



10 CFR Part 53 “Licensing and Regulation of Advanced Nuclear Reactors”

Objectives and Structure & Subpart D Preliminary Proposed Rule Language

February 4, 2021

Agenda

10:00am – 10:20am	Logistics, Introductions, and Goals for Meeting
10:20am – 11:15am	Goals and Success Criteria for Part 53 Rulemaking Activity
11:15am – 12:45pm	Key Concepts and Possible Structures
12:45pm – 1:30pm	Lunch Break
1:30pm – 2:15pm	Approach to Rule Language and Developing Key Guidance Documents
2:15pm – 3:00pm	Discussion of Previously Released Subparts
3:00pm – 4:15pm	Subpart D – Siting Requirements
4:15pm – 4:30pm	Additional Public Comments/Closing Remarks

Welcome/Introductions

Welcome:

John Segala, NRR – Branch Chief of the Advanced Reactor Policy Branch

Speakers/Presenters:

Bob Beall, NMSS – Rulemaking PM & Meeting Facilitator

Nanette Valliere, NRR – Technical Lead

Bill Reckley, NRR – Technical Lead

Nuclear Energy Institute

U.S. Nuclear Industry Council

Union of Concerned Scientists

Public Meeting Slides: ADAMS Accession No. ML21032A045

Purpose of Today's Meeting

- Discuss the broader objectives and overall structure of Part 53
- Review preliminary proposed rule language for Part 53
 - Subpart D – Siting Requirements
- Today's meeting is a Category 3 public meeting, which means that public participation is actively sought in the discussion of the regulatory issues during the meeting.
 - This meeting is being held in a “workshop” format to facilitate the discussion to today's topics.
 - The meeting is being transcribed and the transcription will be available with the meeting summary by March 5, 2021.
- No regulatory decisions will be made at today's meeting.

NRC Staff Plan to Develop Part 53

Subpart B

Subpart C

Subpart D

Subpart E

Subpart F

Subpart G

Project Life Cycle

Requirements Definition

- Fundamental Safety Functions
- Prevention, Mitigation, Performance Criteria (e.g., F-C Targets)
- Normal Operations (e.g., effluents)
- Other

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 Plan

Surveillance Maintenance

Configuration Control

Design Changes

Staffing & Programs

Retirement

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

Clarify Controls and Distinctions Between

NRC Staff Engagement Plan

Stakeholder 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									

	Concept/Introduction
	Discussion
	Interim Staff Resolution

Note that this is a living schedule and will be updated as needed throughout the rulemaking process. Upcoming introductions of concepts and discussions of preliminary rule language will involve a variety of topics that have historically involved specific technical and programmatic specialties. To that end, stakeholders are encouraged to ensure that appropriate subject matter experts are involved in discussions of rule language and plans for guidance documents. An example is concepts and discussions within Subpart F (operations) that involve staffing levels and operator licensing.

Goals and Success Criteria for Part 53 Rulemaking Activity

Part 53 Rulemaking Objectives NRC Staff Perspectives

- Provide reasonable assurance of adequate protection of the public health and safety and common defense and security at reactor sites at which advanced nuclear reactor designs are deployed, to at least the same degree of protection as required for current-generation light water reactors;
- Protect health and minimize danger to life or property to at least the same degree of protection as required for current-generation light water reactors;
- Provide greater operational flexibilities where supported by enhanced margins of safety that may be provided in advanced nuclear reactor designs;
- Ensure that the requirements for licensing and regulating advanced nuclear reactors are clear and appropriate; and
- Identify, define, and resolve additional areas of concern related to the licensing and regulation of advanced nuclear reactors.

Part 53 Rulemaking

Marc Nichol
Senior Director New Reactors

February 4, 2021



Goals and Success Criteria

Vision and Goals

- **Vision:** Licensing new reactors under the new rule will be the most efficient option for all new reactor applicants and will meet industry needs for schedule, cost and predictability, consistent with congressional directives, the NRC's own advanced reactor policies and initiatives, and the agency's Principles of Good Regulation.
- **Goals:**
 - **Safety-Focused:** Focus on reasonable assurance of adequate protection
 - **Technology-Inclusive:** All technologies, high-level requirements
 - **Efficient:** Schedule/cost targets integrated safety/security, commercial quality
 - **Flexible:** Variety of licensing approaches, reactor uses, interface with Part 50/52
 - **Informed:** Insights from previous efforts, near term activities, and other regulators
 - **Clear:** Nexus to adequate protection, interrelationship of requirements, concise

Source: NEI Letter from October 21, 2020

Success Criteria (Project Requirements)

- Purpose: to define what functionality needs to be provided in the final Part 53 rule
 - Guide the Part 53 rule development
 - Plan future discussions between the NRC staff and stakeholders
 - Ensure that the final rule meets the pre-defined success criteria
- Define what Part 53 must accomplish (e.g., establish safety requirements)
 - Not how to do it (e.g., specifying the dose limits for members of the public)
 - Not the process by which to develop the new rule
- Align with the direction in the Nuclear Energy Innovation and Modernization Act, and the vision and goals that we proposed in NEI's October 21, 2020 letter
- Intended to be exhaustive, but there could be additional criteria identified over the course of the rulemaking, and further clarification of scope

Source: NEI Letter from December 23, 2020

Proposed Success Criteria

(Selected Higher-Level criteria)

- Define the scope of Part 53 (e.g., types of licenses granted, types of activities regulated)
- Define the requirements that provide reasonable assurance of adequate protection
 - Define performance criteria to protect the public
 - Define the safety paradigm for reactors to provide reasonable assurance that the public protection performance criteria are met via the safety paradigm (e.g., radiological hazard, events, safety functions, QA)
- Define the information to be included in the licensing bases regulated by the NRC
 - Clarify why required information in the licensing basis is necessary to make a determination of reasonable assurance of adequate protection
 - Include protections against unnecessarily requiring changes to the licensing basis (i.e., finality, backfit and forward fit protections)
 - Include processes to control and change the licensing bases regulated by the NRC
- Establish the requirements for obtaining licenses
 - Identify other Parts of 10 CFR that are applicable to Part 53 licenses (e.g., Part 20, Part 51)
- Establish the requirements for NRC oversight during construction and operations
 - Describe requirements for ensuring the as-constructed plant is the same as the as-approved design
 - Describe requirements for ensuring the plant operations are within the NRC approved limits
- Guidance – *{Success criteria for guidance to be decided during the scoping phase}*

