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Protecting People and the Environment

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

Subparts C and F Preliminary Proposed Rule Language

January 7, 2021

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Agenda

12:00pm – 12:10pm	Welcome/Introductions/Logistics
12:10pm – 2:00pm	Subpart C – Requirements for Design and Analysis
2:00pm – 2:15pm	BREAK
2:15pm – 3:30pm	Subpart F – Facility Safety Program
3:30pm – 4:15pm	Key public comments on Subpart B – Technology-Inclusive Safety Requirements
4:15pm – 4:30pm	Additional Public Comments/Closing Remarks

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Welcome/Introductions

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

Speakers/Presenters:
Bob Beall, NMSS – Rulemaking PM & Meeting Facilitator
Nanette Valliere, NRR – Technical Lead
Bill Reckley, NRR – Technical Lead
Marc Nichol, Nuclear Energy Institute
Cyril Draffin, U.S. Nuclear Industry Council
Michael Keller, Hybrid Power Technologies

Public Meeting Slides: ADAMS Accession No. ML21006A000

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Purpose of Today's Meeting

- Review preliminary proposed rule language for Part 53
  - Subpart C – Requirements for Design and Analysis
  - Subpart F – Requirements for Operations
    - Facility Safety Program
- Discuss stakeholder comments on Part 53 Subpart B from November 18, 2020, public meeting
- Today's meeting is a Category 3 public meeting, which means that public participation is actively sought in the discussion of the regulatory issues during the meeting.
  - The meeting is being transcribed and the transcription will be available with the meeting summary by February 6, 2021.
- No regulatory decisions will be made at today's meeting.

NRC Staff Plan to Develop Part 53

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

Project Life Cycle

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

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

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** →

NRC Staff Engagement Plan

Stakeholder Interactions									
	Framework	**Safety Criteria**	**Design**	**Siting**	**Construction**	**Operations**	**Decommissioning**	**Licensing**	**General/Admin**
Nov 20									
Dec 20									
Jan 21									
Feb 21									
Mar 21									
Apr 21									
May 21									
Jun 21									
Jul 21	Consolidated Technical Sections								
Aug 21									
Sep 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
	Discussion
	Closure

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.

Part 53 General Layout

- Subpart A, General Provisions
- Subpart B, Technology-Inclusive Safety Objectives
- Subpart C, Design and Analysis
- Subpart D, Siting
- 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 C Layout

- **§ 53.400** – Design Objectives and Design Features
- **§ 53.410** – Functional Design Criteria for First Tier Safety Criteria
- **§ 53.420** – Functional Design Criteria for Second Tier Safety Criteria
- **§ 53.430** – Functional Design Criteria for Protection of Plant Workers
- **§ 53.440** – Design Requirements
- **§ 53.450** – Analysis Requirements
- **§ 53.460** – Safety Categorization and Special Treatment

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10 CFR Part 53 Subpart C Layout

- **§ 53.470** – Application of Analytical Safety Margins to Operational Flexibilities
- **§ 53.480** – Design Control Quality Assurance
- **§ 53.490** – Design and Analysis Interfaces

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§ 53.400 – Design Objectives and Design Features

- Design Objectives and Design Features
  - Establishes the overall design objectives by referring to the underlying safety criteria and the identification of safety functions.
  - Design features must be provided such that, when combined with associated programmatic controls and human actions, there is reasonable assurance the safety criteria will be met.

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§§ 53.410 & 53.420 – Functional Design Criteria

- First Tier Safety Criteria
  - Effluents during normal operation do not result in a dose to an individual member of the public exceeding 100 millirem.
  - Design features and functional design criteria for unplanned events are determined through analyses.
- Second Tier Safety Criteria
  - Doses from effluents during normal operation are as low as reasonably achievable (ALARA).
  - Design features and functional design criteria for unplanned events are determined through analyses.

Note that performance-based approaches for Part 53 safety criteria for normal operations are being discussed as part of the advanced reactor content of applications project (ARCAP). Performance-based approaches for licensing basis events are being incorporated into sections on analyses and programmatic controls within Subpart F (Operations).

§ 53.430 – Protection of Plant Workers

- Functional Design Criteria for Protection of Plant Workers
  - Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with occupational dose limits provided in Subpart C to 10 CFR Part 20.
  - Functional design criteria must be defined for each design feature to ensure that plant SSCs achieve occupational doses as low as is reasonably achievable.

Note that inclusion of requirements for protection of plant workers within Part 53 is a topic of ongoing discussions related to Subpart B (Technology-Inclusive Safety Objectives)

§ 53.440 – Design Requirements

- Design features must use generally accepted consensus codes and standards
- Materials must be qualified for their service conditions over plant lifetime
- Safety and security must be considered together
- Design features must be demonstrated capable of accomplishing safety functions without adverse effects to other safety features
  - Analysis
  - Test programs
  - Prototype testing
  - Experience

Note that preliminary rule language refers to “generally accepted consensus codes and standards” and materials being “qualified” for their service conditions. These terms are topics for discussion. Resolution may include rule language, discussions within rulemaking package, and/or developing guidance documents.

§ 53.450 – Analysis Requirements

- Probabilistic risk assessment (PRA)
  - Performed to identify potential failures, degradation mechanisms, susceptibility to hazards, other risks to safety functions
  - Used to determine licensing basis events (LBEs), classify safety significance and human actions, evaluate defense in depth, assess other challenges to plant safety
  - Conforms with generally accepted methods, standards, and practices
  - Maintained and upgraded every two years
- Analytical codes must be qualified for range of conditions for which they are used
- Analyses must assess fire protection, aircraft impacts, and mitigation of select beyond design basis events (BDBEs)
- Analyses must include design basis accidents (DBAs)

§ 53.460 – Safety Categorization and Special Treatment

- Safety Related (SR)
  - SSCs and human actions relied upon to function in response to design basis accidents
- Non-Safety Related but Safety Significant (NSRSS)
  - SSCs and human actions that perform a function that is necessary to achieve adequate defense-in-depth or are classified as risk significant
    - Failure contributes 1% or more to cumulative plant risk
    - Would cause a licensing basis event to exceed safety criteria
- Non-Safety Significant (NSS)
  - SSCs not warranting special treatment

