Part 53 Rulemaking: Industry Perspectives

ACRS Future Plant Subcommittee
December 17, 2021

Marc Nichol, NEI
Senior Director, New Reactors

Cyril Draffin, USNIC
Senior Fellow, Advanced Nuclear

Agenda

- Risk-Informed Licensing Approaches (NEI) 11:45 AM
  - QHOs
  - PRA
  - September white paper

Lunch 1:00 PM

- Standards and Atomic Energy Act (USNIC) 2:00 PM

- Increasing Regulatory Burden without Commensurate Safety Increase (NEI) 2:20 PM
  - ALARA design requirement
  - BDBE in design basis
  - Redundant Programs

- Improving Clarity and Efficiency (USNIC) 3:10 PM
  - Technology-inclusive
  - Goals for Regulatory Efficiency
  - Similar ACRS and Industry Input

- Adjourn 3:50 PM

Risk-Informed Licensing Approaches

Marc Nichol, NEI

Risk-informed Licensing Approaches

Overview of Industry Goals for Part 53

- Usefulness
  - All licensing approaches are viable
  - Less burdensome over the lifecycle of activities
  - Guidance will be important to explain how to meet the regulation
- Risk-Informed
  - NRC PRA policy statement: use of PRA to the extent it is practical
  - Part 53 should allow a variety of roles and uses of the PRA
  - Allow for both “leading” and “confirmatory/supporting” roles
  - Primary expectation is that decisions are informed by the use of a PRA
  - In some cases alternatives to a PRA may provide equivalent benefits

Industry Concerns on Part 53 Rule Language

Subsequent slides present details of industry's perspective on these concerns

1. NRC has stated that performance-based design requirements are not dependent on how PRA is used, but…

   NRC has stated that only LMP and other methods using PRA in a "leading role" can use Part 53

2. NRC has stated that use of PRA in "leading role" is required because QHOs are in the rule, but…

   NRC has not explained why QHOs must be in the rule

3. NRC has stated they are developing Part 5X in response to industry's request to use other risk-informed approaches, but…

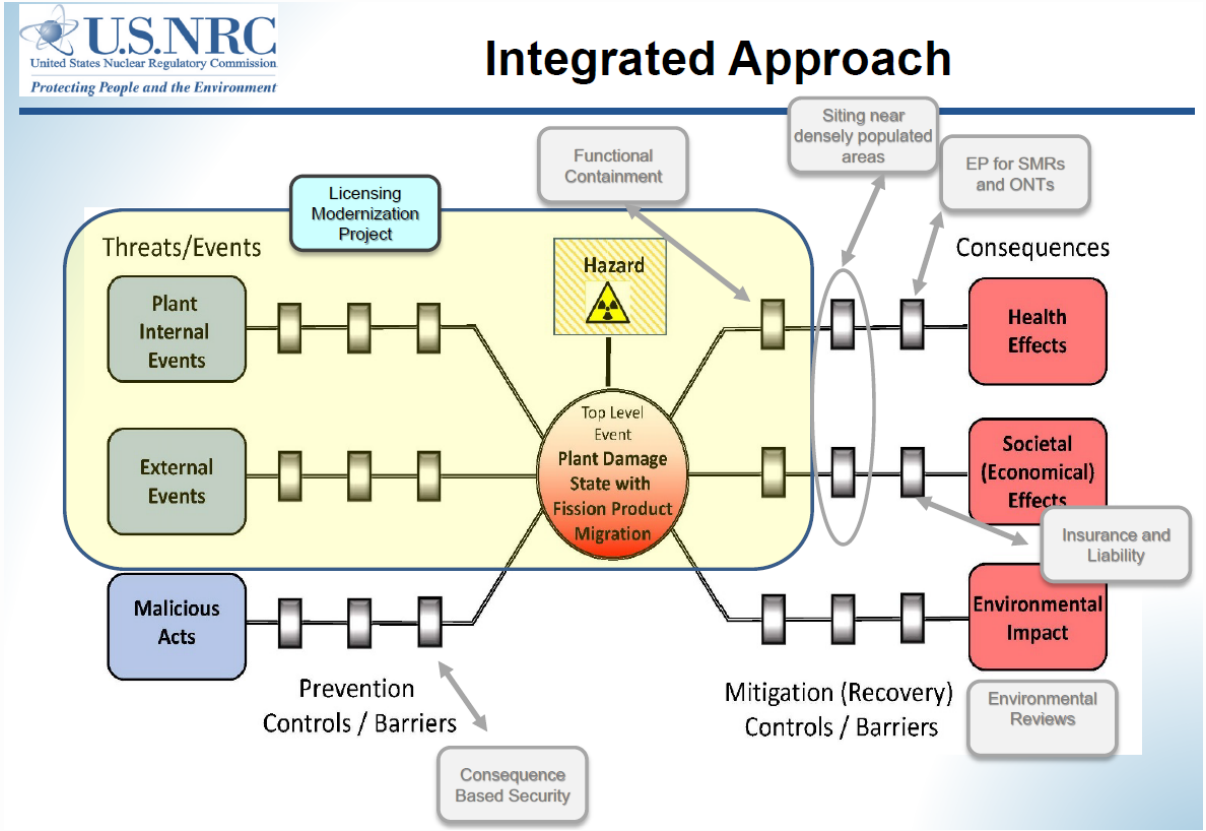
   Industry has requested straightforward changes to Part 53 to accomplish this goal, and industry did not ask for a parallel Part 5X

Benefits of Part 53

Why Part 53 benefits should be available for all risk-informed licensing approaches

- Benefits of Part 53 – performance-based design requirements
  - All requirements are focused back to their relevance to safety criteria
  - Integrated framework of design requirements (see NRC's graphic on next slide)
  - Performance-based acceptance criteria (examples):
    - 53.210 – "{dose} to individual…at EAB {will not exceed} 25 rem TEDE" {for DBA}
    - 53.230 – "primary safety function is limiting release of radioactive material…additional safety functions…must be defined"
    - 53.240 – "LBEs must be identified…must address combinations of malfunctions…human errors…external hazards…{ from AOO to very unlikely}"
    - 53.400 – "design features must be provided {that}...satisfy the safety criteria"
    - 53.410 – "FDC must be defined…to demonstrate compliance with safety criteria"
- We agree with NRC that Part 53 performance-based requirements for plant design are not dependent on how PRA is used

NRC's Integrated Framework



Risk-informed Approach Desired by Industry

Why Part 53 must be inclusive in how PRA is used in the design and analysis

- NEI/USNIC has been asking for a rule that accommodates all risk-informed approaches since mid-2020
  - We wanted Part 53 requirements to be more inclusive, with guidance to address details where necessary
  - We did not want multiple parallel frameworks of requirements in order to enable flexibility
  - Currently Part 50 and 52 requirements achieve inclusiveness through a single design/analysis framework without a reduction in predictability
  - We believe NRC should establish criteria that demonstrates safety, and does not need to require specific methods for design and analysis
- We do not agree with the NRC that only LMP and other methods using PRA in a “leading role” should be able to use Part 53

