United States Nuclear Regulatory Commission

Protecting People and the Environment

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

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

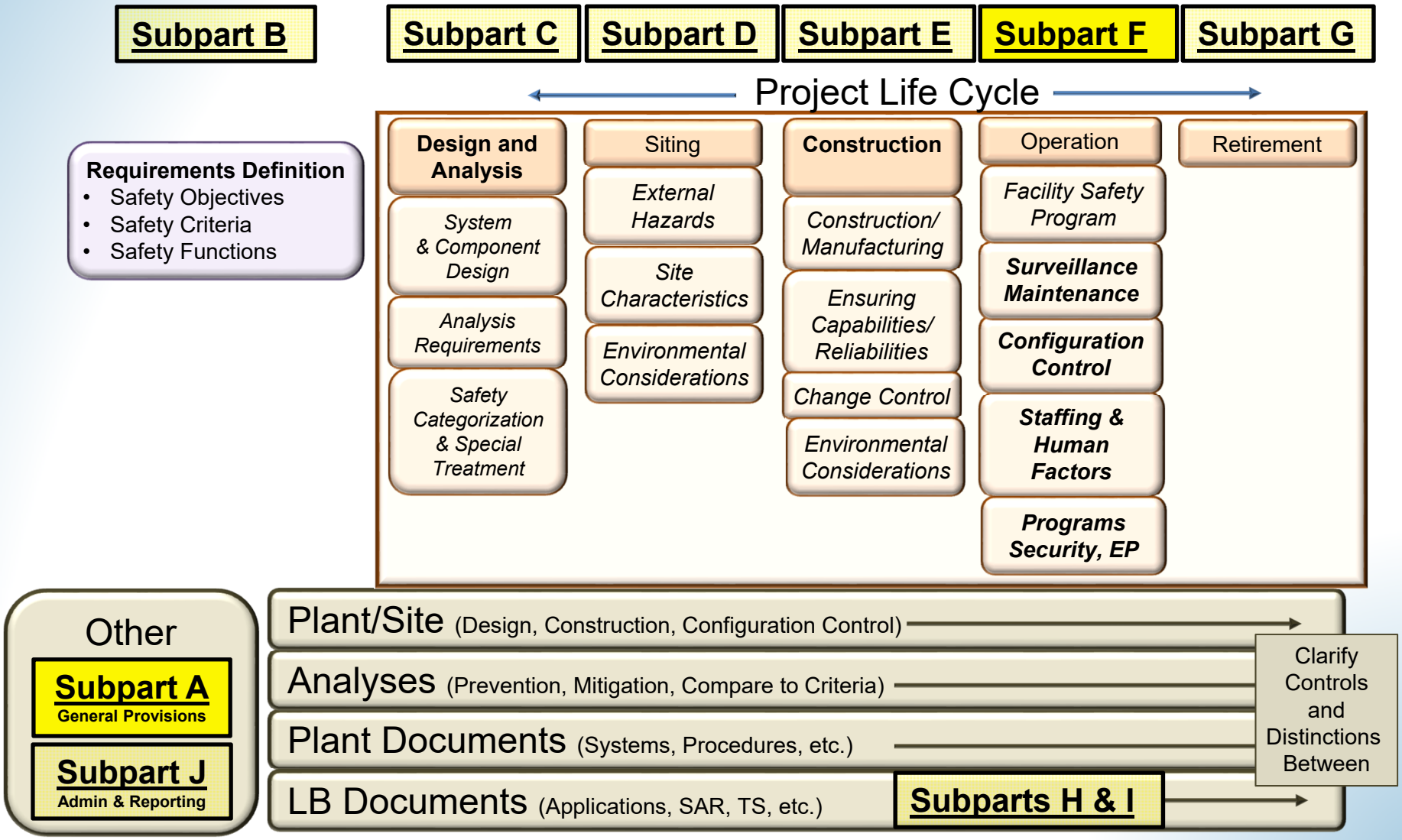
Subparts A and F Preliminary Proposed Rule Language and White Paper on Human Factors

May 20, 2021

Agenda

9:30am – 9:40am	Welcome / Introductions / Logistics / Goals
9:40am – 11:15am	White Paper – "Risk-Informed and Performance-Based Human-System Considerations for Advanced Reactors"
11:15am – 1:00pm	Subpart A – General Provisions
1:00pm – 2:00pm	Lunch Break
2:00pm – 4:00pm	Subpart F – Section 53.700, "Operational Objectives" and Controls on Equipment
4:00pm – 5:30pm	Subpart F – Section 53.800, "Programs"
5:30pm – 6:00pm	Discussion/Closing Remarks

NRC Staff Plan to Develop Part 53



NRC Staff Engagement Plan

ACRS Interactions

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

	Concept/Introduction
	Discussion
	Interim Staff Resolution

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

May 20, 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) requires the NRC to complete a rulemaking to establish a *technology-inclusive*, regulatory framework for optional use for commercial *advanced nuclear reactors* by 2027.
- NRC currently developing 10 CFR 53: *"Licensing and Regulation of Advanced Nuclear Reactors."*