Source: NEI Letter from December 23, 2020

U.S. Nuclear Industry Council Comments for NRC Part 53 Meeting: Goals and Success Criteria

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and Reactor Developers

04 February 2021

Goals and Success Criteria for Part 53

- Risk-informed but not excluding deterministic approach
 - Performance-based with flexibility allowing some combination of risk informed and deterministic
- Adequate protection only
 - Requirements beyond adequate protection only serve to drive up the cost of licensing and operations with no real safety benefit
 - Achieving operational excellence is important but is best achieved through industry self-oversight, e.g., INPO
- Technology-inclusive with all reactor types and sizes covered
- Clear and simple to support streamlined licensing process
 - Licensing requirements are understood and review is straightforward and efficient

Goals and Success Criteria for Part 53 Rulemaking Activity

Discussion

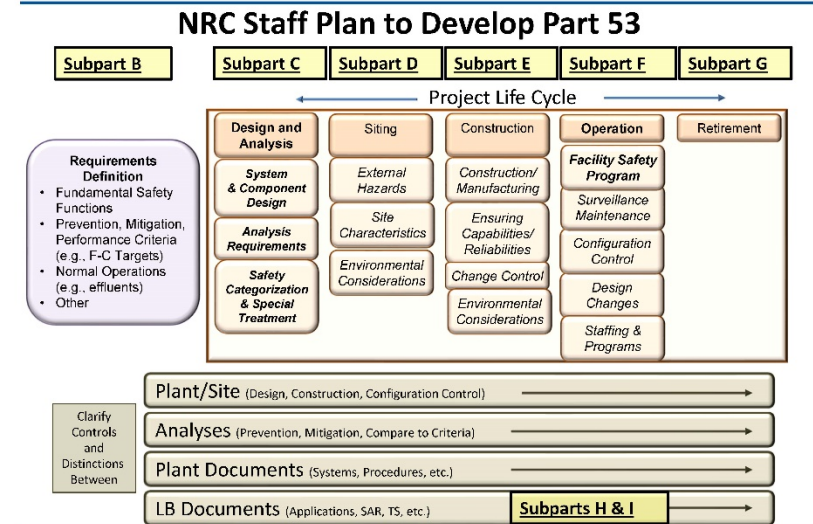
Key Concepts and Structure

Part 53 Key Concepts and Structure

NRC Staff Perspectives

Key Concepts

- Requirements based on defining high level safety criteria
- Two tier structure in safety criteria to support distinctions in regulatory treatment commensurate with safety/risk significance
- Technical areas to be addressed via Subparts that align with stages for a facility's lifecycle
- Licensing, reporting, and other requirements addressed in separate Subparts



U.S. Nuclear Industry Council Comments for NRC Part 53 Meeting: Key Concepts and Possible Structures

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Frank Akstulewicz of Terrestrial Energy

Dennis Henneke of GE

Travis Chapman of X-Energy

Rebecca Norris of NuScale

Ross Moore of Oklo

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Key Concepts and Possible Structures: Process Concern

- Process does not seem to be transparent
 - NRC requests feedback, but no NRC feedback on how comments factored into the rulemaking process and no redrafted rule language.
- Subpart B Safety Criteria is the foundation of Part 53
 - Instead of discussing and agreeing on Subpart B, NRC proceeding to restate Subpart B language and issue language for other parts of the rule based on unaltered Subpart B language.
 - Process is going too fast
- USNIC does not support the preliminary Subpart B language including the new Tier 1 and Tier 2 categories that industry find confusing.
 - USNIC encourages NRC to release revised language for Subpart B before continuing to release other sections based on Subpart B— preferably with some NRC Office of General Council review
 - USNIC offering alternative Subpart B language

Key Concepts for Part 53

- Adequate Protection
 - Rule should specify only that which is necessary for adequate protection and nothing more.
 - Any proposals beyond adequate protection should not be included
 - Proposed language in Subpart B for property protection, defense in depth, and Quantitative Health Objectives (QHOs) not appropriate.
- Risk-informed Regulations
- Performance-based Regulations
- Adequate Defense-in-Depth (DID)
- Quantitative Health Objectives
- Quality Assurance Requirements

Adequate Protection Standard for Part 53

- Focus of Part 53 should provide a clear adequate protection standard (radiological foundation)
 - Requirements predicated by fundamental safety functions (53.210)
 - Any requirements established in Part 53 should have a clear nexus to supporting the adequate protection standard
 - Adequate protection standard should be independent of technology, reactor size, or selected licensing process.
- Avoid regulatory requirements that are not needed for adequate protection
 - Do not ratchet up requirements for Advanced Non-LWRs
 - Do not expand the rule by including Minimize Danger and Protect Property Standard.
 - Necessity of second tier criteria for adequate protection has not been established in rulemaking record to date

Adequate Protection Standard for Part 53 (cont.)

- Other considerations:
 - Part 53 should establish the minimum criteria and supporting information necessary for demonstrating the safety case with a level of detail that is commensurate with its contribution to the safety case arguments
 - Processes for demonstrating the safety case should not be defined in rulemaking

Risk-informed (not-risk based) Regulations (relevant to Subpart C)

- Probabilistic Risk Assessment (PRA) insights should complement the safety review however 53.450 proposed language and criteria make a complete/detailed PRA an implicit requirement for LBE, SSC classification, DID determinations.
 - Want flexibility; use of PRA should be optional if other risk-informed analyses are appropriate to use
 - LBE, SSC classification, and DID determination is supported by RG 1.233 implementation, but not supported by an applicant performing SSC classification using a deterministic approach.
 - Deterministic approaches (e.g., for external hazard assessment, seismic, bounding analyses) may be appropriate and should not be excluded, and some combination of risk informed and deterministic should be allowed.

Risk-informed (not-risk based) Regulations (cont.)

