United States Nuclear Regulatory Commission

Protecting People and the Environment

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

White Paper on Human Factors, Revisions to Previously Released Preliminary Proposed Rule Language, & Subpart E Preliminary Proposed Rule Language

April 8, 2021

Agenda

10:00am – 10:15am	Welcome / Introductions / Logistics / Goals
10:15am – 11:15am	White Paper – “Risk-Informed and Performance-Based Human-System Considerations for Advanced Reactors”
11:15am – 12:15pm	2nd Iteration on Previously Released Rule Language – Subpart B
12:15pm – 1:00pm	Lunch Break
1:00pm – 2:00pm	2nd Iteration on Previously Released Rule Language – Subpart B (continued)
2:00pm – 3:15pm	2nd Iteration on Previously Released Rule Language – Subpart C
3:15pm – 3:30pm	Break
3:30pm – 4:15pm	Subpart E: Construction and Manufacturing
4:15pm – 4:45pm	Development of Key Part 53 Guidance Documents
4:45pm – 5:00pm	Additional Public Comments/Closing Remarks

Welcome/Introductions

Welcome:
Andrea Veil, Office of Nuclear Reactor Regulation (NRR) – Office Director

Speakers/Presenters:
Bob Beall, Office of Nuclear Materials Safety and Safeguards – Rulemaking PM & Meeting Facilitator
Bill Reckley, NRR – Technical Lead
Nanette Valliere, NRR – Technical Lead
Nuclear Energy Institute (NEI)
U.S. Nuclear Industry Council
Union of Concerned Scientists

Public Meeting Slides: ADAMS Accession No. ML21088A279

Purpose of Today's Meeting

- Review NRC staff's draft white paper, "Risk-Informed and Performance-Based Human-System Considerations for Advanced Reactors"
- Discuss NRC's revisions to preliminary proposed rule language
- Review preliminary proposed rule language for Part 53
  - Subpart E – Construction and Manufacturing Requirements
- Discuss key Part 53 guidance document development
- Today's meeting is a "Comment-Gathering" 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 of today's topics.
  - The meeting is being transcribed and the transcription will be available with the meeting summary by May 1, 2021.
- No regulatory decisions will be made at today's meeting.

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NRC Staff Plan to Develop Part 53

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

Project Life Cycle

Requirements Definition
- Safety Objectives
- Safety Criteria
- Safety Functions

Design and Analysis	Siting	**Construction**	Operation	Retirement
System & Component Design	*External Hazards*	*Construction/ Manufacturing*	*Facility Safety Program*	
Analysis Requirements	*Site Characteristics*	*Ensuring Capabilities/ Reliabilities*	*Surveillance Maintenance*	
Safety Categorization & Special Treatment	*Environmental Considerations*	*Change Control*	*Configuration Control*	
		Environmental Considerations	*Staffing & Human Factors*	
			Programs Security, EP	

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** →

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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.

Risk-Informed and Performance-Based Human-System Operation Considerations for Advanced Reactors

NRR – Division of Advanced Reactors and Non-power Production and Utilization Facilities
NRR – Division of Reactor Oversight (DRO)

April 8, 2021

Agenda

- Background
- Nexus to 10 CFR 53
- White Paper Considerations - Overview
- Next Steps
- Questions/Comments

Background

NEIMA

- Nuclear Energy Innovation and Modernization Act (NEIMA) was signed into law in January 2019 and 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

- NRC currently developing 10 CFR 53:

  "Licensing and Regulation of Advanced Nuclear Reactors"

Supporting Guidance

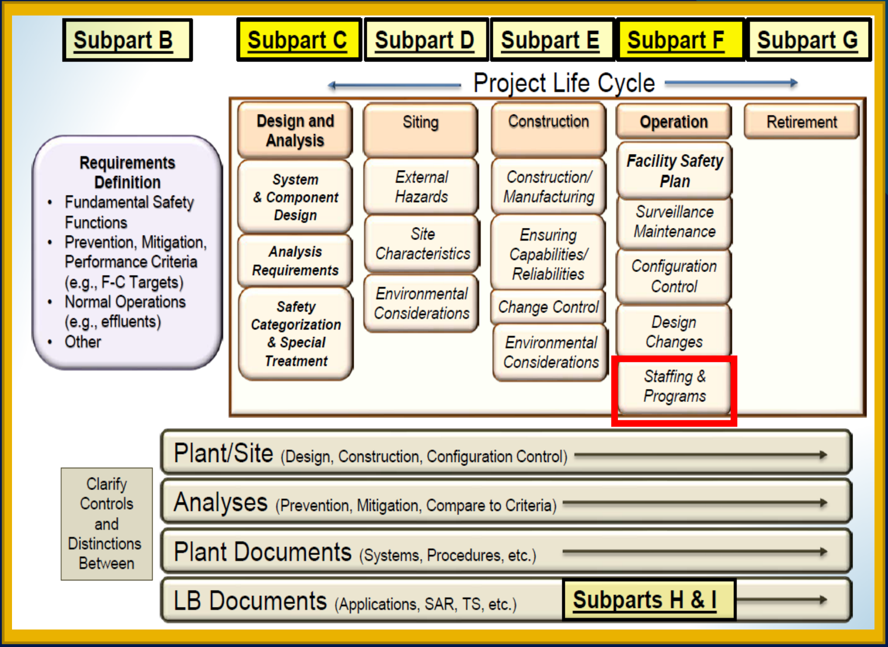
- In some cases, guidance in support of proposed rule may be the driving factor to meet technology-inclusive, performance based criteria that define a modern risk-informed graded approach.

- Development of **key guidance** to 10 CFR 53 - Draft White Paper guidance to be discussed today was developed under that premise.

Key Guidance

White Paper: Risk-Informed and Performance-Based Human-System Operation Considerations for Advanced Reactors*

- Supports Subpart F: "Operations"
- Presented as Key Guidance to Advisory Committee on Reactor Safeguards (ACRS) Future Plant Designs Subcommittee on March 17, 2021
- Topics address diverse and novel operational characteristics, including automation of operations, staffing and qualifications of operations personnel, evolution in control room concepts, and the application of human factors engineering (HFE).
- Draft white paper released to begin external stakeholder interactions



*Released March 25, 2021 (ADAMS Accession No. ML21069A003)

Nexus to 10 CFR Part 53

White Paper – Risk-Informed and Performance-Based Human-System Operation Considerations for Advanced Reactors - Nexus to Part 53

Part 53- Proposed Structure

- A- General Provisions
- B- Tech-Incl Safety Requirements
- C- Design and Analysis Req.
- D- Siting
- E- Const. and Manufacturing
- F- Operations
- G- Decommissioning
- H- Licenses, Cert, and Approvals
- I- Maintaining/Revising LB Info
- J- Administrative requirements

Subpart F – Operations

This subpart is envisioned to address operational areas such as configuration control; maintaining availability and capabilities of SSCs; maintenance, repair and inspection programs; quality assurance; staffing (including operator licensing); emergency preparedness; security; radiation protection; and facility safety program.

Subpart F	Requirements for Operation
53.700	Transition from Construction/Manufacturing to Operation
53.710	Maintaining Capabilities and Availability of Safety Significant Equipment
53.720	Technical Specifications
53.730	SSCs Designated Nonsafety Related with Special Treatment
53.740	Maintenance, Repair, and Inspection Program
53.750	Quality Assurance
53.760	Aging Management Programs
53.770	Design Control
53.780	Programmatic Controls
53.800	Facility Safety Program
53.810	Facility Safety Program Performance Criteria
53.820	Facility safety program plan.
53.830	Review, Approval, and Retention of Facility safety Program Plans
53.900	Staffing, Operations
53.910	Staffing, Other
53.920	Radiation Protection, Public
53.930	Radiation Protection, Occupational
53.940	Emergency Preparedness
53.950	Security Programs
53.990	Preparing for and Transitioning to Decommissioning

Note: The illustrated content structure for Part 53 (including Subpart F) is part of ongoing work and subject to change.

