobile reactors
- Acceptance and Installation
  - Reactor must be certified in compliance with ML prior to installation
- Consideration of transport and disposal post operation in subsequent subparts

§ 53.620 – Manufacturing Factory Fuel Loading

- Revising ML provisions (currently in Subpart F of 10 CFR Part 52) seems logical way to address microreactor strategies (factory assembly)
- ML can be referenced in applications for construction permit or combined license
  - Key role of ML will continue to be supporting the safety case for construction and operation of specific reactors
- Loading fuel at factory is a potential deployment strategy for some microreactors
- Staff evaluating the safety implications within the factory setting and possible roles of ML and requirements within 10 CFR Part 70

§ 53.620 – Manufacturing Transportation

- Staff evaluating the safety and licensing implications of transporting fueled reactors
- Review of safety and security requirements and possible changes to 10 CFR Part 71
- Questions related to transport of fueled reactors from factory to operating site with fresh or recycled fuel
- Questions related to transport of fueled reactor from operating site to factory, recycle facility, or waste facility

Subpart E: Construction and Manufacturing

Discussion

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 (12 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

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Acronyms and Abbreviations

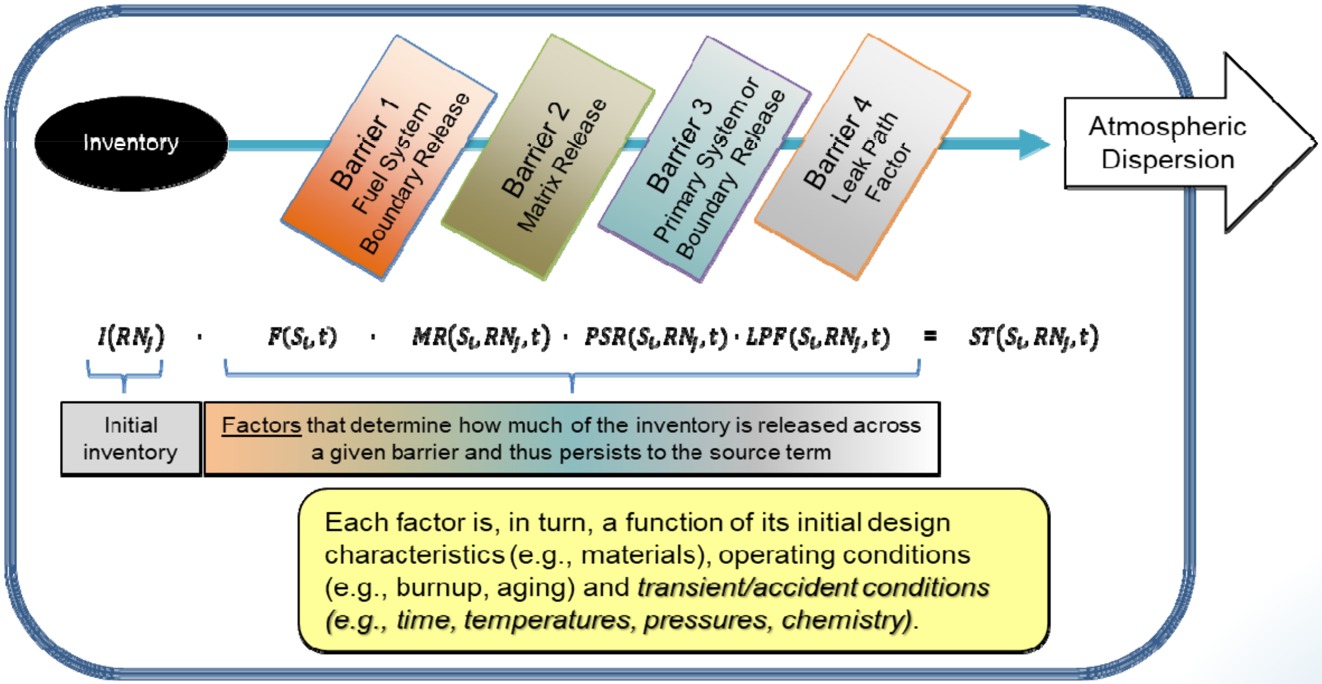
ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Document Access Management System
AEA	Atomic Energy Act
ALARA	As low as reasonably achievable
BDBEs	Beyond design basis events
CFR	Code of Federal Regulations
CP	Construction permit
COL	Combined operating license
DBAs	Design basis accidents
EAB	Exclusion area boundary
EP	Emergency planning
IAEA	International Atomic Energy Agency

