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Protecting People and the Environment

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

Subpart B Preliminary Proposed Rule Language

November 18, 2020

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Agenda

12:00pm – 12:10pm	Welcome/Introductions/Logistics
12:10pm – 2:00pm	Part 53 Rulemaking Strategy & Schedule
2:00pm – 2:15pm	BREAK
2:15pm – 4:00pm	Subpart B – Technology-Inclusive Safety Requirements
4:00pm – 4:30pm	Additional Public Comments/Closing Remarks

Welcome/Introductions

Welcome:
Ho Nieh, NRR – Office Director
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

Public Meeting Slides: ADAMS Accession No. ML20318A007

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Purpose of Today's Meeting

- Discuss U.S. Nuclear Regulatory Commission (NRC) staff plan to address Commission direction on Part 53 rulemaking
- Review preliminary proposed rule language for Part 53
  - This is the first of many public meetings the NRC staff will be hosting to discuss preliminary proposed rule language
- 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 December 18, 2020.
- No regulatory decisions will be made at today's meeting.

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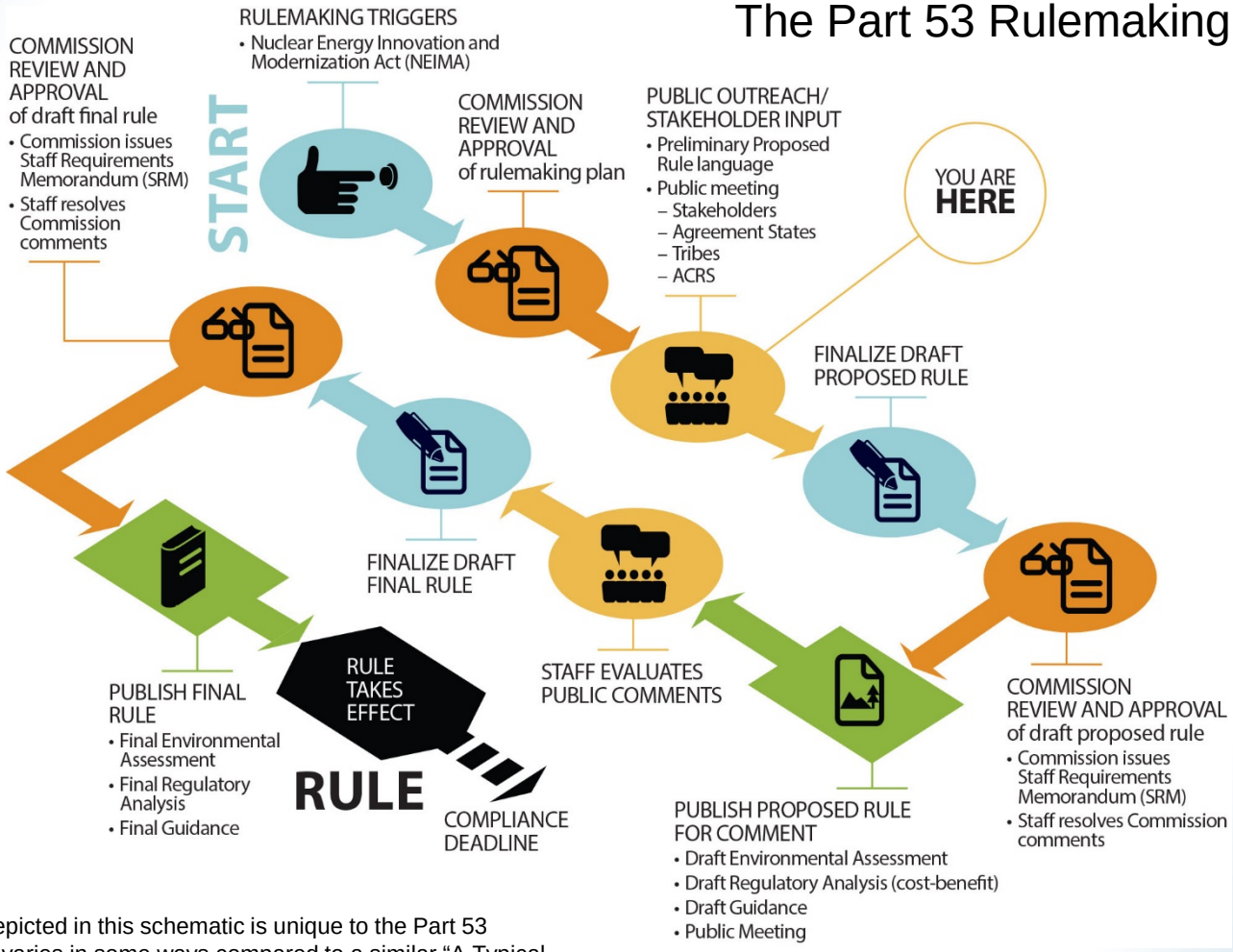
Part 53 Rulemaking