Subpart F "Operations" preliminary rule language

- "Facility Safety Program" was discussed in January 7, 2021 meeting.
- Staffing and Operations language to be released in the coming months.
- Primary purpose of this paper is to inform and support Part 53 rulemaking by proposing guidance related to operations (subpart F).
- Secondary goal is to facilitate the consistent treatment of advanced reactor applications that are received prior to Part 53 being finalized.
- Goal is technology-inclusive, scaled review approaches to the extent practical.

White Paper Considerations

Main Topics

- The regulatory framework for advanced reactors should be capable of addressing novel operational concepts for a wide variety of advanced reactor technologies.

- Some advanced reactor designs may present very low radiological risk and requirements in the current regulatory framework for operation of large light-water reactors (LWRs) may be unnecessary for reasonable assurance of safety.

- The development of a risk-informed, performance-based, and technology-inclusive regulatory framework that appropriately considers the role of humans and human-system integration is warranted for advanced reactors.

White Paper Considerations

New Technologies and Safety Characteristics

- The preceding decades have witnessed evolutionary changes in areas like passive safety and modular construction.
- Technologies that are under various stages of development include small modular reactors (SMRs), non-LWRs, and fusion-based technologies.
- Such technologies warrant careful consideration of design attributes that represent departures from large LWR designs.
- The NRC recognizes the desirability of attributes such as simplified safety features of a passive or inherent nature, reductions in required human actions, incorporation of defense-in-depth, and minimization of the risks associated with severe accidents in advanced reactor designs.

White Paper Considerations

Smaller Source Term Sizes and Reduced Accident Consequences

- Advanced reactors could vary in size from very large to very small; such variations are expected to have potential implications for both source term sizes and accident consequences.

- Accident source terms can serve as a measure of the efficacy of mitigation features.

- Advanced reactor designs may present low potential accident consequences.

- Limiting the hazard posed by a reactor facility reduces the potential for accident consequences and is the most reliable means of ensuring safety.

White Paper Considerations

Passive Safety Features and Inherent Characteristics

- Passive safety features and inherent safety characteristics can influence the role of personnel at advanced reactors facilities.
- Passive safety features tend to place humans into a defense-in-depth role.
- While passive safety features can still fail under certain conditions, inherent safety characteristics can be considered to be absolutely reliable.
- The incorporation of inherent safety characteristics, passive safety features, and automated safety systems influence the concept of operations and can affect the emphasis placed on the HFE aspects of an application review.

White Paper Considerations
Automation of Plant Operations

- Automation is implemented in levels that span from manual to autonomous operation.
- Autonomous operation (full automation) has the potential to support unattended reactor operations.
- Even in an autonomous design, there may still exist a need for humans to implement manual operations under certain circumstances, such as for defense-in-depth.
- Automation generally enhances operational performance, however other operational effects must be considered as well (e.g., operators losing manual control proficiency).

White Paper Considerations

Load Following

- Advanced reactor designers may desire to incorporate load-following capabilities into their designs.

- Load-following where a grid control center can directly adjust plant output is not currently practiced by commercial nuclear facilities in the United States because the practice is precluded by existing NRC regulations; however, that is not the case internationally.

- A nuclear power plant needs to be able to refuse load-following requests when complying with such requests would violate TS or result in unsafe conditions.

White Paper Considerations

Defense-in-Depth and Advanced Reactor Operations

- The NRC has had a long-standing policy of ensuring that defense-in-depth is incorporated into the design and operation of nuclear power plants.

- The key principles of note within the present context are that defense-in-depth approaches should:
  - Not rely solely on a single operational feature
  - Not rely excessively upon human actions (or programs).

- The role of humans in defense-in-depth at advanced reactors is an area that may need further development.

White Paper Considerations

Staffing

- The NRC staff previously recognized the limitations of the prescriptive requirements of 10 CFR 50.54(m) and developed NUREG-1791 in order to allow increased flexibility to LWRs and provide guidance for assessing exemptions to the regulations in 10 CFR 50.54(m).

- Licensing future applications for advanced reactors by exemption from prescriptive requirements may not be a practical long-term regulatory framework.

- An alternative means of that is not reliant upon NUREG-1791 may be beneficial, especially if such a means were to rely upon analyses that can be scaled with the risk of the facility.

White Paper Considerations

Operator Licensing

- The NRC has been licensing reactor operators since the 1950s.
- The Atomic Energy Act of 1954, as amended (AEA), requires the NRC to prescribe uniform operator licensing conditions.
- All license exams are approved and administered by the staff.
- Advanced reactor operational concepts may not align well with the existing power reactor operator licensing framework.
- Examples of appropriate changes for advanced reactors may include allowances for varying licensing examination scope on a facility-specific basis and modified simulator requirements.
- A revised approach to operator licensing should flexibly and efficiently address a wide variety of advanced reactor designs.

White Paper Considerations

Shift Technical Advisor (STA) Position

- Staffing at power reactors also includes the STA position. Unlike licensed operators, STA requirements are primarily rooted in Commission policy, and not regulation or statute.
- The current policy is that, on each shift, there should be at least one person on duty who has a degree in physical science, engineering, engineering technology, or a PE license.
- The function of this person is to provide independent engineering expertise, accident assessment, and technical advice to the main control room operators.
- The elimination of the STA position at a power reactor facility would be a departure from existing Commission policy, as well as from longstanding agency and industry practice.

White Paper Considerations
Training

- The Nuclear Waste Policy Act of 1982, as amended (NWPA), directs the NRC to establish regulations for the training and qualifications of nuclear power plant operators, supervisors, technicians and other operating personnel.

- The NWPA also directs the NRC to establish requirements for simulator training, requalification examinations, operating tests, and instructional requirements.

- The Systems Approach to Training (SAT) plays a central role in current nuclear training and qualification programs.

- The SAT process is generic in nature and can be adapted to any reactor technology, including those associated with essentially any foreseeable advanced reactor designs.

White Paper Considerations

HFE

- The application of HFE in the design of nuclear power plant control rooms is required under existing post-Three-Mile Island regulations.
- Current HFE reviews typically focus on the human-system interfaces located within control rooms.
- Moving forward should include examining how HFE reviews can be implemented most effectively for advanced reactors.
- New approaches, such as the application of scalable HFE review processes and thinking beyond the confines of traditional control rooms, should be considered.
- A Concept of Operations can be valuable in gaining the design understanding necessary to conduct appropriate HFE reviews.

White Paper Considerations

The Evolving Concept of the "Control Room"

- Some advanced reactor facilities may wish to not utilize traditional control rooms in their designs.
- Requirements addressing matters associated with control rooms will need to be revisited in Part 53 with an understanding that the functions involved may become decentralized in an advanced reactor facility.
- HFE requirements will essentially need to be able to "follow" important functions if they are relocated outside of a traditional control room.
- It may also be necessary to account for the potential emergence of functions that have no precedent within traditional control rooms as well.

White Paper Considerations

Additional Organizational Considerations; No Licensed Operators

- For a fully autonomous advanced reactor design, it should be noted that the existing regulatory framework also assigns certain responsibilities and authorities to licensed operators. A key example are the requirements of 10 CFR 50.54(x) and (y) for departures from license conditions.

- Beyond this, there are numerous other licensed operator administrative responsibilities and authorities that are both important to safety and derived from regulatory requirements; such responsibilities and authorities would need to be addressed as well.
    - These include compliance with TS, operability determinations, NRC notifications, emergency declarations, and radiological release limit compliance.

