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Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 0555-0001

Subject: NRC March 12th Meeting Regarding Future Expansion of Regulatory Guide 1.200

Project Number: 689

Dear Ms. Lui:

NRC conducted a public meeting on March 12 to discuss plans for future revisions to Regulatory Guide 1.200 and endorsement of PRA consensus standards. The purpose of this letter is to provide industry's response to the proposals and schedules outlined in that meeting. The industry's strategy for risk-informed regulation and PRA was discussed with the NEI Regulatory Process Working Group on April 15th, including NRC's plans for future endorsement of additional PRA standards, and this letter is based on feedback from that group and additional discussions with key industry risk and PRA personnel, including risk committee chairs of both the BWR and PWR owners groups. We appreciate the opportunity to respond to NRC's plans in this regard.

We believe PRA standards development and endorsement in Regulatory Guide 1.200 has been generally effective in advancing the technical adequacy of licensee PRAs and enabling success of certain risk informed applications, particularly technical specifications improvement. However, we are now at a critical juncture in the development and use of PRA. Industry's fundamental need is to achieve stable, mature methods (similar to the current state of internal events at power PRAs) for the fire and external events portions of the PRA standard that are already endorsed by Regulatory Guide 1.200 R2. Further expansion of PRA standards and NRC endorsement of the standards is no longer a compelling need to further the use of risk information within regulatory submittals. We believe additional standards development should proceed at an orderly and deliberate pace consistent with the state of technology and lessons learned from development and deployment of existing standards. This entails a longer schedule than that presented by NRC at the March 12th meeting. Attachment 1 provides industry's basis and proposal for a schedule consistent with a measured approach for implementation.

There is much work required to achieve the desired level of maturity of methods required under the relatively recently developed fire and external events PRA standards, including the need for methods development, regulatory interaction, refinements to the existing PRA standard, development/refinement of the peer review processes, and further peer reviews once improved methods are in place. These actions are crucial to the eventual widespread use of broader scope PRAs, and should be prioritized over additional standards endorsement by NRC.

Regulatory Guide 1.200 Rev 2 applies to voluntary risk-informed applications. Current applications do not require PRA scope needs beyond those already addressed in Revision 2. Industry PRA resources are finite and their focus on standards development and PRA model maintenance must be considered in light of other plant priorities. The continuing expansion of Regulatory Guide 1.200 Rev 2 with regard to meeting newly-developed and relatively untested PRA standards creates regulatory instability and has detracted from the pursuit of regulatory applications as evidenced by the relatively small number of submittals over the past few years. A stable and predictable regulatory environment for PRA using a measured approach would be most beneficial for encouraging applications and ultimately lead to better PRA technical adequacy and more complete scope.

Our specific comments on the NRC plans for further expansion of Regulatory Guide 1.200 fall into the following areas:

- Lessons learned from implementation of internal events and fire PRA standards and associated NRC guidance documents
- instability of the risk-informed regulatory process for risk-informed applications
- Availability of regulatory applications and their relation to need for additional PRA standards
- NRC-proposed risk management standard
- Commission's phased approach to PRA scope and technical adequacy
- Part 52 plants and requirements of 10 CFR 50.71(h)

Lessons learned from implementation of internal events and fire PRA standards

We now have considerable experience with the development, implementation, and use of PRA to support regulatory applications, using both internal events and fire PRAs. Further, a pilot test of the seismic portion of the ASME/ANS PRA Standard has been performed. Important lessons have been learned from these activities. These insights should be reflected in the plans and schedules for future PRA standard development and NRC endorsement.

The primary insight from recent application of the fire PRA standard is that appropriate development and piloting time is needed for all future PRA standards and their associated methods. Designation of a final consensus standard and subsequent NRC endorsement carries a regulatory implication that the standard and associated methods are ready for use. This should mean that PRAs meeting the standard

will be capable of providing reasonably realistic risk insights in support of regulatory decisions. We have learned from recent experience that there are significant challenges associated with the publication of a final standard and its regulatory endorsement absent full piloting and verification of the analysis methods underlying the standard. NRC's presentation materials from the March 12th meeting do address the need to follow a more structured process of piloting standards prior to endorsement, but the time frames to accomplish this have been underestimated, and the process is more involved than depicted at the meeting.