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, …

SECY-20-0032 Rulemaking Plan

- In SECY-20-0032, “Rulemaking Plan on ‘Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors,’” (ADAMS ML19340A056), dated April 13, 2020, NRC staff proposed:
  - Developing a new 10 CFR part that could address performance requirements, design features, and programmatic controls for a wide variety of advanced nuclear reactors throughout the life of a facility
  - Focusing the rulemaking on risk-informed functional requirements, building on existing NRC requirements, Commission policy statements, and recent activities
  - Seeking extensive interactions with external stakeholders and the Advisory Committee on Reactor Safeguards (ACRS) on the content of the rule

Staff Requirements Memorandum (SRM) - SECY-20-0032, Rulemaking Plan

- In SRM-SECY-20-0032, dated October 2, 2020 (ADAMS ML20276A293), the Commission:
  - Approved the staff's proposed approach for the rulemaking
  - Directed the staff to provide:
    - a schedule with milestones and resource requirements to achieve publication of the final Part 53 rule by October 2024
    - key uncertainties impacting publication of the final rule by that date
    - options for Commission consideration on licensing and regulating fusion energy systems
  - Directed the staff to develop and release preliminary proposed rule language intermittently, followed by public outreach and dialogue

30-Day Commission Memo

- On November 2, 2020, staff submitted a Commission memorandum responding to the SRM direction to provide a schedule with milestones and resources to complete the final rule by October 2024 (ADAMS ML20288A251).
- The memorandum included a discussion of key uncertainties that could impact publication of the final rule by that date.