White Paper Considerations

White Paper alignment with 10 CFR 53

- The rule may recognize that staffing, training, operator licensing, and human factors are interrelated areas; diverse advanced reactor technologies necessitate integrating the review of these areas under a flexible approach.

- The rule may account for varying accident consequences in assessing staffing issues.

- The rule may require an HFE program adequate to ensure that personnel can understand plant status, take action to ensure safety, and perform other important technical and administrative functions with safety implications.
    - Human roles associated with the management and availability of plant-specific safety functions will need to be taken into account when considering HFE requirements.

White Paper Considerations

White Paper alignment with 10 CFR 53 (cont'd)

- The rule may account for designs that do not utilize traditional control rooms.

- The rule may ensure that the operator licensing process accomplishes the following:
  - Compliance with applicable statutory requirements (i.e., AEA and NWPA);
  - Conformance with accepted testing standards;
  - Facilitation of consistent and reliable licensing decisions by the NRC;
  - Efficient use of NRC and vendor/facility licensee resources;
  - Provision of reasonable assurance that operators will be able to manage plant-specific safety functions.

White Paper Considerations

White Paper alignment with 10 CFR 53 (cont'd)

- The rule may allow for consideration of innovative features intended to make new designs safer, while also accounting for uncertainties associated with new approaches.

- The rule may, in a non-prescriptive manner, require staffing levels needed to support safe operation and allow for the possibility of demonstrating that no human presence is necessary.
  - The rule may also prescribe minimal requirements that must be met to not use licensed operators at all.

- The rule may ensure that advanced reactor defense-in-depth approaches do not rely exclusively upon a single operational feature or rely excessively upon human actions.

White Paper Considerations

White Paper alignment with 10 CFR 53 (cont'd)

- The rule may account for the possibility of load-following where the load changes themselves are controlled externally from a grid control center.
- The rule may require that sufficient information be submitted to facilitate reviews as outlined within these goals. Examples of such information may include the following:
  - The Concept of Operations for the design;
  - Functional Requirements Analyses describing the features, systems, and human actions relied upon for safety.
  - A staffing plan, with supporting HFE-based analyses;
  - A SAT-based training program for relevant personnel.

White Paper Considerations

Solutions: Scalable HFE Reviews

- The NRC staff has initiated work under contract with Brookhaven National Laboratory to develop a method for scaling the scope and depth of HFE reviews for advanced reactors.
- The objective of this effort is to enable the staff to readily adjust the focus and level of staff HFE review efforts based upon factors such as risk insights and the unique characteristics of the design or facility operation.
- In the interim, the NRC staff also has the ability to adjust the scope of a NUREG-0711 HFE review on a case-by-case basis should a given license application warrant a reduction in the scope of an HFE-area technical review.

White Paper Considerations

Solutions: Staffing Facilities Without Need for Licensed Operators

To justify not using licensed operators, the applicant must demonstrate that adequate protection of the public health and safety will exist in the absence of any operator action for *preventing or mitigating* accidents. The following are examples of criteria that could potentially be used for assessing the acceptability of an advanced reactor design operating *without using any* licensed operators:

1. The accident analysis must demonstrate that radiological consequence criteria will be met without reliance on human actions for event mitigation, defense-in depth, or safe shutdown.

White Paper Considerations

Solutions: Staffing Facilities Without Need for Licensed Operators (Cont'd)

2. Safety of the design should rely upon inherent safety characteristics. Absent an operator presence, the absolute reliability of inherent safety characteristics would be key.

3. If not fully autonomous, the design should have sufficient autonomy to support safety without human action. If human action is needed for startup, it may be appropriate to:
   a. have a licensed operator conduct the reactor startup; <u>or</u>
   b. demonstrate the safety analyses bound all postulated errors by a non-licensed operator during a reactor startup (warranted because a non-licensed startup operator's abilities would not provide the NRC staff with the same degree of assurance as those of a licensed operator).

White Paper Considerations

Solutions: Staffing Facilities Without Need for Licensed Operators (Cont'd)

4. License conditions could be established for the facility so that those administrative responsibilities with safety implications (e.g., TS compliance) that would otherwise have been allocated to licensed operators are reassigned (e.g., to a designated facility manager position).

5. For the STA position, the staff would need to engage with the Commission on a proposed departure from policy should an applicant propose a staffing plan that does not include on-shift engineering expertise. A key consideration would likely be the applicant's ability to demonstrate that the results of staffing-related analyses remain adequate in the absence of the on-shift engineering expertise provided by an STA.

White Paper Considerations

Solutions: Scalable Approach to Operator Licensing Requirements

- A flexible process that advanced reactor vendors and licensees could use to develop an operator licensing exam program for their sites might consist of the following:
  1. Job Task Analyses to identify knowledge, skills, and abilities related to the facility's licensed operator role.
  2. Training and evaluation methods would be selected using an SAT process, including determining exam composition.
  3. A vendor or licensee would pilot the proposed exam.
  4. Exams would be reviewed and administered by the NRC.
     - A potential option would be for vendors and licensees to also *administer their own license examinations*.

White Paper Considerations

Solutions: Concept of Operations

- There is currently no regulation requiring applicants to provide a Concept of Operations as part of applications.

- New designs will likely conceive of radically different Concepts of Operations for which the staff may have little or no prior understanding. Therefore, there may be a need to explicitly make the Concept of Operations a part of the content of applications under the proposed Part 53 rule.

- A description of the Concept of Operations will help the NRC staff to avoid confusion, understand and confirm to what extent a design relies on the humans for safe operation, determine the appropriate scope of the staff review, and reduce the need for Requests for Additional Information.

White Paper Considerations
Solutions: Staffing Analyses

- It may be appropriate for applicants to propose their own alternative staffing models. At a minimum, an HFE-based staffing analysis of sufficient scope and depth to allow for the NRC staff to adequately assess the acceptability of the proposed staffing levels would be needed.

- Alternative staffing models for advanced reactor applicants could be informed by the existing process of NUREG-1791.

- It may also be appropriate for the Part 53 rule to provide a prescriptive staffing model as an *option* for applicants that prefer not to conduct the staffing analyses needed to support an alternative, flexible staffing model.

White Paper Considerations
Solutions: HFE Programs

- Applications are likely to need to contain specific information related to an HFE program and the resultant assessments (e.g., designs of control room Human-System Interface (HIS) or proposals for alternative staffing models would be expected to be informed by HFE principles).

- Part 53 may require advanced reactor applications to address the incorporation of state-of-the-art HFE principles more comprehensively than existing regulations require at present. An advanced reactor HFE program should be adequate to ensure that humans can perform the full range of tasks necessary to ensure the continued availability of plant-specific safety functions; this may also extend to maintenance and testing activities related to plant safety functions.

White Paper Considerations
Final Thoughts

- Draft concepts in white paper meant to solicit feedback on key areas of advanced reactor operations. Final scope will be determined in coming months.

- Well-defined and unambiguous criteria is critical for a performance-based, graded approach related to Operations. Leveraging results of existing methodologies part of an application such as the Licensing Modernization Project (LMP), maximum hypothetical accident, deterministic insights, probabilistic risk assessment (PRA) insights, etc. will be explored.

- White Paper concepts are intended for future 10 CFR 53 applicants, however, NRC may use the concepts described to inform proposed exemptions from Part 50/52 requirements for near-term applicants.

Next Steps

White Paper: Risk-Informed and Performance-Based Human-System Operation Considerations for Advanced Reactors*

- ACRS and additional public stakeholder interactions will follow in coming weeks and months.

- NRC evaluating resources/schedule to identify what areas of the guidance to prioritize. A more detailed timeline will be presented in future meetings.