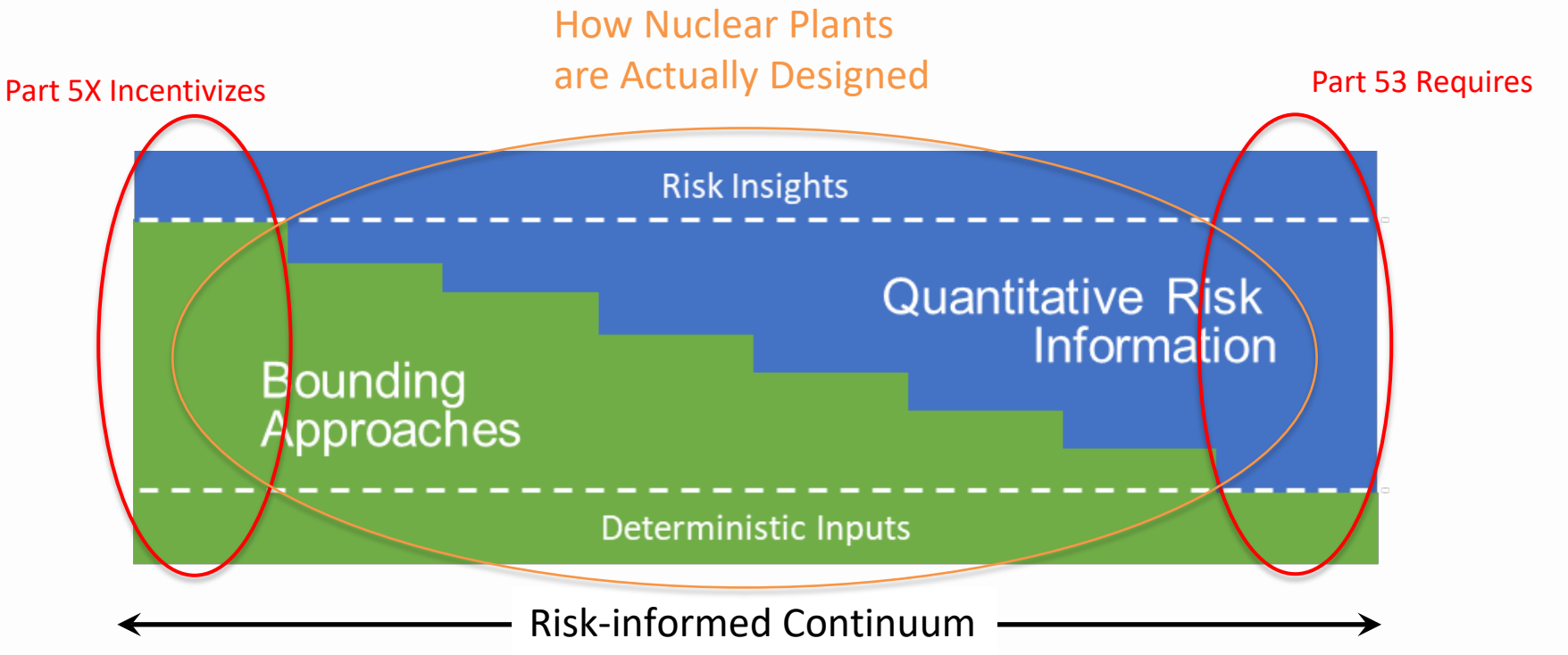
Accomplishing Risk-informing

Benefits of Risk-informing

- Integrated approach of PRA complements deterministic
- Characterize the overall residual risks of a design
- Can help focus on issues of safety significance
- Should yield greater operational flexibility after licensing

Spectrum of Risk-informed Approaches

Parts 53 and 5X don't align with how plants are actually designed and analyzed



NEI September 2021 Paper

"Technology-Inclusive, Performance-Based and Risk-Informed Approaches for Assessing the Safety Adequacy of the Design for Part 53"

- Goals:
  - Advance discussion of how different approaches may fit under Part 53
  - More clearly illuminate the role of PRA and risk information
- Approach:
  - Establish an inclusive framework of principles for a sufficient safety case
  - Build on elements of a TI-RIPB process for assessing safety adequacy
  - Present four examples across the spectrum of potential approaches
  - Demonstrate how each example meets the guiding principles
  - Each example has a different balance between deterministic safety analyses and risk information in what is always a risk-informed process

Key Elements of Part 53 Addressed

- Limits for protecting the public health and safety
- Safety functions
- Licensing basis events
- Defense-in-depth
- Design features
- Functional design criteria
- Safety categorization

Notes

- The paper does not imply an endorsement of the NRC preliminary rule text, but acknowledges that these key elements are important to the safety case
- Other Part 53 elements are important to the licensing basis, but are not included since they do not have a primary effect on the TI-RIPB process
- It is envisioned that the TI-RIPB process in the paper will inform future changes to the Part 53 requirements

Principles for TI-RIPB Process

1. The plant meets the established limits for the adequate protection of the public health and safety.
2. The safety functions, design features and functional design criteria relied upon to meet the safety criteria are established.
3. The systematic selection of LBEs adequately cover the range of hazards that a specific design is exposed to.
4. The SSCs are categorized according to their safety significance.
5. The design reflects the application of an appropriate philosophy of defense-in-depth.
6. The special treatment for SSCs, and associated programmatic controls and human actions, provide reasonable assurance that the SSCs will perform the safety functions for which they are relied upon.
7. The scope and level of detail for the design and analysis of the plant in the licensing basis information adequately describes the safety case. *(Not addressed at this time)*

Examples of Risk-Informed Licensing Approaches

- Four Examples evaluated
  - A: Licensing Modernization Project (NEI 18-04)
  - B: NEI 18-04 with PRA in a complementary role
  - C: Approach compatible with IAEA safety standards
  - D: Bounding Analysis
- Conclusions:
  - All utilize PRA, some use it a little, some use it a lot
  - Use of the PRA in all examples is able to demonstrate safety
  - All can meet Part 53 design requirements, and less prescriptive versions of the PRA requirements
  - All can utilize the Frequency-Consequence curve
  - Specific use of PRA is related to how the designer wishes to approach the design and analysis of the plant

Safety Criteria and QHOs

There has been little discussion of whether QHOs are more appropriate in Policy or the Rule

- NRC has said QHOs must be in the rule, and asked “if not the QHOs, then what?”
  - This is the wrong way to frame the consideration of QHOs and BDBE
- The right framing is “why should QHOs be in the rule”?
  - QHOs have been in Policy Statement for decades, and BDBE is addressed by mitigation requirement
  - What problem is solved by having QHOs in the rule?
  - Are there benefits to QHOs in the rule?
  - Are the disadvantages and risks, of QHOs in the rule, reasonable and being mitigated?
- The NRC has not provided a basis for having QHOs in the rule
  - We provided an assessment of QHOs in rule vs. Policy Statement as early as January 2021, but did not receive any feedback from NRC

Quantitative Health Objectives (1/3)

Industry's Evaluation of advantages/disadvantages of putting QHOs in the rule

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., risk 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 Health Objectives (2/3)

QHOs in the rule do not improve safety, but do create complications

- Safety is the same whether QHOs are in Rule language or the Policy statement
  - Both approaches demonstrate that design meets the QHOs
  - The applicant's design and analysis are the same
  - The NRC scope of review is the same
- The difference is in the legal compliance
  - QHO in policy statement: staff confirm applicant's conclusions that QHOs are met
  - QHO in rule: applicant must demonstrate legal compliance, subject to hearing contention
- NRC stated that QHOs in the rule requires a "leading" PRA approach
- QHOs in the rule is not an evolution of the PRA Policy Statement, but far exceeds the envisioned application of them (SECY 89-102):
  - Evaluate adequacy of requirements to achieve acceptable risk to the public
  - Objectives not to be used as requirements, but useful as basis for guidance
  - Useful, in a generic sense, in making regulatory decision for an application