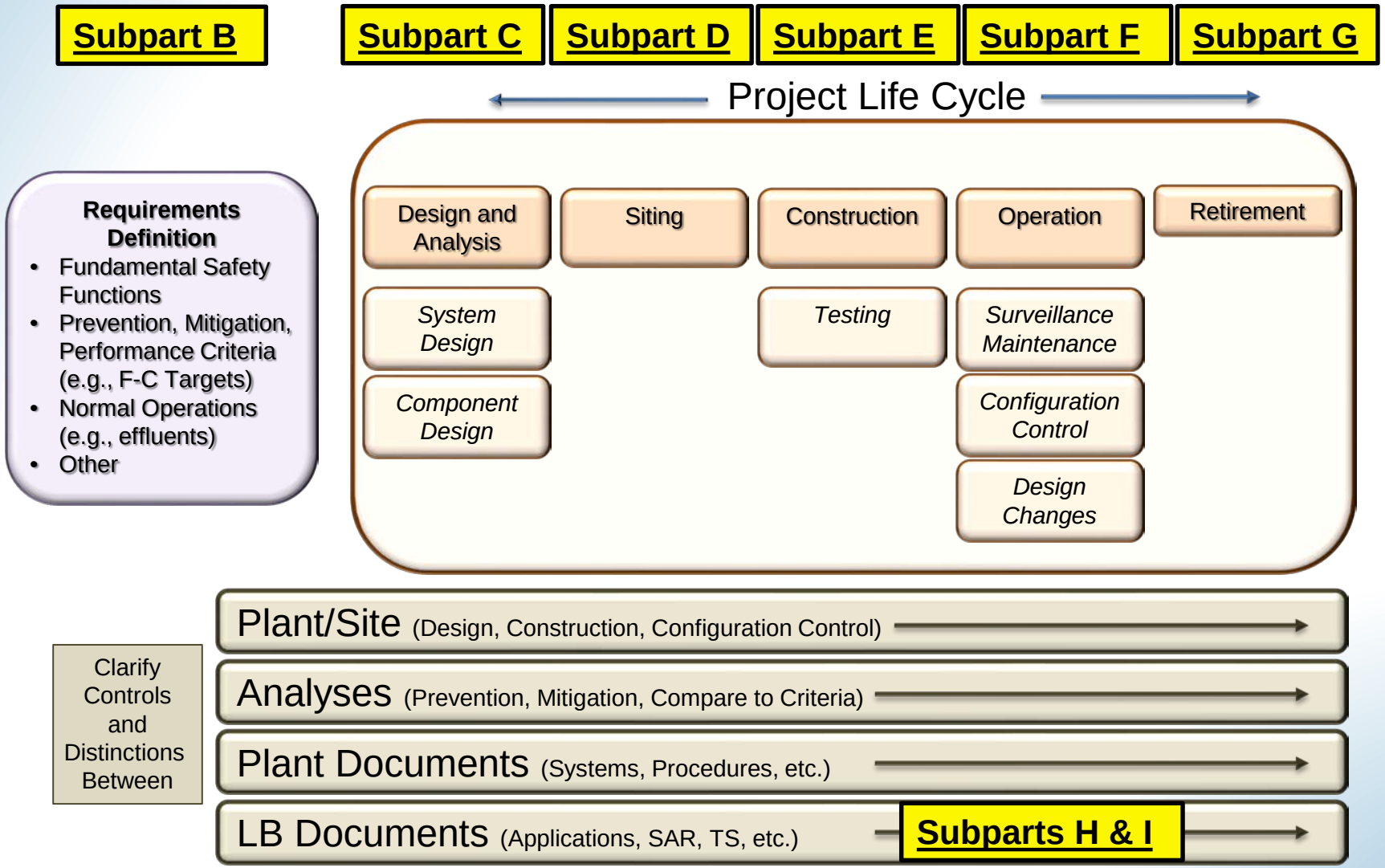
30-Day Commission Memo

Milestone Schedule	
Major Rulemaking Activities/Milestones	Schedule
Public Outreach, ACRS Interactions and Generation of Proposed Rule Package	October 2020 to April 2022 (19 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

30-Day Commission Memo

- Key uncertainties in meeting the Commission directed rulemaking schedule:
  - NRC-stakeholder alignment on the scope of the rulemaking
  - Engagement on key issues within the NRC and communication with external stakeholders and ACRS
  - Timing of guidance document development
  - Ability of the public to review the proposed rule within the proposed 60-day public comment period
  - Ability to include the regulatory framework and requirements for fusion facilities

NRC Staff Plan to Develop Part 53



NRC Staff Engagement Plan

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

	Concept
	Discussion
	Closure

Stakeholder Suggested Plan

- "NEI Input on the NRC Rulemaking Plan on, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)," dated October 21, 2020 (ADAMS ML20296A398)
- NEI letter focuses on three elements recommended for a successful rulemaking:
  - a well-defined vision and suggested goals for the final rule
  - a systematic approach to the rulemaking effort with a proposed five step process
  - predictable and meaningful stakeholder interactions
- NEI suggested a five-step process
  - Step 1 – Frame the Part 53 rulemaking effort (November 2020)
  - Step 2 – Establish the scope of the final rule (January 2021)
  - Step 3 – Create the safety paradigm (June 2021)
  - Step 4* – Identify how to document the regulatory framework (September 2021)
  - Step 5 – Develop the proposed rule (October 2022)

*Write the draft proposed rule language

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Stakeholder Suggested Plan

- NRC staff believes the overall concepts in NEI process are reasonable.
- NRC staff does not believe all steps can be done in series, as suggested, while still completing the rulemaking on the Commission-directed schedule.
- As directed by the Commission, the staff will be using an iterative process to get stakeholder input.

U.S. Nuclear Industry Council Comments regarding Part 53 at NRC Part 53 Rulemaking Meeting

Rulemaking Strategy & Schedule

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

18 November 2020

Rulemaking Strategy & Schedule

USNIC supportive of NRC's effort to develop Part 53 as transformational rule that provides reasonable assurance of public health and safety for advanced reactors

- Regular NRC Part 53 stakeholder meetings (every ~6 weeks) has merit
- USNIC provided comments on Part 53 for:
  - 20 August 2020 NRC meeting (slides)
  - Each of 14 issues that NRC raised in their July 2020 NRC Staff White Paper (50 comments), available at: https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20244A229
  - 22 Sept 2020 NRC meeting (slides)
  - today's meeting

- NRC provided helpful current thinking regarding planned Subparts A-J

Rulemaking Strategy & Schedule (continued)

- Ensure requirements for licensing and regulating advanced nuclear reactors are clear, appropriate, and focused on the adequate protection of public health and safety.
- Avoid regulations not needed to provide reasonable assurance of adequate protection of health and safety
  - eliminating or streamlining requirements that are overly prescriptive or not relevant will reduce the need for future exemptions.
- NRC should not use the development of this rule to rachet up requirements

Rulemaking Strategy & Schedule (continued)

- Because of accelerated timeline, there is tension between having "broad, significant changes from the current regulatory framework" and just repackaging prior safety standards and regulations
  - *NRC: "Some industry stakeholders have expressed a desire for a “clean sheet” approach in the Part 53 rulemaking and are seeking broad, significant changes from the current regulatory framework for licensing new reactors. The staff’s primary goal is to develop a transformational rule that provides reasonable assurance of public health and safety for advanced reactors for Commission consideration. To achieve that goal, it will be necessary to focus the scope of this rulemaking on the essential elements that will enable safety focused, timely licensing decisions, and construction and transition to operation for new advanced reactors.*

Rulemaking Strategy & Schedule (continued)

Agree with NEI 21 Oct 2020 input regarding Part 53 vision and goals:

- Part 53 to be most efficient option for all new reactor applicants
  - meet industry needs for schedule, cost and predictability-- consistent with Congressional directives and NRC's advanced reactor policies, initiatives, and Principles of Good Regulation
- Safety Focused
- Technology Inclusive
- Efficient
- Flexible (licensing for diverse set of uses including process heat, hydrogen production, desalinization)
- Informed (considering international regulatory frameworks)
- Clarity

Rulemaking Strategy & Schedule (continued)

Agree with general approach contained in NRC staff's 2 Nov 2020 memo regarding staff requirements for SECY-20-0032

- Reaching alignment on scope
  - Agree with staff's desire for transformational rule
  - Large studies undertaken suggest zero threshold associated with linear no-threshold model is not appropriate for assessing health effects of radiation--Part 53 should add flexibility as science and analysis improves (e.g. if commission decides zero threshold is no longer justified)
- Timing of guidance document
  - What is possible role of standards organizations such as International Standards Organization (e.g. for ISO 9000 QA standards) or ASME?

Part 53 Rulemaking Strategy & Schedule

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 Requirements
- 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

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10 CFR Part 53 Subpart B Layout

- **§ 53.20** - Safety Objectives
- **§ 53.21** - Safety Functions
- **§ 53.22** - First Tier Safety Criteria
- **§ 53.23** - Second Tier Safety Criteria
- **§ 53.24** - Licensing Basis Events
- **§ 53.25** - Defense in Depth
- **§ 53.26** - Protection of Plant Workers

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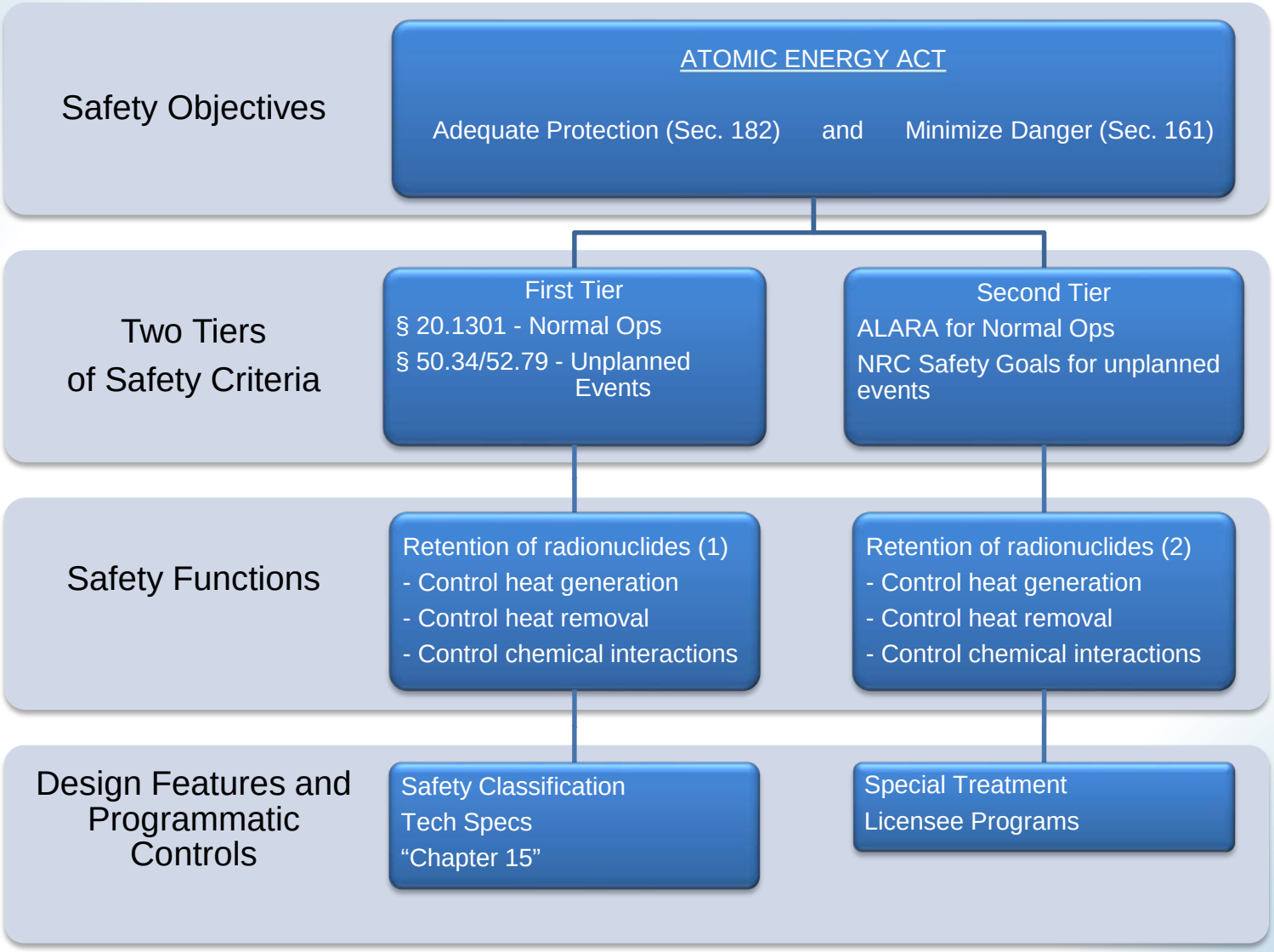
Subpart B Flowchart



