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April 13, 2017

MEMORANDUM TO: Stacey L. Rosenberg, Branch Chief **/RA/**
PRA Licensing Branch
Division of Risk Assessment
Office of Nuclear Reactor Regulation

FROM: Risk Informed Steering Committee,
Working Group 1,
PRA Technical Adequacy
Office of Nuclear Reactor Regulation

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION STAFF
EXPECTATIONS FOR AN INDUSTRY FACTS AND
OBSERVATIONS INDEPENDENT ASSESSMENT PROCESS

As part of an initiative to foster an environment conducive to achieving the full benefits of risk-informed regulation, the industry and NRC developed separate Risk Informed Steering Committees (RISC). The NRC staff identified in the white paper, "Recommendations of the Risk Inform Steering Committee Working Group on PRA Technical Adequacy" (ML15086A063) multiple issues associated with the acceptability of the use of Probabilistic Risk Analysis (PRA) in risk-informed decision making. The RISC established Working Group (WG) 1 with an objective to improve the process for documentation and closure of peer review facts and observations (F&Os).

NRC staff members of WG 1 developed staff expectations (Enclosure 1) for closure of F&Os from a peer review. The staff expectations addresses:

1. F&O Peer review process
2. F&O Peer review scope
3. Team qualifications
4. Documentation

Implementation of the staff expectations is intended to provide the needed confidence in the F&O independent assessment process such that when used in support of an application, it will obviate the need for an in-depth review by NRC reviewers. Consequently, this closure process for F&Os will provide for a more focused and consistent application process.

The staff plans to incorporate these expectations as a staff regulatory position in the next revision of Regulatory Guide (RG) 1.200.

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This staff regulation position will be used as the basis for endorsement of NEI's guidance for the F&O independent assessment process (i.e., F&O closure process), which will be documented in the next revision to RG 1.200.

Enclosure:

As stated

SUBJECT: US NUCLEAR REGULATORY COMMISSION STAFF EXPECTATIONS FOR
AN INDUSTRY FACTS AND OBSERVATIONS INDEPENDENT
ASSESSMENT PROCESS DATED APRIL 13, 2017

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ENCLOSURE 1

Staff Expectations for an Industry Facts and Observations Independent Assessment Process

A Facts and Observations (F&O) independent assessment is performed to determine whether the F&Os identified by the PRA standard peer review (or other comparable peer review) have been adequately resolved. The F&O independent assessment determines whether the resolution of the F&Os have adequately resolved the identified deficiency such that the impacted PRA standard supporting requirements (SRs) have now been met. An acceptable F&O independent assessment approach is one that is performed according to an established process (as approved by the NRC) and by qualified personnel and documents the results. Moreover, in performing an F&O independent assessment, the scope of the independent assessment needs to be identified.

The **F&O independent assessment process** includes a documented procedure used to direct the team in evaluating the acceptability of the F&O resolution and addresses the following:

- The independent assessment process ensures that the F&O resolution is applicable to both the issue identified in the F&O and the associated task in the PRA standard supporting requirement (SR), and therefore is defensible and complete.
- The F&O resolutions are reviewed to ensure that the licensee has adequately incorporated the plant design and procedures to validate that they reflect the as-designed, or the as-built and as-operated plant.
- Assumptions made as part of the F&O resolution are reviewed to determine if they are appropriate and to assess their impact on the affected SRs. If the assumptions are assessed as inappropriate, the F&O is not adequately resolved and remains open.
- F&Os characterized as documentation shortcomings are examined to determine whether the deficiency was either (1) just a documentation deficiency (the peer review team was able to determine that the SRs were appropriately addressed), or (2) both a documentation and technical deficiency. In the former case, the resolution only needs to verify that the documentation has been completed to be considered closed; however, in the latter case, the resolution needs to address both the technical deficiency and the documentation deficiency to be considered closed.
- Methods applied as part of the F&O resolution are assessed to determine whether they are new methods. If not assessed as a new method¹, an assessment is performed to determine that the method is correctly implemented in meeting the intent of the SR to be considered resolved. If the method is assessed as a new method, these F&Os cannot be considered resolved until a new peer review (e.g., focused scope peer review) has been performed.
- F&O resolution is assessed to determine whether it is a PRA model upgrade. If the resolution is assessed as a PRA upgrade, these F&Os cannot be considered resolved until a new peer review (e.g., focused scope peer review) has been performed.
- The licensee may work to fix remaining deficiencies identified by the independent assessment team between the team exit, but before completion of the final report. The independent assessment team should summarize in the F&O closure description how

