

December xx, 2015

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THRU: Joseph J. Giitter, Director  
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FROM: Stacey L. Rosenberg, Chief  
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SUBJECT: REVIEW OF THE INDUSTRY WHITE PAPER ON PROBABILISTIC  
RISK ASSESSMENT TECHNICAL ADEQUACY BY THE NUCLEAR  
REGULATORY COMMISSION RISK-INFORMED STEERING  
COMMITTEE WORKING GROUP

**Purpose**

This memorandum communicates the results of the Nuclear Regulatory Commission (NRC) Risk-Informed Steering Committee (RISC) Working Group (WG) review of the industry white paper, Enclosure 1, on Probabilistic Risk Assessment (PRA) technical adequacy.

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In summary, the NRC's Working Group agrees with the high-level recommendations in Enclosure 1 and provides some clarification on the details for implementation as presented. The context and results of the NRC WG review, as well as clarifications on the white paper from an NRC perspective, are provided in this memorandum.

### **Background**

The NRC RISC and the industry RISC are comprised of counterpart senior management from NRC and industry, respectively, and were formed in October 2013 to advance the use of risk-informed decisionmaking (RIDM) in licensing, oversight, rulemaking and other regulatory areas. The NRC RISC charter is available in the Agencywide Documents and Management System (ADAMS) via Accession Number ML14178B004. As a result of discussions between these two separate RISCs, the NRC RISC directed the formation of two NRC WGs. Concurrently, industry formed two counterpart WGs to interface on specific technical and regulatory aspects. This memorandum pertains to the activities related to the NRC and industry WGs tasked with discussing the evaluation of PRA technical adequacy in support of risk-informed licensing applications. Since the formation of the NRC and industry WGs on PRA technical adequacy, a number of interactions took place through public meetings to accomplish the following objectives:

- Develop a process for making new methods available for risk-informed regulatory applications.
- Improve process for closure of peer review Facts and Observations (F&Os).
- Evaluate gaps in current peer review process.

The industry WG developed a set of recommendations that included consideration of NRC feedback from the related public meetings, which included individual discussions and an informal tabletop exercise related to the use of various criteria for accepting new methods. Enclosure 2 provides the list of public meetings and the associated meeting summaries.

The industry WG conveyed their recommendations via a white paper, which is the subject of the review discussed herein. Hence, the objective of this memorandum is two-fold: (1) to discuss the product of the NRC WG review of the industry white paper, including an evaluation of the industry recommendations, and (2) to provide the NRC WG's suggested path forward to the NRC RISC for the industry recommendations. The most recent version of the industry white paper is included as Enclosure 1 and is publicly available in ADAMS via Accession Number ML15166A214.

### **Overall Review Results**

The NRC WG agrees with the high-level recommendations articulated in the industry white paper. Specifically, the following high-level industry recommendations:

- Develop detailed guidance and pilot the new methods vetting panel process.
- Develop guidance for the hybrid approach to closing out peer review F&Os.
- Develop additional guidance for verification of peer reviewer qualification.
- Develop a catalogue of accepted methods available for use in PRA to support risk-informed regulatory applications.

Some of the recommendations relate to on-going efforts by the NRC to address the use of new methods in PRA and improve the efficiency of reviews of risk-informed licensing applications. The specific actions for a path forward based on the above recommendations are discussed next.

### **Path Forward**

As a result of the NRC WG evaluation of the industry white paper and the on-going NRC activities by the various program offices in these areas, the following is proposed:

#### **Recommendation 1: Develop and Pilot the New Methods Vetting Panel Process**

Ideally, new methods would be approved for use before they are submitted as part of risk-informed licensing applications. This approval would obviate the need to identify, describe, and technically justify the new methods (e.g., including sensitivity studies, as appropriate) as part of the application. Industry is proposing the establishment of a “new methods vetting panel process” as an alternative means of making new methods available for use in PRA to support risk-informed regulatory applications (i.e., Objective 1). The NRC WG notes that this new process is not intended to address all new methods. The goal of the vetting panel process is to greatly expedite the disposition of the majority of new methods or new applications of existing methods. The NRC also notes that the process is limited to the approval of new methods for use in PRA at U.S. nuclear power plants. These methods would not be considered an approved method for evaluation for design basis changes under Title 10 of the Code of Federal Regulations, Section 50.59.

The NRC WG would also like to clarify its perspective on some of the discussion in the industry white paper related to the new methods vetting panel process. Additional discussion and clarification is provided below:

The industry white paper contains extensive discussion about the new methods vetting panel process. The NRC WG notes that much of the benefit of this new process comes from use of the vetting panel concept. The vetting panel allows for more flexible and expedient consideration of new methods, as compared to existing processes (e.g., topical reports), based on a consideration of multiple criteria and expert judgment. As discussed in the industry white paper, the vetting panel’s decisions would be based on a holistic look at the new method in terms of its source, pedigree, maturity and complexity and would determine from that information the level of review that the method should receive prior to being accepted or rejected. Therefore, the NRC WG notes that much of the discussion in the industry white paper related to the “Definition of Terms,” “Process Options,” and “New Method Groups” may be overly prescriptive. Vetting panel participants would be expected to use all the available and relevant information to help them determine the level of review required for a new method.