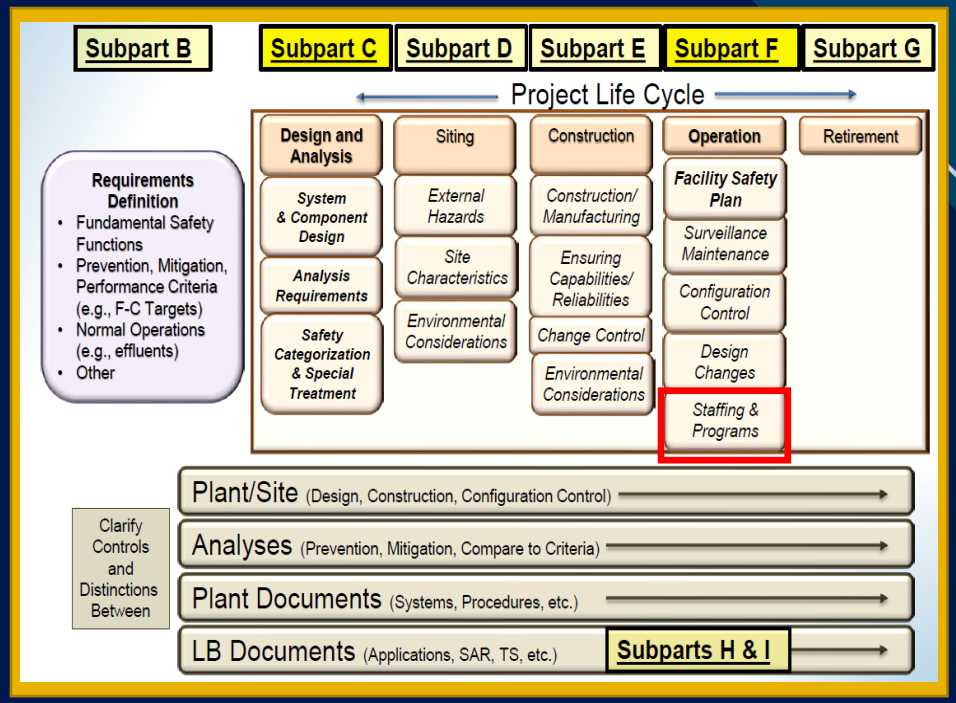
Supporting Guidance

- 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 ACRS 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

Subpart F "Operations" preliminary rule language

- 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 – 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.

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 (DID), 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 DID 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 DID.
- 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 U.S. 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 technical specifications (TS) or result in unsafe conditions.

White Paper Considerations

DID and Advanced Reactor Operations

- The NRC has had a long-standing policy of ensuring that DID is incorporated into the design and operation of nuclear power plants.
- The key principles of note within the present context are that DID approaches should:
  - Not rely solely on a single operational feature
  - Not rely excessively upon human actions (or programs).
- The role of humans in DID 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 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

Human Factors Engineering

- 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 (HSIs) 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 TSs, 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 will need to 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 DID 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 will need to 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 (BNL) 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, DID, 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., Tech Spec 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 a 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 related analyses (e.g., designs of control room HSIs 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.

Next Steps

The objectives are being addressed using the approach below…

Draft Part 53 Rule Language

- Prescriptive criteria for not using licensed operators
- Content of Applications; to address inclusion of the Concept of Operations and the HFE-related information needed to for advanced reactor applications.
- HFE and Operating License (OL) Integration – an overall objective in development of both rule language and guidance.

Regulatory Guidance

- Technology-Inclusive OL - efforts to create an ISG are underway via NRR/RES working group; national lab support is being pursued.
- Flexible Staffing – efforts to create an ISG being coordinated in NRR and RES.
- Scalable HFE Reviews – efforts to create ISG underway via NRR/RES working group with national lab support (BNL).

White Paper Considerations

Final Thoughts

- Draft concepts in white paper meant to solicit feedback on key areas of advanced reactor operations. Final scope and guidance outcome 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 as part of an application (such as Licensing Modernization Project (LMP), maximum hypothetical accident (MHA), 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*

- Additional stakeholder interactions will follow in coming months. Industry feedback expected July 2021 timeframe.
- The NRC staff are evaluating resources/schedule to identify what areas of the guidance to prioritize.
- Initial discussions with national labs to assist with expertise
- White Paper guidance in final form will support development of proposed 10 CFR 53 rule language and regulatory guidance.
- Final form of guidance is still being evaluated. For example:
  - Interim Staff Guidance
  - Regulatory Guide

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

Thank You!

Questions/Comments?

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Human-System Operation Considerations

Discussion

General Provisions and Definitions – Subpart A

Part 53 General Layout

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

10 CFR Part 53 Subpart A Layout

- § 53.010 – Scope
- § 53.020 – Definitions
- § 53.040 – Written Communications
- § 53.050 – Deliberate Misconduct
- § 53.060 – Employee Protection
- § 53.070 – Completeness and Accuracy of Information
- § 53.080 – Specific Exemptions
- § 53.090 – Combining Licenses; Elimination of Repetition
- § 53.100 – Jurisdictional Limits
- § 53.110 – Attacks and Destructive Acts
- § 53.120 – Information Collection Requirements: Office of Management and Budget Approval

Subpart A – § 53.020 Definitions

- Advanced nuclear plant
  - "*Advanced nuclear plant [or facility]* means a utilization facility consisting of one or more advanced nuclear reactors [as defined in NEIMA] and associated co-located support facilities, which may include one or more reactor modules, [*using nuclear fission, nuclear fusion, or accelerator-driven reactor technologies*] that are used for producing power for commercial electric or other commercial purposes. The advanced nuclear plant includes the collection of sites, buildings, radionuclide sources, and structures, systems, and components for which a license is being sought under this part."