- White Paper guidance in final form will support proposed 10 CFR 53 rule language.

- Final form of guidance is still being evaluated. For example:
  - Interim Staff Guidance
  - Regulatory Guide

- Final Human-Systems Operations guidance will be incorporated by reference into other key guidance:

  (i.e.: Advanced Reactor Content of Applications Project (ARCAP)-to inform the SAR of any advanced reactor application)

*Released March 25, 2021 (ADAMS Accession No. ML21069A003)

Thank You!

Questions/Comments?

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NEI Comments

U.S. Nuclear Industry Council Comments for NRC Part 53 Public Meeting: Human-System Considerations

Cyril Draffin
Senior Fellow, Advanced Nuclear
U.S. Nuclear Industry Council

8 April 2021

Staff white paper on human-system interactions

Overall, an easy-to-read 51 page document; multiple helpful summary sections

- Appropriately refers to need for “reasonable assurance of adequate protection” (p5)
- Recognizes that some advanced reactor designs may present very low radiological risk and some requirements in current framework may be unnecessary (p5)
- Appropriate to include Canadian experience in allowing autonomous operation of nuclear reactors (p14), and French acceptance of load following (p17)
- Does not consider industrial experience and regulations for autonomous operations of simple or complex systems (e.g. petrochemical analogy to small microreactor or small advanced reactor system operations)
- Recognizes current staffing requirements under 10 CFR 50.54 are prescriptive in nature (p36)
- Not clear why “setting more restrictive accident doses limits for plant where licensed operators are not present” is necessary (p42)

Staff white paper on human-system interactions

- Refueling “outage” language should be modified or removed to allow for alternate refueling/fueling technologies (p22)
- Requiring “written” operator exams is an antiquated requirement and should be revised (p25)
- Requirements for an STA or SRO should be revised to allow alternatives (p29)
- Language specifying “supervision” or “direction” from an SRO to an RO should be revised to allow for alternative delegation of responsibilities and staffing
- “Cold Licensing” requirements should be clarified

We look forward to understanding how the analysis and potential approaches would be considered in Part 53

Human-System Operation

Discussion

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

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 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
    - 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 licensing basis events in relation to safety criteria

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Additional Discussion – First Tier

- Possible Applications of First Tier Safety Criteria
  - Minimally acceptable level of safety
  - Met by satisfying the safety functions
  - 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
  - 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 – Two Tiers

- First Tier
  - Stakeholders generally accepted first tier criteria
  - Difficulty in communicating alignment with adequate protection while needing to go beyond for appropriate level of safety
- Second Tier
  - Proposal by some stakeholders to eliminate second tier
- NRC Iteration: Reworded objectives and safety criteria to remove specific references to AEA (i.e., adequate protection & minimize danger)

Second Iteration

- Safety Objectives

FIRST ITERATION
§ 53.200 Safety Objectives.
Each advanced nuclear plant must be designed, constructed, operated, and decommissioned such that there is <u>reasonable assurance of adequate protection of the public health and safety and the common defense and security</u>. <u>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</u> 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.

SECOND ITERATION
§ 53.200 Safety Objectives.
Each advanced nuclear plant must be designed, constructed, operated, and decommissioned <u>to limit the possibility of an immediate threat to the public health and safety</u>. In addition, each advanced nuclear plant must <u>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</u>.

Second Iteration

- Maintain 2-Tier Structure
- First Tier Safety Criteria largely unchanged

FIRST ITERATION
§ 53.210 First Tier Safety Criteria
a) Normal Operations – 10 CFR Part 20, Subpart D (100 millirem per year)
b) Unplanned Events – 25 rem at exclusion area boundary (EAB)/ low population zone (LPZ) over 2 hours/event duration
c) As established by Commission for adequate protection

SECOND ITERATION
§ 53.210 First Tier Safety Criteria
a) Normal Operations – 10 CFR Part 20, Subpart D (100 millirem per year)
b) Unplanned Events – 25 rem at EAB/LPZ over 2 hours/event duration
(deleted (c) to reflect separation from adequate protection standard)

MEETING BREAK

Meeting to resume in 45 minutes

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Feedback – ALARA

- As low as reasonably achievable (ALARA)
  - 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 ARCAP 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 – 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)

Proposed Second Iteration

- 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.

Feedback – Safety Functions

- Safety Functions
  - Proposal by some stakeholders to explicitly cite fundamental safety functions.
  - Some ACRS members favor approach more like general design criteria (GDC)
- NRC Iteration: Maintained 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)

Note that specific mention of safety functions (e.g., GDC-like approach) better aligns with establishing prescriptive design criteria for a more deterministic or structuralist approach to developing the regulation.

Feedback – Occupational Dose

- Protection of Plant workers
  - Proposal by some stakeholders to exclude occupational dose from Part 53 or to confine to reference to Part 20.
  - Some ACRS members favored retaining occupational dose limits.
- NRC Iteration: Revised to reference Part 20.

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

Feedback – Occupational Dose

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

Feedback – 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

Feedback – Defense in Depth

SECOND 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 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.

Note that consideration of how to address inherent characteristics is under review and will be addressed in a future iteration

U.S. Nuclear Industry Council Comments for NRC Part 53 Public Meeting: Subpart B: Safety Requirements

Cyril Draffin
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U.S. Nuclear Industry Council

Jeff Merrifield
Chairman, Advanced Nuclear Working Group
U.S. Nuclear Industry Council

8 April 2021

Overall comments based on 2nd iteration of preliminary rule text for Subpart B and C

- USNIC appreciates the extensive work the staff has done to prepare preliminary language and provide discussion
- Stakeholders only have an incomplete view of Part 53 and we look forward to having a better understanding of the Staff's intentions regarding a complete Part 53
- Although NRC Staff Engagement Plan milestone charts have shown April 2021 "interim staff resolution" for Safety Criteria and Design, USNIC understands and appreciates that discussions and iterations of Subpart B and C will continue (and these Subparts are open) until complete rule is fully drafted and discussed
- USNIC wants Part 53 to be transformative and flexible-- and hopes the NRC staff shares that perspective
- Based on current path some aspects of draft language are helpful and there are other portions that we would like to better understand or that may need further modification/clarification
- USNIC is hopeful that this effort will result in a proposed Part 53 that is useful and used

United States NIC Nuclear Industry Council

NEIMA Expectations and Objectives – and relationship with Subparts B and C*

- NEIMA Expectations:
  - Technology inclusive (use by any fission reactor technology)
  - Risk-informed (focus on safety-significant elements of safety case)
  - **Performance-based** (clear, consistent, and understandable criteria)
- Success Criteria (Objectives) from USNIC perspective:
  - **Clear**, effective regulatory framework and guidance resulting in significant improvements
  - Framework founded on demonstration of reasonable assurance of adequate protection of public health and safety
  - **Regulatory burden should be reduced** (not increased)

** Presented to March 2021 ACRS Part 53 meeting*

United States NIC Nuclear Industry Council

Overall comments based on 2nd iteration of preliminary rule text for Subpart B and C

- USNIC appreciates the changes that were made in the proposal
  - How PRA could be used, allowing other generally accepted risk-informed approaches (IAEA as alternative), and considering PRA graded approach
  - Consideration of value of inherent characteristics of advanced reactors
  - Use of generally accepted QA standards

- USNIC has other areas where concerns remain
  - ALARA remains in the regulatory language
  - We don't fully understand the staff's views on Adequate Protection
  - We remain concerned about the two Tiers
  - We expect further dialog on DID
  - We think quantitative frequencies and QHO values should be in guidance rather than regulation
  - We remain committed to language and an approach that is performance-based and simpler

Nuclear Industry Council

First and Second Tier Safety Criteria

- Understand that going to risk-informed regulations require~~s~~ tradeoffs, but we are concerned that the rule appears to adds regulations that **increase burden**
  - Expansion of the imposition of the first/second tier safety criteria, by applying in 53.230 the primary and additional safety functions to Tier one and Tier two safety criteria. This continues through the defense in depth, design features, functional design criteria and through the PRA and analysis.

