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To:	RulemakingComments Resource
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The U.S. Nuclear Industry Council (USNIC) is providing stakeholder input to the NRC regarding Preliminary Rule 10 CFR Part 53 [Docket ID NRC-2019-0062], based on comments made to the Advisory Committee on Reactor Safeguards (ACRS) Future Plant Designs Subcommittee Meeting on 17 March 2021.

Material on USNIC slides and verbal comments (slightly edited) are attached. USNIC's comments were prepared with the active engagement and edits of multiple advanced nuclear developers.
Some key points include:

Success Criteria

- Regulatory burden should not increase for designs that are establishing increased margins of safety compared to an already very safe operating fleet.

Rulemaking

- USNIC provided revised preliminary Part 53 Subpart B language and discussion for 4 February 2021 NRC Part 53 meeting (ML21035A003).
- Simplify the staff's Tier 2 proposal by using 10 CFR Part 20 for normal-operations radiation protection.
- Rule should not be driven by the Licensing Modernization Project (LMP) process but should fully enable its use. Additional guidance is worthwhile for risk-informed applications that don't fully comport with the LMP methodology. The LMP process and its supporting guidance like Technology Inclusive Content of Application Project (TICAP) have not had sufficient precedent to establish their effectiveness in the licensing process-- so writing LMP-based expectations into the rule before we've established those precedents may cause challenges in future licensing applications.

Adequate Protection

- Requirements such as normal operating dose are not newly needed to address safety analysis and design of a facility-- rather than traditionally used operating practices and programmatic controls.
- ALARA (as low as reasonably achievable) is an important concept and certainly good practice that we expect to continue, but we do not believe it should be included in Part 53 regulation.

Dose Consequence-Based Performance

- Concerned about inclusion of regulatory limits for Quantitative Health Objectives (QHOs) in the rule itself, without clearly describing the benefits its inclusion would bring.
- Staff has yet to demonstrate that the application of QHO regulatory limits in the rule is a necessary element of a risk-informed approach. A related concern is the extent to which this QHO approach would elevate the Probabilistic Risk Assessment (PRA) to a legal compliance tool for demonstration of a regulatory limit.

Risk-Insights

- USNIC supports using insights from a risk assessment like PRA to meet the risk-informed elements of Part 53, as well as a graded approach to robustness and application of the risk assessment.
- We do not believe that the framework should require using the LMP-like approach that implicitly requires a mature PRA as the basis to determine licensing basis events; structures, systems and components (SSCs) safety classifications; and defense-in-depth adequacy evaluation. This could effectively preclude the use of Part 53 for applications that are based on less-than-final level of design detail. Rather, applicants should be free to use risk information from a PRA or other risk tool in a more flexible manner to support the technical demonstrations required by the rule.

DID

- Defense in Depth (DID) is important as a design philosophy in supporting an adequate safety case for LMP applications, and applications taking a different approach.
- DID details should be described in guidance, not regulation. Guidance needs to explain how DID would be implemented and used.

Quality Assurance

- Specify the minimum quality control program requirements and leave open more options for implementation.
- Guidance should support approaches such as more broadly used ISO 9000 series (e.g., ISO-9001), IAEA, commercial dedication programs, and other approaches presented by industry.
- Use of quality assurance standards different from Appendix B or NQA-1 may provide opportunities to expand the supply chain beyond the current limited suppliers of nuclear grade materials.

Flexibility and Predictability *(Additional point that arose because of discussions)*

- Part 53 Rule can have predictability and stability as well as flexibility.
- Predictability is having specific performance criteria that must be demonstrated, and every applicant must show that they meet the criteria that forms the basis for the staff findings of safety. Stability is having regulatory guidance that when implemented does not evolve as the design is undergoing a licensing review.

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United States Nuclear Industry Council (USNIC)

U.S. Nuclear Industry Council (USNIC) Comments
NRC Advisory Committee on Reactor Safeguards (ACRS)
Future Plant Designs Subcommittee Meeting
Preliminary Rule 10 CFR Part 53

17 March 2021

Introduction

Good morning and thank you for the opportunity to speak today. The U.S. Nuclear Industry Council, or USNIC, is a business consortium for nuclear energy and the promotion of the American supply chain globally. USNIC represents key technology developers, utility movers, manufacturers, and service providers.