¹ A PRA method is new if it has not been reviewed by the NRC staff. There are two ways new methods are considered accepted by the NRC staff, (1) explicitly accepted by the NRC (i.e. it has not been reviewed and the acceptance has been documented in a safety evaluation, Frequently Asked Question (FAQ), or other publicly available management endorsement), or (2) implicitly accepted by the NRC (i.e. it has no documented denial) in multiple risk-informed licensing applications.

ENCLOSURE 1

Staff Expectations for an Industry Facts and Observations Independent Assessment Process

- The licensee completed the resolution and how the independent assessment team verified the resolution was completed for the work that was performed after the review period but prior to completion of the independent assessment final report.
- The PRA model, as a result of the F&O resolution, is checked for fidelity to ensure the F&O resolutions have been appropriately implemented into the PRA model.
- In the course of the independent assessment, the team may discover a new deficiency. While this new deficiency may not be classified as an F&O, these deficiencies are documented in the final report by the independent assessment team.

The **team qualifications** determine the credibility and adequacy of the F&O independent assessment reviewers. The qualifications include the following:

- The F&O independent assessment reviewers will not have performed any actual work on the PRA. Another potential conflict of interest may exist if an independent assessment reviewer is assigned an area for review where their immediate supervisor performed the actual technical analysis.
- Each member of the F&O independent assessment team must have technical expertise in the general PRA technical element in which the F&O belongs and in the SR which the F&O is written against, and experience in the specific methods that are used in addressing the F&Os. This technical expertise includes experience in performing (not just reviewing) the work in the element assigned for review.
- Knowledge of the key features specific to the plant design and operation is essential.
- Each member of the peer review team needs to be knowledgeable about the F&O independent assessment process, including the desired characteristics and attributes (e.g., related PRA standard supporting requirements) used to assess the adequacy of the F&O resolution.

Documentation provides the necessary information and details to ensure that the F&O resolutions are applicable, defensible, and complete. The documentation includes:

- Descriptions of the qualifications of the F&O independent assessment team members
- Description of F&O independent assessment process
- Description of the scope of the independent assessment (i.e., identification and description of the F&Os being reviewed for closure)
- The results of the F&O independent assessment of the F&O's resolutions:
 - an assessment of how the F&Os were addressed (e.g., what changes were made to either the plant or PRA model or both),
 - why the resolutions were acceptable (e.g., why the impacted PRA standard SRs are now met) for the F&O's considered resolved and closed (i.e., no additional work is needed including documentation)
 - why the resolutions were not acceptable (e.g., why the impacted PRA standard SRs are still not met) for the F&O's identified as remaining open
 - the importance of any remaining open F&Os on the PRA model and results
 - deviations from accepted methods are identified as a new PRA method and an unresolved F&O
 - an assessment of each F&O resolution as to whether a PRA upgrade and basis for determining not an upgrade
- Description of any new deficiencies

ENCLOSURE 1

Staff Expectations for an Industry Facts and Observations Independent Assessment Process

Table 1 summarizes the characteristics and attributes of an acceptable F&O independent assessment. For new reactor designs that have not yet gone into commercial operation, it is recognized that an F&O independent assessment reviewer will not have knowledge of plant operation, and familiarity with some plant features (e.g., passive mitigation systems) may be limited. This lack of knowledge is not to be construed as a limitation for performing an F&O independent assessment using personnel who are otherwise qualified and generally familiar with the design and operation of similar plant types (e.g., pressurized-water reactors).