Safety Objectives

- Rule does not appear to simplify regulations (or make regulations more concise), and we are concerned that the recent iteration of Safety Objectives rule may be more confusing-- but look forward to better understanding the intentions of the staff
  - In revised 53.200 the NRC no longer uses the objectives of “reasonable assurance of adequate protection” and “minimize danger to life or property”, but instead references standards to “limit the possibility of an immediate threat to the public health and safety” and “potential risks to public health and safety”

United States NIC Nuclear Industry Council

Subpart B

<u>53.200 Safety Objectives</u>

- Rule: First objective changed from providing “reasonable assurance of adequate protection” to limiting “the possibility of an immediate threat to the public health and safety”
- Rule: Second objective from “protect public health and minimize danger” to “as may be appropriate when considering potential risks to public health and safety”
- USNIC did **not** recommend change in first objective (or second objective), and indeed was supportive of using adequate protection as the main standard in part because it has case law
- Need to better understand of why change was made in second iteration and its ramifications-- including why adequate protection, a term which is specified in the Atomic Energy Act, was dropped

United States NIC Nuclear Industry Council

Subpart B

<u>53.210 First Tier Safety Criteria</u>

- Rule: Split into normal operations and unplanned events
- Referred to Part 20 section D for normal operations, as USNIC recommended.
- As rule discussion indicates, normal operations should be considered like protection of plant workers
- Our membership is considering, but believes Frequencies would be better placed in guidance and not in regulations

United States NIC Nuclear Industry Council

Subpart B

53.220 Second Tier Safety Criteria

- Rule: split into normal operations and unplanned events
- Detailed discussion was helpful but not persuasive
- USNIC continues to prefer an approach where ALARA is addressed by reference to Part 20 rather than incorporating in the draft
- USNIC had recommended dropping second tier safety criteria – with new section 53.200
- We do not understand the intention of the current draft and believe it adds burdensome requirements for applicants (without clarity of its usefulness) without adding value
- Discussion does not explain why NRC changed QHO language and continues to question the appropriateness of including it in the draft

United States NIC Nuclear Industry Council

Subpart B

53.250 Defense in Depth (DID)

- Rule: editorial changes; Discussion suggests could be moved to Subpart C (which would be more appropriate location)
- USNIC continues to have concerns about the approach the staff is making on Defense in Depth and seeks to better understand what the staff is intending in this area
- Important to understand how inherent features will be credited within the context of satisfying the proposed regulation (addition of “engineered” to design feature); inherent features are more reliable
- DID is important design philosophy for LMP and “non-LMP” applications
  - Further discussion needed on adequate DID for license applications, accounting for the range of potential reactor designs and features that prevents and mitigates accidents
  - DID demonstration will vary across range of designs and features
  - LMP example level of detail (rule should enable, not require)

Subpart B

<u>53.260 Protection of Plant Workers</u>

Rule: refer to Subpart B of Part 20; leaves section in safety requirements

- USNIC recommended reference to Subpart C and D in Part 20; section does **not** apply to design of facility
- USNIC continues to believe that ALARA is best addressed within the context of Part 20
- Not sure how these operational requirements will be demonstrated

United States NIC Nuclear Industry Council

U.S. Nuclear Industry Council Contacts

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NEI Comments

Discussion

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

Feedback – Role of PRA

- Analysis Requirements
  - Proposal by some stakeholders to not require PRA
  - Proposal by some stakeholders to support more deterministic approach to design and analysis
- NRC Iteration: Maintain requirement in Part 53 for PRA consistent with evolution of risk-informed approaches but provide alternatives to PRA for design and analysis processes

Feedback – Role of PRA

SECOND ITERATION

§ 53.450 Analysis Requirements

(a) *Requirements to have a probabilistic risk assessment*. Maintain requirement to perform PRA (in part to support QHO assessment)

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

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

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

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

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

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

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
    - Do stakeholders have feedback on this topic that could inform the Staff’s ongoing considerations?

NEI Comments

U.S. Nuclear Industry Council
Comments for NRC Part 53 Public Meeting: Subpart C: Design and Analysis Requirements

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8 April 2021

Subpart C

53.400 Design Features

- Rule: editorial changes
- USNIC does **not** agree First and Second Tier safety criteria, so does **not** agree with building on the them in Subpart C

53.410/420/430 Functional Design Criteria for First Tier Safety Criteria, Second Tier, and Protection of Plan workers

- Rule: editorial changes
- USNIC does **not** agree First and Second Tier safety criteria, so does **not** agree with building on the them in Subpart C
- Why are the constructions of 53.410(a) and 53.410(b) different? Are the words "relied upon" in 53.410(b) a typo?
- USNIC continues to recommend occupational safety not be included in Part 53. Not appropriate to regulate occupational dose one way for Advanced Reactors and another way for the current fleet.

United States NIC Nuclear Industry Council

Subpart C

<u>53.440 Design Requirements</u>

- Rule: use generally accepted consensus codes and standards
- Rule: requires safety and security be considered together in design process such that (where possible) security issues are effectively resolved through design and engineered security features
- New words "interdependent effects" in 53.440(d) are not defined, and we don't understand the intention of this language
- We look forward to the staff's proposal on security
  - Meaning of and rationale for the words "safety and security must be considered together in the design process" is not clear
  - Industry agrees it is prudent to consider security in the design process, but NRC should regulate outcomes, not process

United States NIC Nuclear Industry Council

Subpart C

53.450 Analysis Requirements

- Rule: “Requirement to have a probabilistic risk assessment." Modified the PRA requirement, which allows flexibility for “other generally accepted risk-informed approaches”, and the Discussion mentions the IAEA approach

- USNIC concerned about how PRA tool is being used in regulations-- language in 53.450(a) still says "Requirement to have a probabilistic risk assessment" (formalized PRA tool) and not "Requirement to have a risk-informed assessment"

- USNIC **supports flexibility** on use of PRA or generally accepted risk-informed approach (and the planned NRC actions to develop guidance on graded approach)

- USNIC would like to understand how NRC would handle an applicant that wishes to use deterministic methods to show adequate safety? (Exemptions to the Part 53 PRA requirement? Refer to Part 50?)

Subpart C: Development and Application of Risk-Insights and relation to PRA *(section 53.450)**

- Risk tool (PRA today) insights complement the safety case
- Attributes of a useful Part 53 framework for the use of risk tools:
    - Provide flexibility without focusing on a specifically mandated analytical approach
    - Allow flexibility for incorporation of PRA insights in areas like LBEs, SSC classification, and DID determinations, as appropriate
    - Enable RG 1.233 implementation, but **not require** it
    - Enable combinations of risk-informed and deterministic approaches where appropriate (e.g., external hazards, seismic, bounding analyses, especially for designs with very small source terms such as microreactors)– which seems allowed
    - Support international regulatory frameworks (e.g., IAEA SSR-2/1 and markets with dual-DSA/PSA requirements) as regulations seem to imply
- PRA matures with plant design and site selection/characterization. Requiring extensive PRA with application submittal may not be feasible for all application types, especially for plants in early phases of application (e.g. CP)
    - Application content should be limited to information central to the safety case findings
    - Application content should be developed as part of ongoing regulatory guidance activities