NRC WG members held discussions with the NRC Office of the General Counsel (OGC) regarding the new methods vetting panel process to ensure that the vetting panel would not constitute an advisory committee under the Federal Advisory Committee Act (FACA). If the panel were subject to FACA, similar to the Advisory Committee on Reactor Safeguards, there would be additional requirements that would greatly increase the resources required to implement and use the vetting panel. It was determined that the vetting panel would not constitute an advisory committee, as defined under FACA, as long as: (1) the vetting panel was

not “established” by the NRC, and (2) the vetting panel was not “utilized” by the NRC. The NRC WG notes that the NRC would not select the industry vetting panel participants. Therefore, the panel would not be established by the NRC. Additionally, the NRC would not manage/coordinate the activities of the vetting panel. The NRC staff would only participate as members of the vetting panel. Therefore, the panel would not be utilized by the NRC. The appropriate NRC program offices can follow-up with the NRC OGC to make sure there are no concerns with FACA once the final guidance on the new methods vetting panel process is ready for NRC endorsement.

The NRC WG also notes that a formal regulatory closure process is still required after the vetting panel provides its recommendation to the NRC so that there is no delegation of an inherent government function. This is similar to how the NRC participates in the consensus standards process. As discussed in the industry white paper, confirmation and acceptance of panel decisions would be requested by the Nuclear Energy Institute (NEI) in a letter to the appropriate NRC program offices. The NRC would then respond to the letter by accepting or rejecting the results, including any kind of additional comments, considerations, or qualifications. In the interim, if a licensee were to use a new method to support a risk-informed application after approval by the vetting panel but pending acceptance by the NRC, the method would be treated similarly to other methods not yet accepted by the NRC for the review of that application.

The industry white paper notes that all meetings of the vetting panel would be Category 2 public meetings. After further discussion with the industry WG, the NRC WG notes that the meetings would not be Category 2 public meetings because they would be hosted by NEI as opposed to the NRC. However, the NRC can still notice when it participates in vetting panel meetings, similar to how the NRC may notice its participation in other public meetings that it is not hosting.

Finally, the industry white paper suggests new responsibilities be assigned to the NRC and industry RISCs, such as monitoring the performance of the vetting panel process. For all such instances, the NRC WG notes that the appropriate NRC program offices and associated line management would be assigned the responsibilities to manage and monitor the NRC staff participation in the new methods vetting panel process. The NRC program offices would communicate status and lessons learned to the NRC RISC, as appropriate. Public meetings would continue to be held between the NRC and industry RISCs to discuss the process, as necessary.

Given the above discussion, the NRC WG recommends that the appropriate NRC program offices continue to work with industry to pilot the new methods vetting panel process based on draft NEI guidance. Following incorporation of lessons learned from the pilot activities into the industry guidance, the NRC would review with the intent of endorsing, with any clarifications or exceptions, the new guidance. Initially, the NRC endorsement may be via NRC Interim Staff Guidance (ISG). The final NRC endorsement would occur once the staff positions are incorporated into the next revision of Regulatory Guide (RG) 1.200, as well as the Standard Review Plan (SRP), Inspection Procedures, and RG 1.174, as applicable. As necessary, the NRC can develop additional internal guidance for NRC participants on the vetting panel, similar to guidance for NRC participation on consensus standards.

### Recommendation 2: Develop the Hybrid Approach to Closing Out Peer Review F&Os

In order to improve the closure process for peer review F&Os (i.e., Objective 2), industry is proposing a new hybrid approach to allow additional options for F&O close-out. The hybrid approach to closing out peer review F&Os is a combination of (1) the current process of using subsequent peer reviews to evaluate whether F&Os were appropriately dispositioned by the licensee, (2) a new process allowing the licensee to solely determine the appropriate disposition for certain F&Os, and (3) NRC review and close-out of certain F&Os. The hybrid approach would involve (1) the identification of attributes of F&O findings for grouping into types of findings, and (2) the determination of which of the options (i.e., peer reviews, licensee close-out, and NRC close-out) are appropriate for close-out of specific types of findings. This approach is only presented in conceptual form in the industry white paper and detailed implementation guidance still needs to be developed. The industry white paper also discusses current challenges and best practices associated with documentation of peer review F&Os and their disposition in risk-informed applications.

The NRC WG recommends that the appropriate NRC program offices continue to work with industry to develop the hybrid approach to F&O close-out. The product of this effort would be revised industry peer review guidance which the NRC would review and endorse, if acceptable. The NRC would endorse the resulting guidance via ISG and incorporation into the next revision to RG 1.200, as well as the SRP and Inspection Procedures, as applicable.

