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**Recommendations of the Risk Informed Steering Committee
Working Group on PRA Technical Adequacy**

December 2014

Issue Overview

As part of the work undertaken by the industry's and NRC's separate Risk Informed Steering Committees (RISCs), several high-priority issues relative to fostering an environment conducive to achieving the full benefit of risk-informed regulation were identified. A common theme in several of these issues was the difficulty associated with evaluation of Probabilistic Risk Assessment (PRA) technical adequacy in review of risk-informed licensing applications, and the RISCs formed working groups to address this issue.

Although the NRC's regulatory position on PRA technical adequacy for licensing applications is documented in Regulatory Guide (RG) 1.200, the NRC and industry have expressed concerns regarding the sufficiency of the process for new methods, while the industry has encountered frustration when attempting to pursue innovative approaches. Therefore, a process for the use of new methods in risk-informed regulatory applications needs to be developed. In addition, there have been disagreements, in some cases, regarding the appropriate level of staff review of the PRA supporting the licensing applications. The peer review process currently laid out in RG 1.200 and supporting NRC and industry documents may need clarification and/or enhancement to realize the full value of the PRA standards and peer reviews, and to reduce unnecessary burden to licensees and the NRC. Three major objectives to achieve resolution of the above difficulties were evaluated by the working groups.

Comment [NRC1]: . It should be recognized that RG 1.200 (and for that matter the ASME/ANS PRA Standard) was not developed to support the determination of the adequacy of new methods. The Standard, and hence RG 1.200, only address the "what" in the PRA, not the "how". The "how" is the specifics of methodologies and their use. That said, the "how" (in this sense the appropriate use of methods) is within the scope of the peer reviews.

Working Group Major Objectives

1. *Develop a process suitable for making new methods available for risk-informed regulatory applications*

There is a need to have an agreed upon process that ensures that the methods used have received an appropriate level of technical scrutiny by experts before being used and that the peer review teams have the appropriate expertise to review the application of these methods. An important aspect of ensuring an appropriate level of technical scrutiny is the process by which new methods are accepted for use. Some examples of current approaches for gaining review and acceptance of new methods include Topical Reports, the Frequently Asked Question (FAQ) process, and License Amendment Requests (LARs). However, at present there is not a clear understanding of what constitutes a "consensus method" and so all "new methods" are subjected to a ~~detailed~~ review by the NRC when used in licensing applications.

2. *Improve process for documentation and closure of Peer Review Facts and Observations (F&Os)*

The requirement to retain and report all past Peer Review F&Os until re-evaluated by another Peer Review is an administrative burden that provides minimal benefit to the licensee. The current process results in additional burden to the licensee due to the effort required for the preparation of the discussion of PRA technical adequacy section in an LAR which is followed by the documentation of the NRC's review of the F&O resolution. The NRC review frequently generates subsequent NRC Requests for Additional Information (RAIs) which increases the effort of the licensee in preparing RAI responses. The only currently accepted F&O closure path is the use of the Peer Review process, which is an additional cost and strain on limited PRA resources. In order to reduce this burden on the licensees to retain, report, and review the previously resolved F&Os, there is a need to provide an additional cost effective, robust process to allow licensees to close F&Os and obviate the need for an in-depth NRC review of the base PRA.

This new process needs to be developed to allow closure of peer review findings that address both the technical expertise required to close a finding as well as the documentation required to support peer review finding closure. In addition, once a finding has been considered appropriately closed, no further licensee or NRC review of the finding should be required to support a risk-informed regulatory application.

3. *Evaluate any additional gaps in current peer review process*

To ensure that all open issues are addressed, the working groups will ~~conduct a thorough evaluation of the~~ evaluate other difficulties that the NRC and industry have encountered with the peer review process. This will involve a benchmark of current practices against documented, NRC-endorsed Nuclear Energy Institute (NEI) peer review guidance.