** Presented to March 2021 ACRS Part 53 meeting*

Subpart C

<u>53.450 Analysis Requirements (continued)</u>

- (a) "… and other contributing factors to unplanned events" is unclear
- (a) don't understand the distinction between (b)(1) determining LBEs and (b)(5) identifying events that challenge plant control and safety systems
- (b)(5): Seems to be convolving two separate ideas – events challenging "plant control" and safety system failures– should clarify
- (g) requires things be assessed, but against what? Will there be any acceptance criteria for aircraft impact, fire, etc.? Also, what if fire is addressed in the PRA itself? Does that satisfy (g)(1)?
- (g) seems to be outside of the PRA

United States NIC Nuclear Industry Council

Subpart C

<u>53.460 Safety Categorization and Special Treatment</u>

- Rule: include Safety related, NSRSS, and Non-Safety Significant
- USNIC does not understand the rationale for the new facility safety program suggested in Subpart F because the net safety value of this program has not been explained (also referenced in 53.470 and 53.490)

<u>53.470 Application of Analytical Safety Margins to Operational Flexibilities</u>

- Section is confusing

- Not clear if the benefits of the proposed ideas will be achieved or be durable. Substantial additional discussion is needed, as well as written detailed guidance and direction to reviewers

- Benefits of smaller emergency planning zones can be achieved from Part 50/52 without additional safety margins, so benefit of this section is unclear

Subpart C

<u>53.480 Design Control Quality Assurance</u>

- Rule: QA program must conform with generally accepted consensus codes standards
- USNIC **supports** use of generally accepted QA standards, and guidance is needed to provide clarity

<u>53.490 Design and Analyses Interfaces</u>

- (raised in January 2021 Part 53 meeting) Meaning of “control of interfaces” is unclear-- it seems to be change control, configuration management, etc.; please explain last sentence *[“Changes to design features and related programmatic controls over the lifetime of an advanced nuclear plant must be considered along with the state of technology, the economics of improvements in relation to the state of technology, operating experience, and benefits to the public health and safety, and other factors included in the assessments performed under the facility safety program required by § 53.800.”]* because intent of requirement is not clear.
- What is “state of technology” and “economics of improvements”? Is this something that is done once or continuously?
- What does it mean to “consider risk reduction measures?”
- Does NRC plan to provide guidance for “economics of improvement?”
- Does this imply that licensees must self-backfit if someone can identify an enhancement?

United States NIC Nuclear Industry Council

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

Discussion

MEETING BREAK

Meeting to resume in 15 minutes

Subpart E
Construction and Manufacturing Requirements

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 E Layout

- **§ 53.600 – Scope and Purpose**
- **§ 53.610 – Construction**
  - Management and Control
  - Construction Activities
  - Inspection and Acceptance
  - Communication
- **§ 53.620 – Manufacturing**
  - Management and Control
  - Manufacturing Activities
  - Fuel Loading
  - Communication
  - Transportation
  - Acceptance and Installation at the Site

§ 53.600 – Scope and Purpose

- Subpart applicable to construction and manufacturing activities authorized by Construction Permit, Combined License, Manufacturing License (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
  - Quality Assurance (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 ML, conform to generally accepted codes and standards
  - Procedures in place to appropriately handle special nuclear material, fresh fuel, fire protection, emergency planning, 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

U.S. Nuclear Industry Council Comments for NRC Part 53 Public Meeting: Subpart E: Construction and Manufacturing

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8 April 2021

Subpart E: Construction

- USNIC previously provided comments in February 2021 Part 53 meeting on NRC draft white paper *"SAFETY REVIEW OF POWER REACTOR CONSTRUCTION PERMIT APPLICATIONS"*

- Discussion held to facilitate discussion of the safety review of LWRs and non-LWR construction permit (CP) applications, which is important because US DOE Advanced Reactor Demo Program CP applications expected in a few years

  Q: Will that NRC white paper and stakeholder comments be reflected in future iterations if this Subpart E, and if so how and when?

Subpart E: Manufacturing

- Industry interest in a Manufacturing License (ML)
- Industry currently evaluating Subpart E
- Initial Impressions and areas for further dialogue:
  - Focus Part 53 ML on ultimate reactor safety and security
  - Allow current Part 70 licensing process to address manufacturing process and facility safety
  - Allow current Part 71 licensing process to address transportation
  - Incorporating manufacturing process and facility safety from Part 70 and transportation from Part 71 into ML likely to be difficult and of minimal value
  - Address unique aspects of manufacturing that impact reactor safety in Part 53 ML (e.g., design and fabrication for transport, factory acceptance testing, post transport inspection)
  - Consider an appropriate line of demarcation between what is covered satisfactorily in Part 70 or 71 and what needs to be in Part 53

Subpart E: Manufacturing (continued)

- Focus Part 53 on reactor safety so it does not perturb or confuse current licensing of a reactor with a “supplier” who delivers an assembled reactor
  - May wish to distinguish between manufacturing vendor doing "built to print" and a developer/designer which plans to manufacture themselves
- Want Part 53 ML that results in design and delivery finality (FSAR and SER) for use by a COL
- Recommend specific focused dialogue on ML with current Part 70 licensees and NMSS

Subpart E: Construction and Manufacturing Requirements

NEI Comments

Subpart E: Construction and Manufacturing Requirements

Discussion

Key Guidance

Key Guidance by Subpart

Subpart A: General Provisions	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	
Subpart B: Safety Criteria	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	▪ Further explanation of criteria and two-tier structure in the Statements of Consideration
Subpart C: Design and Analysis	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ NEI 18-04 & RG 1.233, LMP ▪ American Nuclear Society (ANS) / American Society of Mechanical Engineers (ASME)-RA-S-1.4 (Non-LWR PRA Standard) ▪ ANS/ASME Standards ▪ Fuel Qualification ▪ RG 1.232, Advanced Reactor Design Criteria	▪ Application of Analytical Margins ▪ Treatment of Chemical Hazards
Subpart D: Siting Requirements	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ SECY-20-0045/RG 4.7, Siting ▪ External Hazard Updates ▪ Risk-Informed Seismic Design (RES); ANS 2.26	N/A