- Definition of "advanced nuclear reactor" (NEIMA)
  - "a nuclear fission or fusion reactor, including a prototype plant (as defined in sections 50.2 and 52.1 of title 10, Code of Federal Regulations (as in effect on the date of enactment of this Act)), with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act, including improvements such as— (A) additional inherent safety features; (B) significantly lower levelized cost of electricity; (C) lower waste yields; (D) greater fuel utilization; (E) enhanced reliability; (F) increased proliferation resistance; (G) increased thermal efficiency; or (H) ability to integrate into electric and nonelectric applications."
- SECY-20-0032
  - "The staff interprets NEIMA's definition of an advanced nuclear reactor, which states that such a reactor will have 'significant improvements compared to commercial nuclear reactors under construction' as of January 14, 2019, as excluding 'Generation III+' designs from the definition because the AP1000 reactors were under construction at the time of NEIMA's enactment."

Subpart A – § 53.020 Definitions

- Consensus code or standard
  - "means any technical standard (1) developed or adopted by a voluntary consensus standard body under procedures that assure that persons having interests within the scope of the standard that are affected by the provisions of the standard have reached substantial agreement on its adoption, (2) formulated in a manner that afforded an opportunity for diverse views to be considered, and (3) designated by the standards body as such a standard for the safe design, manufacture, construction, or operation of nuclear power plants."

Subpart A – § 53.020 Definitions

- End state
  - "means the set of conditions at the end of an event sequence that characterizes the impact of the sequence on the plant or resulting releases of radionuclides to the environment. In most probabilistic risk assessments, end states typically include success states (i.e., those states with negligible impact) and release categories."
- Event sequence
  - "means a postulated initiating event defined for a set of initial plant conditions followed by system, safety function, and operator successes or failures, and terminating in a specified end state depending on the system, safety function, and operator successes and failures (e.g., prevention of release of radioactive material or release in one of the reactor-specific release categories). An event sequence may include many unique variations of events (e.g., minimal cut sets) that are similar in terms of how they impact the performance of safety functions along the event sequence."

Subpart A – § 53.020 Definitions

- Normal plant operation or normal operation
  - "means operations that are expected to occur during planned operations or shutdown of the reactor."
- Licensing basis events (LBEs)
  - "mean a collection of event sequences considered in the design and licensing of the advanced nuclear plant. LBEs are unplanned events and include AOOs, unlikely event sequences, very unlikely event sequences, and DBAs."
- Design basis accidents (DBAs)
  - "mean postulated event sequences that are used to set functional design criteria and performance objectives for the design of safety-related structures, systems, and components. DBAs are a type of licensing basis event and are based on the capabilities and reliabilities of safety-related structures, systems, and components needed to mitigate and prevent event sequences, respectively."
- Anticipated operational occurrences (AOOs)
  - "mean anticipated event sequences expected to occur one or more times during the life of a nuclear power plant. An event sequences with a mean frequency of 1×10^{-2}/plant-year and greater is an AOO. AOOs take into account the expected responses of all SSCs within the plant, regardless of safety classification. AOOs are a type of *licensing basis event*. [*Based, in part, on Appendix A to part 50.*]"

Subpart A – § 53.020 Definitions

- Unlikely event sequences
  - "mean event sequences that have estimated frequencies below the frequency of AOOs. Unlikely event sequences are a subset of LBEs. [*For example, within the licensing modernization project, this would equate to design basis events with a frequency range of between* $1x10^{-4}$ *and* $1x10^{-2}$ *per plant year with an accounting for uncertainties.*]"
- Very unlikely event sequences
  - "mean event sequences that have estimated frequencies well below the frequency of events expected to occur in the life of an advanced nuclear plant. Very unlikely event sequences are a subset of LBEs. [*For example, within the licensing modernization project, this would equate to beyond design basis events with a frequency range of between* $5x10^{-7}$ *and* $1x10^{-4}$ *per plant year with an accounting for uncertainties.*]"

- The frequency ranges were incorrect in the publicly-released preliminary proposed rule language. The NRC staff have corrected the error in the definitions above and will update the definitions in a future iteration of subpart A, General Provisions.

Subpart A – § 53.020 Definitions

- Safety-related (SR)
  - "means those SSCs and human actions that warrant special treatment and are relied upon to demonstrate compliance with the safety criteria in § 53.210(b)."
- Non-safety related but safety significant (NSRSS)
  - "means those SSCs and human actions that warrant special treatment and are not safety-related but are relied on to achieve defense-in-depth or perform risk-significant functions."
- Non-safety significant (NSS)
  - "means those SSCs not warranting special treatment, are not safety-related, and are not relied on to achieve adequate defense-in-depth or to perform risk-significant functions."

Subpart A – § 53.020 Definitions

- Special treatment
  - "means those requirements, such as measures taken to satisfy functional design criteria, quality assurance, and programmatic controls, that provide assurance that certain SSCs will provide defense-in-depth or perform risk-significant functions and that provide confidence that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in § 53.210(b) and § 53.220(b)."
- Defense in depth
  - "means inclusion of multiple independent and redundant layers of defense in the design of a facility and its operating procedures to compensate for potential human and mechanical failures so that no single layer of defense, no matter how robust, is exclusively relied upon. Defense-in-depth includes, but is not limited to, the use of access controls, physical barriers, redundant and diverse key safety functions, and emergency response measures."