OBJECTIVE 1: Develop a Process for Making New Methods Available for Regulatory Application

The purpose of this ~~discussion~~ proposed process is to provide an efficient approach to getting new PRA methods into mainstream use as quickly as possible, while also ensuring that these new methods have a sufficient technical basis for their acceptance. It is intended as an alternative, not replacement, for existing processes currently being used. The proposer of a new method could choose to utilize one of these existing processes, such as a FAQ, submission of a Technical Report (resulting in the issuance of a ~~SE~~ Safety Evaluation by the NRC), requesting an Interim Staff Guidance (ISG), pursuing Standards Developing Organization (SDO) development of a standard followed by NRC endorsement, ~~etc~~ etc, if they decide that such is their preferred path versus that described below.

Definition of New Method:

A new method is defined in the context of U.S. Nuclear Power PRA practice and NRC familiarity in regulatory application, and also represents a fundamentally new approach (or fundamentally new application of an existing approach) in addressing a technical aspect of PRA. Therefore, a new method is one that has the following ~~two~~ attributes:

1. It is new to usage in nuclear plant PRAs in the U.S., regardless of the extent of its use in risk assessments outside the U.S. or in other industries (e.g., chemical, telecommunications, defense), **AND-OR**
2. It is sufficiently different from methods currently in use that it would be considered an "upgrade" in accordance with the definition of upgrade (and the examples of upgrades) in RG 1.200 and the ASME/ANS PRA standard.

A special case of a "new method"² would be one that meets the following definition.

3. It is a sufficiently different application of an existing accepted approach such that this new application would be considered an "upgrade" in accordance with the definition of upgrade (and the examples of upgrades) in RG 1.200 and the ASME/ANS PRA standard.¹²

Comment [NRC2]: Are there any other processes Industry prefers to use? If so, it may be useful to provide the full list of available processes here.

Comment [NRC3]: It would be helpful to the reader to have an additional paragraph or two after this paragraph that provides an overview to the reader of the process description. For example, "Before going into the detailed description of the proposed process, definitions are provided for the following key terms...

Without as much, it is confusing whether the definition of New Method is intended to be part of the process description.

Comment [NRC4]: It should be noted that Item 3 is a subset of Item 2. It could also be argued that Item 1 would also be included as part of Item 2, because it would also be considered an upgrade.

Comment [NRC5]: This could use elaboration. The ASME/ANS PRA Standard has the following definition of PRA upgrade:
"The incorporation into a PRA model of a new methodology or significant changes in scope or capability that impact the significant accident sequences or the significant accident progression sequences. This could include items such as new human error analysis methodology, new data update methods, new approaches to quantification or truncation, or new treatment of common cause failure."
This definition does not address the new methods themselves.

¹ Perhaps the best analogy for this would be as it is applied in the medical industry. A drug approved for treatment of hypertension would need a completely new evaluation if it were proposed to be used as a treatment for anxiety.

² Note that methods that meet this condition will always be treated as Group C methods (see section on Definition of New Methods Groups) and be subjected to a peer review for the new application.

Definition of Terms:

Source: Refers to the "lead" organization in the development of the method. The lead may not be the organization that performed most of the work, but rather the organization whose involvement would give the greatest "credibility" to the method *in the context of regulatory application*. Sources (not in any order) would generally be as follows:

- NRC
- EPRI
- Utility
- Owners Group
- Federal or State Government (method intended for Nuclear Power Plant (NPP) PRA)
- Federal or State Government (method not intended for NPP PRA)
- University or similar non-profit research organization (method intended for NPP PRA)
- University or similar non-profit research organization (method not intended for NPP PRA)
- Non-US organization (method intended for NPP PRA)
- Non-US organization (method not intended for NPP PRA)

Pedigree: Refers to the extent to which the method has been vetted. Pedigree would generally be considered as follows:

- No independent peer review
- Peer reviewed and published
- Formally or implicitly accepted by NRC
- Formally or implicitly accepted by another (i.e., non-US) nuclear regulator
- Formally or implicitly accepted by a non-nuclear regulator or generally accepted in a non-nuclear industry
- Commonly considered by a standards development organization to meet the requirements of its standard(s)

Maturity: Refers to the extent to which the method has been applied. Maturity would generally be considered as follows:

- New. Has not yet been applied.
- Has been piloted only
- Has been used over a few to multiple years
- Commonly used over some years

Comment [NRC6]: For clarity, "use" of the new method for several years is based on non-NPP PRA applications in these cases?

Complexity: Refers to the extent to which the method is or is not intuitive or obvious, and the extent to which it is ~~multi-disciplinary~~multi-disciplinary, as follows:

- Simple, obvious, and intuitive.
- Complex with a narrow field of expertise.
- Complex with interaction/integration of multiple disciplines of expertise.

Process Options (for acceptance of any given method): Refers to possible ways in which new methods could be processed such that they become available for use. These are high level statements of the general approach to the acceptability processes that could be applied based on the source, pedigree, and maturity. For each process options, details would need to be worked out as to the criteria that would be applied to the option and the details of the actual process. Process options include:

1. Usage of the method is acceptable immediately upon issuance of ~~draft~~the interim use method. Requires a determination that the interim use ~~draft~~method has clear support from both NRC and industry.
2. Usage of the method is acceptable immediately upon conclusion of the comment period ~~on for the interim use draft~~method. Requires a determination that the resolution of the comments received are minor and their resolution will not affect the application of the method.
3. Usage of the method is acceptable immediately upon favorable resolution of industry/NRC comments
4. Usage of the method is acceptable immediately following a favorable ~~gap assessment~~ against requirements of RG 1.200. In a gap assessment, the ~~detailed~~ technical details of the method are considered acceptable, and the only issue is whether and to what degree (Capability Category (CC) CC I or CC II) the application of the method as described would meet the requirements of R.G. 1.200. The assessment would be against the applicable Supporting Requirements (SRs) of the ASME/ANS standard as modified by NRC clarifications and qualifications, and the determination would address CC I versus CC II where such distinction is made for the ~~SR~~SR.
 - a. Assessment of NPP Applicability: For methods not originally intended for use for nuclear facilities, the requirement for a gap assessment would include an assessment of whether the method can be applied to a nuclear plant (i.e., that its scope of applicability has an analogy in a nuclear plant.)
5. Usage of the method is acceptable immediately following peer review of the method and disposition of review comments. This would be a peer review of the technical aspects of the method against the requirements of R.G. 1.200³. The assessment would be against the applicable SRs of the ASME/ANS standard as modified by NRC clarifications and qualifications. Depending on the process selected by the vetting panel, this could be an industry peer review of the method (done in the same manner as is currently done for

Comment [NRC7]: As has been raised previously, why is performing a gap assessment or peer review against RG 1.200 an option for determining the acceptability of a new method when the PRA standard describes what do to, not how to do it?

Additionally, new methods by their definition would typically fall into the "upgrade" region, it is not clear this option is necessary or could ever be invoked. At a minimum, it should be recognized that the use of a gap assessment is not adequate for "upgrades."

³ Note that this does not refer to a peer review of a PRA that includes a new method, but rather a peer review constituted specifically for the ~~purpose of a peer review~~evaluation of the method.

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PRAs) or an industry/NRC peer review, where NRC observers would be present at the peer review. In either case, the peer review would be conducted by a team specifically selected for their expertise related to the method in question.

Comment [NRC8]: It is unclear what an Industry/NRC peer review would constitute. Would special guidance need to be developed?

Additionally, there is the concern that this could transition into something more like Option 6?

- a. Assessment of NPP Applicability: For methods not originally intended for use for nuclear facilities, the requirement for a peer review would include an assessment of whether the method can be applied to a nuclear plant (i.e., that its scope of applicability has an analogy in a nuclear plant.)