In order to ensure the viability of future NRC endorsed PRA standards, we believe the following process steps are necessary:

1. Draft standard is developed (not issued as final) and endorsed as suitable for trial application
2. Methods gap assessment is performed with respect to standard's high level and supporting requirements
3. Methods are identified and/or developed to address identified gaps
4. Pilot development of a PRA meeting the draft standard, preferably at multiple sites
5. Industry (or joint) peer review of pilot models
 - a. If additional methods enhancements are identified, then develop methods enhancements
 - b. If methods gaps remain or standards enhancements identified, then revise standard
6. Licensee use of PRA to support regulatory pilot application
7. NRC review of PRA in pilot application
8. Revision of standard as necessary based on pilot and remaining gaps
9. Revision of RG 1.200 based on NRC pilot
10. Implementation period established for remainder of industry

Much of the above process steps were followed for internal events PRA models, which benefited from over 15 years of methods development and refinement prior to initiation of the standards effort. The piloting of the internal events PRA standard, its subsequent refinement, and NRC approval of several risk-informed pilot applications in concert with the final promulgation of Regulatory Guide 1.200 was a laudable effort by NRC. This process was not followed for Regulatory Guide 1.200 Rev 2, and has resulted in a less desirable situation based on the implication (i.e. final NRC approved standard) that fire PRA was ready for widespread regulatory application.

For situations where significant methods development is required (and this is true for practically all remaining PRA scopes, operating modes, and hazards), the above process can be lengthy. Based on the internal events experience, it may require ten years or longer to achieve realistic methods that are

usable in support of regulatory and licensee decision making. Industry is now committed to a multi-year effort to improve fire PRA methods and data, even though a final approved standard already exists. This will lead to changes to existing fire PRA methods, the subsequent need for repeat peer reviews, and potential changes to the standard. This is not the most efficient process, and can detract from our mutual goal of greater use of PRA and risk-informed approaches. Attachment 2 provides a summary of industry's concerns related to the additional PRA scope being addressed in new Standards.

Therefore, for the remaining PRA scopes and initiators, we believe a much longer time frame for standards development will ultimately produce a better product and lead to more successful use of PRA. A realistic schedule for standards development will allow industry to improve methods for existing endorsed standards, enable the necessary peer reviews to be performed, build infrastructure, and "catch up" to Regulatory Guide 1.200 Rev 2 in support of applications.

Instability of the risk informed regulatory process

While we recognize NRC's needs to base decisions on rigorous and technically adequate information, we are concerned that the regulatory process for risk-informed regulation involves continually rising regulatory expectations, based in part on the revision process for Regulatory Guide 1.200. These evolving expectations include PRA scope, pedigree, conformance to NRC "guidance" documents, as well as standards and peer review. This has been demonstrated by a disproportionate focus on PRA model details, rather than a more balanced approach to risk-informed applications under RG 1.174 . Regulatory stability is not evidenced in this area, and this uncertainty diminishes the enthusiasm and management support for risk-informed applications. For operating plants, risk-informed approaches are not a requirement but instead are based on a value proposition for improved safety and improved regulation. The burden required to develop, maintain, and use PRA in a regulatory context has increased, and while this was expected, there is now a need to stabilize the regulatory environment and allow applications and model development to proceed with reduced uncertainty.

Availability of regulatory applications and their relation to need for additional PRA standards

At the March 12th meeting, NRC presented a slide entitled "Summary of risk-informed regulatory activities and PRA needs" (Slide 17). We believe this slide in general accurately depicts the PRA scope needs for operating plants, with the following observations:

1. Risk-Informed Technical Specification Initiative 4B will require an at power fire PRA at power for most, if not all operating plants.
2. Existing applications were designed to use CDF and LERF as decision metrics. It is not clear how these applications are "enhanced" through development and use of standards beyond those already endorsed in Regulatory Guide 1.200 R2, with a few exceptions. 10 CFR 50.69 might be enhanced by LPSD, but there are more fundamental issues with this rulemaking that merit priority over expanded PRA scope.

3. Since SAMA is not an application that falls under Regulatory Guide 1.200, it is not clear how NRC endorsement of level 2 and 3 PRA consensus standards would enhance that application, which is being successfully performed today absent these standards.
4. Risk-Informed Technical Specification Initiative 5B is also being successfully implemented using internal events at power PRA, and NRC has indicated this will continue to be an acceptable approach.
5. Configuration Risk Management under the requirements of Maintenance rule, 50.65(a)(4) does not require quantitative methods, and is being successfully implemented without the need for additional standards. Since this application requires consideration of various initiators in a holistic context, it could be detrimental to this approach to prematurely apply quantitative methods or standards for LPSD and/or hazards other than internal events at power until they are fully vetted and proven to provide results that can be compared to internal events without creating distortion or bias. For example, the current state of fire PRA is not well positioned to support 10 CFR 50.65(a)(4), and it will likely require years of additional methods development to reach that point.

In conclusion, operating plants are not in need of standards beyond those already endorsed in Regulatory Guide 1.200 R2.

Proposed risk management standard

NRC discussed a proposed "risk management standard" during the March 12th meeting. This standard has previously been discussed within the PRA consensus standards committees, and has not been supported by a majority of constituents of these groups. As we have noted, the primary need for success of risk-informed regulation is stability of the regulatory environment. The existence of additional standards or potential standards that purport to address risk management activities beyond PRA itself will only serve to introduce further uncertainty into the regulatory environment. One of the central tenets to the application of risk-informed decision-making is the process each utility employs to incorporate and address risk information for a particular decision. The suggestion to develop a standard that would dictate such a process is well beyond the purview of the standards organizations or writing groups.