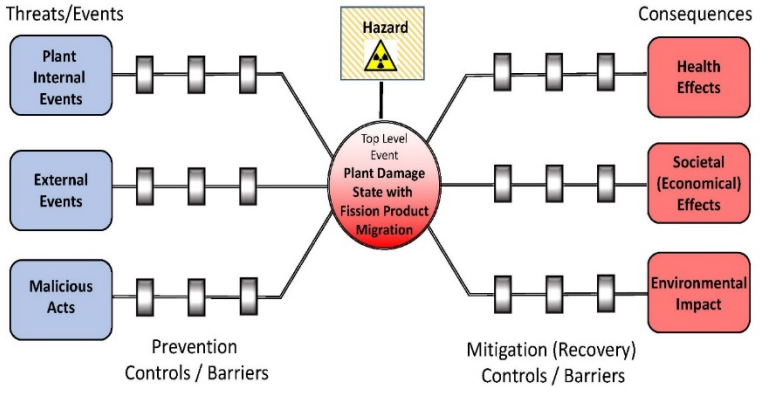
§ 53.460 – Safety Categorization and Special Treatment

- Special treatment
  - Must be established to provide appropriate confidence that the SR and NSRSS SSCs will perform under the service conditions and with the reliability assumed in the required analysis to provide reasonable assurance of meeting the safety criteria
- Human actions
  - Must be capable of being reliably performed under the postulated environmental conditions present and be addressed by programs to provide confidence that those actions will be performed as assumed in the required analysis

§ 53.470 – Application of Analytical Safety Margins to Operational Flexibilities

- Allows adoption of more restrictive criteria to obtain safety margin for application to other areas
- Requires use of a design goal to ensure analysis, design features, and programmatic controls are established to support analytical margins

Note that this provision would support integrated approach historically discussed for use in justifying alternatives in areas such as emergency preparedness and population-related siting considerations



§ 53.480 – Design Control Quality Assurance

- Establishes quality assurance requirements for design and analysis activities
- Derived from Criterion III in Appendix B to 10 CFR Part 50
- QA program must conform with generally accepted consensus codes and standards

Note that preliminary rule language refers to “generally accepted consensus codes and standards”. This term is a topic for discussion. Resolution may include rule language, discussions within rulemaking package, and/or developing guidance documents.

§ 53.490 – Design and Analysis Interfaces

- Requires applicants and licensees to identify, control, and maintain interfaces between design and analyses activities and other activities
  - For example, configuration controls in Subpart F and the proposed facility safety program

Other Possible Topics for Discussion

A topic for possible discussion is the consideration and treatment of inherent design features. An inherent design feature is one where the safety function is achieved through natural processes governed by the physical laws without reliance on the activation or operation of supporting active or passive systems. It may be helpful to develop guidance on how inherent design features are credited in analyses, verified and validated, and considered under safety classification and special treatment provisions of this Subpart.

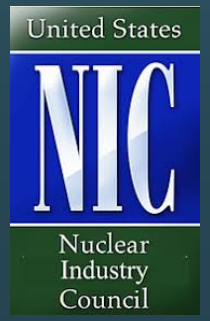
U.S. Nuclear Industry Council Comments for NRC Part 53 Meeting: Introductory Comments and Subpart C

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

Jeff Merrifield
Chairman, Advanced Nuclear Working Group,
U.S. Nuclear Industry Council
U.S. NRC Commissioner (1998-2007)

Steve Nesbit, LMNT Consulting

07 January 2021



USNIC – Introductory Comments

- USNIC appreciates the NRC providing us with their draft of Subparts C and F for our review.
- We have provided comments and questions regarding the proposed Subparts C & F, but due to the timing over the holidays we are not in a position to provide detailed recommendations at this time.
- We have prepared more detailed comments to Subpart B and will providing those comments later in the meeting.
- Additionally, there are a number of elements in the Subparts that cross-reference other subparts that are currently being drafted by the NRC and its contractors.
- In order to provide more detailed comments about Subparts C & F, USNIC will need to have a better understanding of what is meant by the totality of the rule so that we can understand these Subparts in context.

USNIC – Introductory Comments *(cont.)*

- USNIC recognizes that the staff has put considerable time and effort into Subparts C & F and we look forward to the staff providing an explanation of its intentions.
- For example, the staff has outlined its efforts to create a Facility Safety Program (FSP) in Subpart F. We are uncertain what this FSP is intended to accomplish or include, and we look forward to gaining a greater understanding of the staff's need for and supporting basis for this section.
- To promote continued development of the rule, we will ask constructive questions to further our understanding of the draft rule requirements and their implementation. Such interactive discussion will put us in a position to provide more detailed comments within the next 2-3 weeks.

USNIC – Introductory Comments *(cont.)*

- USNIC believes there should be future opportunities to discuss Part 53 in a "workshop format" that focuses on the total picture of what is intended in the proposed rule and goes beyond commenting on individual Subparts as currently envisioned. Toward that end, USNIC believes it would be helpful to reconvene in about 3-4 weeks to engage in a continuing dialogue about the overall expectations for Part 53.
- It would be helpful for our members to have a more complete picture of the Parts or Subparts of 10 CFR that the staff intends to incorporate, by reference or otherwise, in Part 53.
- Further, USNIC has long supported a phased approach to licensing advanced reactor designs and we would like to understand how this concept could be incorporated in a future Part 53.

Subpart C – Design and Analysis Topics

NRC suggested Topics for discussion – with USNIC preliminary responses

- **53.420:** whether this subpart and/or § 53.240 (Licensing Basis Events) should define specific event categories such as anticipated operational occurrences, design basis events, and beyond design basis events.
  - **Response:** It is a useful, accepted structure provided that there is a use of those specific categories within the rule structure.
- **53.430:** whether to address occupational dose within Part 53 by referring to Part 20 or to avoid duplication and have occupational dose addressed only within Part 20 is a topic of ongoing discussions.
  - **Response:** USNIC recommends 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.
- **53.440:** use of "generally accepted" or similar wording, which is used to encourage use of consensus codes and standards while not being prescriptive. A possible solution is to use a phrase such as generally accepted and then use guidance to differentiate between unique design standards, common but not NRC-endorsed standards, and NRC endorsed standards.
  - **Response:** While currently used in Parts 50 and 52, "generally accepted" is an uncertain phrase that lack regulatory clarity.
  - **Q:** Should this be review guidance, not a licensee requirement?