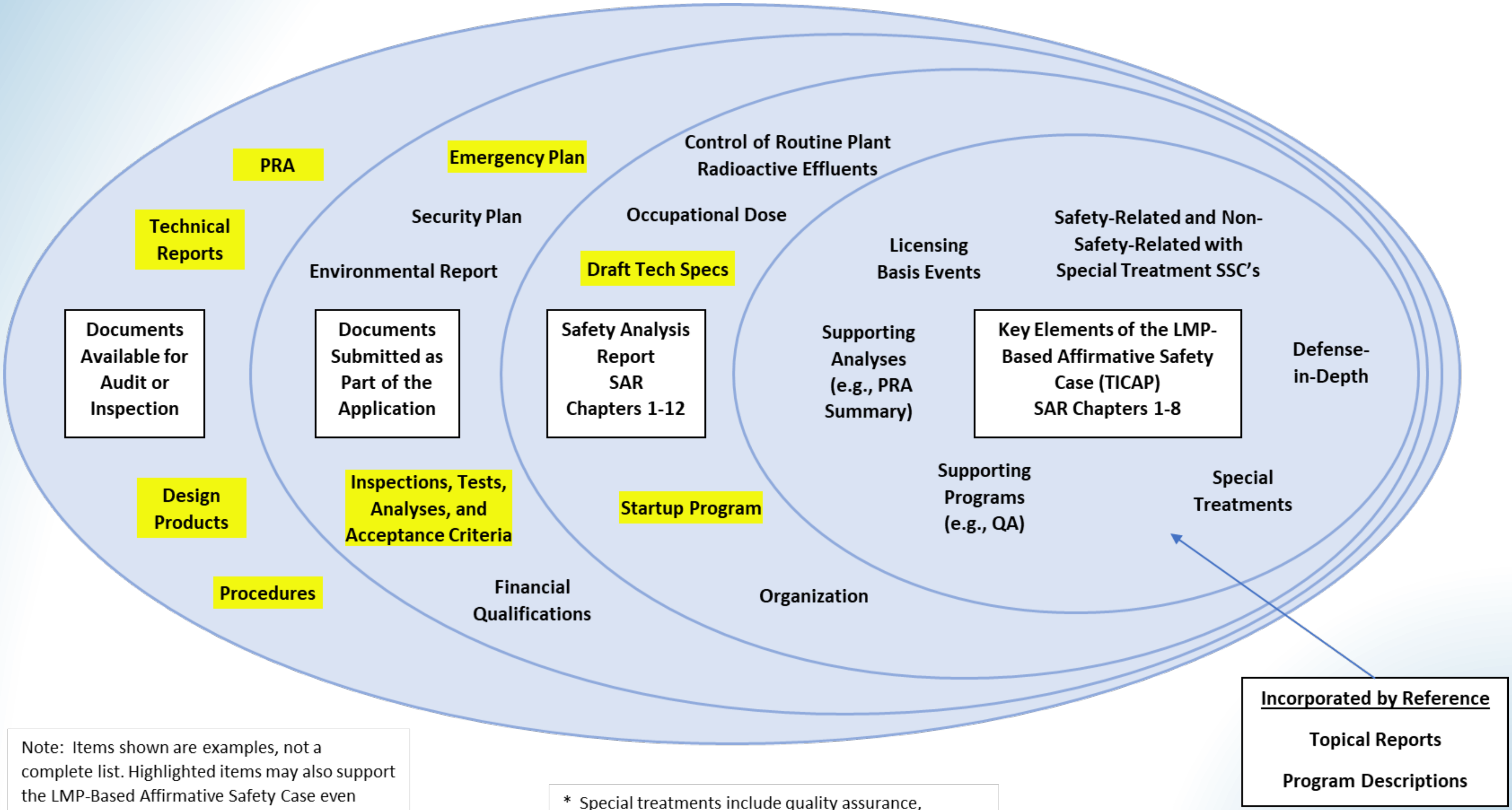
Key Guidance by Subpart

Subpart E: Construction and Manufacturing	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	▪ Manufacturing Guidance ▪ QA Alternatives
Subpart F: Operations	
SSCs	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ NEI 18-04 & RG 1.233, LMP	▪ TS ▪ Special Treatment (possible industry initiative) ▪ Maintenance, Repair & Inspection
Personnel	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ DRO Paper/preliminary Interim Staff Guidance	▪ Concept of Operations
Programs	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ EP for SMRs / Other New Technologies Final Rule, RG 1.242 ▪ Radiation Protection	▪ Emergency Preparedness ▪ Security Programs ▪ Facility Safety Program

Key Guidance by Subpart

Subpart G: Decommissioning	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	N/A
Subpart H: Licensing	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ Technology Inclusive Content of Applications Project (TICAP) ▪ ARCAP	▪ MLs ▪ Possibly Conceptual Design
Subpart I: Maintaining Licensing Basis	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	▪ 50.59 Equivalent ▪ Final Safety Analysis Report / PRA Updates
Subpart J: Administrative/Misc.	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	▪ Reporting Requirements ▪ Financial/Liability

Visual Depiction of TICAP Guidance in Context of an Advanced Reactor Application (Taken from Industry TICAP presentation)



Note: Items shown are examples, not a complete list. Highlighted items may also support the LMP-Based Affirmative Safety Case even though they are not inside the TICAP area.

* Special treatments include quality assurance, reliability assurance, protection against design basis external events, equipment qualification, in-service inspection, etc., as described in NEI 18-04 Table 4-1.

NEI Comments

Key Guidance

USNIC Comments

Discussion of Key Guidance

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

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 May 6, 2021.
  - The preliminary proposed rule text will be posted on regulations.gov under docket ID NRC-2019-0062 before the public meeting.
- The NRC staff is tentatively scheduled to meet with the ACRS Future Plants Subcommittee on April 22, 2021.

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 Document Access Management System
AEA	Atomic Energy Act
ALARA	As low as reasonably achievable
ANS	American Nuclear Society
ARCAP	Advanced Reactor Content of Applications Project
ASME	American Society of Mechanical Engineers
CFR	Code of Federal Regulations
COL	Combined operating license
CP	Construction permit
DBAs	Design basis accidents
DID	Defense in depth

DOE	U.S. Department of Energy
DRO	Division of Reactor Oversight
DSA	Deterministic safety analysis
EAB	Exclusion area boundary
FSAR	Final safety analysis report
GDC	General design criteria
HFE	Human factors engineering
IAEA	International Atomic Energy Agency
LBE	Licensing basis event
LMP	Licensing Modernization Project
LPZ	Low population zone
LWRs	Light water reactors

Acronyms and Abbreviations

ML	Manufacturing license
NEI	Nuclear Energy Institute
NEIMA	Nuclear Energy Innovation and Modernization Act
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
NSRSS	Non-safety related but safety significant
NWPA	Nuclear Waste Policy Act
PRA	Probabilistic risk analysis
PSA	Probabilistic safety assessment
QA	Quality assurance
QHOs	Quantitative health objectives

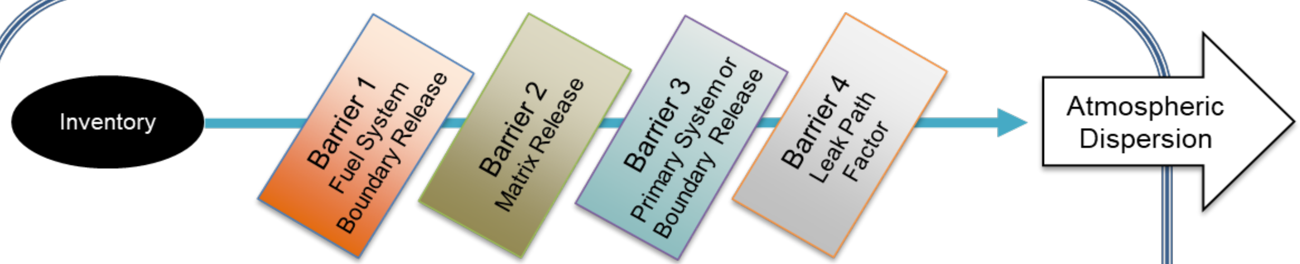
RO	Reactor operator
SAR	Safety analysis report
SAT	Systems approach to training
SER	Safety evaluation report
SMRs	Small modular reactors
SRO	Senior reactor operator
SSCs	Structures, systems, and components
STA	Shift technical advisor
TICAP	Technology-Inclusive Content of Applications Project
TS	Technical specifications
USNIC	U.S. Nuclear Industry Council

Background Slides

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

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



$$\underbrace{I(RN_j)}_{\text{Initial inventory}} \cdot \underbrace{F(S_i,t) \cdot MR(S_i,RN_j,t) \cdot PSR(S_i,RN_j,t) \cdot LPF(S_i,RN_j,t)}_{\text{Factors}} = ST(S_i,RN_j,t)$$