Table 1. Summary of the Characteristics and Attributes of an F&O independent assessment

Elements	Characteristics and Attributes
Technical Review Process	<ul style="list-style-type: none">• Uses documented process• Uses as a basis for review a set of desired PRA characteristics and attributes (e.g., PRA standard supporting requirements)• Reviews F&O resolution for applicability, defensibility, and completeness• Determines if PRA represents as-built and as-operated plant after F&O resolution• Reviews any assumptions in the resolution and assesses their validity and appropriateness• Assesses F&Os characterized as documentation to determine if adequate information was available for peer review to determine whether just a documentation deficiency or both a documentation and technical deficiency• If methods applied to resolve the F&O are inconsistent with accepted methods, the F&O is not closed until a new peer review is done• F&O resolutions considered a PRA upgrade is not closed until a new peer review is done• Process to close F&Os remaining open after completion of assessment but prior to final report• Ensures that PRA is updated for F&O resolution• Identifies unrelated PRA deficiencies
Technical review scope	<ul style="list-style-type: none">• Identifies whether applicable to the base PRA application or limited to specific application• Identifies the specific application(s)• Documents resolution is applicable to base PRA or specific applications
Team Qualifications	<ul style="list-style-type: none">• Independent with no conflicts of interest (i.e., have not performed any work on the PRA or colleagues or immediate supervisor was not involved in performing any of the work)• Collectively represent expertise in all the technical elements of a PRA including integration• Expertise in the technical element to which the SR belongs, and the SR• Knowledge of pertinent methods with respect to F&O• Knowledge of the plant design and operation as applied to the F&O• Knowledge of the technical review F&O process

ENCLOSURE 1

Staff Expectations for an Industry Facts and Observations Independent Assessment Process

Documentation	<ul style="list-style-type: none">• F&O independent assessment team qualifications• F&O independent assessment process• The scope of the technical review for F&Os performed (i.e., what was reviewed by the technical review team)• Which F&O are considered closed and which remain open• Whether resolutions are adequate or inadequate, including basis for decision• Significance (importance) of remaining open F&Os to the PRA model and results• Deviations from acceptable methods identified as new PRA methods• F&O resolution considered not a PRA upgrade or a PRA upgrade and basis for decision• F&O independent assessment on base PRA, or separate from resolution of the F&Os
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The ASME/ANS standard requires a PRA Standard peer review to be performed. The Standard, however, does not require the PRA owner to resolve the F&Os resulting from the PRA standard peer review. An F&O independent assessment methodology (i.e., process) is provided in the industry-developed peer review program. This guidance needs to be comparable to the peer review guidance provided in the standard for a PRA standard peer review. When the staff's expectations have been appropriately accounted for in the NEI guidance, use of an F&O independent assessment can be used to demonstrate that the F&Os have been adequately addressed (i.e., resolved) and the PRA model of record reflects the resolution.

The implementation of these staff expectations is intended to provide the needed confidence in the resolution of the F&Os from the PRA standards peer review such that when used in support of an application, it will obviate the need for an in-depth depth review of the licensee's F&O resolutions by NRC reviewers, allowing them to focus their review on key assumptions and areas identified by the PRA standard peer reviewers as being of concern. Consequently, these staff expectations will provide for a more focused and consistent review process.

As stated earlier, the F&O independent assessment is to be performed against an established process accepted by the NRC. If a different process is used other than the accepted process, then it needs to be demonstrated that this different process is consistent with the process, as accepted by the NRC.

Archival documentation regarding the F&O closure process associated with the base PRA includes the following:

- The results of the peer review (i.e., facts and observations), and a description of the resolution of all the peer review facts and observations are included. The results are documented in such a manner that it is clear why each requirement is considered to have been met. This can be done, for example by providing a reference to the appropriate section of the PRA model documentation and a reference to the final F&O Closure report.

To demonstrate that the acceptability of the PRA used in an application with regard to the F&O Closure process, the staff expects the following information will be submitted to the NRC. Previous documentation may be referenced if it is adequate for the subject submitta

ENCLOSURE 1

Staff Expectations for an Industry Facts and Observations Independent Assessment Process

- A discussion of the open F&Os (i.e., those F&O not closed via the F&O independent assessment process)-that are applicable to the parts of the PRA required for the application.
- This discussion should describe where the PRA model is impacted and how the PRA model and results are impacted. If an F&O independent assessment has not been performed, then a discussion of the resolution of all the F&Os that are applicable to the parts of the PRA required for the application is included. This discussion includes where the PRA model is impacted and how the PRA model and results are impacted for the application.