I'm Cyril Draffin, Senior Fellow with USNIC for Advanced Nuclear. With me today to answer questions is Peter Hastings with Kairos Power, our vice chair of our USNIC Advanced Nuclear Working Group, Dennis Henneke of GE Hitachi and ANS Chair for ANS/ASME PRA standards development, and Frank Akstulewicz of Terrestrial Power.

We are the first of several industry groups to speak, and you'll notice many common observations. You may notice some areas where we have slightly different perspectives. This is mainly a result of fluid evaluation of a complex topic. Several issues you'll hear today are the subject of ongoing discussions, including discussions across the various industry groups presenting this morning.

Goals for Part 53

This slide is simply a restatement of the goals for Part 53:

- Safety-Focused: Focus on reasonable assurance of adequate protection
- Technology-Inclusive: All technologies, high-level requirements
- Efficient: Schedule/cost targets, integrated safety, commercial quality
- Flexible: Variety of licensing approaches, reactor uses, interface with Part 50/52
- Informed: Insights from previous efforts, near term activities, and other regulators
- Clear: Nexus to adequate protection, interrelationship of requirements, concise

We won't dwell on details and observe that we think there's good alignment between us, NEI, and the NRC staff on these goals.

NEIMA Expectations and Objectives

- Expectations:
  - Technology inclusive (use by any fission reactor technology)
  - Risk-informed (focus on safety-significant elements of safety case)
  - Performance-based (clear, consistent, and understandable criteria)
- Success Criteria (Objectives):
  - Clear, effective regulatory framework and guidance resulting in significant improvements
  - Framework founded on demonstration of reasonable assurance of adequate protection of public health and safety
  - Regulatory burden should not be increased

To put our observations in context, we want to review one of the primary drivers for Part 53, which is the Nuclear Energy Innovation and Modernization Act.

We believe that NEIMA sets forth the direction for a rule that:

> Will be technology inclusive, such that there will be no fundamental challenges to apply this regulation to any fission reactor technology regardless of type and size;
>
> Will be risk-informed, to focus licensing development, review, and maintenance on the most safety-significant elements of the safety case, with provision for deterministic insights when appropriate;
>
> And will be performance-based, establishing clear, consistent, and understandable criteria for an applicant to demonstrate.

We believe that some of the key success criteria, or objectives, for this effort include:

> A regulatory framework and necessary implementing guidance that is clearly understood, effectively applied, and results in significant improvements to the efficiency, timeliness, cost-effectiveness, and predictability of the NRC's role in regulating nuclear energy.
>
> A regulatory framework founded upon demonstration of reasonable assurance of adequate protection of the public health and safety. Reasonable assurance needs flexibility and regulatory stability, and in some cases, we observe that the preliminary language is directly tied to adequate protection. We'll have more comments on Adequate Protection later in our presentation.
>
> Importantly from the perspective of the motivation to develop and deploy advanced reactor technologies, the regulatory burden should <u>not increase</u> for designs that are establishing increased margins of safety compared to an already very safe operating fleet.

<u>Rulemaking Process</u>

USNIC has been very active stakeholder engaged in the rulemaking process. We offered comments and questions in support of NRC's November, January, and February public meetings, and submitted proposed alternative language for Subpart B last month. The ADAMS accession numbers for our feedback are noted in the event the committee members wish to peruse them.

- *ML20318A007 (November 2020)*
- *ML21006A000 (January 2021)*
- *ML21032A045 (February 2021)*
- *ML21035A003 (Subpart B language, February 2021)*

Relevant comments we provided to the NRC in the February Part 53 public meeting include:

> Recommendations on clarifying Transient & Accident Radiological Safety Criteria, which that are alternatives to the staff's proposed first tier safety criteria that more closely resemble current performance requirements. We do support using 25 rem criteria the NRC staff recommended.
>
> With respect to Tier 1, suggest that postulated events be treated in guidance, with perhaps an upper bound event frequency of once per hundred years; and
>
> Simplifying the staff's Tier 2 proposal by using 10 CFR Part 20 for normal-operations radiation protection, and not bringing it into Part 53

We support the perspective that the rule should <u>not be driven</u> by the LMP process but should fully enable its use. LMP is an endorsed process via Reg Guide 1.233, and the rule should allow for continued

evolution of similar processes or even different processes. We recognize additional guidance might be worthwhile for risk-informed applications that don't fully comport with the LMP methodology.