Subpart A – § 53.020 Definitions

- Design features
  - "means the active and passive structures, systems, or components and inherent characteristics of those structures, systems or components that contribute to limiting the total effective dose equivalent to individual members of the public during normal operations and prevent or mitigate the consequences of unplanned events."
- Inherent characteristic
  - "means an attribute of a design feature that has such a high degree of certainty in its performance that uncertainties need not be quantified."
- Functional design criteria
  - "means requirements for the performance of SSCs. For safety-related SSCs, these criteria define requirements necessary to demonstrate compliance with first tier safety criteria in § 53.210(b). For non-safety-related but safety-significant SSCs, these criteria define requirements necessary to meet the second tier safety criteria in § 53.220(b)."

Subpart A – § 53.040 - § 53.120 Other Administrative Requirements

- Subpart A consistent with Part 50 and currently includes bracketed references to existing requirements in Parts 50, 52, etc.
- Intending to develop Part 53 with largely no pointers to Parts 50 and 52; this will require copying and pasting the Part 50 or 52 language into Part 53 instead of using pointers.
- Subpart A will include many pointers to other sections of Part 53 that will be added in future iterations.

Subpart A – Stakeholder Feedback

- Advanced nuclear plant
  - Allow broad applicability for advanced reactors under Part 53.
- Design basis accident
  - Clarify the relationship between DBAs and 'unlikely event sequences' and 'very unlikely event sequences.'
- Consensus codes and standards
  - Questioned use of "must" in definition and asked if term includes general engineering standards, such as IEEE.
- Defense in depth
  - Update subpart B to match the definition in subpart A because the definition excludes the clause that no single feature should be exclusively relied upon.
- Safe, stable end state
  - Clarify if this term requires complete shutdown or demonstration of no further inventory release.
- Safety related, Non-safety related, Non-safety related but safety significant
  - Clarify these terms in a way that reduces overlap.

Subpart A – General Provisions

Discussion

U.S.NRC

United States Nuclear Regulatory Commission

Protecting People and the Environment

MEETING BREAK

Meeting to resume in 1 hour

Subpart F – Operational Objectives

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
  - Operational Objectives
- Subpart G, Decommissioning Requirements
- Subpart H, Applications for Licenses, Certifications and Approvals
- Subpart I, Maintaining and Revising Licensing Basis Information
- Subpart J, Reporting and Administrative Requirements

Subpart F – § 53.700 Operational Objectives

- Licensee must:
  - Define structures, systems, and components (SSCs)
  - Maintain capabilities and reliabilities of SSCs
  - Ensure plant personnel have adequate knowledge and skills to perform their assigned duties to support safety functions
  - Implement plant programs sufficient to ensure the performance of identified safety functions

Subpart F – § 53.710 Transition to Operation

- Prepare a transition plan from construction to operations
  - Demonstrate the SR and NSRSS SSCs are appropriately constructed and capable to perform
  - Plant personnel are appropriately licensed and trained to perform safety functions
  - Programs, procedures and controls are implemented to support the safety functions

Subpart F – § 53.720 Maintaining Capabilities

- Capabilities and reliability of SSCs, when combined with associated programmatic controls and human actions, provide reasonable assurance that the safety criteria defined in §§ 53.210(b) and 53.220(b) will be met.
- Paragraph (a) defines controls for SR SSCs (technical specifications).
- Paragraph (b) defines controls for NSRSS SSCs (reliability assurance and other special treatment).

Subpart F – § 53.720(a) Technical Specifications (TS)

- TS required to define conditions or limitations on SSCs to fulfill safety functions (§ 53.230) and first tier safety criteria (§ 53.210(b))
  - Inventories of radioactive materials
  - Operating limits
  - For each SSC classified as safety related
    - Limiting Conditions for Operation
    - Surveillance Requirements
  - Design Attributes
  - Administrative Controls
  - *Decommissioning*

- First iteration does not include:
  - Safety limits or associated limiting safety system settings
  - Criteria for limiting conditions for operation
- Some stated preferences to use deterministic approaches may be better addressed within Part 50.

Subpart F – § 53.720(b) Special Treatment of NSRSS SSCs

- Configurations and special treatments for NSRSS SSCs ensure capabilities, availabilities, and reliabilities to satisfy second tier safety criteria (§ 53.210(b)).
- Controls must:
  - Identify authorities and processes for configuration changes
  - Describe means by which special treatments for each NSRSS SSC will be provided and maintained

- Controls for NSRSS SSCs needed to implement a performance-based approach used to gain operational flexibilities and as part of methods that include replacing the single-failure criterion with a probabilistic (reliability) approach.
- Deterministic approaches with different supporting analysis, safety classification schemes, and design approaches (e.g., inclusion of the single failure criterion) may be better addressed within Part 50.

Subpart F – § 53.730
Maintenance, Repair and Inspection

a) Develop a program to maintain and repair SR and Safety Significant SSCs.
b) Take appropriate corrective action when NSRSS SSCs do not meet special treatment requirements or performance goals.
c) Evaluate performance and preventive maintenance activities every 24 months.
d) Conduct risk-informed assessment of the impact and scope of any maintenance activities.