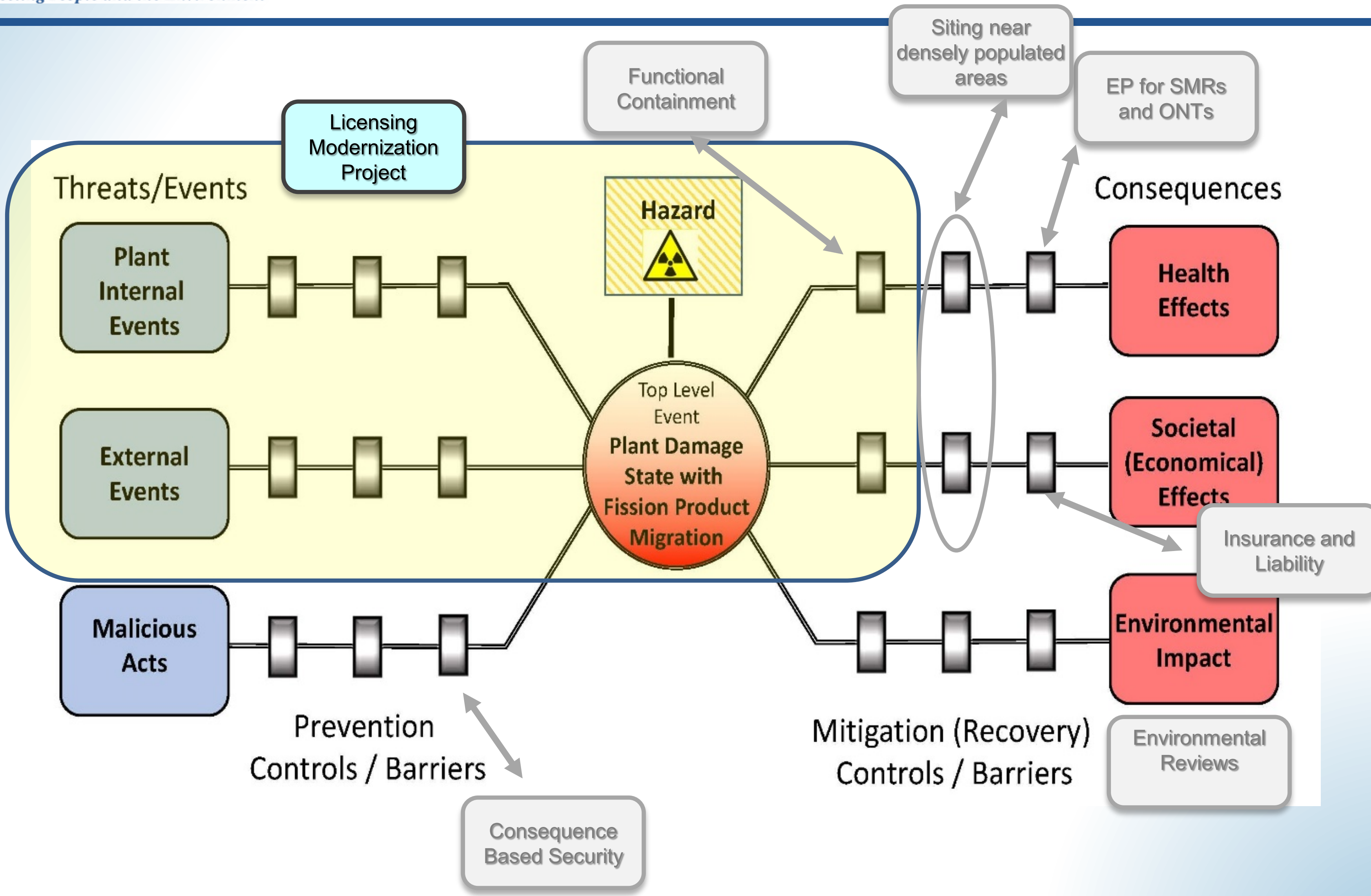
Initial inventory

Factors that determine how much of the inventory is released across a given barrier and thus persists to the source term

Each factor is, in turn, a function of its initial design characteristics (e.g., materials), operating conditions (e.g., burnup, aging) and *transient/accident conditions (e.g., time, temperatures, pressures, chemistry)*.

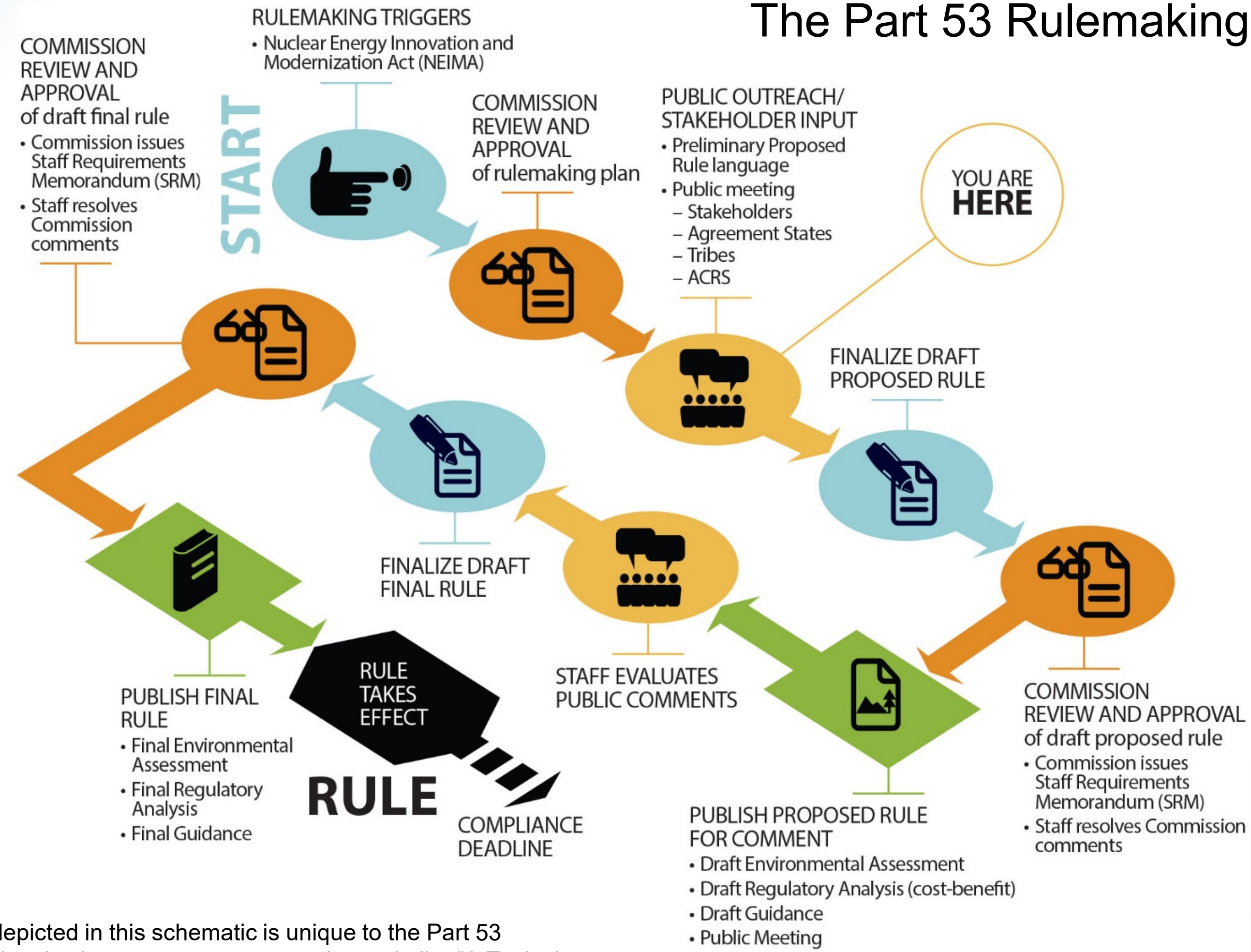
See: SECY-18-0096, “Functional Containment Performance Criteria for Non-Light-Water-Reactors,” and INL/EXT-20-58717, “Technology-Inclusive Determination of Mechanistic Source Terms for Offsite Dose-Related Assessments for Advanced Nuclear Reactor Facilities”

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, …