While based on substantive engagement and historic non-LWR licensing experience, the LMP process and its supporting guidance like TICAP have not had sufficient precedent to establish their effectiveness in the licensing process-- so writing LMP-based expectations into the rule before we've established those precedents may cause challenges in future licensing applications.

Our previous, current, and future comments are made with the intent of supporting a rulemaking whose scope and content addresses the expectations from NEIMA.

Topics for Consideration

We are going to go into some detail on the five important topics:

- Adequate Protection Standard
- Dose Consequence-Based Performance
- Development and Application of Risk Insights
- Evaluating Defense in Depth Adequacy
- Quality Assurance

Adequate Protection Standard for Part 53

- Provide clarity for adequate protection (radiological foundation)
    - Requirements predicated by fundamental safety functions (53.210)
    - Requirements established in Part 53 should have a clear nexus to supporting the adequate protection standard
    - Adequate protection standard should be independent of technology, reactor size, or selected licensing process
- Avoid regulatory requirements that are not needed for adequate protection
    - Requirements need not exceed existing requirements under Part 50 (do not ratchet requirements compared to existing reactors)
    - Necessity of "second tier" has not been established
- Part 53 should establish the minimum criteria and supporting information necessary for demonstrating the safety case

Regarding the adequate protection standard, there is still work needed between industry and the staff. I think you'll hear more about this, but one of our main concerns is that the discussion of Tier 1 and Tier 2 is confusing, and risks the perception that concepts (such as normal operation dose) are being rolled into the time-honored category of nuclear safety. Said another way, we should avoid the perception that additional requirements such as normal operating dose are somehow newly needed to address safety analysis and design of a facility-- rather than traditionally used operating practices and programmatic controls. Some of our other earlier comments about clarifying safety criteria are intended to address the potential Tier 1/Tier 2 confusion.

One option we've discussed is not to pull Part 20 requirements into Part 53, but rather use the Part 20 requirements.

As a note, ALARA is an important concept and certainly good practice that we expect to continue, but we do not believe it should be included in Part 53 regulation.

Dose Consequence-Based Performance

- Section 53.23 requires analysis of QHO
    - Need for new requirement not clear
    - QHO calculations would be required in addition to quantitative limits at site boundary
    - QHO method introduced in 1986 but deemed impractical and CDF and LERF surrogates were introduced instead (not applicable to non-LWRs); no QHO requirement in 10 CFR 20, 50, 52
    - QHOs virtually guarantee a specific analytical methodology (i.e., PRA) is required
    - Recommend removing (b)(2) from 53.23 in NRC preliminary Subpart B, Second Tier Safety Criteria, unless clear benefits shown
- Continue to have QHOs as NRC policy
- Quantitative frequencies could be included in guidance

We are concerned about inclusion of regulatory limits for Quantitative Health Objectives in the rule itself, without clearly describing the benefits its inclusion would bring. The draft language in 53.23(b)(2) requires analysis of QHOs to 5E-6 immediate and 2E-6 latent effects per year, but it's not apparent why it's needed in Part 53. We desire to understand staff's intent and how results would be achieved. QHO implementation could be a challenge for some advanced LWRs; surrogate risk metrics were developed for LWRs and the path to implementation for technology neutral QHOs is not clear. Further, as stated in the draft rule, QHOs would appear to require a level 3 PRA, which is difficult at the time a Construction Permit is submitted. A related concern is the extent to which this approach would elevate the PRA to a legal compliance tool for demonstration of a regulatory limit.

Under the staff's proposed approach, QHO calculations would be required in addition to the demonstration of compliance with quantitative limits at the site boundary, which seems duplicative. The QHO method was introduced in 1986 but was determined to be impractical, and surrogates of core damage frequency and large early release fraction were introduced instead. These LWR surrogates don't apply here, so demonstration is unclear. It's also relevant that the targets for Core Damage Frequency (CDF) and Large Early Release Frequency (LERF) surrogates were developed in guidance, not in regulation. The 1E-4/year and 1E-5/year target values meant to align with QHOs do not appear in regulation.

Additionally, the use of QHOs in regulation seem to require the use of specific analytical methodology (i.e., PRA), and as you'll hear later, we're concerned over the notion of using PRA as a compliance tool for the first time.