6. Usage of the method is acceptable immediately following Industry/NRC methods panel consensus. This refers to the convening and operation of a methods consensus panel (e.g., similar to the EPRI/NRC MOU methods panel process) that will take the submitted method under review to determine if there is sufficient documented technical bases (the “how”) to support the use of the method in PRAs for nuclear power plants. The panel would also review the method to ensure it meets the endorsed ASME/ANS PRA Standard (the “what”) at the appropriate level for its intended use. Finally, the panel would likely review examples of how the method is used in a licensee PRA to fully understand its implementation and the implication/impacts of the use of the method on the PRA. ~~This refers to the convening and operation of a methods panel that will take the submitted method and, if necessary, revise the method in order to reach a consensus of the panel (i.e., as in the EPRI/NRC MOU methods panel process).~~

~~6.~~ Many of the options identified above would allow usage of a method prior to completing the full process. In all such cases the usage should be identified in any licensee application. This would allow the NRC to consider the new method in the context of the application, while still going through the review process, to determine if the method might have a significant impact on the application and if so, what additional measures might be needed to address the increased uncertainty associated with using the new method at this stage.

Comment [NRC9]: Revised wording to mitigate concern that this could become a methods development panel which would defeat the purpose of this process.

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Definition of New Method Groups:

Below are examples of new method groups that consider a high-level categorization of new methods with an aim towards focusing on the process option that best suits the characteristics of the new method.

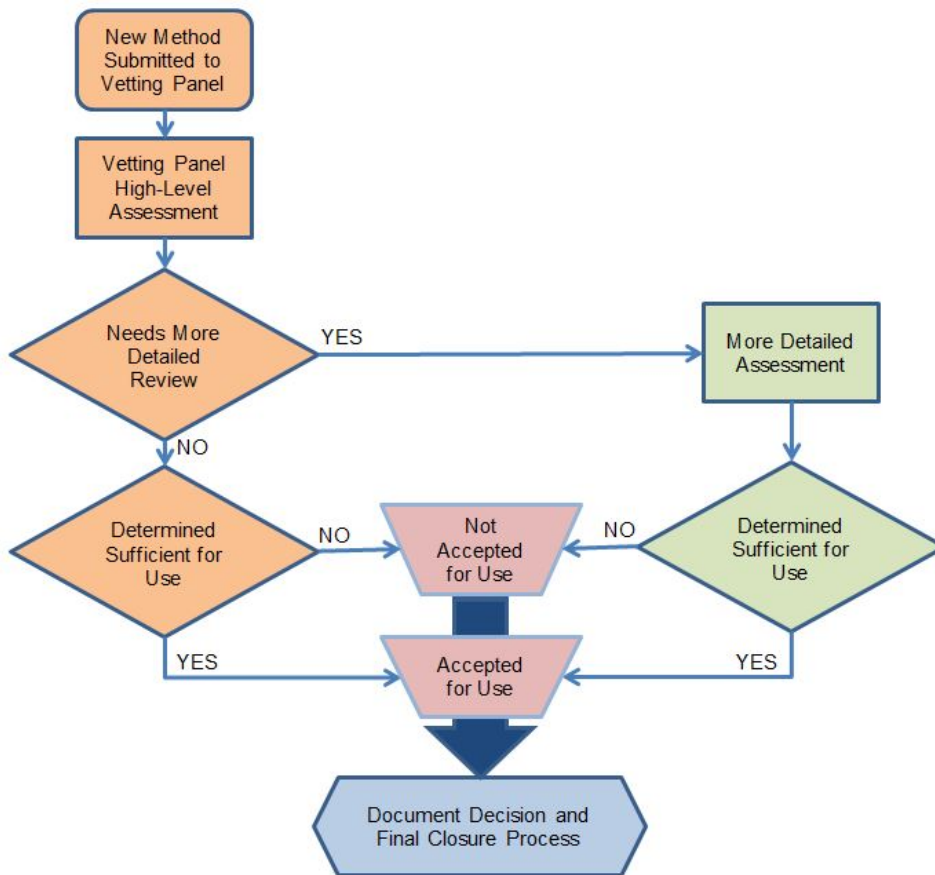
Group	Description	Available Process Options
A	NRC or NRC-Collaboration: Refers to new methods developed as a result of research performed by NRC or with substantial NRC involvement in collaboration with others (e.g., EPRI, NEI). It is anticipated that these results would enter into the process at the draft for use stage in order to determine the suitability for early acceptance.	1, 2, 3
B	Accepted by Non-US Nuclear Regulator (Explicitly or Implicitly): Refers to any method that has been approved or accepted for use, or is in general use, outside the US where either the official nuclear regulatory agency has either issued a specific notification of acceptance or has accepted PRAs that use the method without objection. Would also apply to methods that were developed by the regulatory agency. While not strictly a regulatory agency, methods developed or accepted by the IAEA would fall here.	4, 5
C	Peer Reviewed and Published Independent Research for Nuclear Application. Refers to methods that are developed intended for application to nuclear facilities by organizations that are not affiliated with nuclear regulatory agencies or nuclear industry organizations. Finding something to be in this category requires a determination that the work was “unbiased” by regulatory or industry interests. Funding from either or both interests would not, a priori, mean that a method could not be in this group, but the extent of influence would need to be considered.	5
D	Peer Reviewed and Published Independent Research for Non-Nuclear Application. Refers to methods that are developed intended for application to other than nuclear facilities. Finding something to be in this category requires a determination that the work was “unbiased” by regulatory or industry interests.	4a, 5a
E	Peer Reviewed and Published Collaborative Industry Research for Nuclear Application: Refers to methods that are developed in an inclusive way by the industry, involving a broad range of technical contributors and reviewers. Most EPRI and Owners Group research programs would fall into this category.	4, 6
F	Non-Collaborative Industry Research for Nuclear Application: Refers to methods that are developed by a single utility, consultant, vendor, etc., and therefore not involving a broad range of technical contributors and reviewers.	6