Quantitative Health Objectives (3/3)

Industry's Proposal for QHOs in Part 53 to Achieve acceptable risk to the public

- Apply consistent with the Safety Goal Policy Statement
- Ensure requirements achieve acceptable risk to the public
  - Dose to the public less than 1 rem (§ 53.260)
  - Occupational exposures less than 5 rem (§ 53.270)
  - Anticipated Operational Occurrences: can set 1 rem limit (if necessary)
  - Design Basis Accidents, dose less than 25 rem (§ 53.210)
  - Beyond Design Basis events: Mitigation similar to 10 CFR 50.155 (§ 53.220)
  - Establish requirements for systematic search for events (§ 53.240, 53.450)
- Inform basis for guidance to establish risk-based metrics
  - Can use QHOs directly for comparison (as in LMP)
  - Can use QHOs to develop surrogates (e.g., core damage frequency)

Performance-Based Requirements for PRA

Why NRC prescriptive use of PRA in the Rules is not necessary

- NRC Part 52 requirement:
  - Applicants to provide a description of the plant-specific PRA and its results.
- Practical use of the PRA in Part 52:
  - Identify and address potential design and operational vulnerabilities (e.g., assumed individual or common-cause failures could drive plant risk to unacceptable levels with respect to the Commission's goals)
  - Demonstrate how risk compares against the Commission's Policy Goals (e.g., QHOs)
  - Demonstrate whether RTNSS is sufficient
  - Support regulatory oversight
  - Support development of specifications for ITAAC, TS, etc.
  - Scope: Level 1 and 2 including internal and external events and all modes
  - Risk insights: SSC most effective at reducing risk, major contributors of risk and uncertainty

Prescriptive Requirements for PRA

Why NRC prescriptive use of PRA in the Rules is not necessary

- NRC Part 53 PRA requirements (red are not in Part 50/52 rule language):
  - Consider events that challenge plant control and safety (internal and external)
  - Conform with generally accepted methods
  - Be maintained and upgraded every two years
  - Identify potential failures, degradation mechanisms, susceptibility to internal and external hazards, other contributing factors to unplanned events that might challenge safety functions
  - Determine licensing basis events
  - Used for classifying SSCs and human actions according to safety significance, and environmental conditions
  - Evaluate adequacy of defense-in-depth measures
  - Assess all plant operating states where there is a potential for uncontrolled release

Industry Proposed Requirements for Part 53

Why NRC prescriptive use of PRA in the Rules is not necessary

- Performance-based analysis requirements:
  - Analyses of licensing basis events must be performed
  - Must systematically identify event sequences from initiation to safe stable end state
  - Must demonstrate compliance with safety criteria
  - May perform a single of multiple bounding analyses
- Performance-based PRA requirement:
  - Must perform PRA to incorporate risk insights into the design, as appropriate
  - PRA completeness commensurate with completeness of design
  - Be maintained and upgraded every four years
- Performance-based requirements achieve same outcome as NRC's prescriptive requirements (e.g., rigor, confidence)
  - They are also inclusive to accommodate all roles of the PRA

NRC's Prescriptive Requirements for PRA

Concern that NRC will require more of the PRA to be submitted as part of licensing basis

- Industry concern has been that QHOs in the rule and more prescriptive PRA requirements will lead to NRC requiring more of the PRA to be submitted in the licensing basis
- NRC stated at December 9, 2021 Commission briefing, that it is not their intent to require the PRA to be submitted to and reviewed by the NRC
  - We support this intention and do not think the PRA should be part of the licensing basis, but is available for NRC inspection
- However, the preliminary rule language and staff statements have not reflected this intention
  - 53.1185: "The SAR must include…an analysis of {*all*} LBEs…to determine compliance with…53.220 {*QHOs*}…must address elements in 53.450(e) and (f) {*PRA requirements*}"
  - NRC statement at 5/27/21 meeting that NRC would need to review PRA
  - NRC's endorsement of TICAP must include more PRA details (e.g., reliability and capability targets for SSCs)

A Part 53 Inclusive of All Licensing Approaches

Why pursuit of Part 5X is not necessary, inefficient and increasing confusion

	NRC's Approach	Industry's Proposal
Approach to include all risk-informed approaches	Two+ Rigid frameworks (53, 5X, maybe MA)	Single inclusive framework (Part 53)
Proposal for Part 53	Only allowed for LMP and leading PRA role	Straightforward changes to QHO and PRA requirements to allow all risk-informed approaches
Proposal for Part 5X	80%-90% of Part 50/52 requirements, attempt to make tech-inclusive	Delete and abandon
Proposal for TIRIMA	Considering whether to include	Potential use for guidance, may need exemptions to Part 53
Level of effort and clarity	Significant effort needed, complex and confusing	Very little effort needed, clear and straightforward

- NRC should revise Part 53 to be inclusive of all risk-informed approaches, abandon Part 5X
- Industry is developing guidance that would implement the inclusive Part 53 recommended in 11/5/21 comments

Standards and AEA

Cyril Draffin, USNIC

Standards and AEA – NRC Iterations

Standards in statutory requirements in Atomic Energy Act

- Section 182, *"adequate protection to the health and safety of the public"*
- Section 161, "*to protect health or to minimize danger to life or property.*"

NRC 1st iteration of preliminary rule language established the AEA statutory standards identified above as basis for Part 53 (ML20311A004) for 53.200

NRC 2nd & 3rd iteration of preliminary rule language reduces regulatory clarity

- Current version replaces AEA language with different safety standards that do not clearly relate back to the AEA and have no regulatory precedent
- 53.200, *"limit the possibility of an immediate threat to the public health and safety"* and "*considering potential risks to public health and safety*"

Standards and AEA – NRC Perspective – written (in NRC Discussion of 2nd Iteration of Subpart B, § 53.200 Safety Objectives)

"The change is to revise the first objective from providing "reasonable assurance of adequate protection" to limiting "the possibility of an immediate threat to the public health and safety." This language generally aligns with standards the Commission has used for determining the content of technical specifications. The change also revises the second objective from "protect public health and minimize danger" to "as may be appropriate when considering potential risks to public health and safety." The purpose of these objectives is clarified by adding the statement that they will be carried out by meeting the safety criteria identified in this subpart (§§ 53.210 and 53.220).

This change resulted from stakeholder comments and internal NRC discussions regarding the difficulties in using the Atomic Energy Act (AEA) Sections 182 and 161 authorities as the safety objectives for part 53, and in turn as the bases for the two-tier safety criteria framework. Instead, the use of "adequate protection" is expected to be used in its traditional role as an NRC regulatory finding, which is presumed through compliance with NRC regulations including part 53 or other license requirements. While Sections 182 and 161 of the AEA will be cited as enabling legislation within the rule package (e.g., in the Federal Register Notice), the staff does not foresee incorporating language from the AEA into the safety objectives or tiers in part 53."