So, most of our members believe that implementation of QHOs as radiological consequence criteria should remain in policy or guidance documents, and not in Tier 2 safety criteria. The staff has yet to demonstrate that the application of QHO regulatory limits in the rule is a necessary element of a risk-informed approach.

Development and Application of Risk-Insights

- Risk tool (PRA today) insights complement the safety case
- Attributes of a useful Part 53 framework for the use of risk tools:
    - Provide flexibility without focusing on a specifically mandated analytical approach (like PRA)

    - Avoid prescriptive requirement for approach on defining LBEs, SSC classification, and DID determinations
    - Enable RG 1.233 implementation, but not require it
    - Enable combinations of risk-informed and deterministic approaches where appropriate (e.g., external hazards, seismic, bounding analyses, especially for designs with very small source terms such as microreactors)
    - Support international regulatory frameworks (e.g., IAEA SSR-2/1 and markets with dual-DSA/PSA requirements)
- PRA matures with plant design and site selection/characterization. Requiring extensive PRA with application submittal may not be feasible for all application types, especially for plants in early phases of application (e.g., CP)
    - Application content should be limited to information central to the safety case findings
    - Application content should be developed as part of ongoing regulatory guidance activities

Risk-insights are associated with how a tool such as PRA is reflected in the licensing basis and in the application. We recognize that the current PRA construct works well and is flexible to allow the LMP approach endorsed Reg Guide 1.233. But it's not at all clear that the approaches used by Oklo and NuScale would comport with a prescriptive use of PRA as a compliance tool.

PRA *insights* are what are important, not specific numerical results. As mentioned previously, we don't feel "the PRA" should be elevated to a compliance tool as part of the application.

Moreover, a technology-inclusive rule that we will live with for years should not be married to today's specific analytical approach.

Recognizing what's worked well in the past-- insights from the tool used to assess the safety case should be reflected in the rule (not the tool itself). Therefore, we do not support the proposed 53.450 language and criteria that make a complete/detailed PRA an explicit requirement.

We support a framework that is flexible when it comes to selecting a risk tool; that avoids prescriptive requirements for a specific approach; that enables but does not require RG-1.233 approach; that supports appropriate consideration of deterministic methods; and that supports risk-informed regulatory frameworks from non-US markets that some of our developer members are pursuing.

For Non-LWR reactor PRAs, low risk hazards can be analyzed using simple PRAs using a bounding approach.

As discussed after our presentation, USNIC supports using insights from a risk assessment like PRA to meet the risk-informed elements of Part 53, as well as a graded approach to robustness and application. of the risk assessment We do not believe that the framework should require using the LMP-like approach that implicitly requires a mature PRA as the basis to determine licensing basis events, SSC safety classifications, and defense-in-depth adequacy evaluation. This could effectively preclude the use of Part 53 for applications that are based on less-than-final level of design detail. Rather, applicants should be free to use risk information from a PRA or other risk tool, or even a qualitative risk evaluation for designs where a PRA would not provide benefits to the design and review, in a more flexible manner to support the technical demonstrations required by the rule.

With what we know about the current state of development, with multiple developers working on several different approaches, the rule should support a spectrum of options, from "full" PRAs, to simplified risk analyses, to qualitative risk assessments, as appropriate to the applicable design and level of potential hazard. PRA can be used for insights, and USNIC member said the PRA standard supports the development of simplified PRA models, and although a full plant simplified PRA has not been performed, specific scenarios and hazard analysis for previously performed PRAs have used simplified approach (e.g., PRISM).

Evaluating Defense in Depth (DID) Adequacy

- DID important design philosophy for LMP and "non-LMP" applications
    - Further discussion needed on adequate DID for license applications, accounting for the range of potential reactor designs and features that prevents and mitigates accidents
    - DID demonstration will vary across range of designs and features
    - LMP example level of detail (rule should enable, not require)
- Rule implies DID must include BDBE mitigation measures, which seems to expand existing requirements
- DID details should be described in guidance, not regulation
- Guidance should also clarify what DID is required when prevention/mitigation is physics or passive/inherent

Defense in Depth is important as a design philosophy in supporting an adequate safety case for LMP applications, and applications taking a different approach. But we believe this is another area where we'll benefit from further discussion to better understand the level of detail that will be needed to demonstrate adequate DID for license applications-- accounting for the range of potential reactor designs and features that prevent and mitigate accidents. The adequacy of Defense in Depth will be different for different designs, and much like the larger risk-informed approach, the LMP approach provides a good way to implement DID adequacy, but we wouldn't want the rule itself to mandate too prescriptive a level of implementation detail.