### Recommendation 3: Additional Guidance to Verify Peer Reviewer Qualifications

The industry and NRC working groups discussed current issues with the peer review process to determine if there were any additional issues associated with the peer review process that the working groups could address (i.e., Objective 3). The industry working group identified a potential gap associated with peer review team qualifications. In order to address insufficient guidance in the peer review process with regard to peer reviewer qualification, industry is proposing to revise industry peer review guidance documents (i.e., NEI 05-04, NEI 07-12, and NEI 12-13) to better describe the process for documentation and verification of peer reviewer qualifications. The NRC-endorsed PRA standard provides high-level requirements for peer reviewer qualifications, but does not elaborate on how to meet these requirements. The current NRC-endorsed NEI peer guidance provides additional clarification and requires reviewers provide their resumes for inclusion in the final peer review report. The revised NEI guidance would better demonstrate how to meet the requirements in the PRA standard, as endorsed by the NRC. For example, this guidance would include describing the role of peer review team members (e.g., observers or individuals being trained on the process versus reviewers). The guidance would note that the host utility for a peer review has the responsibility to ensure that the team identified to perform the peer review meets the qualifications in advance of the review.

The NRC WG agrees that the revisions to these documents should be made with a goal of endorsement by the NRC, if acceptable, via ISG and incorporation into the next revision to RG 1.200. The NRC WG recommends that the appropriate NRC program offices continue to work with industry to support the development and endorsement of this guidance. The NRC staff notes that this guidance would be generic and independent of the hazard being evaluated, and that it may be more efficient to have a single NEI guidance document as opposed to revising three guidance documents. This would also ensure consistency and consequently reduce resources required for future updates.



#### Recommendation 4: Catalogue accepted methods available for use in PRA

Industry is proposing to catalogue acceptable methods available for use in PRA to support risk-informed regulatory applications at U.S. nuclear power plants. As part of this recommendation, NEI would also maintain a catalogue of the outcome of all new methods vetting panel decisions.

The NRC WG agrees that these activities will greatly facilitate the use of methods and the review of PRA technical adequacy for risk-informed licensing applications. The NRC WG recommends that these catalogues be made publically available to benefit all stakeholders. At this time, no further action would be expected for the NRC related to this activity.

#### **Conclusion**

The NRC and industry WGs successfully participated in activities to identify specific challenges, gaps, and enhancements to the evaluation of PRA technical adequacy in support of risk-informed licensing applications. The industry WG developed a set of recommendations based, in part, on public meeting discussions and a tabletop related to vetting new methods. The NRC WG provided feedback on those recommendations. The industry white paper incorporates the majority of the NRC WG observations and commentary. The NRC and industry perspectives may differ on certain details which can be resolved during the development and endorsement of more detailed implementation guidance. The NRC WG agrees with the industry-recommended follow-up actions identified in Recommendations 1 – 4, with the additional clarifications presented in the above discussion.

The NRC WG recommends that the NRC RISC consider the activities of this WG complete and that the proposed follow-up actions be transferred to the appropriate NRC program offices. Specifically, given management approval, NRR will continue to pursue the piloting and development of the new methods vetting panel process as well as additional guidance for closure of F&Os; and RES will continue to incorporate feedback and update regulatory guidance, as necessary.

#### Enclosures:

1. Recommendations of the Industry Risk Informed Steering Committee Working Group on PRA Technical Adequacy (ADAMS Accession Number ML15166A214)
2. Summary of Public Meetings

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## Summary of Public Meetings

1. NRC and industry RISCs Public Meeting on February 7, 2014 (Summary) Agencywide Documents Access and Management System (ADAMS) Accession Number ML14057A519.
2. Public Meeting between NRC and industry Working Groups on June 3, 2014 (Summary) ADAMS Accession Number ML14170A872.
3. Public Meeting between NRC and industry Working Groups on June 23, 2014 (Summary) ADAMS Accession Number ML14188A515.
4. Public Meeting (and informal tabletop) between NRC and industry Working Groups on September 3, 2014 (Summary) ADAMS Accession Number ML14188A515.
5. NRC and industry RISCs Public Teleconference on September 29, 2014 (Summary) ADAMS Accession Number ML14275A209.
6. Public Meeting between NRC and industry Working Groups on October 24, 2014 (Summary) ADAMS Accession Number ML14301A457.
7. NRC and industry RISCs Public Teleconference on October 30, 2014 (Summary) ADAMS Accession Number ML14309A230.
8. Public Meeting between NRC and industry Working Groups on December 2, 2014 (Summary) ADAMS Accession Number ML14349A165.
9. NRC and industry RISCs Public Meeting on December 17, 2014 (Summary) ADAMS Accession Number ML15009A139.
10. Public Meeting between NRC and industry Working Groups on March 30, 2015 (Summary) ADAMS Accession Number ML15097A065.
11. Public Meeting between NRC and industry Working Groups on June 10, 2015 (Summary) ADAMS Accession Number ML15169A293.
12. NRC and industry RISCs Public Meeting on July 9, 2015 (Summary) ADAMS Accession Number ML15211A479.
13. Public Meeting between NRC and industry Working Groups on December 1, 2015 (Summary) ADAMS Accession Number **ML15XXXAXXX**.