- PRA matures with plant design and site selection/characterization. Therefore, requiring extensive PRA (meeting the PRA standard) with application submittal may not be feasible for all application types.
- Unclear how different levels of PRA usage will impact application content. Recommend considering the TICAP recommendations in this area – where PRA level of information is minimized to include scope of the PRA, discussion on use of the PRA standard including peer review, and results pertinent to NEI 18-04
- International regulatory frameworks have risk-informed approaches that certain vendors may choose to pursue
- Desire that Part 53 would accommodate such approaches (i.e., IAEA SSR-2/1 and markets with dual-DSA/PSA requirements)

Performance-based (and Risk-informed) Regulations

- Performance-based
 - Clear performance-based acceptance criteria to allow flexibility in implementation of design features and programmatic controls while improving predictability in the review process (minimum criteria needed for adequate protection allowing applicant selection of approaches and methodologies).
 - Performance-based requirements should focus on measurable outcomes (does “x” perform the way it was committed to perform) and avoid prescription of methods to achieve that performance.

Performance-based (and Risk-informed) Regulations

(cont.)

- Other considerations
 - Part 53 should accommodate an implementation of Licensing Modernization Project (LMP), but not implicitly require it.
 - Performance-based, risk-informed regulations can provide the applicant with flexibility on how to demonstrate compliance.
 - Part 53 should be technology and design neutral to minimize the need for exemptions.
 - Consider the overall impact and level of detail requirements for Part 53, and its prospective applicant types, and how the language can be used to improve regulatory predictability, efficiency, and certainty.

Adequate Defense in Depth (DID)

- DID is important in supporting an adequate safety case for both LMP and non-LMP applications, but is best addressed in guidance rather than regulations.
- Further discussion is needed to better understand and define what is adequate DID for LMP and Non-LMP applications, accounting for the range of potential reactor designs and features that prevents and mitigates accidents that release radiation materials.
 - Adequate DID may be different for unique reactors
 - No precedent or guidance on establishing DID acceptance criteria or what is sufficient DID analysis

Adequate Defense in Depth (DID) (cont.)

- Multiple DID barriers applied only to DBEs in Part 53?
 - Inferred is that DID will have to look at BDBEs in Part 53 – but we just don't know what that looks like without a systematic review of DID like that performed under LMP.
- In guidance, NRC staff needs to explain how DID would be implemented and used, and provide clarity on how a licensee could translate this approach into preparing an application
- In guidance, NRC should clarify what Defense in Depth analysis is required when physics or inherent features of a design have already resolved or removed the potential for releases of large amounts of radioactivity

Quantitative Health Objectives (QHO)

- Draft Subpart B, Technology-Inclusive Safety Requirements, Section 53.23, Second Tier Safety Criteria, (b)(2) requires the applicant to analyze QHO for LBE to ensure $<5E-6$ immediate and $<2E-6$ latent health effects per year
 - No parallel QHO requirement in 10 CFR 20, 50, or 52. QHO calculations would be required in addition to quantitative limits at site boundaries in 53.23. Q: What was the underlying goal in changing the wording of the existing safety goals in 53.23 (from ML011210381, 51 FR 30028)?
 - The QHO method was attempted in 1986 but was deemed impractical and replaced by core damage frequency (CDF) and large early release frequency (LERF) in 1990
- Recommend removing (b)(2) from 53.23

Quality Assurance Requirements

- Part 53 provides opportunity for NRC to take a fresh look at Appendix B and NQA-1 Program, and consider alternatives
- Level of quality of commercially available components may meet and exceed prior “nuclear standards” without the need for the overly burdensome reporting requirements
- Recommend rule should state quality control program is necessary, but not provide direction on approaches to use.

Quality Assurance Requirements (cont.)

- Recommend guidance should indicate that approaches such as ISO 9000 series, IAEA, commercial dedication programs, and other approaches presented by industry could be used— this would facilitate licensing of US reactors in Canada, Europe, Asia, and other parts of the world
 - International acceptance of a single approval could be important in international marketability
 - Guidance could address the broader topic of universal acceptance of codes and standards (mechanical, electrical, etc.)
- Concurrent guidance should be developed to show that the ISO standards and IAEA approaches can meet whatever the requirements are in Part 53, and potentially other Parts.

Possible Structures for Part 53

- NRC proposed subparts can work
 - But need understanding/agreement on Subpart B on Safety Criteria before proceeding
- NRC should maintain public list of other Parts or regulations Part 53 will reference
- Definitions of Terms used in the rule language are needed, and list should be maintained
 - Licensing basis events, reasonable assurance, and other terms if not defined in existing Parts 50 and 52
- Integrated Part 53 licensing initiative
 1. Regulatory text (current focus)
 2. Guidance (topics requiring guidance need to be identified as regulations are drafted)
 3. Review process

Key Concepts and Possible Structures

Key Concepts (1/2)

- Structured around NRC regulatory functions
 - Determine the standards for reasonable assurance of adequate protection in terms of direct impacts on the of the public health
 - Determine the facility characteristics that are needed to ensure the facility will meet the public protection criteria
 - Determine how to provide reasonable assurance that the facility is designed to achieved the facility safety characteristics
 - Determine how to provide reasonable assurance that the facility is constructed and will operate in accordance with the design
 - Determine the types of licenses, permits and design approvals that the NRC may issue, and the process to obtaining them
 - Determine the information from an applicant or holder of a license, permit or design approval that needs to be reviewed and approved by the NRC to facilitate the regulation of the facility

Key Concepts (2/2)

- Key Technical Topics
 - Safety criteria and safety paradigm
 - Performance-based safety, security, siting and emergency preparedness
 - Role of PRA
 - Reasonable assurance of design/analysis, construction and operations
 - Commercial grade QA standards
 - Radiation protection and ALARA
- Key Process Topics
 - Level of detail/prescription in regulations vs. use of guidance
 - Organization of technical requirements and documentation requirements
 - Relationship with Part 50 and 52 licensing processes (e.g., reference vs. include in Part 53)
 - Licensing basis documentation, including changes