Comment [NRC10]: In later discussion, the paper points out that the intent is that the vetting panel have considerable flexibility. In that vein, the following provides potentially useful but not rigid guidance.

Comment [NRC11]: There may be cases where NRC may need to take a larger role (particularly for process options 4 and 5). Note that there are various levels of scientific peer review and that, as a practical matter, the criteria for publication don't necessarily match those for regulatory acceptance.

Vetting Panel

Appendix 1 | The figure below visually depicts the overall process for achieving acceptance of new methods. The key to this process is the Industry/NRC Vetting Panel. This is a panel of senior technical experts representing industry and NRC that will (1) take a high level look at the proposed method, (2) agree as to the appropriate category the method falls into and, (3) agree to which acceptance process option should be used. The panel will consist of an equal number of members appointed by the NRC and NEI. Note that this panel also may be called upon to perform a gap assessment against RG 1.200, and so should be knowledgeable about the RG and the ASME/ANS standard.



Comment [NRC12]: The narrative about the vetting panel needs to come before or have integrated into it the description of the process options.

Comment [NRC13]: The NRC agrees that more detailed guidance (similar to Appendix 1) is needed as part of the pilot process to determine its practicality and revise the guidance as appropriate.

However, for this part of the discussion in the whitepaper, the NRC staff considers a high-level conceptual flowchart to be more useful for explanatory purposes.

See recommended insert.

Comment [NRC14]: Should point out that the (apparent) intent is that there be one Vetting Panel (not one panel for each new method).

Comment [NRC15]: This is a secondary decision; it's role is to support the justification of the option-selection decision (which is the key point). Consider deleting – the discussions could be distracting especially if the Vetting Panel feels tied to the process options associated with the categories.