Subpart F – § 53.740
Design Control

- Assess the potential for adverse effects on safety, security, emergency preparedness (EP), operations, or other items related to plant safety during the design process and before implementing design or operational changes.
  - Physical modifications, procedural changes, operator actions, maintenance activities, system reconfigurations, access modifications or restrictions, changes to the emergency plan and security plan or their implementation.
  - Establish measures for the identification and control of interfaces among plant activities.

Subpart F, Operational Objectives – Stakeholder Feedback

- NRC does not need to regulate NSS SSCs.
- In general, reduce the duplication of requirements for quality assurance, testing, and review language for interactions across sections.
- Clarify safety objectives (§ 53.200), operational objectives (§ 53.700), and programs (§ 53.800) to avoid scope creep in future licensing reviews.
- Allow automated plant surveillance and testing.

Subpart F – Operational Objectives

Discussion

Subpart F – Programs

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
  - Programs
- Subpart G, Decommissioning Requirements
- Subpart H, Applications for Licenses, Certifications and Approvals
- Subpart I, Maintaining and Revising Licensing Basis Information
- Subpart J, Reporting and Administrative Requirements

Subpart F – § 53.800 Programs

- Programs must be provided for each advanced nuclear plant such that, when combined with associated design features and human actions, the plant will satisfy the first and second tier safety criteria defined in §§ 53.210 and 53.220.

Subpart F – § 53.810 Radiation Protection

- Implement a radiation protection program to limit occupational exposure in accordance with Part 20.
- Limit exposure to the public.
  - Develop procedures and remedial actions in an Offsite Dose Calculations Manual (ODCM).
  - ODCM
    - Define methodology used in the calculation.
    - Contain radioactive effluent controls and environmental monitoring activities.
    - Annual Radiological Environmental Operating and Radioactive Effluent Release Reports.

Subpart F – § 53.820 Emergency Preparedness

- Develop and implement an EP Program for operations that is commensurate with the risks posed by the licensing basis events as analyzed in accordance with § 53.450.
  - Staff is developing preliminary proposed rule language for Part 53 in coordination with activities related to the "Emergency Preparedness for Small Modular Reactors and Other New Technologies" rulemaking.

Subpart F – § 53.830 Security Programs

- Develop and implement security programs:
  - Information security
  - Physical security
  - Cyber security
  - Access authorization
  - Material control and accounting

Subpart F – § 53.840
Quality Assurance (QA)

- Develop and execute a QA program:
  - Define duties and responsibilities for QA of SSCs
  - Written QA manual
  - Written procedures
    - Qualified personnel
    - Procurement
    - Handling, shipping and storage of materials
    - Testing and inspection
    - Corrective action
    - Document and configuration control
    - Design control
    - Record keeping
    - Auditing
  - Document results of QA activities

Subpart F – § 53.850
Integrity Assessment Program (IAP)

- Develop and implement an IAP.
- Monitor, evaluate and manage:
  - Effects of aging on SR and NSRSS SSCs whose failure could affect performance of safety functions.
  - Cyclic and transient loads are maintained within applicable design limits.
  - Degradation related to chemical interactions, operating temperatures, irradiation, and other environmental factors to ensure the capabilities and reliabilities of SSCs satisfy the functional design criteria of §§ 53.410(b) and 53.420(b).

Subpart F – § 53.860
Fire Protection

- Develop and implement a fire protection plan:
  - Identify responsible parties and authorities
  - Outline plans for fire protection, detection, suppression capability, and limitation of damage
  - Administrative controls, personnel requirements, and suppression activities
  - Means to limit damage to SR and NSRSS SSCs
- Specific features of program:
  - SR and NSRSS SSCs designed to minimize effect of fires
  - Use noncombustible and fire-resistant materials wherever practical in facility
  - Appropriate capacity and capability
  - Design such that inadvertent operation does not impair SR SSCs

Subpart F – § 53.870
Inservice Testing (IST) and Inservice Inspection (ISI)

- Develop programs for ISI and IST:
  - ISI and IST includes codes and standards supplemented by risk insights
  - Testing and frequency done to maintain reliability of SSCs
  - Documented procedures
- Perform baseline inspections prior to starting operations:
  - Determine benchmarks
  - Develop acceptance criteria
  - Results provided to plant manager and determine need for corrective action

Subpart F – § 53.880 Criticality Safety Program

- The program must address the requirements in 10 CFR 70.24 for maintaining a monitoring system capable of detecting a criticality, having emergency procedures, and providing radiation protection for plant workers.

A topic for discussion is whether the alternatives to 10 CFR 70.24 provided in 10 CFR 50.68, “Criticality accident requirements,” are appropriate and useful in Part 53.

Subpart F – § 53.890
Facility Safety Program (FSP)

- Establish an FSP using a risk-informed, performance-based process to proactively identify new or revised hazards and performance issues.
- Routinely evaluate potential hazards, operating experience, human actions, and programmatic controls.
- Consider measures to mitigate or eliminate the resulting risks.

Subpart F – § 53.892
FSP Performance Criteria

- Take measures to protect public health and minimize danger to life or property as may be reasonably achieved when considering costs.
  - Assess risk reduction measures related to radionuclide release during normal operation.
  - Assess risk reduction measures for contributors to the overall cumulative risk from unplanned events.
- Certified designs/manufacturing licenses must also use change control from Subpart H.