Key Concepts and Structure

Discussion



MEETING BREAK

Meeting to resume in 45 minutes

Approach to Rule Language and Developing Key Guidance Documents

Approach to Rule Language and Developing Key Guidance Documents NRC Staff Perspectives

- Regulatory Guide 1.233, endorsing NEI 18-04, is one acceptable way to satisfy requirements of Part 53
- Work in progress to supplement with guidance documents on content of applications (TICAP/ARCAP)
- Consistent with ongoing activities in areas such as emergency preparedness, security, siting, and environmental reviews
- Work in progress by standards development organizations (SDOs) in areas such as high temperature materials, design standards, and probabilistic risk assessment
- Work being initiated in areas such as human factors, technical specifications, and appropriate special treatments
- Acknowledge need to identify other key guidance documents and engage stakeholders on their development/endorsement

Approach to Rule Language and Developing Key Guidance Documents

Key Regulatory Guidance

- Higher-level requirements will rely more on guidance for
 - Details that have historically been in regulations
 - Technology-specific considerations
 - Licensing approach considerations
- Potential topics for guidance
 - Application guidance (scope/content) – e.g., TICAP and NRC ARCAP (including security-related content)
 - Safety and security paradigm (licensing approach) – e.g., NEI 18-04 and risk-informed, performance based approach to security
 - Technology-specific guidance (e.g., key safety functions, design and operation considerations) – *None currently*
 - Specific technical topics (e.g., graded-approach to PRA, commercial QA standards)

U.S. Nuclear Industry Council Comments for NRC Part 53 Meeting: Rule language and Previously Released Subparts

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Approach to Rule Language and Guidance Documents

- USNIC does not support the preliminary Subpart B, C or F language
 - USNIC strongly encourages NRC to redraft Subpart B
 - USNIC is very skeptical of the Facility Safety Program in Subpart F
 - USNIC encourages NRC to release revised language for Subpart C, Subpart D, and Subpart F (and any other subparts) only after language for Subpart B has been redrafted.
- List of expected guidance should be kept and updated

Approach to Rule Language and Developing Key Guidance Documents

Discussion

Discussion of Previously Released Subparts

Discussion of Previously Released Subparts NRC Staff Perspectives

- Overall Framework
- Released (ML21012A284)
 - Subpart B (Safety Criteria)
 - Subpart C (Design and Analyses)
 - Subpart F (Facility Safety Program)
 - Subpart D (Siting)
- Under Development
 - Subpart E (Construction)
 - Subpart F (Configuration Control, Personnel, Programs)
 - Subpart G (Decommissioning)
 - Subparts H/I (Licensing)
 - Subparts A/J (General, Administrative, Miscellaneous)

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Subpart B – Technology-Inclusive Safety Requirements Topics

- Safety Objectives
- Transient and Accident Radiological Safety Criteria (replaces NRC Tier 1)
- Routine Operation Radiological Safety Criteria (refers to Part 20 Subpart C & D; no need for separate “Protection of Plant Workers” section)
- NRC Tier 2 section not needed for Adequate Protection
- Safety Functions (better logic to place after Safety Criteria than before)
- Licensing Basis Events
- Defense in Depth Objectives

Discussion of Previously Released Subparts

Subpart B – Safety

- Simplify and clarify the safety criteria
 - Adequate protection – 25 rem for events not expected during lifetime
 - Extra-adequate protection (*if necessary*) – 0.1 rem for normal operations, and beyond design basis
- Establish the facility characteristics needed for safety and security
 - Aligned with NRC’s “bow tie” diagram
 - Performance-based safety, security, siting and emergency preparedness
 - Radiological hazard
 - Characteristics of the site
 - Required facility functions necessary and sufficient to meet safety criteria
 - Event sequences
 - Design features and human actions to perform required facility functions

Subpart C: Design and Analysis

- Simplify and clarify around updated safety criteria
 - Features that are necessary and sufficient to provide reasonable assurance that the design and analyses demonstrate that the facility is able to meet the safety and security criteria
- High level requirements that allow flexibility
 - Method for determining facility characteristics (required functions, events, design features)
 - Analysis of SSCs performance of required functions
 - Design requirements and performance criteria for SSCs
 - Method of evaluating risk
 - Measures to address design and analysis uncertainties
 - Qualification of SSCs
 - Categorization of SSCs