Standards and AEA – NRC Perspective -verbal

During public meeting discussing change in safety objectives, NRC staff explained that because entirety of Part 53 satisfies the AEA, AEA standards do not need to be referenced in Part 53, and NRC thus should establish new standards to frame the Part 53 requirements.

Standards and AEA – Observations

NRC change seemed to be in support of two tier structure – that has now been dropped responsive to ACRS and Industry comments

NRC refers to stakeholder input

Approach inconsistent with longstanding practice of NRC and appears to reject decades of Commission precedent, with no compelling benefit or indication of Commissioners' approval

Standards and AEA – Concerns with 3rd Iteration

New approach requires extra resources

- NRC would need to invest significant resources in defining these new standards, to ensure consistency with the AEA

New approach reduces regulatory clarity and efficiency

- No clear connection between the Part 53 requirements and the AEA safety standards.
- No equivalent in Parts 50 and 52, no regulatory precedent

Could greatly expand NRC's regulatory control beyond what is in place for existing reactors without increase to safety

- Appears to be regulatory overreach that contravenes longstanding safety policy embraced by the Commission for decades consistent with safety standards established by AEA
- No explanation on what new safety standards mean, how they can be met, or how they relate to all requirements in Part 53

Standards and AEA – Lack of Clarity

Lack of clarity on how requirements relate back to AEA safety standards

- Even after decades of implementing standard of “adequate protection” NRC had to issue multiple recent memos to staff to avoid misapplication of this standard in application reviews (ML19015A290, ML18240A410, and ML19260E683)
- Such challenges will be exacerbated in Part 53 if it introduces new standards rather than providing clarity on how requirements relate back to AEA standards

NRC should utilize the safety standards from the AEA, as done in 1st iteration, rather than creating new standards (2nd/3rd iterations)

Increasing Regulatory Burden without Commensurate Increase in Safety

Marc Nichol, NEI

Achieving Safety More Efficiently

Overview of Industry Goals for Part 53

- Usefulness
  - Less burdensome over the lifecycle of activities
  - Performance-based requirements with clear/objective acceptance criteria
  - Guidance will be important to explain how to meet the regulation
- Efficiency
  - Achieve equivalent level of safely more efficiently than Parts 50 and 52
  - Reduced cost and schedule in licensing and oversight
  - Do not include requirements that Part 50/52 have shown are not needed to protect the public
  - Do not include new requirements that are not needed to protect the public
- Recognize confidence in licensee controls
  - NRC imposes requirements that are effective even after the NRC issues a license
  - Licensee is competent in fulfilling their responsibility to meet programmatic requirements
  - NRC oversight and inspection to ensure compliance

Industry Concerns on Part 53 Rule Language

Subsequent slides present details of industry's perspective on these concerns

- ALARA design requirement
- BDBE in design basis
- Proliferation of Redundant and unnecessary Programs
- Facility safety program

As-Low-As Reasonably Achievable (1/3)

NRC including design requirement, beyond the currently requirement program requirement

- Part 53 doesn't need to have any requirement for ALARA
  - Part 20 ALARA requirements will still apply
- Part 20 Requirements on ALARA, Subpart B (20.1101):
  - Must use, to the extent practical, procedures and engineering controls to achieve ALARA
  - Must implement an RP program to ensure compliance with Part 20, including achieving ALARA
  - No requirement for design to consider ALARA
- NRC's Part 53 requirement for ALARA is clearly expanding to include design :
  - 53.260(b): "Design features and programmatic controls must be established such that the TEDE…are ALARA in accordance with Part 20"
  - 53.270(b): "As required by Subpart B of Part 20, design features and programmatic controls, to the extent practical, be based on RP principles to achieve occupational doses that are ALARA."

As-Low-As Reasonably Achievable (2/3)

- ALARA design requirements not consistent with past Commission decisions*
  - "the ALARA concept is intended to be an operating principle rather than an absolute."
  - ALARA can be achieved solely through the implementation of the licensee's radiation protection program, required by Part 20
  - "expressly intended that the level of this program and efforts to document it are commensurate with the size of the licensed facility and the potential hazards from radiation exposure and the intake of radioactive materials."
- ALARA as a design requirement increases regulatory burden without a safety benefit
  - No practical endpoint for additional measures, and it is left to negotiation between the NRC and the designer as to how much is good enough
  - Addressing ALARA through programs has been effective for decades
  - Inconsistent with the development of more risk-informed, performance-based and efficient regulatory framework for advanced reactors

*See: Standards for Protection Against Radiation; Final Rule, 56 Fed. Reg. 23359, 23366, 23367 (May 21, 1991)

As-Low-As Reasonably Achievable (3/3)

- NRC stated in December 9, 2021 Commission briefing on Part 53
  - Not intent to elevate ALARA as a design requirement
  - Perhaps more of an “option” during the design, provides flexibility
- Part 53 requirements do not achieve NRC intention
  - 53.260(b) and 53.270(b) require design features and programmatic controls for ALARA, they don’t allow an option
- It is unclear how an option for ALARA design requirement would work
  - If applicant meets requirements for design to achieve ALARA, would they not be required to consider ALARA in their radiation protection program?
  - Who would want to meet a voluntary design requirement for ALARA if they are still required to meet ALARA in RP program?
  - Without ALARA design requirement: Developer can still optimize design for addressing ALARA in RP program.
  - What flexibility does an ALARA design requirement provide?
- Best solution is to delete the ALARA requirement from Part 53

Beyond Design Basis in the Design Basis

NRC expanding requirements for BDBE

- NRC stated in December 9, 2021 Commission briefing on Part 53
  - Part 53 benefit is more up front *{BDBE requirements}*, downstream flexibility
  - Not intent to include BDBE in design basis
  - Treated the same as today, BDBE doesn't need to rely on safety-related SSCs
- Part 50/52 requires mitigation for BDBEs – 10 CFR 50.155
- Part 53 requirements do not achieve NRC's intentions
  - Part 53 requires mitigation for BDBE's in 53.450(g)(3)
  - Part 53 also establishes requirements for BDBE design through QHOs in the rule
    - 53.400 requires design features to meet 53.220
    - 53.420 requires functional design criteria to meet 53.220
    - 53.440 establishes design requirements to meet 53.220
    - 53.460 requires special treatment for NSRST similar to SR to meet 53.220
    - 53.220 includes BDBE through QHOs in the rule
- Part 5X also includes BDBE in design basis

Beyond Design Basis in the Licensing Basis

BDBE in design basis is inconsistent with Commission decisions to treat through mitigation

- Commission directed the staff to remove design requirements for BDBE for new reactors in the Proposed Rulemaking for Mitigation of Beyond Design Basis Events in SRM-SECY-15-0065 (ML15239A767).
  - Commission recognized the NRC ability to provide oversight for mitigation
- Commission specifically noted that requirements should not establish a separate standard for new reactors
  - "A more flexible approach for new reactor applicants [mitigation] is preferred"
- Advanced reactor policy statement has led to designs with reduced reliance on human actions
  - "this rule allows an applicant for a new reactor license…to provide innovative solutions to address the need to effectively prioritize event mitigation and recovery actions"
  - "regulatory requirements should not impose unnecessary burden or divert attention from more important safety objectives"

Beyond Design Basis in the Licensing Basis

Industry's proposal for a more technology-inclusive mitigation requirement

- Keep QHOs in Policy, do not include in rule, since they drive the BDBE design basis requirements,
- Replace 53.220 with the following (technology-inclusive version of 50.155):

  For BDBEs, each applicant or licensee shall develop, implement, and maintain mitigation strategies and guidance that are capable of being implemented site-wide and must include the following:

  (a) The capability to maintain or restore the safety functions necessary to meet the safety criteria in 53.210.