Subpart C – Design and Analysis Topics *(cont.)*

NRC suggested Topics for discussion- with USNIC preliminary responses

- **53.440:** meaning of “qualified” or the potential use of an alternative word in its place.
  - **Response:** the word “qualified“ is OK.
- **53.460:** identification and treatment of human actions needed to support design basis accidents and the first tier safety criteria and those included in safety-significant functions within the PRA.
  - **Response:** we are not sure what information the NRC needs.
- **53:** consideration and treatment of inherent design features. An inherent design feature is one where the safety function is achieved through natural processes governed by the physical laws without reliance on the activation or operation of supporting active or passive systems. It may be helpful to develop guidance on how inherent design features are credited in analyses, verified and validated, and considered under safety classification and special treatment provisions of this Subpart.
  - **Response:** It is vitally important to understand how inherent features will be credited within the context of satisfying the proposed regulation. Inherent features should be more reliable, but that is not a matter for regulation.

53.440(c) Consideration of Safety and Security

- Basis for addressing security in an advanced reactor SAR is not clear
  - All substantive information will be in the Security Plan
  - All substantive information will be Safeguards and not available to the general public
  - Part 52 SARs include only a brief mention of security in Chapter 13 – Conduct of Operations
- **Proposed Part 53 requirement:** "Safety and security must be considered together in the design process such that, where possible, security issues are effectively resolved through design and engineered security features."
  - Statement is inappropriate in that it addresses the design process, not the resulting facility
- USNIC agrees that it is prudent to address security during the design process, but that does not justify the proposed regulation
  - Adequacy of security should be assessed against NRC performance requirements
  - Recommend that security requirements not be in Part 53 regulation
  - **Q:** If a facility meets all of safety and security performance requirements but safety and security were not "considered together in the design process," would NRC refuse to grant a license or require the licensee to seek and obtain an exemption?

Subpart C – Design and Analysis Questions

Additional USNIC Comments and Questions:

- **53.450a:** Wording "contributing factors to unplanned events" is unclear.
  - **Q**: Could NRC clarify: Contributing to what? Probability? Consequences?
  - **Q**: Is the language referring to prevention or mitigation?
- **53.450 (5):** Seems to be convolving two separate ideas – events challenging "plant control" and safety system failures.
  - **Q**: Could NRC clarify, including explaining what is meant by plant control?

Subpart C – Design and Analysis Questions *(cont.)*

Additional USNIC Comments and Questions:

- **53.450:** While consistent with LMP, PRA insights should complement the safety review, but submittal of a complete PRA should not be required.
  - **Q**: How does the agency intend to address microreactors and other designs that want to pursue a deterministic approach for selected portions of its application, such as seismic events?
  - **Q**: Is a PRA needed for microreactors?
- **53.490:** Meaning seems uncertain- mentions "interface control" but it really seems to be change control, configuration management, etc.
  - **Q**: 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.
  - **Q**: 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?

Subpart C

Discussion

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MEETING BREAK

Meeting to resume in 15 minutes

Part 53 General Layout

- Subpart A, General Provisions
- Subpart B, Technology-Inclusive Safety Objectives
- Subpart C, Design and Analysis
- Subpart D, Siting
- 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 F Layout – Facility Safety Program

- **§ 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

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§ 53.800 – Facility Safety Program

- Establish a facility safety program (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

§ 53.810 – Facility Safety Program 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 Part 52/Subpart H

§ 53.820 – Facility Safety Program 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

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§ 53.830 – 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

U.S. Nuclear Industry Council Comments for NRC Part 53 Meeting: Subpart F

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

Jeff Merrifield
Chairman, Advanced Nuclear Working Group
U.S. Nuclear Industry Council
U.S. NRC Commissioner (1998-2007)

07 January 2021

Subpart F – Operations (Facility Safety)

NRC suggested Topic for discussion-- with USNIC preliminary response:

- **53.800:** The staff is interested in stakeholder views on whether the desire to assess and, as appropriate, address new or revised information on potential hazards could be better addressed by embedding sections within other expected requirements (e.g., requirements to update PRAs).
  - **Response:** We are uncertain what this FSP is intended to accomplish or include, and find the current language troublesome, so we look forward to gaining a greater understanding of the intentions of the NRC staff.
  - **Q**: What is the NRC trying to accomplish with this new program, and how do they expect it to be implemented?

USNIC Comments and Questions

- **53.80 Facility Safety Program:**
  - **Comment:** The program does not appear to be performance based and is prescriptive in its content. We are concerned about the potential for increased regulatory uncertainty and regulatory burden and are concerned about the potential adverse impacts to the Backfit Rule.

Subpart F – Operations (Facility Safety) *(cont.)*

USNIC Comments and Questions:

- **53.810 Facility Safety Program Performance Criteria:** *["(a) Each licensee for an advanced nuclear plant must take measures to protect public health and minimize danger to life or property as may be reasonably achieved when considering technology changes, economic costs, operating experience, new or revised hazard assessments, or other factors included in the FSP plan required by § 53.820."]*
  - **Comment:** There is no NRC precedent for this program, and it could well create many problems and duplicative paperwork (e.g. regulatory burden of updating this as well as FSAR). It seems to be requirement to continually second-guess the finding of reasonable assurance made when a license is granted. Once the license is in place, it isn't feasible to be constantly revisiting risk reduction, ALARA, etc. decisions that were made back in the design process.
  - **Comment:** Seems inconsistent with streamlining regulations.
  - **Q**: Could NRC clarify intent of this section, what it is trying to accomplish, and justification for including?
  - **Q**: What is scope for maintenance and would this apply to the current fleet of reactors?
  - **Q**: Could NRC clarify if they are trying to establish a mechanism whereby licensees assess new information (e.g., post-Fukushima) and make plant changes to address them?