We have inferred that the rule requires DID to include measures for BDBE mitigation – but that seems to be an expansion of requirements beyond what is in Part 50.

DID details should be described in guidance, not regulation. Guidance needs to explain how DID would be implemented and used (perhaps in a graded approach) and provide clarity on how a licensee could translate this approach into preparing an application.

Guidance should clarify what Defense in Depth analysis is required when physics or inherent features of a design have already resolved or removed the potential for releases of large amounts of radioactivity

Clarity in Quality Assurance Requirements

- Clarify QA requirements and facilitate application across industry (vendors, suppliers, and operators)
    - Opportunity for a fresh look at alternatives to Part 50 Appendix B and 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, 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)

Our final point is on quality assurance.

The new rule provides an opportunity to clarify the fundamental requirements for ensuring quality in a way that facilitates more straightforward and less prescriptive implementation across vendors, suppliers, and operators. It's an opportunity for a fresh look at alternatives not only to NQA-1 as the implementing standard but also to Part 50 Appendix B.

Over the years, the level of quality of commercially available components has risen, in part as a function of market demand, so that many commercial materials meet or exceed what used to be considered "nuclear standards." At the same time, the market for actual NQA-1-certified suppliers has shrunk dramatically, in part because of the cost of maintaining what has become a relatively niche standard.

We recommend taking advantage of this opportunity to specify the minimum quality control program requirements and leave open more options for implementation. Guidance should support approaches such as more broadly used ISO 9000 series (e.g., ISO-9001), IAEA, commercial dedication programs, and other approaches presented by industry.

Suppliers that can compete with more broadly applied quality standards can itself increase quality because of greater simplicity and increased familiarity with those standards. Opportunities to use QA standards different from Appendix B or NQA-1 may provide opportunities to expand the supply chain beyond the current limited suppliers of nuclear grade materials. This approach would reduce barriers to commercial competition and facilitate licensing of US reactors abroad. It also can help support international harmonization of standards, which is important for international marketability.

Guidance can be developed to show that the ISO standards and IAEA approaches can meet whatever the requirements are in Part 53, and potentially other Parts.

On a related point, Part 53 guidance also could address the topic of more universal acceptance of codes and standards (such as mechanical or electrical).

Flexibility and Predictability *(additional point that arose from discussion at the ACRS meeting)*

Part 53 rule can have predictability and stability as well as flexibility.

> Predictability is having specific performance criteria that must be demonstrated, and every applicant must show that they meet the criteria that forms the basis for the staff findings of safety. Stability is having regulatory guidance that when implemented does not evolve as the design is undergoing a licensing review.

Flexibility is in the means of demonstration and needs to be a function of the technology. Establishing a prescriptive process in the rule does not recognize the diversity within the advanced reactor community or the innovation that new licensing organizations can bring.

Increasing focus on the "performance based" goal of the rule, by establishing a rule with clear and necessary performance criteria as well as allowing flexibility in demonstration of the safety case would be a desirable outcome for regulators and industry as NRC seeks a Part 53 regulation, and associated guidance, that is useful and used.

Planned Guidance *(additional point that arose from discussion at the ACRS meeting)*

The slides NRC presented on Guidance (slides 70-72 in the ACRS meeting) are useful departure for discussion, although they did not include some topics (like Defense in Depth) that industry had recommended.

Conclusion

- Encourage ongoing participation and engagement of stakeholders
- Continue working to clarify more appropriate rulemaking objectives and implementation detail
- Achieve NEIMA goals without increase in regulatory burden for deployment of Advanced Reactors

In conclusion, we continue to be committed to working with the NRC staff and other stakeholders; we hope to continue making suggestions to clarify objectives of the rule and encourage the staff to consider our proposals; and hope to be able to help develop a rule that achieves the vision of NEIMA without increasing regulatory burden for designs with increased safety margins.

Thank you for the opportunity to speak with you today.

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