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§§ 53.20 & 53.22/53.23 Objectives and Criteria

- Safety Objectives
  - Reasonable assurance of adequate protection of the public health and safety and the common defense and security
  - Additional measures to minimize danger to life and property, when considering various factors
- Safety Criteria
  - Two-Tiered structure

§ 53.22 – First Tier Safety Criteria (Adequate Protection)

- Normal operations *(§ 20.1301)*
  - Contribution to total effective dose equivalent (TEDE) to individual members of the public from normal plant operation does not exceed 0.1 rem (1 mSv) in a year
  - Contribution to dose in any unrestricted area does not exceed 0.002 rem (0.02 millisievert) in any one hour
- Licensing basis events *(§§ 50.34(a)(1)(ii)(D) & 52.79(a)(1)(vi))*
  - Upper bound frequency > once per 10,000 years
  - An individual located at exclusion area boundary for any 2-hour period following the onset of release would not receive a radiation dose in excess of 25 rem (250 mSv) TEDE
  - An individual located at outer boundary of the low population zone exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (250 mSv) TEDE
- Additional requirements established by the NRC for reasonable assurance of adequate protection

§ 53.23 – Second Tier Safety Criteria (Substantial Additional Protection)

- Estimated TEDE to the public from effluents during normal plant operation are as low as reasonably achievable (ALARA)
  - Performance objectives for liquid and gaseous effluents (*10 CFR Part 50, Appendix I*)
- Design features and programmatic controls must:
  - Ensure plant structures, systems, and components (SSCs), personnel, and programs provide necessary capabilities & reliabilities to address licensing basis events
  - Provide measures for defense-in-depth
  - Maintain overall cumulative plant risk from licensing basis events within NRC safety goals

§ 53.21 – Safety Functions

- Safety Functions
  - Primary safety function is to limit the release of radioactive materials from the facility
  - Additional functions supporting the retention of radioactive materials must be defined
  - Design features and programmatic controls fulfill the safety functions

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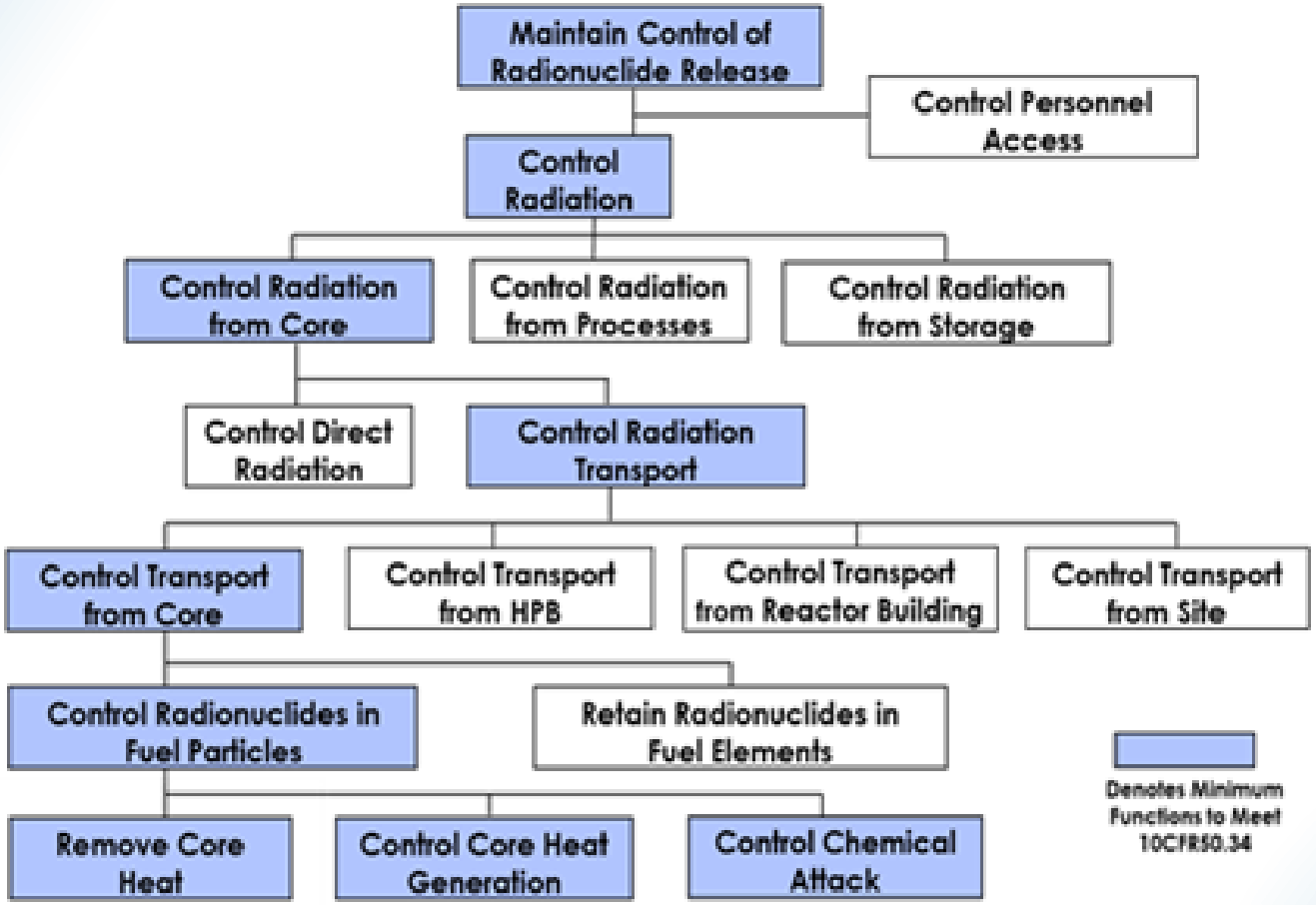
Safety Functions Concept