Subpart F – Facility Safety Program

Discussion

Recap of November 18, 2020 Public Meeting

- Subpart B preliminary proposed rule language
  - Safety Objectives
  - Safety Functions
  - First Tier Safety Criteria
  - Second Tier Safety Criteria
  - Licensing Basis Events
  - Defense in Depth
  - Protection of Plant Workers

Key Public Comments on Subpart B, Technology-Inclusive Safety Objectives

- Adequate protection standard
  - Avoid regulations that are not needed to provide reasonable assurance of adequate protection of health and safety
  - Using the qualifier of “reasonable assurance” can erode public confidence
  - Could we add some text to the rule language to help clarify exactly what reasonable assurance of adequate protection means?
- Safety case
  - Flexibility is important for applicants to use different approaches to define their safety case
- Site boundary
  - Consider using “site boundary” (like EP rule) vs. “exclusion area boundary” in first tier safety criteria.
- Numerical probabilities in rule vs. guidance
  - Consider replacing with qualitative probability
- Licensing basis event categories
  - Clarify how rule addresses specific event categories such as beyond design basis events

Key Public Comments on Subpart B, Technology-Inclusive Safety Objectives

- Requirements for beyond design basis events
  - Should approach focus on mitigation, like § 50.155?
  - Is inclusion of the QHOs necessary? Are there other options to address cumulative risk?
    - QHOs don't specify the dose value for prompt fatalities and latent health effects
- Additional requirements for adequate protection
  - Is § 53.220(c) necessary and, if so, in the right subpart?
- The two-tier concept is complex and difficult to understand. Is there a more efficient way to organize it?
- Do you really need a requirement to maintain doses ALARA to meet adequate protection or to minimize danger to the public in Part 53?
- A requirement for limitations on effluent releases during normal operations may not be needed.
- Could Subpart B be less prescriptive?

Key Public Comments on Subpart B, Technology-Inclusive Safety Objectives

- Make the rule accessible to the general public
  - For example, in use of terminology
- Defense-in-depth requirement should allow more flexibility
  - Concerns with its deterministic nature
- Avoid uses of the term "high confidence" in the rule language
- Remove requirements for occupational dose from safety criteria
  - Consider moving to radiation protection program
- Pull specific criteria out of Part 50, Appendix I rather than referring to Part 50, Appendix I

U.S. Nuclear Industry Council Comments for NRC Part 53 Meeting: Section B (Technology-Inclusive Safety Requirements)

Frank Akstulewicz of Terrestrial Energy
Dennis Henneke of GE
Rebecca Norris of NuScale
Travis Chapman of X-Energy
Ross Moore of Oklo

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

Jeff Merrifield
Chairman, Advanced Nuclear Working Group
U.S. Nuclear Industry Council
U.S. NRC Commissioner (1998-2007)

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Subpart B – Technology-Inclusive Safety Requirements Topics

- Adequate Protection Standard for Part 53
- Adequate Defense in Depth
- Quantitative Health Objectives
- Quality Assurance Requirements
- Performance-based Risk-informed Regulations

Adequate Protection Standard for Part 53

- Focus of Part 53 should provide a clear adequate protection standard (radiological foundation)
  - Requirements predicated by fundamental safety functions (53.210)
  - Any requirements established in Part 53 should have a clear nexus to supporting the adequate protection standard
  - Adequate Protection standard should be independent of technology, reactor size, or selected licensing process.
- Avoid regulatory requirements that are not needed for adequate protection
  - Do not ratchet up requirements for Advanced Non-LWRs
  - Do not add Beyond Design Basis Accidents or expand the rule by including Minimize Danger and Protect Property Standard.
  - Necessity of second tier criteria for adequate protection has not been established in rulemaking record to date
- Second tier safety criteria appears to circumvent or obviate provisions of the backfit rule
- Other considerations:
  - Part 53 should establish the minimum criteria and supporting information necessary for demonstrating the safety case with a level of detail that is commensurate with its contribution to the safety case arguments
  - Processes for demonstrating the safety case should not be defined in rulemaking

Adequate Defense in Depth

- DID is important in supporting an adequate safety case for both LMP and non-LMP applications.
- Further discussion is needed to better understand and define what is adequate DID for LMP and Non-LMP applications, accounting for the range of potential reactor designs and features that prevents and mitigates accidents that release radiation or hazardous materials.
  - Adequate DID may be different for unique reactors, such as reactor design using TRISO fuel (e.g., fuel that doesn't melt at extreme temperatures), and a reactor with highly reliable passive cooling (e.g. Reactor Vessel Auxiliary Cooling System)
  - May need acceptance criteria for Part 53
  - No precedent or guidance on establishing what will be sufficient

Adequate Defense in Depth *(cont.)*

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

Quantitative Health Objectives (QHO)

- Draft Subpart B, Technology-Inclusive Safety Requirements, Section 53.23, Second Tier Safety Criteria, (b)(2) requires the applicant to analyze QHO for LBE to ensure <5E-6 immediate and <2E-6 latent health effects per year
  - No parallel QHO requirement in 10 CFR 20, 50, or 52.
  - QHO calculations would be required in addition to quantitative limits at site boundaries in 53.23.
- The QHO method was attempted in 1986 but was deemed impractical and replaced by core damage frequency (CDF) and large early release frequency (LERF) in 1990
  - IAEA TecDoc Series IAEA-TECDOC-1874, “Hierarchical Structure of Safety Goals for Nuclear Installations” Annex V has a historical summary.
  - **Q:** What new information is available that would suggest that use of QHO method will now be successful?
- Recommend removing (b)(2) from 53.23
  - Remaining portions of 53.23 are adequate to ensure public safety and parallel Part 50 and 52.
  - NRC’s Office of Regulatory Research has conducted studies similar to what would be required by 53.23 (b)(2) for each existing LWR generically, and this could be continued for new applicants as desired.
- **Q:** What was the underlying goal in changing the wording of the existing safety goals in 53.23 (from ML011210381, 51 FR 30028)?

Quality Assurance Requirements

- Part 53 provides opportunity for NRC to take a fresh look at Appendix B and NQA-1 Program, and consider alternatives
- Level of quality of commercially available components may meet and exceed prior “nuclear standards” without the need for the overly burdensome reporting requirements
- Recommend rule should state quality control program is necessary, but not provide direction on approaches to use.
- Recommend guidance should indicate that alternative approaches such as ISO 9000 series, IAEA, commercial dedication programs, and other approaches presented by industry could be used– this would facilitate licensing of US reactors in Canada, Europe, Asia, and other parts of the world
  - International acceptance of a single approval could be important in international marketability
  - Guidance could address the broader topic of universal acceptance of codes and standards (mechanical, electrical, etc.)
- Concurrent guidance should be developed to show that the ISO and IAEA standards can meet whatever the requirements are in Part 53, and potentially other Parts.