Discussion of Previously Released Subparts

Discussion

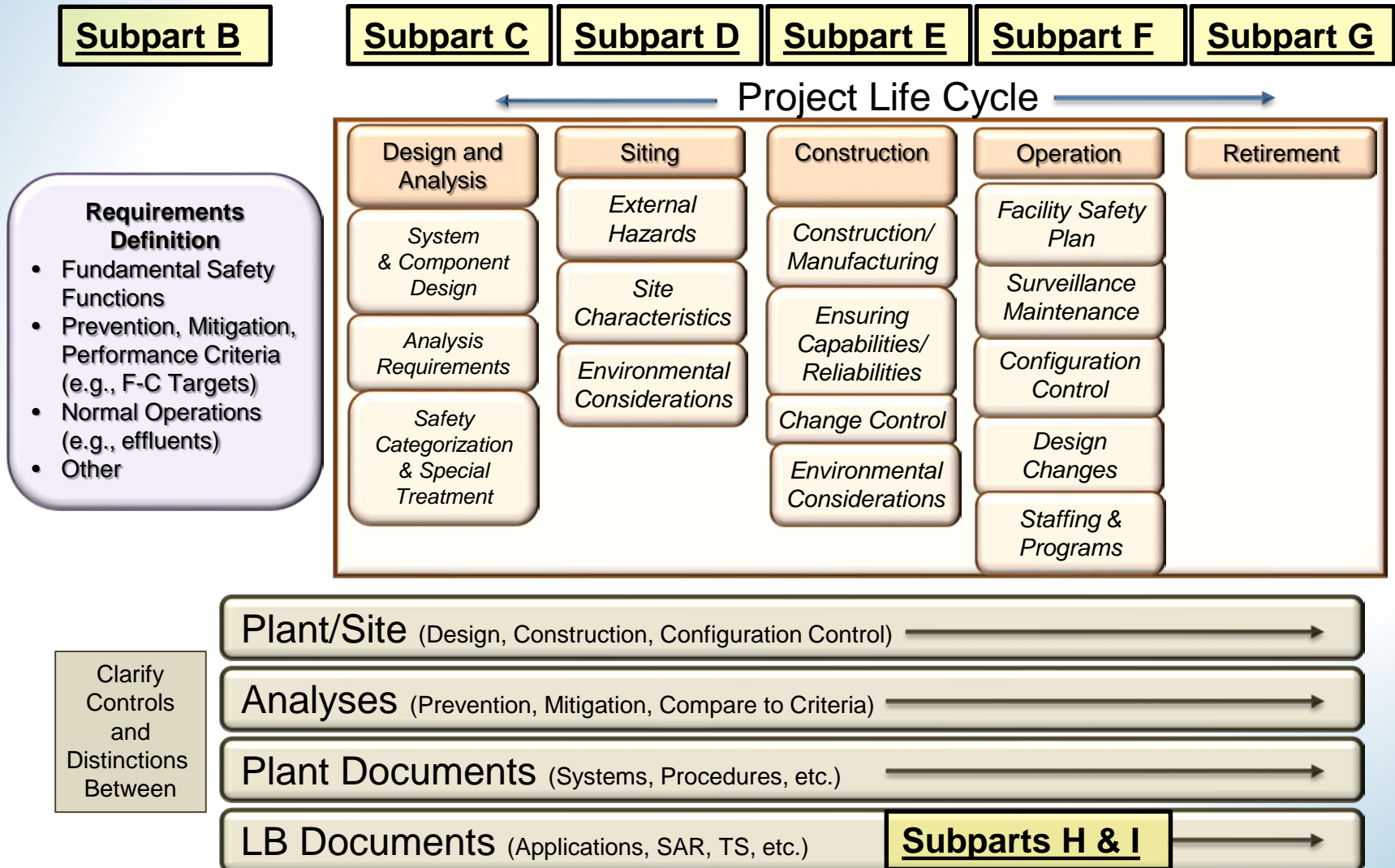
Subpart D

Siting Requirements

Part 53 Outline

- Previous request to provide outline of preliminary Subpart structure and content
- Outline being provided to support continuing discussions of preliminary subparts and staff efforts to develop additional subparts
- Structure and outline subject to change based on ongoing discussions

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: OMB Approval

Subpart B – Safety Criteria

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

Subpart C – Design and Analysis

- Design Objectives and 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 Criteria 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

- Transition from Construction/Manufacturing to Operations
- Part 1 – Maintaining Capabilities and Reliabilities of Safety Related and Safety Significant Equipment
 - Design Features and Programs for Normal Operations (53.220(a) Criteria)
 - Design Features and Programs for Normal Operations (53.220(b) ALARA Criteria)
 - 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
 - Aging Management Programs
 - Design Control
 - Facility Safety Program

Subpart F – Operations, Cont'd.

- Part 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

Subpart F – Operations, Cont'd.

- Part 3 – Radiation Protection
- Part 4 – Emergency Preparedness
- Part 5 – Security Programs
- Part 6 – Preparing for and Transitioning to Decommissioning

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
 - Manufacturing, Transportation, Deployment
- Site & Design
 - Construction Permit
 - Operating License
 - Combined Licenses
- Appendix A (Content Table)

Subpart I – Maintaining Licensing Basis

- Amendments to a license
 - Application
 - Public notice and consultations
 - Issuance
- Updating FSAR
 - Including PRA
- Revocation, suspension, modification of license for cause
- Retaking 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/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 TS (50.54(dd))
- Share SNM and Byproduct Material between Units (50.54(ee))
- Need to Address FEMA Deficiencies (50.54(gg))
- Receipt of Aircraft Threat (50.54(hh))
- ASME (50.55a) & Quality Standards (50.54(jj))
- SNM (50.54(b)-(d))
- Antitrust (50.54(g))
- Subject to Laws & Regulations – (50.54(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
 - 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

10 CFR Part 53 Subpart D Layout

- **§ 53.500** – General Siting
- **§ 53.510** – External Hazards
- **§ 53.520** – Site Characteristics
- **§ 53.530** – Population-related Considerations
- **§ 53.540** – Siting Interfaces
- **§ 53.550** – Environmental Considerations

§ 53.500 – General Siting

- Overall siting considerations
 - Consider site in combination with design features and programmatic controls to satisfy first and second tier safety criteria.
 - Identify and assess external hazards and site characteristics that could contribute to initiation, progression, or consequences of licensing basis events.
 - Address potential adverse impacts on nearby environs as a result of normal operations or potential accidents.

§ 53.510 – External Hazards

- Structures, systems, and components (SSCs) needed to meet first tier safety criteria must be designed to withstand natural phenomena and man-made hazards.
 - SSCs designed to withstand hazards up to design basis levels.
 - Design basis external hazard levels must address hazards occurring with both routine frequency and up to 1 in 100,000 years, with added margin.
- Geologic and seismic factors must be considered to determine Safe Shutdown Earthquake Ground Motion (SSEGM).
 - SSEGM is level of seismic activity at which SSCs must remain functional.
 - The SSEGM for the site is determined considering the results of the geological, seismological, and engineering characteristics of a site and its environs.

§ 53.510 – External Hazards (cont.)

- Analyses required by § 53.450 must address external hazard frequencies and related SSC fragilities.
 - Analyses must assess external hazards in order to meet second tier safety criteria.
 - Functional design criteria and programmatic controls must be established to maintain performance of SSCs relied upon to meet safety criteria.

§ 53.520 – Site Characteristics

- Meteorological, geological, seismological, topographical, hydrological, and other characteristics of the site and surrounding area that could affect radioactive material escape should be identified, estimated, and considered in the analyses required by Subpart C (Design and Analysis).

§ 53.530 – Population-related considerations

- Every site must have an exclusion area, low population zone, and provide a population center distance as defined in § 53.120. Offsite radiological consequences estimated by analyses required by § 53.450 are used to define:
 - Exclusion area such that any individual on the boundary for any two hour period following a release would not receive more than 25 rem total effective dose equivalent (TEDE).
 - Low-population zone such that any individual on the boundary following a release would not receive more than 25 rem TEDE.