Commission's phased approach to PRA scope and technical adequacy

The Commission's phased approach to achieving an appropriate quality (later called technical adequacy) for PRAs for NRC's risk-informed regulatory decision-making and the plan developed for its implementation were significant milestones for risk-informed regulation. The plan defined the needed PRA quality for current or anticipated applications and the process for achieving this quality, while allowing risk-informed decisions to be made using currently available methods until all the necessary

guidance documents defining the PRA quality are developed and implemented. However, the activities outlined in the plan have not been completed. In particular, Task 1.7: Development of Phase 3 Guidance, described in the plan as an umbrella document that represents the union of all the documents related to quality for the PRAs addressing contributors to risk that are significant to any of the envisioned applications, has not been written. We encourage the NRC to complete this document, describing a process for determining which contributors are significant to the decision therefore and should be addressed using a PRA model that meets an endorsed standard, consistent with the intent of the original Commission SRM. However, given that current PRA approaches for contributors such as fire and seismic events can result in unrealistically conservative results, we encourage the staff to emphasize the importance of recognizing the uncertainty associated with the various contributors, and particularly the relative degree of conservatism, when making a risk-informed decision, following the guidance provided in NUREG-1855 and the associated EPRI documents. As part of this effort, industry would like to reiterate our offer made in our March 3, 2010 letter to Mark Cunningham, to work with the NRC in developing guidance on the treatment of risk contributors that are not quantified using a full RG 1.200 PRA. We believe this would contribute to establishing a more predictable and stable regulatory framework for risk-informed regulatory activities, and would be consistent with the spirit of the original SRM to continue to benefit from risk-informed activities while recognizing that the methods available are still in need of improvement.

Part 52 plants and requirements of 10 CFR 50.71(h)

Plants licensed under Part 52 must meet the requirements of 10 CFR 50.71(h), as follows:

(h)(1) No later than the scheduled date for initial loading of fuel, each holder of a combined license under subpart C of 10 CFR part 52 shall develop a level 1 and a level 2 probabilistic risk assessment (PRA). The PRA must cover those initiating events and modes for which NRC-endorsed consensus standards on PRA exist one year prior to the scheduled date for initial loading of fuel.

(2) Each holder of a combined license shall maintain and upgrade the PRA required by paragraph (h)(1) of this section. The upgraded PRA must cover initiating events and modes of operation contained in NRC-endorsed consensus standards on PRA in effect one year prior to each required upgrade. The PRA must be upgraded every four years until the permanent cessation of operations under § 52.110(a) of this chapter.

(3) Each holder of a combined license shall, no later than the date on which the licensee submits an application for a renewed license, upgrade the PRA required by paragraph (h)(1) of this section to cover all modes and all initiating events.

The requirement for an all modes and all initiating events PRA is effective at the time of license renewal application, which is approximately 2050 for the first plant to be licensed under Part 52 (expected operating date: 2016; expected license renewal date: 2056; expected license renewal application:

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2050). The rule does not discuss the need to rapidly develop standards prior to operation of plants licensed under Part 52. The slide from the March 12th NRC meeting summarizing "Regulatory Activities and PRA Needs" does not, in industry's opinion, properly reflect the regulatory requirements of 10 CFR 50.71(h). We believe that the existing scope of Regulatory Guide 1.200 R2 already represents a significant development effort for new plants, especially given the recognition that several years of additional methods development is needed for fire and (potentially) external events PRA, even though Regulatory Guide 1.200 R2 is already effective. We believe that new plant licensing stability would be enhanced by limiting further expansion of Regulatory Guide 1.200 until well after the first new plants are operating.

Conclusion

We appreciate the opportunity to respond to the NRC proposals from the March 12th meeting. We understand that PRA scope expansion efforts on the part of NRC and the standards development organizations are well-intended. However, we believe serious consideration of lessons learned, and attendant recognition of realistic development goals and schedules is paramount if success is to be achieved with risk-informed regulatory improvement. We believe improved PRAs are a shared goal, and that the path taken for internal events, from initial development through standardization, represents a success that should be emulated. True PRA improvement cannot occur artificially, or purely through schedule pressure in a resource constrained world. Success is best incentivized through value added from applications, and we need time and regulatory stability to produce and implement these applications.

We look forward to discussing this with NRC in an upcoming meeting and working with you to develop a pragmatic approach and realistic schedule for the development, testing, deployment, and endorsement of future PRA standards. If you have any questions or desire additional information, please contact me at 202.739.8083, reb@nei.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Biff Bradley", with a stylized flourish at the end.

Biff Bradley

Attachments

c: Mr. Mark A. Cunningham, NRR/DRA, NRC
Mr. Charles E. Ader, NRO/DSRA, NRC