Risk-informed, Performance-based Regulations

- Risk-informed (not Risk-based)
  - Probabilistic Risk Assessment (PRA) insights should complement the safety review however 53.450 proposed language and criteria make a complete/detailed PRA an implicit requirement for LBE, SSC classification, DID determinations.
    - Achievable approach for RG1.233 implementation, but unclear how an applicant would comply if not adopting RG1.233.
    - Deterministic approaches (e.g., for external hazard assessment, seismic, bounding analyses) may be appropriate.
    - PRA matures with plant design, therefore, requiring extensive PRA use with application submittal may not be feasible for all application types.
    - Unclear how this will impact application content.
  - International regulatory frameworks have risk-informed approaches that certain vendors may choose to pursue; desire that Part 53 would accommodate such approaches (i.e., IAEA SSRs and markets with dual-DSA/PSA requirements)

Risk-informed, Performance-based Regulations *(cont.)*

- Performance-based
  - Clear performance-based acceptance criteria to allow flexibility in implementation of design features and programmatic controls while improving predictability in the review process (minimum criteria needed for adequate protection allowing applicant selection of approaches and methodologies).
  - Performance-based requirements should focus on measurable outcomes (does “x” perform the way it was committed to perform) and avoid prescription of methods to achieve that performance.
- Other considerations
  - Part 53 should accommodate an implementation of Licensing Modernization Project (LMP), but not implicitly require it.
  - Performance-based, risk-informed regulations can provide the applicant with flexibility on how to demonstrate compliance.
  - Part 53 should be technology and design neutral to minimize the need for exemptions.
  - Consider the overall impact and level of detail requirements for Part 53, and its prospective applicant types, and how the language can be used to improve regulatory predictability, efficiency, and certainty.

Part 53 Rulemaking

Marc Nichol
Senior Director New Reactors

January 7, 2020

NUCLEAR ENERGY INSTITUTE

Safety Criteria

Safety Objectives and Two-Tier Criteria

- Reasonable assurance of adequate protection is the legal standard for NRC licensing
  - NRO 2018 Memorandum (ML18240A410)
  - Does not mean elimination of all risk
- Extra-adequate protection is at the discretion of the Commission
  - UCS v. NRC – 824 F.2d 108, 118 (D.C. Cir. 1987)
  - Focus on substantial safety benefits and justified by economic costs
  - Reflected in NRC's well-established backfitting regulations
- Two-tiers of criteria
  - Not clear how each tier relates to adequate and extra-adequate protection
  - Overly complex and includes unnecessary criteria
- Proposed changes
  - Adequate protection requirement – dose to public criterion for infrequent events
  - Extra-adequate protection – dose to public criteria for normal and rare events

As Low As Reasonably Achievable (ALARA)

- NRC requirements for ALARA would
  - Drive regulatory compliance cost without associated substantial safety benefit
  - Be inconsistent with a more risk-informed, performance-based regulatory framework
- ALARA does not have a clear nexus to Atomic Energy Act statutory requirements
  - ALARA not needed to meet extra-adequate protection safety criteria
    - 100 mrem to public during normal operations
    - 5 rem to occupational workers
- ALARA is a wise practice
  - “the ALARA concept is intended to be an operating principle rather than an absolute” 56 Fed. Reg. 23359, 23366 (May 21, 1991)
  - Licensees will implement ALARA practices even without an NRC requirement
- Proposed change to not include ALARA requirements in Part 53

Quantitative Health Objectives (1/3)

- Rule language vs. Policy statement
  1. Rule language (NRC proposal) – no additional criterion for beyond design basis events (e.g., events between 1 in 10,000 years and 5 in 10,000,000 years)
  2. Policy statement – additional safety criterion similar to 50.155 for mitigation of rare events (beyond design basis)

- In both approaches
  - Level of safety is the same
  - The applicant's design and analysis, and the NRC scope of review are the same
- The difference is in the legal compliance with the requirements that exist for the licensee and the potential to eliminate other requirements, if the QHOs are in the rule language.

Quantitative Health Objectives (2/3)

Rule Language 10 CFR Part 53.21 – Extra-Adequate Protection

- QHO in the Rule Language
  - *"The cumulative plant risk to an average individual:*
    - *for early fatalities within 1 mile of the site boundary does not exceed 5 in 10,000,000 years*
    - *for latent cancer fatalities within 10 miles of the site boundary does not exceed 2 in 1,000,000 years."*
- QHO in Policy Statement, 10 CFR 50.155 equivalent in rule language
  - *Each applicant or licensee shall develop, implement, and maintain mitigation strategies and guidance for rare event sequences that are not addressed in 53.20, which may include one or more reactor modules, and that [are not expected to occur in the life of a nuclear power plant] OR [have an expected frequency greater than five times in 10,000,000 years] that are capable of being implemented site-wide and must include the following:*
    - *The capability to maintain or restore the fundamental safety functions identified pursuant to 53.2X.*
    - *The acquisition and use of offsite assistance and resources to support the functions required by paragraph (b)(1) of this section indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies*
    - *Strategies and guidance to provide the capabilities in (b)(1) under the circumstances associated with loss of large areas of the plant impacted by the event, due to explosions or fire, to include the following areas:*
      - *Firefighting;*
      - *Operations to mitigate fuel damage; and*
      - *Actions to minimize radiological release.*

Quantitative Health Objectives (3/3)

Advantages	Disadvantages
1. Enhances regulatory stability by making it harder for the NRC to change the limits, or make arbitrary judgements.	1. Increases regulatory uncertainty by establishing requirements without specifying the consequence limits (i.e., dose for immediate fatalities and latent cancers).
2. Enhanced clarity by providing specific limits of acceptable risk to the public for beyond design basis events (BDBEs).	2. Reduces regulatory stability since changes to the consequence limits (i.e., dose for immediate fatalities and latent cancers) will now be regulatory limits instead of policy goals.
3. Ensures that regulations explicitly result in risk levels that comply with the QHO limits.	3. Is counter to Commission's intent that the QHOs are goals, and not limits.
4. The QHOs are more understandable to the public because they are expressed in terms of public health effects.	4. Not having consequence limits, and the complexity of demonstrating the QHOs are met, increases licensing risk.
5. The QHOs are the maximum acceptable consequences, and therefore avoid more conservative surrogate requirements.	5. Changes to societal risks can result in changes to the requirements that can force changes to the facility design.
6. Potential to eliminate the need for some other requirements (e.g., mitigation of beyond design basis events).	6. Analyses and calculations related to demonstrating the QHOs are met are now used for legal compliance with requirements.
	7. Risks a revision to the QHOs. The NRC discontinued its efforts circa 2000 to update the safety goals so that improvements can be more significant and incorporate experience with risk-informed decision making.