§ 53.530 – Population-related considerations (cont.)

- Offsite radiological consequences estimated by analyses required by § 53.450 are used to define:
 - Population center distance that must be at least one and one-third times the distance from the reactor to the outer boundary of the low population zone.
 - Reactor sites should be located away from very densely populated centers. Areas of low population density are, generally, preferred.

§§ 53.540 & 53.550 – Siting Interfaces and Environmental Considerations

- External hazards and site characteristics must be addressed by design features, programmatic controls, and supporting analyses to demonstrate compliance with first and second tier safety criteria.
- Applicants must demonstrate compliance with environmental protection regulations in accordance with 10 CFR Part 51.

Subpart D: Siting Requirements

Subpart D: Siting Requirements

- Incorporation of siting into Part 53 makes sense
- Opportunity to more efficiently integrate siting into the safety of the facility
 - Integrate into Subpart B: Safety
 - Internal and external events considered in establishing required facility functions, design features and human actions
 - Site characteristics considered (as appropriate)
 - Use of site boundary (align with EPZ) to replace EAB and LPZ
 - Performance-based focus on safety criteria obviates need for considering distance to population center (i.e., prescriptive 53.530 not necessary)
- Higher level to allow flexibility
 - Characteristics of the site that have a significant impact on the ability to meet the safety criteria (examples, e.g., seismology, rather than prescriptive)
 - Locate detailed expectations in guidance (e.g., seismic hazard)

U.S. Nuclear Industry Council Comments for NRC Part 53 Meeting: Subpart D Siting Requirements

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and Reactor Developers

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04 February 2021

Subpart D – Siting Requirements- General Comments

- Siting requirements retain language from original Part 100 text that unnecessarily prohibit advanced reactors from being co-located with populated areas (e.g. to replace old coal-fired power plant), without a clear tie to a safety goal.
- Scope of required site characteristics and associated analyses should be first informed by risk/safety profile of the facility, and then the specific site as necessary.
 - In some cases, restricting guidance language is proposed to be incorporated in rule text (where it was not before) for risk categories that will likely far exceed those of most advanced reactor designs.
- Some of draft NRC Subpart D language could be put in guidance and not regulations
- Q: How does the staff plan to coordinate Part 53 requirements for siting with the proposed siting options pertaining to population density in SECY 20-0045?

Subpart D – Siting Requirements- Specific Comments

Part 53 Subpart D	USNIC Discussion
53.500 General Siting.	As stated in prior public meetings, USNIC does not support Tier 1 and Tier 2 categories
53.510 External Hazards	<p>Q: (a) Clarify why 1 in 100,000 years was chosen (because frequencies should be informed by safety and risk profile of facility not most limiting criteria). Does “sufficient margin” refer to margin in the magnitude of the hazard, or margin in the frequency?</p> <p>Q: (b) Should the size of region and type of data be based on reactor design first, and the nature of the region second?</p> <p>Q: (c) Should term “external hazard frequencies” be dropped or guidance written about how applicant must address external hazard frequencies? External hazard frequencies language is ambiguous.</p>

Subpart D – Siting Requirements- Specific Comments (continued)

53.520 Site Characteristics.	This language seems appropriate and generally represents key information that should be sufficient to address requirements for siting.
53.530 Population-related Considerations.	<p>Q: Clarify “Every site must have an exclusion area, low population zone, and provide a population center distance” because Part 53 should apply to reactors with and without offsite emergency plans, including microreactors, and the inclusion of separate boundaries beyond the Exclusion Area Boundary is arbitrary in that it does not consider risk-informed, performance based criteria, but rather presumes some large release without any basis.</p> <p>Q: Explain population center distance paragraph, including if there is a statutory or technical basis behind the “one and one third times”? Many advanced reactors (e.g., microreactors) may be considered for higher population locations and this language seems arbitrarily to limit such an option.</p> <p>Q: Similarly, please explain how “away from densely populated centers” comports with risk-informed, performance-based regulation. This language, which is similarly ambiguous in Part 100, seems to impose arbitrary limits on siting in a way that cancels out the benefit of increased safety margins in advanced designs.</p> <p>Q: Is intent of 53.530 (c) and (d) to be prescriptive siting criteria, or performance-based criteria integrated with Emergency Planning considerations?</p>
53.540 Siting Interfaces.	The NRC continues to reference requirements its initial preliminary language (such as the facility safety program) without recognizing the comments received from stakeholders.

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Subpart D

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 (15 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

Future Public Meetings

- The NRC staff will continue to host monthly public meetings, estimated to be the first Thursday of every month, to discuss and receive feedback on various regulatory topics and preliminary proposed rule text.
 - The next Part 53 public meeting will be scheduled for March 4, 2021.
 - The preliminary proposed rule text will be posted on regulations.gov under docket ID [NRC-2019-0062](#) before the public meeting.

Future Public Meetings

- The NRC staff is tentatively scheduled to meet with the ACRS Future Plants Subcommittee on February 18, 2021.
 - The staff will be presenting the Part 53 subparts C and D preliminary proposed rule text.
 - The staff will continue to meet with the ACRS subcommittee every month.

Closing Remarks

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Regulations.gov docket ID: **NRC-2019-0062**

Please provide feedback on this public meeting using this link:

<https://www.nrc.gov/public-involve/public-meetings/contactus.html>

Acronyms and Abbreviations

ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Documents Access and Management System
ALARA	As low as reasonably achievable
ARCAP	Advanced Reactor Content of Applications Project
ARDC	Advanced Reactor Design Criteria
CDF	Core Damage Frequency
CFR	Code of Federal Regulations
DBE	Design-basis event
DID	Defense in Depth
DSA	Deterministic Safety Analysis
EAB	Exclusion Area Boundary
EPZ	Emergency Planning Zone

F-C	Frequency – Consequence
FEMA	Federal Emergency Management Agency
FSAR	Final Safety Analysis Report
FSP	Facility Safety Program
IAEA	International Atomic Energy Agency
INPO	Institute of Nuclear Power Operations
ISO	International Organization for Standardization
LB	Licensing basis
LBE	Licensing basis event(s)
LERF	Large Early Release Frequency
LMP	Licensing Modernization Project
LPZ	Low-Population Zone
LWRs	Light-water Reactors