  (b) The acquisition and use of offsite assistance and resources to support the functions required by paragraph (a) of this section indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies

  (c) Strategies and guidance to provide the capabilities in (a) under the circumstances associated with loss of large areas of the plant impacted by the event, due to explosions or fire, to minimize radiological releases.

Operational Programs

Overview of industry's perspective

- NRC's prior assertions that: increased design and analysis burden would lead to a reduction in operational burden does not appear accurate
- NRC needs to reassess the program requirements in Part 53
  - 11 program areas have equivalents in Part 50/52
  - 13 program areas do not have a Part 50/52 equivalent or duplicate others
  - Over 20 instances of open ended requirements for "programmatic controls"
- NRC needs to establish a regulatory philosophy for Part 53 that defines the regulatory purpose of programs
  - Having clarity on why programs are needed will ensure that the program requirements are efficient
- NRC should ensure needed programs are performance-based, graded and appropriately scoped with entry criteria
  - Some programs (with Part 50/52 equivalents) are more burdensome, without increasing safety, than Parts 50/52

Evaluating NRC Proposed Part 53 Programs

Programs with a Part 50/52 Equivalent

Required in NRC Part 53 Preliminary Language	Part 50/52 Equivalent Requirements
53.710(a)* - Initial Startup Testing	50.34(b)(6(iii)
53.870 Inservice Inspection/Inservice Testing	50.55a
53.730 Maintenance, repair, and inspection programs	50.65 - although some elements may not have Part 50/52 counterpart
53.720 Maintaining capabilities and availability of SSCs	50.36 and 50.69
53.710(b)* - Training (Expected in future Subpart F requirements on human actions)	50.2, Part 55, 50.120
53.710(c)* - Operating Plans (Expected in future Subpart F requirements on human actions)	50.34(b)(6)(iv and v)
53.860 Fire Protection	50.48
53.810 Radiation Protection	Part 20
53.820 Emergency Preparedness	50.47 or 50.160 (in development)
53.830 Security Programs	Part 73 (73.54, 73.55, 73.56) and Part 26
53.550 Environmental Considerations – Points to Part 51	50.36b – Points to Part 51 (if applicable)

*Note that at the time this slide was developed the NRC has not yet released the Subpart F regulations for human actions, which could include duplicative requirements

Evaluating NRC Proposed Part 53 Programs

Programs that duplicate the Quality Assurance Program

Required in NRC Part 53 Preliminary Language	Part 50/52 Equivalent Requirements
53.840 Quality Assurance	Most of Appendix B QA Program
53.480 Design Control Quality Assurance	None - Duplicates QA Program
53.610(a)(1&7) and 53.620(a)(1&6) Construction and Manufacturing Quality Assurance	None - Duplicates QA Program
53.490 Design and Analyses Interfaces	None - Duplicates QA Program
53.740 Design Control	None - Duplicates QA Program
53.620(b)(1)(IV)(vii) – Manufacturing, Manufacturing Activities	None - Duplicates QA Program

- NRC should eliminate requirements that duplicate the QA Program
- NRC should put all of the QA Requirements together similar to Appendix B
  - Preserve the ability to use Appendix B QA program for those that wish to
  - Enable the use of ISO-9001 and other commercial QA standards
- NRC does not need to specify QA requirements for non-safety-related but safety significant SSCs

Evaluating NRC Proposed Part 53 Programs

NRC Required Programs without any Part 50/52 equivalent

Required in NRC Part 53 Preliminary Language	Part 50/52 Equivalent Requirements
53.700 Operational Objectives	None – Duplicates most other operational programs
53.800 Operational Programs	None – Duplicates most other operational programs
53.850 Integrity Assessment Programs	None – Duplicates Maintenance, ISI/IST, Technical Specifications, and creates an aging management program from Day 1
53.890, 53.892, and 53.894 Facility Safety Program, Criteria and Plan	None – Duplicates other programs, codifies periodic safety review, and circumvents backfit protection
53.880 Criticality Safety Program	None – Not necessary to require a program for compliance with each requirement. 50.68 is a better model for Part 53 requirement.
53.610 (a)(2-5), (c&d) and 53.620(a)(2-4), Construction and Manufacturing Organization and Procedures	None – Not necessary for NRC to approve the organization and plan during construction and manufacturing
53.1225 PRA Maintenance Program for 53.450(c)	None – Not necessary for NRC to approve the controls for updating the PRA
53.460(c) Human Action Performance Program	None – Duplicates the training and other operational programs related to performance of human actions

- NRC should eliminate all of these programs as they are not needed for reasonable assurance of adequate protection

NRC Approach to Programs in Part 53

An unstructured approach is inefficient and creates unintentional challenges

- NRC's approach to administrative controls results in:
  - Dramatic expansion of NRC regulatory footprint over licensee controls
  - An unclear and unbounded set of programmatic information subject to NRC approval
- Part 53 requires more programs and administrative controls be approved by the NRC, as compared to Parts 50/52
- Part 53 requires approval of programmatic controls not required by Part 50/52
  - *Programmatic controls* mean administrative procedures that govern the actions of equipment and personnel of an advanced nuclear plant.
  - Required in 53.210, 53.220, 53.230, 53.240, 53.250, 53.260, 53.270, 53.400, 53.410, 53.420, 53.425, 53.430, 53.440, 53.460, 53.470, 53.490, 53.500, 53.510, 53.540, 53.610, 53.1225, etc.
  - Typically stated as "Design features and programmatic controls must be provided for…" – Not performance-based, clear or predictable

Programs Need to be Created with the Broader Regulatory Framework in Mind

- Programs work together with design features and human actions to for the technical basis for protecting the public
  - The role of programs is to provide reasonable assurance that the design features and human actions will perform the actions described in the licensing basis
  - Not all of the programs used by the licensee need to be required to be approved by the NRC
- The NRC imposes requirements that are effective even after the NRC issues a license for a new reactor
  - NRC has an oversight and inspection program to ensure compliance
  - NRC does not need to approve licensee controls related to compliance
- The licensee is competent in fulfilling their responsibility to perform administrative controls
  - QA Program permeates the plant at each stage; comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service
  - Very little need for NRC approval of other administrative controls to achieve reasonable assurance that design features and human actions will perform functions in the licensing basis

Performance-Based Approach to Part 53 Programs

Leads to a clear, predictable and flexible regulatory framework

- Recognize that the QA Program provides substantial assurance that design features and human actions will perform functions in the licensing basis
- Establish the purpose for programs (e.g., by stage)
  - **Design** - Provide reasonable assurance that the plant design is in accordance with the license and regulations.
  - **Manufacturing and Construction** - Provide reasonable assurance that the plant is constructed and manufactured according to the license and regulations.
  - **Maintenance** - Provide reasonable assurance that the SSCs are capable of performing their intended functions described in the SAR.
  - **Operations** - Provide reasonable assurance that the plant is operated according to the license and regulations.
- Establish performance criteria for each program, and entry criteria (graded)
- Evaluate suitability of historical programs required by Part 50/52
- Identify historical administrative controls not required to have NRC approval