NGNP Concept

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§ 53.24 – Licensing Basis Events

- Licensing basis events must address combinations of malfunctions of plant SSCs, human errors, and the effects of external hazards
- Licensing basis events must be used to
  - Confirm the adequacy of design features and programmatic controls needed to satisfy first and second tier safety criteria
  - Establish related functional requirements for plant SSCs, personnel, and programs

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§ 53.25 – Defense in Depth

- Measures must be taken to ensure appropriate defense in depth is provided to compensate for uncertainties
- Measures can include increased safety margins and provide alternate means to accomplish safety functions
- No single design or operational feature should be exclusively relied upon

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§ 53.26 – Protection of Plant Workers

- Ensure radiological dose to plant workers does not exceed occupational dose limits from 10 CFR Part 20
- Use procedures and engineering controls to keep occupational dose levels ALARA

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Additional Discussion Topics

- Consideration of “unmitigated consequences” from event scenarios to support Part 53
  - Department of Energy Orders & American Nuclear Society Standard 2.26 (Seismic design)
- Embedded mechanisms to apply analytical safety margins to gain operational flexibilities
  - Example is alternative offsite dose thresholds being considered for emergency planning zones and siting

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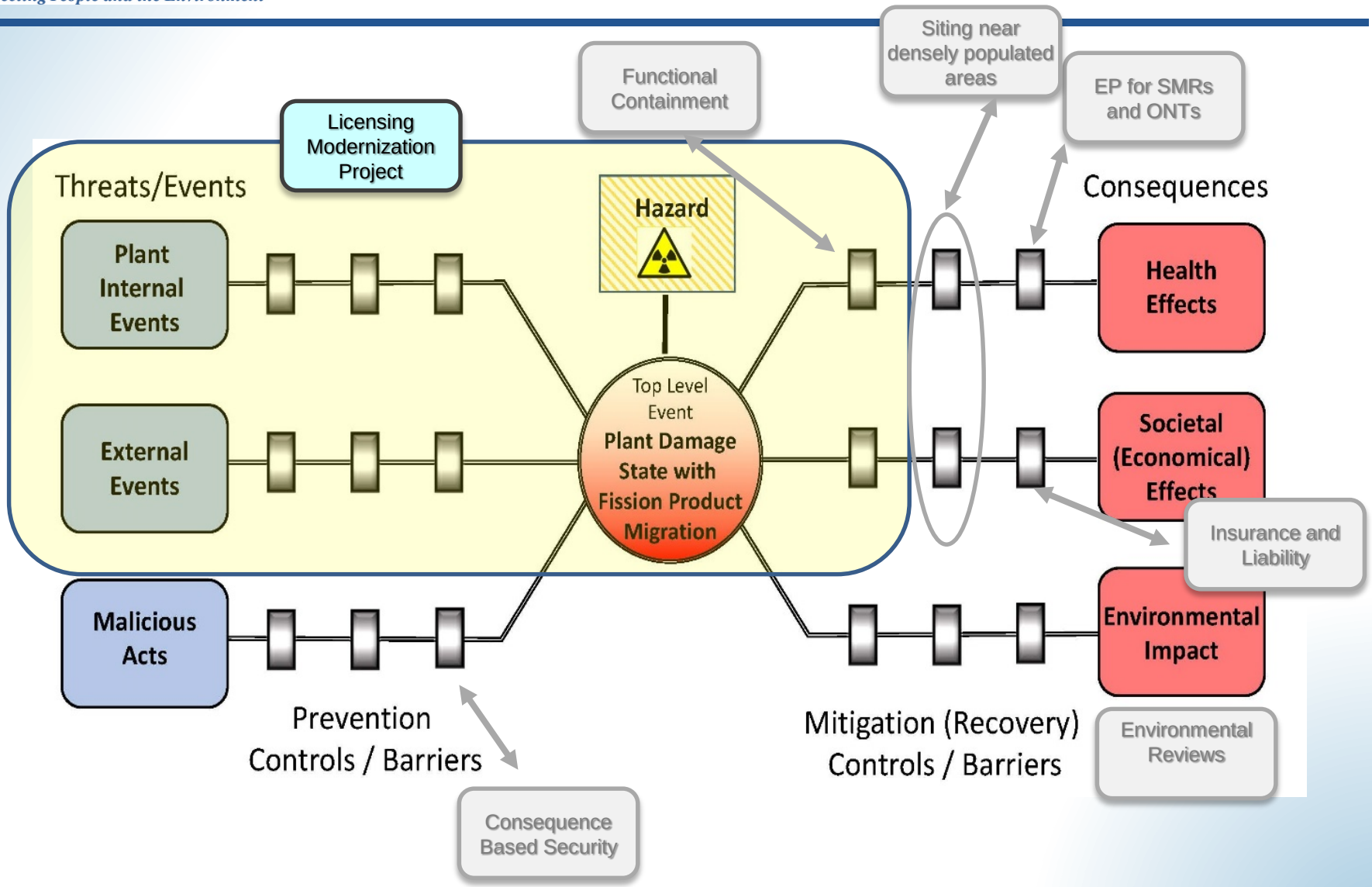
Integrated Approach