Acronyms and Abbreviations

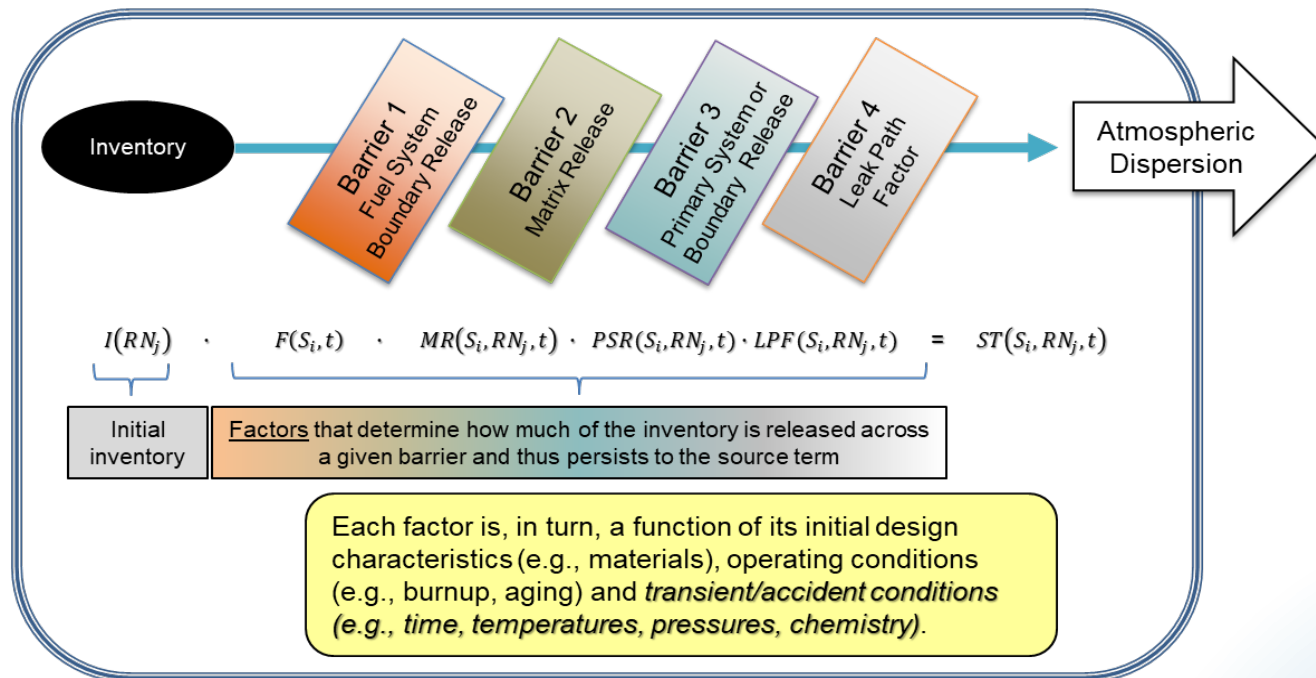
NEI	Nuclear Energy Institute
NEIMA	Nuclear Energy Innovation and Modernization Act
NMSS	Office of Nuclear Material Safety and Safeguards
NQA	Nuclear Quality Assurance
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
OMB	Office of Management and Budget
PRA	Probabilistic risk assessment
PSA	Probabilistic Safety Assessment
QA	Quality assurance
QHO	Quantitative health objective
rem	Roentgen-equivalent man

SAR	Safety Analysis Report
SDOs	Standards Development Organizations
SNM	Special Nuclear Material
SRM	Staff Requirements Memorandum
SSCs	Structures, systems, and components
SSEGM	Safe Shutdown Earthquake Ground Motion
TEDE	Total effective dose equivalent
TICAP	Technology-Inclusive Content of Applications Program
TS	Technical Specifications
UCS	Union of Concerned Scientists
USNIC	U.S. Nuclear Industry Council

