Part 53: Approach, QHOs, BDBE, ALARA, Facility Safety, Other

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

10 CFR Part 53 Discussion of Selected Part 53 Topics

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General Approach and Part 53 Issues

General Approach and Part 53 Issues

We recognize NRC has addressed some Preliminary Proposed Rule Language issues (listed on slide 8, e.g., eliminating two-tiered approach)

Questions for NRC discussion:

1. Has NRC evaluated whether Part 53 reduces, increases, or has same regulatory burden as Parts 50/52 to achieve similar level of safety?
2. Can NRC provide estimates for efficiency of Part 53 in meaningful terms, for example the duration of licensing reviews or annual fees (for which NRC has Parts 50 & 52 estimates)?
3. If Part 53 is not more efficient than Parts 50/52 to achieve similar level of safety, then why does NRC believe that industry will use it?

Quantitative Health Objectives

Why QHOs (Quantitative Health Objectives) in regulation?

To date, it is unclear the need for QHOs in rule text *(updated March 2022)*

- QHOs have been in Policy Statement for decades
- BDBE is addressed by mitigation requirements
- NRC slides provide basis for **using** QHOs, but not why QHOs need to be included in rule language

Questions for NRC discussion:

1. Why is including QHOs in Part 53 rule language (versus in Policy Statement) needed for the staff to make their safety finding?
2. Has NRC provided a written comparison of both the benefits and disadvantages of the QHOs in the rule?
3. Does NRC want QHOs in the rule because it is a risk-based performance metric? If not, then what do QHOs achieve that mitigation of BDBE does not?

Use of QHOs as a performance metric for design improvements vs. acceptability of licensing

- QHOs traditionally been used to assess whether design improvements would make any substantial difference in risk associated with operation of a nuclear plant-- they have never been used to determine the acceptability of licensing a nuclear plant.
- Current use of QHOs is by Commission direction.

Question for NRC discussion:

1. Why such a transition is needed?

Use of QHOs as a performance metric

Other Questions for NRC discussion:

1. Has NRC general counsel considered the impact on hearing contentions if the QHO are in the rule?
2. Were QHOs included in the rule to justify NRC's enhanced use of PRA (i.e., using LMP as the basis for Part 53)?
3. Will the PRA need to be part of licensing basis, submitted for NRC review, or subject to NRC control (e.g., through 50.59) if QHOs are a formal requirement in the regulations?
4. Will QHOs be a requirement for Framework B, if not then what?

QHO Language as a performance metric– are they formulated correctly?

Big difference between health effects and fatalities.

- Meaning of **fatality** is quite clear, which is probably why NRC used it in 1986.
- Terms "health effects" or "**immediate life-threatening health effects**" are not defined, which is quite troubling. Does it include cancers that are treated and cured? (It should not, because NRC was clear in 1986 when it used term "cancer fatality risk.") Does it include any observable change to human tissue? (Those occur at relatively low doses, thanks to our constantly improving ability to measure such changes, but that would be an inappropriate expansion on the term "cancer fatality") Is immediate 1 hour, 12 hours, 1 day, 30 days? (and what is basis).

Question for NRC discussion:

1. Why did the NRC change the terminology? (creating ambiguity and decreasing clarity)

QHOs in Safety Goals Policy Statement (1986)

"The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent (0.1 percent of the sum of cancer fatality risks resulting from other accidents to which members of the U.S. population are generally exposed."

The risk to the population in the area near a nuclear power plant of cancer fatalities that might result from nuclear power plant operation should not exceed one-tenth of one percent (0.1 percent) of the sum of cancer fatality risks resulting from all other causes."

§ 53.220 Safety criteria for licensing basis events other than design basis accidents. (March 2022)

Design features and programmatic controls must be provided to:

a) Ensure plant structures, systems and components (SSCs), personnel, and programs provide the necessary capabilities and maintain the necessary reliability to address licensing basis events in accordance with § 53.240 and provide measures for defense-in-depth in accordance with § 53.250; and

b) Maintain overall cumulative plant risk from licensing basis events other than design basis accidents analyzed in accordance with § 53.450(e) such that the calculated risk to an average individual within the vicinity of the plant receiving a radiation dose with the **potential for immediate life-threatening health effects** remains below five in 10 million years, and the calculated risk to such an individual receiving a radiation dose with the potential to cause latent life-threatening **health effects** remains below two in one million years.

Use of QHOs as a performance metric- response to NRC input and question

- Providing numerical targets (e.g., five in ten million years and two in one million years) instead of using percentages provides more certainty (and may enhance regulatory stability).
- But lack of dose criteria reduces regulatory clarity and predictability

Question for stakeholders

- What is a proposed performance metric for Framework A?
    - Response: Mitigation of BDBE is performance-based, and is the approach in Parts 50/52. QHOs in a Policy Statement.

Beyond Design Basis Events

Beyond Design Basis Events

Commission directed 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)

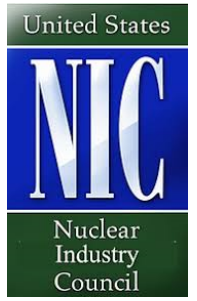
Questions for NRC discussion:

1. Why do NRC slides advocate for including BDBE in design basis, rather than just treating as part of licensing basis?"
2. Why does NRC think that LMP guidance needs to be codified so that alternative approaches are not allowed?"
3. Can NRC verify statement at December 9, 2021 Commission briefing on Part 53 that they did not intend to include BDBE in design basis?