Performance-Based Approach to Part 53 Programs

Leads to a clear, predictable and flexible regulatory framework

	Performance Criteria	Part 50 Programs Requiring NRC Approval	Programs not needing NRC Approval
Design	Provide reasonable assurance that the plant design is in accordance with the license and regulations. 1. Applicable regulatory requirements and the design basis specified in the license are correctly translated into specifications, drawings and procedures. 2. The design process used appropriate quality standards, selected materials, parts and processes, controlled interfaces among participating organizations, suitable to the safety significance of the SSCs, and provided for verifying the adequacy of the design. 3. Performance characteristics of SSCs that serve as the basis for the design and analyses are supported by validation data. 4. Design changes are subject to the same design control measures and approved by the same design organization used for the original design.	• Criterion III – Design Control (Appendix B)	• Change Control (50.59) • Records, reports and • FSAR Update (50.71) • Reliability Assurance Program (SRM-SECY-95-132) • Environmental Qualification (50.49(a))

Performance-Based Approach to Part 53 Programs

Leads to a clear, predictable and flexible regulatory framework

	Performance Criteria	Part 50 Programs Requiring NRC Approval	Programs not needing NRC Approval
Manufacturing and Construction	Provide reasonable assurance that the plant is constructed and manufactured according to the license and regulations 1. As-built SSCs are consistent with their as-designed specifications. 2. The applicable regulatory requirements are referenced in the procurement documents. 3. Procured material, equipment and services conform to the procurement specifications. 4. As-built SSCs, prior to operation, are capable of performing the functions described in the license.	• Criteria IV, VI thru XV – for safety-related SSCs (Quality Assurance - Appendix B) • Defined by Applicant - for non-safety related but risk important (50.69 Augmented Quality) • Initial startup testing program (50.34(b)(6(iii))	• NSR SSC – Any commercial quality program • Procurement program • Receipt and verification programs • Turnover and routine startup program • Reporting of Defects and Nonconformances (Part 21)

Performance-Based Approach to Part 53 Programs

Leads to a clear, predictable and flexible regulatory framework

	Performance Criteria	Part 50 Programs Requiring NRC Approval	Programs not needing NRC Approval
Maintenance	Provide reasonable assurance that the SSCs are capable of performing their intended functions described in the SAR. 1. SSCs, during operations, continue to be capable of performing the functions described in the license. 2. SSCs, for which the code or regulations require periodic inspection or testing, are confirmed to have not experienced unexpected degradation.	• Maintenance Monitoring Program (50.65) • ISI/IST (50.55a) • Material Surveillance Program – if applicable (Part 50 Appendix H)	• FLEX Equipment - if applicable (50.155) • Maintenance procedure development

Performance-Based Approach to Part 53 Programs

Leads to a clear, predictable and flexible regulatory framework

	Performance Criteria	Part 50 Programs Requiring NRC Approval	Programs not needing NRC Approval
Operations	Provide reasonable assurance that the plant is operated according to the license and regulations. 1. Plant stays within the licensed conditions of operations. 2. Administrative controls provide reasonable assurance that human actions credited for protection of public health and safety will be performed when needed. 3. Humans relied upon are trained and capable of performing assigned actions as described in the license.	• Technical specifications (50.36) • Training and Requalification Programs for Operators, Fuel Handlers and Other Identified Positions (50.2, Part 55, 50.120) • Operating Plans, Normal and Emergency (50.34(b)(6)(iv and v)) • Fire Protection Plan (50.48) • Radiation Protection (Part 20) • Emergency Planning (50.47 or 50.160) • Security (Physical, cyber, access and FFD) (Part 73, Part 26) • Environmental Protection – if applicable (51.50)	• Effluent release program • Worker safety training programs and effectiveness assessments • OSHA worker safety • Procedure development for operations and emergencies • Event Reporting (50.72/50.73)

Operational Programs

NRC creating duplicative and unnecessary programs

- Industry presented the preceding to NRC on September 15, 2021
- NRC response during the meeting
  - Can't compare Part 53 requirements with Part 50/52 requirements
  - Industry doesn't understand that NRC requirements are reducing regulatory burden
  - Regulatory burden within each program is less, so shouldn't be concerned that there are more programs
- NRC has not provided a basis for requiring any of the programs in Part 53 that duplicate other programs or have no equivalent in Parts 50/52

Improving Clarity and Efficiency: Technology Inclusive

Cyril Draffin, USNIC

Technology Inclusive – All types of reactors

- During October 26, 2021 NRC Part 53 public meeting, NRC stated that they intend to revise preliminary language so that Part 53 is not restricted to only being used by “advanced reactors”
  - We agree this should be the intention
- Part 53 allows all types of nuclear reactor technologies
  - Avoid parallel rule frameworks for different technologies
  - Have separate guidance if necessary
  - Exclusion of any nuclear plant that is not considered “advanced” might unnecessarily exclude technologies that could meet Part 53 safety