Background Slides

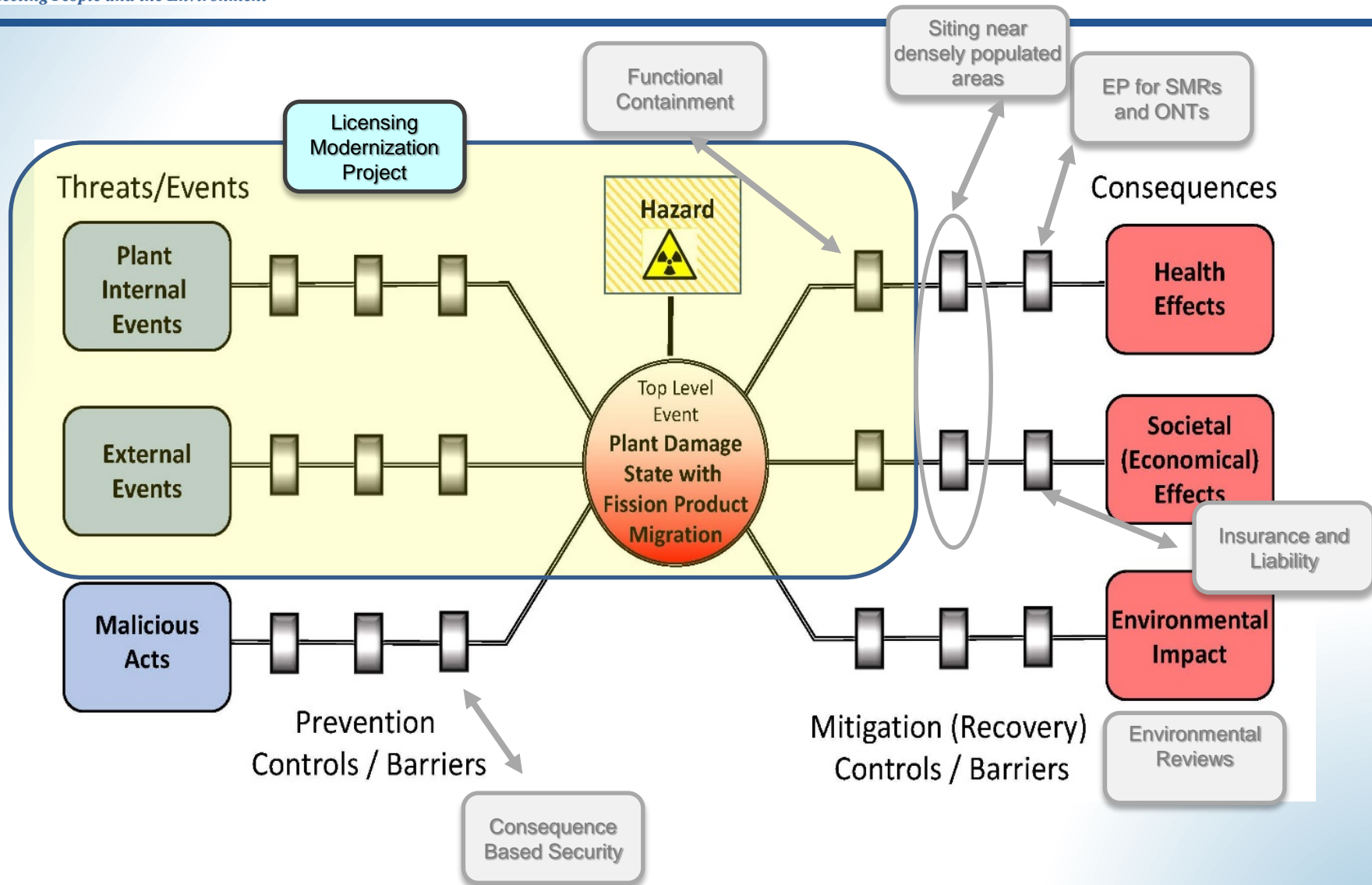
First Principles

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



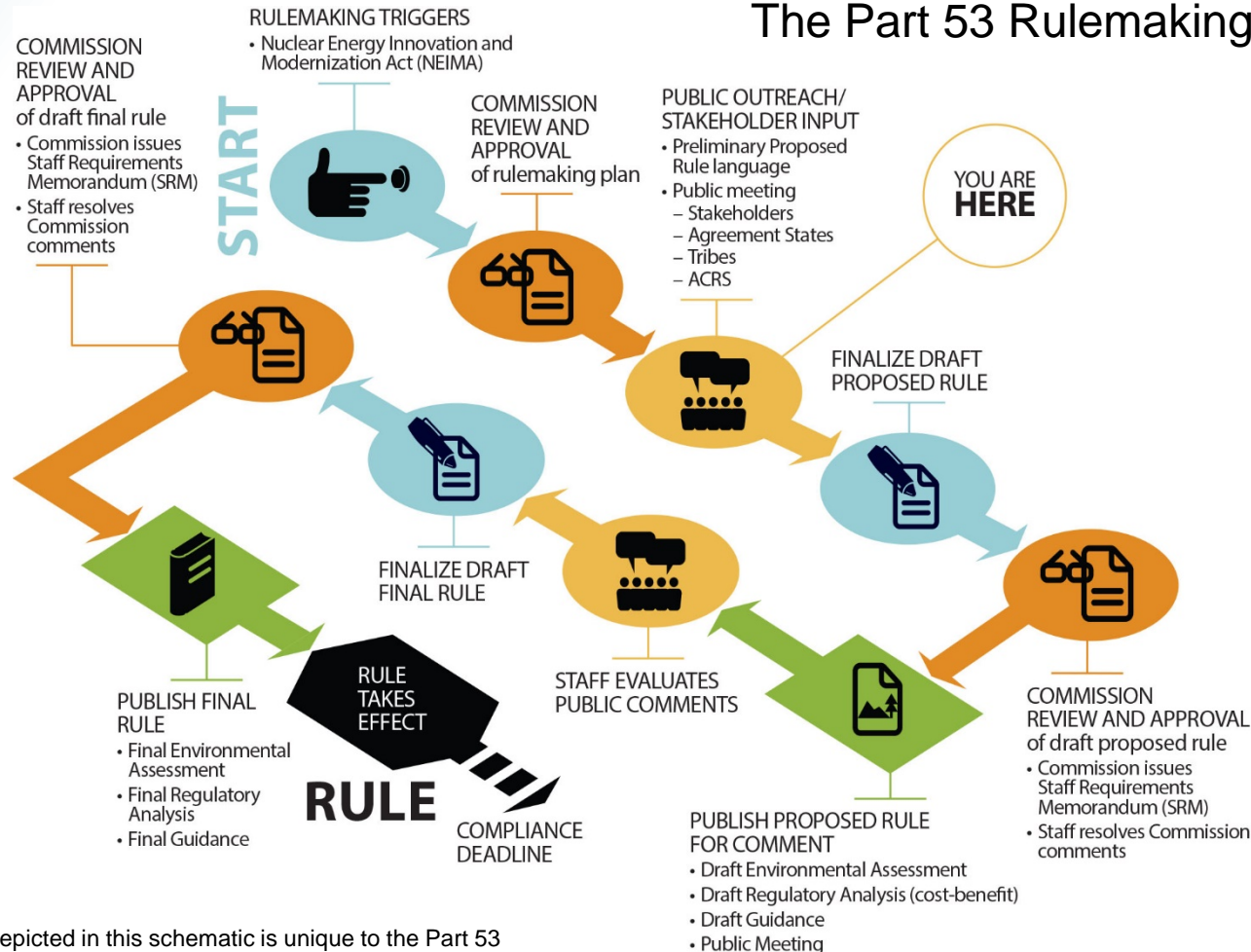
See: SECY-18-0096, “Functional Containment Performance Criteria for Non-Light-Water-Reactors,” and INL/EXT-20-58717, “Technology-Inclusive Determination of Mechanistic Source Terms for Offsite Dose-Related Assessments for Advanced Nuclear Reactor Facilities”

Integrated Approach



Part 53 Rulemaking

The Part 53 Rulemaking Process*



*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, ...