Quantitative Frequencies

- Same level of safety whether quantitative frequencies are in rule or guidance
  - The applicant's design and analysis, and the NRC scope of review are the same
  - If in guidance, rule would include qualitative frequencies
  - "The contribution of total effective dose equivalent to an individual member of the public at the site boundary for infrequent event sequences, which may include one or more reactor modules, that *{are not expected to occur in the life of a nuclear power plant} OR {have an expected frequency greater than once in 10,000 years}* does not exceed:"
- Including quantitative frequencies in the rule would be first-of-a-kind
  - Arguably more stability; more difficult for values to change in the future
  - But need to consider potential for significant unforeseen complications
    - Role of PRA in demonstrating legal compliance with regulations
    - Compliance and licensing impacts due to improving PRA state-of-the-art

Related Requirements

- Overall safety construct (e.g., safety functions, licensing basis events)
  - Intend to address after clarifying safety criteria
- Occupational exposure
  - NRC proposal not consistent with current Part 50/52 approach
    - Effectively expands to regulation of design
  - Should retain Part 20 approach, with the exception of ALARA
- Administrative requirements
  - Need to address NRC authority for new requirements (e.g., Fukushima) with limitations (e.g., 10 CFR 50.109)
- Performance-based language
  - Avoid unnecessary and ambiguous language that can lead to complications (E.g., high-confidence, upper bound)
  - Avoid repeating same requirement in multiple places (undermines clarity)

Success Criteria
(Project Requirements)

Success Criteria (Project Requirements)

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

Industry Proposed Success Criteria

(Selected Higher-Level criteria)

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

ACRS Recommendations

Feedback on ACRS Recommendations

- Addressing Uncertainties
  - Need systematic approach to address uncertainties for novel technologies
  - Risk-informed approach is possible due to progress in modern analysis methods that allow licensees to systematically identify initiating events, sequences and address uncertainties (including NEI 18-04)
  - Use of deterministic “postulated worst case” approach should be permitted but not required
  - Prototype license should be an optional approach, but not required
- General Design Criteria
  - Use of design criteria should be addressed by Part 53
  - Inclusion of GDC in the Part 53 requirements is problematic
    - Variation in reactor designs for a technology-inclusive rule
    - RG 1.232 for ARDC demonstrated impossibility for a single set of GDC
  - Intend to propose approach as part of overall safety construct

QUESTIONS?

By Third Way, GENSLER

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Hybrid Power Technologies Presentation

Michael Keller, President


Get In Lane
Bad
TODAY
Worse
?
Licensing
Extremely
Expensive
10CFR53

HOW DOES NRC's proposed 10CFR53 Reduce Costs?

How is it RISK INFORMED, PERFORMANCE BASED?

Complex Statute

To Pile On Desired Administrative Rules?

SIMPLIFIED 10 CFR 53

Should be only applicable to Passively Fail-Safe Advanced Reactors that

<u>SIGNIFICANTLY REDUCE RISK</u>

and <u>OFF-SITE EXPOSURES</u>

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Final Discussion and Questions

U.S. Nuclear Industry Council Comments for NRC Part 53 Meeting: Closing Comments

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

Jeff Merrifield
Chairman, Advanced Nuclear Working Group
U.S. Nuclear Industry Council
U.S. NRC Commissioner (1998-2007)

07 January 2021

Closing Comments

- USNIC appreciates the opportunity to continue the dialog with NRC staff to achieve a Part 53 rule that meets the Adequate Protection Standard-- but in an efficient way to enable the streamlined licensing of Advanced Reactor designs
- USNIC proposes to provide more detailed comments on the proposed Subparts C and F of Part 53 in the next 2-3 weeks.
- We suggest scheduling a more interactive workshop on Part 53 that would be intended to facilitate more dialogue among the NRC and interested stakeholders and obtain a greater understanding of the plans of the NRC staff.

Closing Comments *(cont.)*

- Advanced nuclear reactors may be used for other applications than power generation, and Part 53 needs to be more flexible and efficient than Parts 50 or 52, including how it would apply for non-power applications.
- Every element of the licensing process, including technical, administrative and procedural requirements (including the role of Advisory Committee on Reactor Safeguards (ACRS) and Atomic Safety and Licensing Board (ASLB)) should be subject to a fresh look.
- Consider international regulatory agency approaches and regulatory standards so Part 53 enables efficient international licensing of NRC approved designs

U.S. Nuclear Industry Council Contacts

For questions or comments contact:

Cyril W. Draffin, Jr.

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

Cyril.Draffin@usnic.org

Jeffrey S. Merrifield

Chairman, Advanced Nuclear Working Group,
U.S. Nuclear Industry Council
U.S. NRC Commissioner (1998-2007)
Jeff.Merrifield@pillsburylaw.com

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 (16 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

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Future Public Meetings

- The NRC staff will continue to host a public meeting every 4 to 6 weeks to discuss and receive feedback on various regulatory topics and preliminary proposed rule text.
  - The next Part 53 public meeting will be scheduled for early February 2021.
  - The preliminary proposed rule text will be posted on regulations.gov under docket ID NRC-2019-0062 before the public meeting.
- Issue:
  - Managing an increasing number of technical areas as we move from higher level criteria to areas such as design, analyses, and operations (with need to address topics such as staffing)

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Future Public Meetings

- The NRC staff will be meeting with the ACRS Future Plants Subcommittee on January 14, 2021.
  - The staff will be presenting the Part 53 subparts B and F (Facility Safety Program) preliminary proposed rule text.
  - The staff will continue to meet with the ACRS every one to two months.

- The NRC staff will be holding a series of separate public and ACRS meetings in 2021 on developing options for Commission consideration on a regulatory framework for fusion energy systems.
  - The first public meeting will on January 26, 2021.