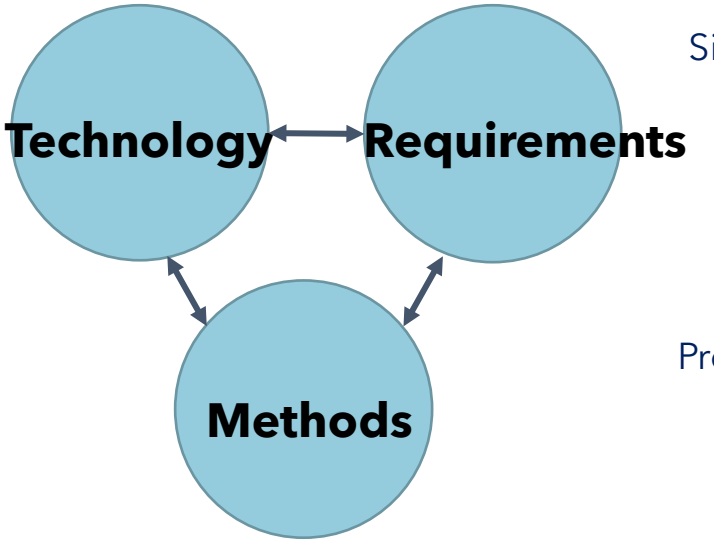
Technology Inclusive – All developers

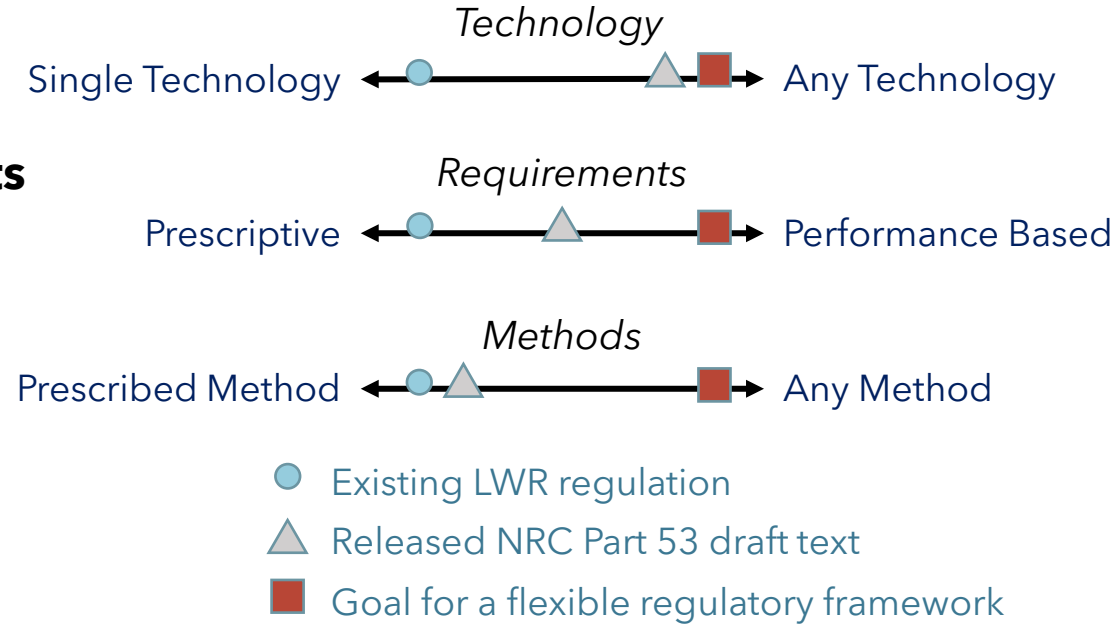
- Apply to all reactor developers and applications
  - Part 53 requirements are screening criteria determining if developer would use (and applicant would meet relevant safety requirements)
  - May be used for electricity, process heat, hydrogen production, and other applications
- Part 53 does not need to be limited in scope, and rule could easily be applicable to all production and utilization facilities licensed under AEA Section 103 or 104

Technology Inclusive – Consistent with NEIMA

- While NEIMA defined "advanced nuclear reactor" when it provided statutory requirements for NRC to develop Technology-Inclusive Regulatory Framework, it did not limit such framework only to "advanced" reactors, but rather stated that it should be "*flexible and practicable for application to a variety of reactor technologies*"
- NRC should not limit use of Part 53 to facilities according to features defined as advanced nuclear reactor in the NEIMA (B thru H), such as "*lower levelized cost of electricity*," "*increased thermal efficiency*" and "*ability to integrate into electric and nonelectric applications*," because these fall outside NRC's authority of regulating nuclear safety
- NRC should not limit use of Part 53 to reactors that have additional inherent or passive safety features because that establishes a "moving target" for applicability that could disrupt regulatory stability
- No benefit for NRC to create artificial screening criterion to compare Part 53 applicant's use of inherent or passive safety features in design to "significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act." If proposed design can meet Part 53 requirements for safety, that should be sufficient justification for utilizing Part 53
- Creating screening criterion to use Part 53 based on increased use of inherent or passive safety features is unnecessary, and is contrary to NRC's Advanced Reactor Policy Statement, which encourages but does not require enhanced safety of advanced reactors

Part 53 regulations can balance certainty and flexibility across multiple characteristics





source: Nuclear Innovation Alliance, 9 December 2021 presentation to NRC Commissioners

Goals for Regulatory Efficiency

Cyril Draffin, USNIC

Complexity Creates Problems – guidance might help resolve (1/2)

- For effective licensing, NRC needs to have high-level plan on how Part 53 will integrate all aspects of regulation
  - Including rules, guidance, staff interpretations, and oversight during operations
  - To date, Part 53 guidance limited (other than TICAP designed for Part 50/52)
    - Without guidance (e.g. for change control) not possible to fully assess NRC preliminary approach
    - NRC provided list of needed guidance earlier in 2021, and 9 month delay offers time
  - Limited clarity on how to have timely reviews and avoid submission of unnecessary information in applications under Part 53
  - Limited clarity on scope and extent of inspections during operations, and what operational flexibility will be allowed

Complexity Creates Problems – guidance might help resolve (2/2)

- Without clarity, overlapping requirements and programs may make it harder for NRC staff to approve applications and implement rule
  - Goal is to focus on safety significant aspects of technology, and not be distracted by minor issues with very limited impact on safety
  - Rapid scale up of advanced reactor applications could challenge the staff's ability to make timely regulatory decisions

NRC Internal Goals for Part 53 Regulatory Efficiency

- With potential order of magnitude increase in applications, NRC needs metrics to judge their internal regulatory efficiency
  - Shorter and predicable timeframes (e.g. number of months) to review license applications
  - Effective use of prior Topical Reports and other approvals (include documentation submitted and approved by other regulatory organizations)
  - Lessons learned
  - RAIs (reduce requests for additional information, especially for non safety-significant matters)
  - Benefits of pre-application reviews focused on key issues; early escalation of key policy issues
  - Effectiveness of core teams for licensing reviews of FOAK and subsequent applications
  - Constraints on unnecessary oversight reviews and inspections
  - Long term regulatory stability
  - Develop scalable process
  - Eliminating inefficiency and making best use of NRC staff resources (importance of both efficiency and effectiveness)

NIA Dec 2021, Promoting Efficient NRC Advance Reactor Licensing Reviews to Enable Rapid Decarbonization

Clear Vision and Specific Goals for Final Rule (1/2)

- Encourage NRC to establish clear vision and specific goals for the final Part 53 rule, and to utilize systematic approach to developing rule
- From Unified Industry Position (letter dated July 14, 2021) re Part 53
  1. Available for use by all technologies and risk-informed licensing approaches
  2. Less burdensome over the lifecycle of activities (e.g., licensing, construction, operations, oversight), than regulating under the existing Parts 50 and 52
  3. Built upon performance-based requirements that define clear and objective acceptance criteria
- Vision, goals and systematic approach are important to ensure that the final rule will be successful
  - Rule to effectively accommodate large number of reactor applications
  - Provide different pathway for new reactor designs

Clear Vision and Specific Goals for Final Rule (2/2)

Industry has proposed Principles in Adopting New Part 53 as far back as 10 October 2019 NRC public meeting-- USNIC "10CFR Part 53: Ideas for Risk-informed, Technology Inclusive Regulatory Framework for Advanced Reactors Rulemaking"

- New Part 53 should be focused on technical requirements and should minimize administrative requirements inconsistent with efficient licensing
- Eliminating or streamlining requirements that are overly prescriptive or not relevant will reduce need for future exemptions
- Need to avoid putting too much detail in FSAR – simplicity is the key
- Revisit content of application requirements to right-size FSAR to reflect safety-significance of systems, structures or components (also applies to operational programs like maintenance rule, QA, radiation protection, in-service inspection, startup)
- Consider required reviews in fixed period of time (e.g. 2-3 years for Small Modular Reactors; 6 months for micro-reactors) once initial SMRs and micro-reactors have been approved
- Commission needs to address ongoing policy questions associated with security and emergency planning zone requirements to recognize the reduced source term and size of these designs, in order to avoid potential conflicts in a future Part 53

and NEI's October 21, 2020 letter - ML20296A398

Path for Exemptions in Part 53

- For non-LWRs, substantively fewer Part 53 exemptions likely to be required vs. Part 50 & 52
- But smooth process for Part 53 exemptions also may be needed
  - Many potential applications might be presented to NRC (with different coolants, fuels, technology designs and sizes)
  - NRC could make process easier in Part 53, and proactively recommend exemptions