Part 53 Rulemaking

Marc Nichol
Senior Director New Reactors

November 18, 2020

NUCLEAR ENERGY INSTITUTE

“Project Requirement” for Safety Criteria

- Goal: Define performance-based safety criteria that demonstrate adequate protection
- Constraints
  - Define in terms of direct radiological risks to public heath and safety to the maximum extent possible (e.g., dose and probability)
  - Address categories of individuals for protection: Public and occupational workers
  - Address plant operating conditions: Normal, design basis accident, beyond design basis
  - Consistency: Safety goals, Part 50 dose limits, NEI 18-04
  - Flexibility: able to approve a design without a site, allow applicants to propose functional surrogates

Safety Criteria – Adequate Protection of Public

- Adequate protection – Design Basis Accidents
  - NRC proposed 53.22(b) is necessary and sufficient
  - Consistent with 50.34(a)(1)
  - Further consideration of boundary type (e.g., site boundary)
  - Further consideration of location of numerical probability
  - Consideration of implications that most designs expected to meet more restrictive EPA PAG (site boundary EPZ)

Safety Criteria – Minimize Danger to Public

- Normal Operations
  - NRC proposed 53.22(a) is necessary and sufficient
  - Consistent with 20.1301
- Beyond design basis events
  - Not consistent with current approach 50.155(b) – mitigation
    - Need technology-inclusive equivalent
  - 53.22(c) is problematic – requirements created for each applicant
  - 53.23(b)(2) is not necessary – QHO addressed by other requirements
    - Also lacks clarity, difficult to implement

As Low As Reasonably Achievable

- NRC should not have ALARA requirements in Part 53
  - ALARA not necessary to protect the public health, minimize danger or to meet other requirements in the Atomic Energy Act
- Furthermore, NRC proposed approach 53.23(a) and 53.26(b) is problematic
  - Appears inconsistent with 20.1003 and 20.1101
  - Part 50 Appendix I based on large LWRs

“Reasonable Assurance of Adequate Protection” (NRC Proposed 53.20)

- No current equivalent in Part 50 (presumed by meeting requirements)
- A separate requirement by itself lacks clarity on “what else” will need to be required on case-by-case basis
- Benefits to clarifying “reasonable assurance of adequate protection” in the regulations
  - E.g., high-level principles from NMSS memo
- Could be introduction for performance based criteria
  - 53.22(b), 53.22(a) and 50.155(b)-equivalent

Requirements Related to Safety Construct (How) – Not Safety Criteria (What)

- Revisit when creating the safety paradigm (how to demonstrate safety criteria are met)
  - Safety Functions – 53.21
  - “Design features and programmatic controls…”
  - Licensing Basis Events – 53.24
  - Defense in Depth – 53.25
  - Reliability – 53.23(b)(1)

Rule text observations

- Use “reasonable assurance” standard rather than “high confidence”
- Opportunities to make more performance-based
- Phrasing, terms and specifics may need more work

Occupational Worker Dose

- NRC Proposed 53.26(a)
  - Refers to 20.1201 through 20.1208
  - Appears appropriate for Part 53 licensees

QUESTIONS?