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Closing Remarks

Rulemaking Contacts

Robert.Beall@nrc.gov
301-415-3874
William.Reckley@nrc.gov
301-415-7490

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

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Acronyms and Abbreviations

ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Documents Access and Management System
ALARA	As low as reasonably achievable
ARCAP	Advanced Reactor Content of Applications Project
ARDC	Advanced Reactor Design Criteria
ASLB	Atomic Safety and Licensing Board
BDBE	Beyond design-basis event
CDF	Core Damage Frequency
CFR	Code of Federal Regulations
DBA	Design-basis accident
DBE	Design-basis event
DID	Defense in Depth

DSA	Deterministic Safety Analysis
EP	Emergency preparedness
FSAR	Final Safety Analysis Report
F-C	Frequency – Consequence
FSP	Facility Safety Program
GDC	General Design Criteria
IAEA	International Atomic Energy Agency
ISO	International Organization for Standardization
LB	Licensing basis
LBE	Licensing basis event(s)
LERF	Large Early Release Frequency
LMP	Licensing Modernization Project
LWRs	Light-water Reactors

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Acronyms and Abbreviations

NEI	Nuclear Energy Institute
NEIMA	Nuclear Energy Innovation and Modernization Act
NMSS	Office of Nuclear Material Safety and Safeguards
NQA	Nuclear Quality Assurance
NRO	New Reactors Office
NRR	Office of Nuclear Reactor Regulation
NSRSS	Non-Safety Related but Safety Significant
NSS	Non-Safety Significant
PRA	Probabilistic risk assessment
PSA	Probabilistic Safety Assessment
QA	Quality assurance

QHO	Quantitative health objective
rem	Roentgen-equivalent man
SAR	Safety Analysis Report
SMR	Small modular reactor
SR	Safety-related
SRM	Staff Requirements Memorandum
SSCs	Structures, systems, and components
TRISO	Tri-structural Isotropic (particle fuel)
TS	Technical specifications
UCS	Union of Concerned Scientists
USNIC	U.S. Nuclear Industry Council

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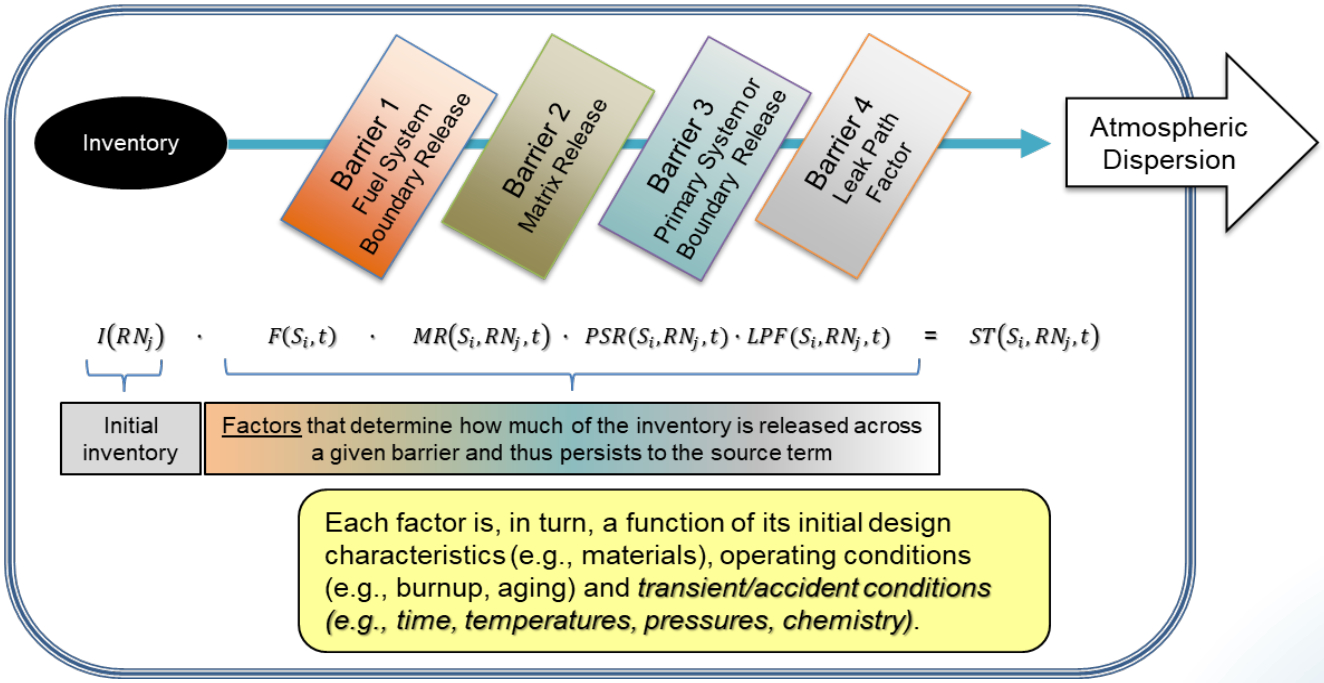
Background Slides

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"