Subpart F – § 53.894
FSP Plan

- FSP must use written plan and address:
  - Scope of facilities covered
  - How FSP will be implemented
  - How personnel will be trained in FSP
  - Risk-informed hazard management program
  - Technology assessment program
  - Internal facility safety program assessment

- Note that staff is looking at the possibility that some of the administrative details in the first iteration language might be addressed within guidance documents.

Subpart F – § 53.896 Review, Approval, and Retention of FSP

- FSP plan is part of the application
- NRC to review/approve FSP plan
- Will define staff process for reviewing FSP plan changes and amendments

Subpart F – § 53.900 Procedures and Guidelines

- Integrated set of procedures and guidelines to maintain normal operations and respond to unplanned events
- Plan must address:
  - Plant operations
  - Maintenance under § 53.730
  - Program requirements under this subpart (e.g., radiation protection, QA, Integrity Assessment)
  - Emergency operating procedures if human intervention required
  - Accident management guidelines

Subpart F, Programs – Stakeholder Feedback

- Industry stakeholder feedback focused on regulatory burden
  - Industry stakeholders urged NRC to reduce net burden with Part 53 rule. Concern new subpart F provisions will increase burden, including transition to operations (§ 53.710), integrity assessment programs (§ 53.850), criticality safety program (§ 53.880), and facility safety program (§ 53.892).
  - Industry stakeholders concerned regulatory burden makes rule unattractive.
- NGO stakeholder disagreed with industry feedback and suggested NRC staff revert to traditional notice and comment rulemaking process.

Subpart F: Programs

Discussion

Discussion on Previously Released Subparts and Integration of Subparts

(if time allows)

Stakeholder Feedback on Previously Released Subparts

- Subpart B – Technology-Inclusive Safety Requirements
  - Some stakeholders commented that the NRC need not regulate NSS SSCs.
  - A stakeholder asked the NRC to clarify how inherent characteristics could be credited for DID.
  - Industry stakeholders characterized the NRC's second iteration of subpart B as less than transformational and reiterated concerns about the two-tiered safety construct.
- Subpart C – Design and Analysis Requirements
  - Industry stakeholders would prefer NRC adopt a graded approach to PRA.

Stakeholder Feedback on Previously Released Subparts

- Subpart D – Siting Requirements
  - Industry stakeholders expressed support for the potential to collapse the exclusion area boundary and the low population zone to the site boundary.
- Subpart E – Construction and Manufacturing Requirements
  - Stakeholders asked the NRC to clarify the scope and applicability of a manufacturing license (ML) as it may relate to subcontractors, transportation, the completion status of the reactor, and linkage to the combined license.
  - Industry stakeholders will provide input on potential business models for ML applicants and the timeframe for these business models so that the NRC can develop appropriate and timely requirements.

Previously Released Subparts

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 (11 months)
Submit Draft Proposed Rule Package to Commission	May 2022
Publish Proposed Rule and Draft Key Guidance	October 2022
Public Comment Period – 60 days	November and December 2022
Public Outreach and Generation of Final Rule Package	January 2023 to February 2024 (14 months)
Submit Draft Final Rule Package to Commission	March 2024
Office of Management and Budget and Office of the Federal Register Processing	July 2024 to September 2024
Publish Final Rule and Key Guidance	October 2024

Acronyms and Abbreviations

ACRS	Advisory Committee on Reactor Safeguards
AEA	Atomic Energy Act
AOO	Anticipated operational occurrence
BNL	Brookhaven National Laboratory
CFR	Code of Federal Regulations
DBA	Design basis accident
DID	Defense in depth
EP	Emergency preparedness
FSP	Facility Safety Program
HFE	Human factors engineering
HSI	Human-system interface
IAP	Integrity Assessment Program

ISG	Interim staff guidance
ISI	Inservice testing
IST	Inservice inspection
LBE	Licensing basis event
LMP	Licensing Modernization Project
LWR	Light water reactor
MHA	Maximum hypothetical accident
ML	Manufacturing license
NEIMA	Nuclear Energy Innovation and Modernization Act
NGO	Non-governmental organization
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation

Acronyms and Abbreviations

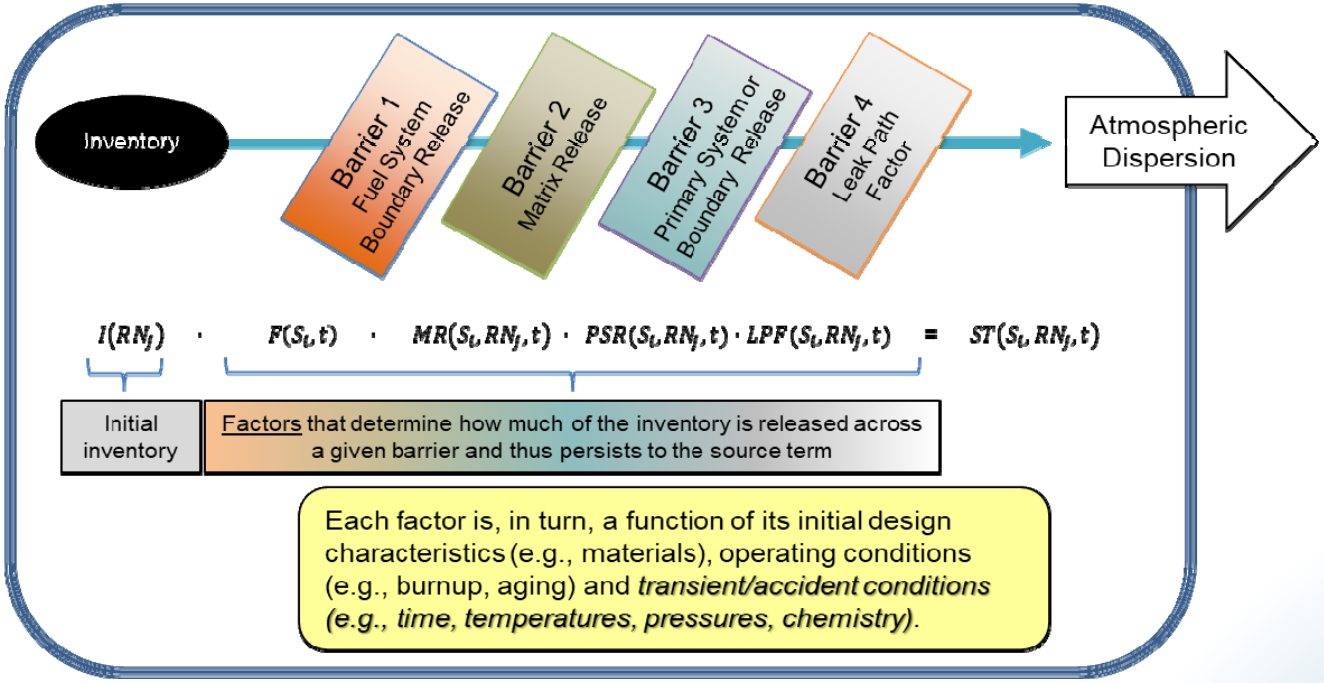
NSRSS	Non-safety related but safety significant
NSS	Non-safety significant
NWPA	Nuclear Waste Policy Act of 1982
ODCM	Offsite Dose Calculations Manual
OL	Operating license
PRA	Probabilistic risk assessment
QA	Quality assurance

RES	Office of Nuclear Regulatory Research
SAT	Systems Approach to Training
SMR	Small modular reactor
SR	Safety related
SSC	Structures, systems, and components
STA	Shift technical advisor
TS	Technical specifications