LBE	Licensing basis event
LPZ	Low population zone
ML	Manufacturing license
NRC	U.S. Nuclear Regulatory Commission
NSRSS	Non-safety related but safety significant
NSS	Non-safety significant
PRA	Probabilistic risk assessment
QA	Quality assurance
QHO	Quantitative health objective
SAR	Safety analysis report
SNM	Special nuclear material
SSCs	Structures, systems, and components
SR	Safety related
TS	Technical specifications

Background Slides

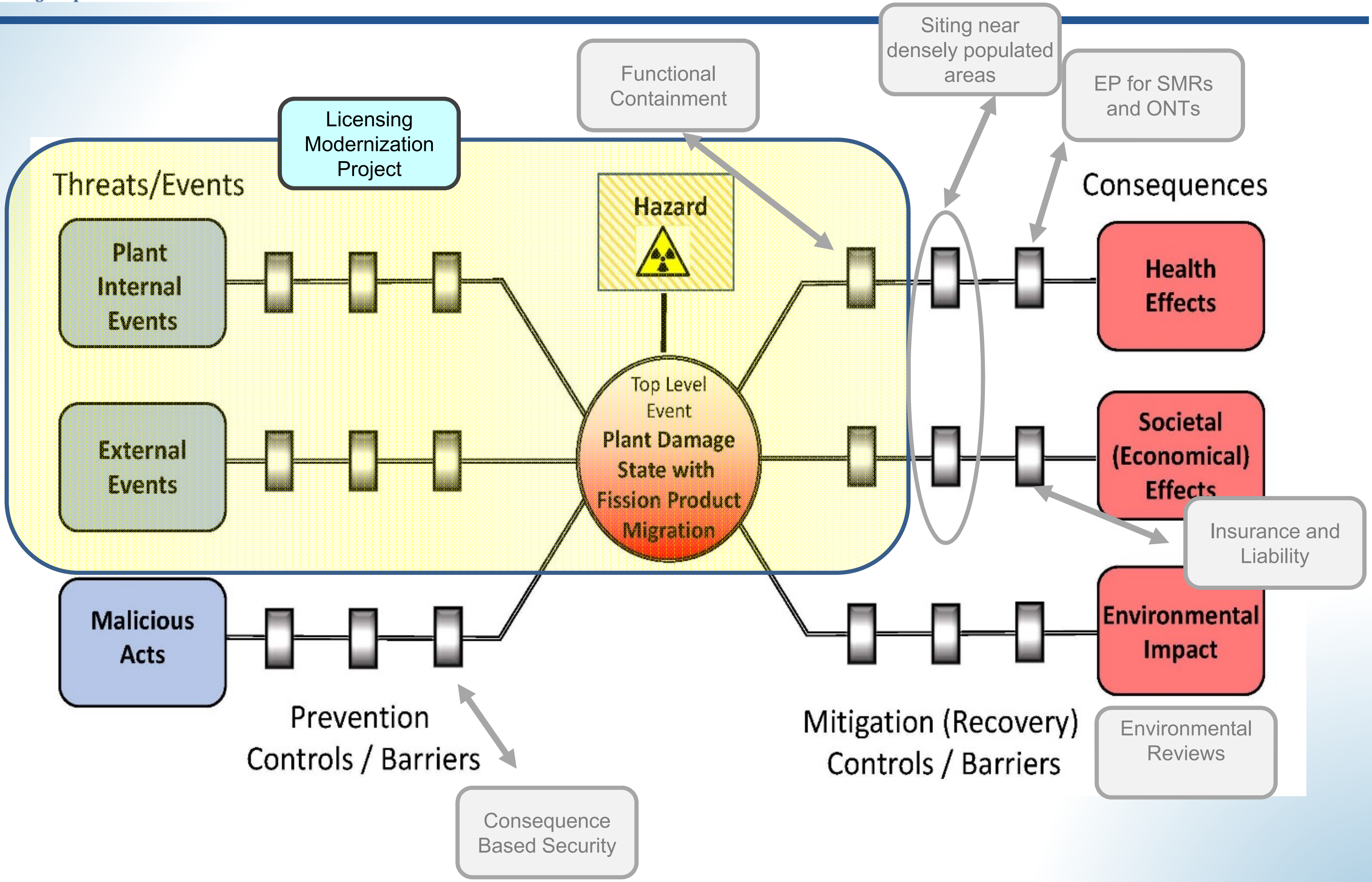
First Principles

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

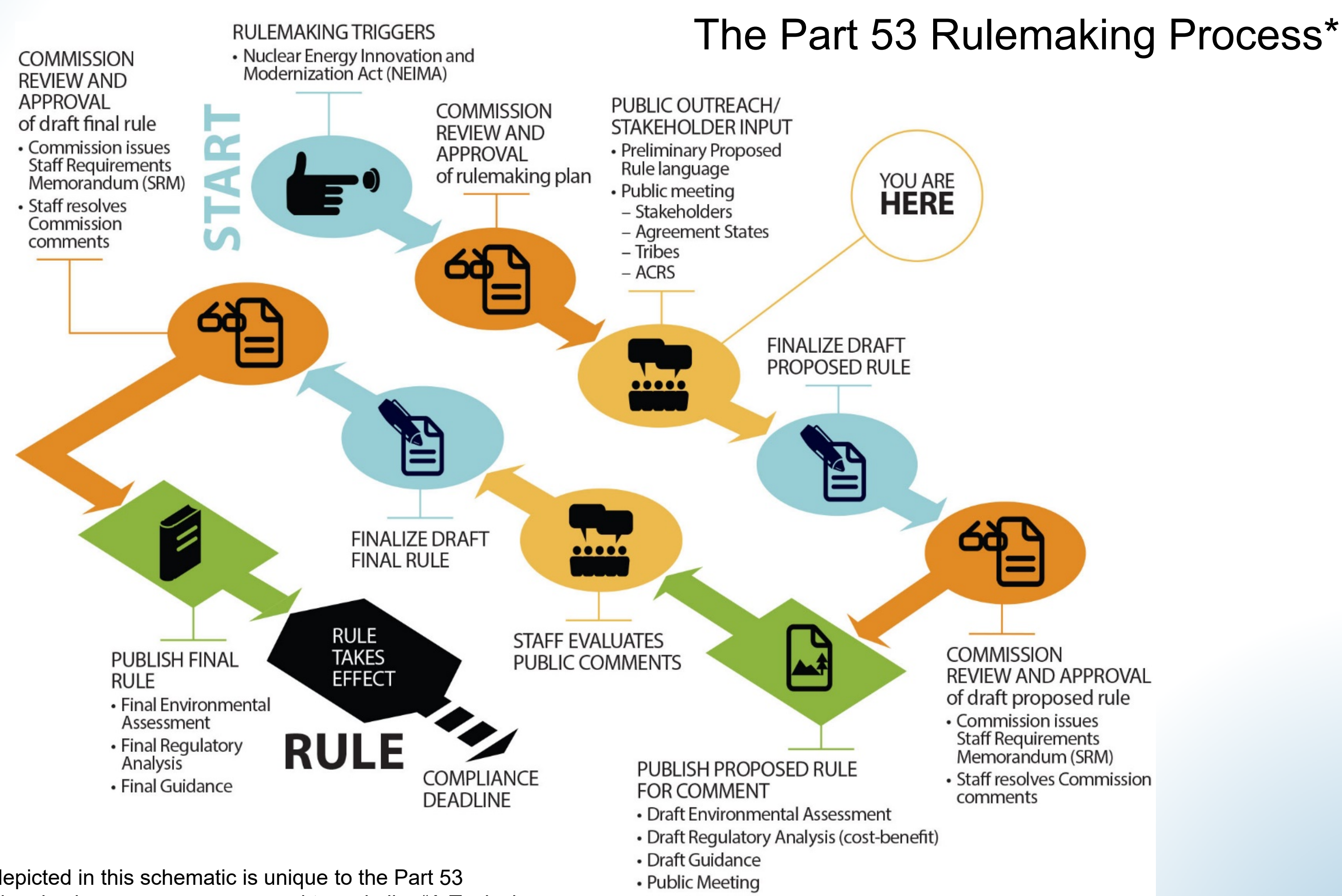


See: SECY-18-0096, "Functional Containment Performance Criteria for Non-Light-Water-Reactors," and INL/EXT-20-58717, "Technology-Inclusive Determination of Mechanistic Source Terms for Offsite Dose-Related Assessments for Advanced Nuclear Reactor Facilities"

Integrated Approach



Part 53 Rulemaking



*The process depicted in this schematic is unique to the Part 53 rulemaking and varies in some ways compared to a similar “A Typical Rulemaking Process” schematic available on the NRC’s public website.

Background

- Nuclear Energy Innovation and Modernization Act (NEIMA; Public Law 115-439) signed into law in January 2019 requires the NRC to complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use for commercial advanced nuclear reactors no later than December 2027
  - (1) ADVANCED NUCLEAR REACTOR—The term "advanced nuclear reactor" means a nuclear fission or fusion reactor, including a prototype plant… with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act, …