Beyond Design Basis Events- response to NRC question

Question to Stakeholders:

- What alternatives might be proposed for addressing very unlikely event sequences under Framework A?
    - Response: Mitigation of BDBE, similar to what is currently done in Parts 50/52



ALARA

ALARA (As-Low-As Reasonably Achievable) as a Design Requirement

- The preliminary rule text states:
  - 53.260(b): “Design features and programmatic controls must be established such that the TEDE (total effective dose equivalent)…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.”
  - 53.430, Functional Design Criteria for Occupational Dose ALARA, which sems to be significant expansion of current operational ALARA requirements into design space

- Questions for discussion:
  1. If safety goals are met with 53.210 (like Parts 50 and 52) why is ALARA needed in rule for the staff to make their safety finding?
  2. Why does Part 53 need to include a requirement for ALARA in Part 53, rather than relying on the Part 20 ALARA requirements?
  3. What is the purpose of expanding ALARA (beyond 50.34a focused on gaseous and liquid effluents) to include additional design requirements?
  4. Does NRC believe that ALARA as a design requirement will not increase cost of design by forcing increases in things like wall thickness in order to meet “safer than safe” expectations?

ALARA (As-Low-As Reasonably Achievable) as a Design Requirement

Additional Questions for discussion:

1. How does the NRC envision meeting the (as currently written) ALARA language?
2. How are the Part 53 ALARA design requirements consistent with past Commission decisions*
   - "the ALARA concept is intended to be an operating principle rather than an absolute."
   - "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."
3. Which regulation currently allows the NRC to require design changes to address ALARA?

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

ALARA as a Design Requirement- response to NRC questions

Questions to Stakeholders:

- What alternatives from the existing requirements and recent applications are being contemplated?
  - Response: Pointing to ALARA in Part 20, consistent with Parts 50/52. Could incorporate 50.34a requirement on equipment to control releases, if necessary
- Are some issues not being addressed by the guidance being developed under ARCAP?
  - Response: NRC explanation is vague without specific reference. Is NRC proposing that ARCAP guidance be codified into Part 53 requirements?

Facility Safety Program

Overlap of Facility Safety Program and other operational programs

- Preliminary rule text operational programs include:
  - ~11 program areas that have equivalents in Part 50/52
  - ~13 program areas that do not have a Part 50/52 equivalent or duplicate others
  - ~20 instances of open ended requirements for “programmatic controls”

- Questions for NRC discussion:
  1. How does NRC believe Facility Safety Program (53.890) and Integrity Assessment Program (53.850) interplay with each other and other proposed operational programs?
  2. Can NRC provide clarity on the scope of programmatic controls? (There is no clear criteria for knowing what is NRC regulated programmatic control, and what is licensee controlled programmatic control. NRC rule language on programmatic controls appears to be substantial expansion of scope of NRC regulatory control.)
  3. Can NRC share how additional NRC staff, including resident and regional inspectors who are familiar with operational programs, reviewed the proposed Part 53 operational program language?
  4. Are Facility Safety Program requirements a "one-size fits all" approach; and if so, how is that consistent with a risk-informed approach?

Overlap of Facility Safety Program (FSP) and other operational programs- response to NRC questions

Questions for Stakeholders:

- How could an FSP be considered within an overall model of licensing and regulating future plants?
    - Response: FSP is not necessary and would increase regulatory burden-- it should be removed and not further considered for Part 53.
- In assessing preliminary proposed rule language, are the suggestions on the performance criteria for evaluating new information and consider risk-reduction measures?
    - Response: FSP is not necessary and would increase regulatory burden-- it should be removed and not further considered for Part 53.

Other Topics

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Questions for NRC Discussion:

Special Treatments and QA (53.460)

- Is graded QA for safety-related SSCs allowed?

Earthquake Engineering (53.480)

- Among all natural phenomena hazards, why did staff single out earthquakes for more rigorous treatment that goes beyond NEI 18-04?

Fire Protection Requirements (53.440)

- Can the NRC describe how the proposed deterministic requirements align with a risk-informed and performance-based approach?

Part 53 Licensing Framework A & B

- Can rule language be a single framework that is performance-based and high level, with details on licensing approaches provided in guidance?

+ items raised in 5 November 2021 detailed NEI/USNIC comments

Reference: Example USNIC Input on Part 53

(of over 40 submissions USNIC has made on Part 53 since October 2019)

- 2021-07-15: (https://www.nrc.gov/docs/ML2119/ML21196A499.pdf)
  - Comments on stakeholder engagement, USNIC Part 53 survey results, lack of roadmap and clarity on safety expectations, rule development, ALARA, QHOs, Quality Assurance, Subpart F, Decommissioning, Defense in Depth, Two Tiers, Reasonable Assurance of Adequate Protection
- 2021-11-05: Joint NEI/USNIC letter (https://www.nrc.gov/docs/ML2130/ML21309A578.pdf)
  - With three detailed attachments (112 pages) incl. QHO, ALARA, Facility Safety Program
  - Attachment C provides 41 USNIC submissions/presentations from October 2019 to October 2021)
- 2021-12-17: NEI/USNIC presentation to ACRS (https://www.nrc.gov/docs/ML2202/ML22024A447.pdf)
  - Comments on QHO, PRA, ALARA, safety standards/AEA, BDBE in design basis, redundant programs, regulatory efficiency
  - NEI/USNIC Part 53 slides 681-754; transcript of NEI/USNIC Part 53 remarks start at 400
- 2022-03-16: USNIC presentation to Advanced Reactor Stakeholders (ML22074A190)
  - Process and other concerns (slides 43-52)