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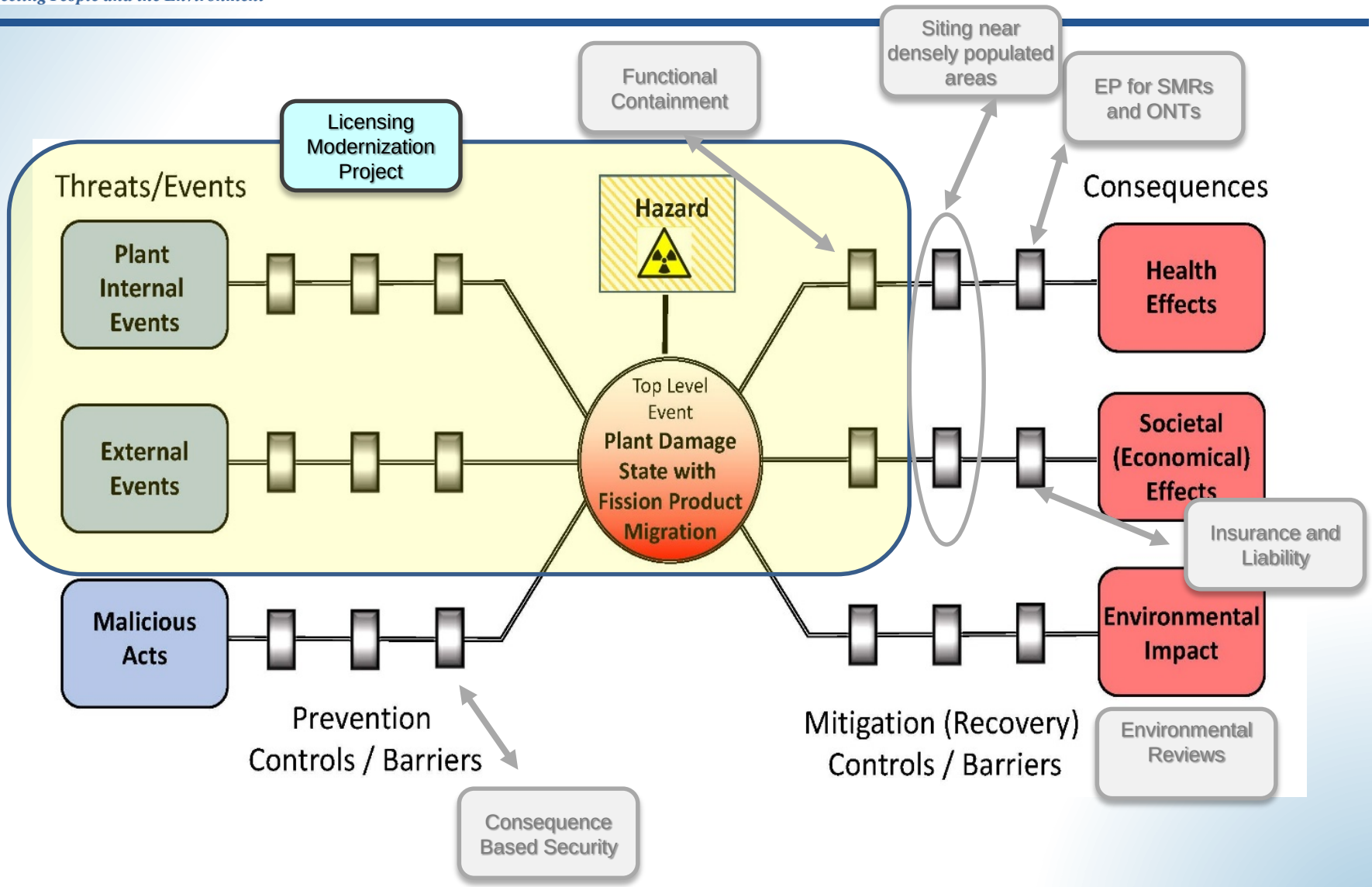
Integrated Approach



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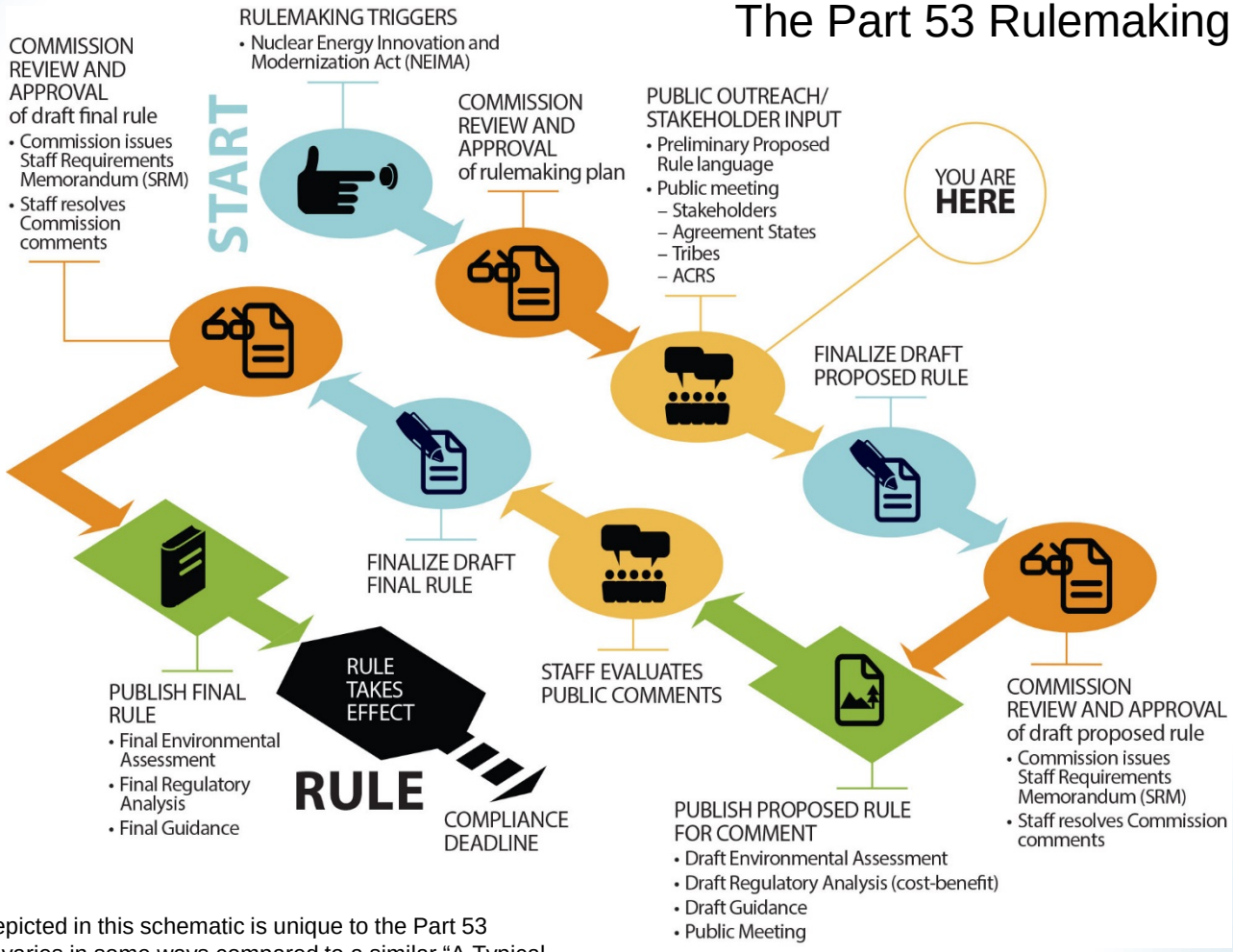
Part 53 Rulemaking

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, …