Part 53 Coordination with other Rulemakings

Important contemporaneous efforts underway:

- Emergency planning
- Security
- GEIS (Environmental reviews)

As appropriate, NRC should better integrate safety, security, EP, and siting

Similar ACRS and Industry Input

Cyril Draffin, USNIC

Similar ACRS and Industry input on Part 53 (1/2)

- Drop two tier structure
- Flow of objectives, safety criteria, safety functions
- Decouple requirement for normal operation
- Not require or rely on just LMP approach or IAEA approach
- Part 53 can be methodology neutral, and PRA language should be modified to enable use of PRA in ways applicants expect to use the tool
- Applicants use spectrum of risk-based and deterministic approaches
- Part 53 should be risk-informed not risk-based
- Broad interpretation of credible event increases regulatory uncertainty

Similar ACRS and Industry input on Part 53 (2/2)

- Add requirements for safe, stable end state conditions
- Unify QA requirements (allow broader set of codes and standards)
- Provide detailed explanation of the integrated intent of the rule
- Duplication in draft
- More guidance is needed to clarify regulations
- Questioned ALARA in rule

Other topics

Cyril Draffin, USNIC

Quality Assurance Requirements

- Unify all QA references in single location in Part 53
- Opportunity for fresh look at alternatives to NQA-1
  - Commercially available components quality may meet/exceed “nuclear standards” with reduced artificial burden
  - Rule should require quality control program, but not specify approach
- Guidance should support broad standards and approaches, e.g., ISO 9000 series, IAEA, commercial dedication
  - Reduce barriers to commercial competition, and facilitate licensing abroad– recognizing greater supply chain base can improve quality
  - International acceptance of a single approval could be important in international marketability
  - Guidance should show ISO standards and IAEA approaches meet requirements
  - Guidance could address topic of universal acceptance of codes and standards (mechanical, electrical)
- NEI is developing guidance on using ISO-9001 to meet Appendix B QA requirements
  - Available to operating fleet, new reactors licensing under Parts 50/52, and for Part 53 (if Part 53 QA requirements consistent with Appendix B)

5 November 2021 NEI/USNIC letter & attachments

Goal for Part 53 consolidated industry comments:
Provide clarity and detail on perspectives provided to NRC in meetings and letters over the past year, especially in areas where NRC has not addressed our concerns or described why they aren't addressing our concerns

- Attachment A: Comments by specific topical areas; addresses beneficial features and significant challenges (22 pages)
- Attachment B: Detailed comments on nearly all of preliminary Part 53 rule language, regulation-by-regulation; specific proposed revisions provided (83 page table)
- Attachment C: Prior submissions made by USNIC/NEI since 2019 (4 pages; 40 submissions)

Backup or reserve slides

Example A: NEI 18-04 (Leading Role)

TI-RIPB Principle	Approach to Meet Principle in Example A
1. Meet established limits for adequate protection	• PRA frequencies and consequences ensure LBEs are within the F-C curve, and QHOs are not challenged • Deterministic safety analyses for DBAs validate safety case made by PRA
2. Establish the safety functions, design features and functional design criteria	PRA delineates the relevant safety functions, which define safety features, which are used to select functional design criteria for each type of LBE
3. Selected LBEs adequately cover the range of hazards	• PRA is the primary component of an iterative process to select the LBEs in a systematic and comprehensive manner • Deterministic methods are used to support the iterative process to select LBEs based on the PRA
4. SSCs are categorized according to their safety significance	PRA is used to categorize SSCs according to the roles they play in satisfying the safety functions
5. Design reflects the application of an appropriate philosophy of defense-in-depth	PRA is used to establish DID through systematic evaluation of LBEs, with systematic determinations of adequacy, including the need to account for uncertainties
6. Special treatment for SSCs, programmatic controls and human actions are appropriate	• PRA input to integrated decision-making panel to identify special treatment beyond safety-related SSCs • Quantitative reliability targets set for significant SSCs

Example B: NEI 18-04 (Confirmatory Role)

TI-RIPB Principle	Approach to Meet Principle in Example B
1. Meet established limits for adequate protection	• Deterministic analyses determine the limits are met • PRA confirms F-C curve and the QHOs are not challenged
2. Establish the safety functions, design features and functional design criteria	• Deterministic analyses systematically establish safety functions, safety features and functional design criteria (e.g., use of ARDC) • PRA confirms or identifies vulnerabilities to address
3. Selected LBEs adequately cover the range of hazards	• Deterministic methods are primary component of iterative and systematic process to select the LBEs • PRA supports deterministic methods in iterative process
4. SSCs are categorized according to their safety significance	• Deterministic methods used to categorize SSCs according to the roles they play in the DBA analysis • PRA determines additional SSCs with special treatment
5. Design reflects the application of an appropriate philosophy of defense-in-depth	• Deterministic methods systematically establish DID and adequacy, including the accounting for uncertainties • PRA confirms or adjusts DID to establish adequacy
6. Special treatment for SSCs, programmatic controls and human actions are appropriate	• Categorization establishes need for special treatments • PRA input to integrated decision-making to identify ST for SSCs other than SR

Example C: IAEA

TI-RIPB Principle	Approach to Meet Principle in Example C
1. Meet established limits for adequate protection	• Deterministic analyses determine the limits are met • PRA searches for cliff-edge effects, and can be used to confirm F-C curve and the QHOs are not challenged
2. Establish the safety functions, design features and functional design criteria	• Deterministic assessments and requirements establish safety functions, “principal technical requirements” and design requirements (equivalent to NRC) • PRA is used to confirm deterministic results
3. Selected LBEs adequately cover the range of hazards	• Deterministic methods establish LBEs (Normal, AOO, DBA, and BDBE) and characterize plant response • PRA informs through systematic search and perspective on frequencies
4. SSCs are categorized according to their safety significance	• Deterministic assessments are primary means of categorizing SSCs and are informed by PRA insights
5. Design reflects the application of an appropriate philosophy of defense-in-depth	• Deterministic assessment of DID adequacy through formal framework • PRA results provide further assurance of DID adequacy
6. Special treatment for SSCs, programmatic controls and human actions are appropriate	• Deterministic engineering analyses and judgement • PRA insights to confirm and inform

Example D: Bounding Analysis

TI-RIPB Principle	Approach to Meet Principle in Example B
1. Meet established limits for adequate protection	• Deterministic analyses determine the limits are met • Risk information* provides perspective on the margin and demonstrates that the QHOs are not challenged
2. Establish the safety functions, design features and functional design criteria	• Deterministic analyses systematically establish safety functions, safety features and functional design criteria (e.g., use of ARDC) • Risk information in limited role to confirm most challenging accidents included
3. Selected LBEs adequately cover the range of hazards	• Deterministic methods identify and confirm adequacy of events (one or small set) with bounding consequences • Risk information in limited role confirm events are bounding
4. SSCs are categorized according to their safety significance	• Deterministic assessments conservatively categorize SSCs
5. Design reflects the application of an appropriate philosophy of defense-in-depth	• Deterministic methods systematically and conservatively establish DID and adequacy • Risk information provide additional assurance of DID adequacy
6. Special treatment for SSCs, programmatic controls and human actions are appropriate	• Deterministic engineering analyses

*Risk information includes a PRA; however, the PRA would be simplified and limited in scope