By Third Way, GENSLER

U.S. Nuclear Industry Council Comments regarding Part 53 at NRC Part 53 Rulemaking Meeting

Safety Requirements

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

18 November 2020

Safety Requirements - Introduction

- Goal to meet adequate protection standards in way that focuses on public health and safety
- Criteria should be focused on what information is essential to demonstrating the safety case with a level of detail that is commensurate with its contribution to the safety case arguments– and not add additional requirements not necessary for safety case.
- Reduced source term for advanced reactors and high level performance-based requirements bring significant opportunities to reduce requirements to just those providing adequate safety protection.

Safety Requirements – Specific Comments/Questions

- 53.20 For additional measures, how does NRC plan to balance the factors indicated (including public health, economic costs, technology changes, operating experience)?
- 53.20 How will NRC determine what is needed for facility safety program?
- 53.22 c) Why does NRC need to add additional requirements?
  - Seems like an open ended path to load on requirements not required under first tier safety criteria that will undermine NRC's goal of predictability
- 53.23 Why would transformational new regs use Part 50 criteria (e.g. Appendix I)? ALARA not necessary to include in this rule— covered in Part 20. Language such as risk to individual be "below two in one million years" not necessary-- Atomic Energy Act does not require

Safety Requirements – Protection of Plant Workers

- 53.26 Why do worker protections need to be put in this rule when they are covered in Part 20 (and there appears to be no changes in the exposure limits)?
  - Although worker protection is important, it is adequately covered elsewhere and we oppose inclusion of worker protection under the definition of “safety.”
  - Thresholds for public and worker protection are and should be significantly different. Workers are subject to substantial training and informed consent in a way that the public is not.
  - The inclusion of worker protection under the umbrella of “safety criteria” can lead to the significant over-designation of SSCs and administrative controls as “safety related.” This approach probably reduces safety by diluting safety focus on the most important items for protection of public health and safety.

Safety Requirements – Licensing Basis Events & AEA

- 53.22 & 53.24
  - Is thinking that the "licensing basis events" includes the full spectrum of events covered in NEI 18-04 - AOOs, DBEs, DBAs, and BDBEs? Clarity of the scope of events is needed.
  - If there is to be requirements for beyond design basis events (BDBE), will there be a separate section within the rule that provides the performance objectives or criteria for those accidents?
  - Is "licensing basis events" a defined term in Part 50 or Part 52?– if not it needs an explanation
- Relationship between Atomic Energy Act (AEA) section 182 (license applications) and section 161 (general provisions) needs a explanation with respect to how those sections will influence the construction of this rule.

Closing Remarks

- Timely development and implementation of **transformation** Part 53 is important in providing greater certainty and efficiency for future advanced reactor applicants.
- Current regulatory approval process should continue, including appropriate licensing modernization efforts, so no momentum is lost.

U.S. Nuclear Industry Council Contact

For questions or comments contact:

Cyril W. Draffin, Jr.

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

Cyril.Draffin@usnic.org

Subpart B – Technology-Inclusive Safety Requirements

Discussion

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Final Discussion and Questions

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Future Public Meetings

- The NRC staff plans 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 January 2021.
  - Any preliminary proposed rule text will be posted on regulations.gov under docket ID NRC-2019-0062 before the public meeting.
- The NRC staff will be meeting with the ACRS Future Plants Subcommittee every one to two months starting in January 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**

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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
AEA	Atomic Energy Act
ALARA	As low as reasonably achievable
ASME	American Society of Mechanical Engineers
AOO	Anticipated operational occurrence
BDBE	Beyond design-basis event
CFR	Code of Federal Regulations
DBA	Design-basis accident
DBE	Design-basis event
EDO	Executive Director of Operations
EP	Emergency preparedness
EPA	U.S. Environmental Protection Agency

EPZ	Emergency Planning Zone
F-C	Frequency – Consequence
ISO	International organization for standards
LB	Licensing basis
LWRs	Light water reactors
mSv	millisieverts
NEI	Nuclear Energy Institute
NEIMA	Nuclear Energy Innovation and Modernization Act
NGNP	Next generation nuclear plant
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
ONT	Other new technologies

Acronyms and Abbreviations

PAG	Protective action guides
QA	Quality assurance
QHO	Quantitative health objective
rem	Roentgen-equivalent man
SAR	Safety Analysis Report
SMR	Small modular reactor
SRM	Staff Requirements Memorandum
SSCs	Structures, systems, and components
TEDE	Total effective dose equivalent
TS	Technical specifications
USNIC	U.S. Nuclear Industry Council