Background Slides

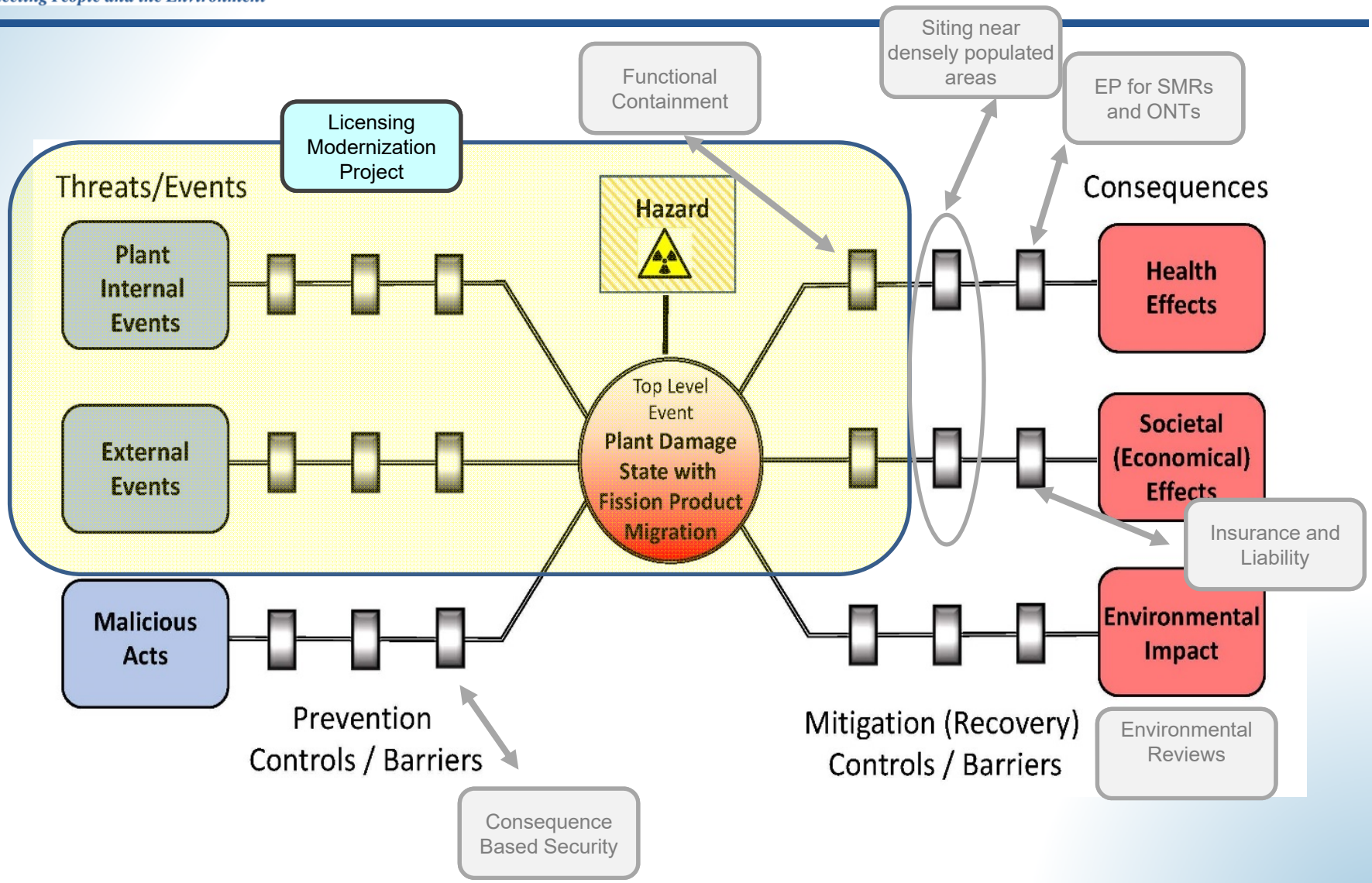
First Principles

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



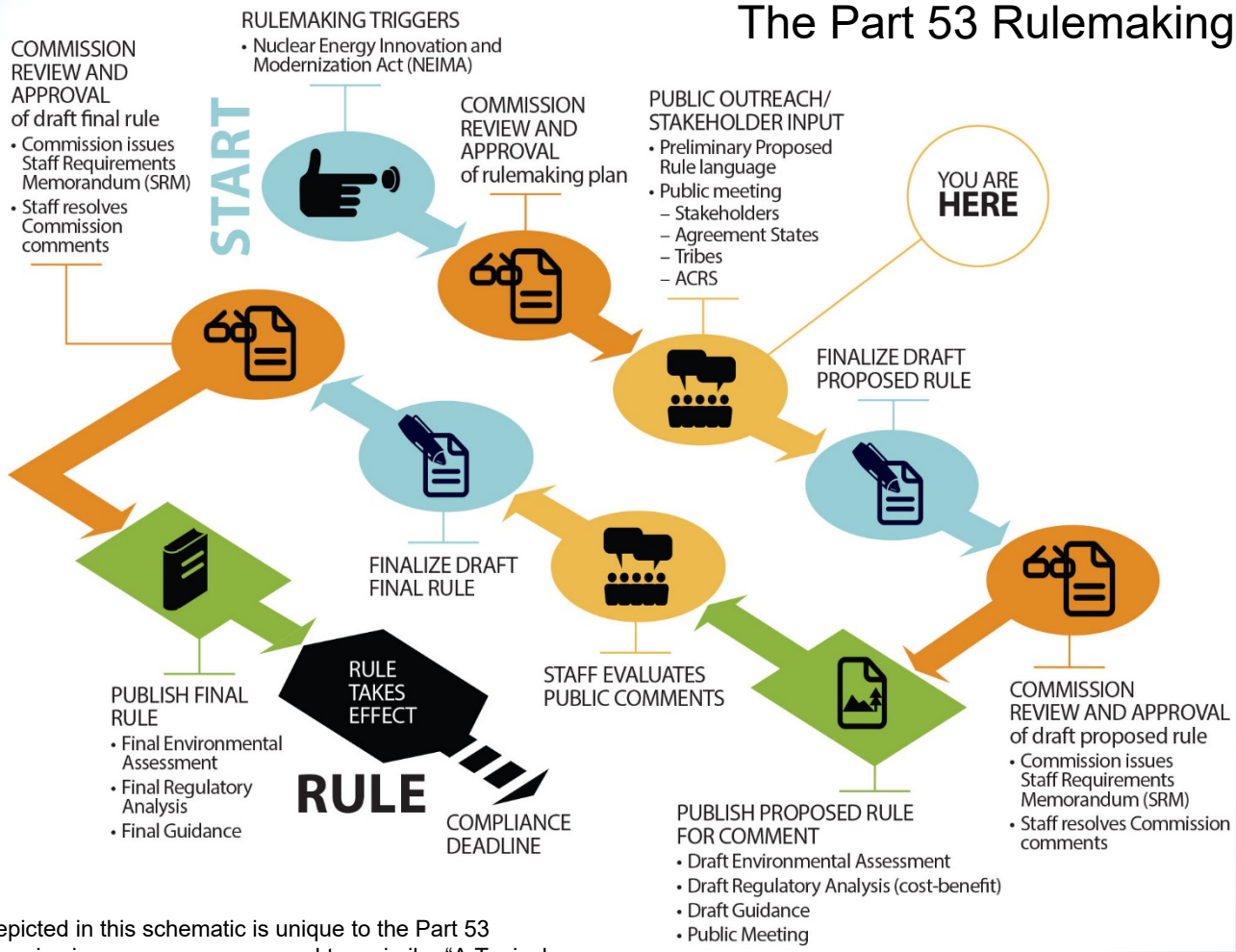
See: SECY-18-0096, "Functional Containment Performance Criteria for Non-Light-Water-Reactors," and INL/EXT-20-58717, "Technology-Inclusive Determination of Mechanistic Source Terms for Offsite Dose-Related Assessments for Advanced Nuclear Reactor Facilities"

Integrated Approach



Part 53 Rulemaking

The 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, …