Comment [NRC16]: How formal should the appointment process be? What level of decision maker has the responsibility? Does a policy for substitutes need to be established? Should the panel member qualifications be documented?

The panel's decisions will be based on a holistic look at the method in terms of its source, pedigree, maturity and complexity (terms that were previously defined) and determining from that information the level of review that the method should receive prior to being accepted. Each of these attributes is a continuous distribution, and there are too many possible permutations to make any hard-and-fast rules. What may be considered sufficient maturity from one source may

not be for another. The same could be said about pedigree. This necessitates a panel that can weigh each attribute and select the appropriate path.

The panel's decisions can take a number of forms, including addressing the following considerations:

- a. Has the method already achieved Consensus? Applied only to NRC or NRC-Collaboration draft [for use](#) methods, this is a determination whether the method is sufficiently robust and balanced that it is unlikely to result in significant technical comments that result in major changes to the method. It allows the panel to weigh opinions expressed about the method and determine whether both the NRC developers and the other stakeholders are in general agreement and would like to see the method put into use quickly. The primary considerations would be the pedigree and complexity of the method. It is expected that maturity would have no bearing, since these methods would likely be submitted prior to much application.
- b. Is the extent of application sufficient? This refers to whether the method is proven enough in application to provide a level of comfort that it is robust, stable, and valid; that there are unlikely to be hidden traps or snares. The primary considerations would be the pedigree and maturity, the weights of which could be influenced by the source. Complexity may influence the determination of maturity where there have been only a few pilot applications.
- c. Is the credibility sufficient? This refers to the overall rigor of the development of the method. It speaks to the inclusiveness of the development process, the quality assurance and checking that was involved, the importance afforded to the development and similar such considerations. The primary considerations would be the source and pedigree, the weights of which could be affected by complexity. Maturity may influence the final decision if the method is submitted to the panel after it has been applied a number of times.

The entire process will be held in open, and there will be formal closure.

- All meetings of the Vetting Panel will be Category 2 public meetings. Vetting panel members may seek input from other individuals and organizations as they see fit to aid them in their decision. All such input will be part of the public record of the panel meetings.
- The decisions of the Vetting Panel will be documented in the public record of the meeting. Consensus shall be **achieved** when a majority of NRC panel members AND a majority of Industry panel members are in agreement. Confirmation and acceptance of the Panel decision will be requested in a letter (sent within one week of the panel decision) from NEI to the Director, Office of Nuclear Reactor Regulation, who shall respond with accepting or rejecting the results (i.e., the selection of the process to be used) within 30 days. Dissenting opinions of the Vetting Panel should be included in the letter.
- Where the decision of the Vetting Panel is to follow a process that requires the conduct of a gap assessment or a peer review, a formal report of the gap assessment or peer review team will be developed. **The gap assessment or peer review will be performed against RG 1.200 and consist of an SR-by-SR evaluation of the method. As with the current PRA Peer Review process, the gap assessment or peer review report is not submitted to NRC for approval, but licensees who use any of these methods must address any F&Os resulting from the review (if any) or show why they do not apply to their application.**
- Where the decision of the Vetting Panel is to follow a process that requires the formation of a panel of experts to form a NRC/Industry Methods Consensus Panel (~~e.g., a~~ **“MOU Panel”**) **the results of that assessment will be provided in a letter (sent within one week of issuance of the panel’s consensus report) from NEI to the Director, Office of Nuclear Reactor Regulation, who shall respond ~~with~~ by accepting or rejecting the results, including any kind of additional comments, considerations, or qualifications ~~within 30 days~~. Panel consensus will be documented in a formal report, including dissenting opinions. Consensus will consist of a majority of both the NRC-appointed members and the industry-appointed members. Panel meetings will be Category 2 public meetings.**
- It is noted that following the closure a given methods process, there is still a possibility of individuals contesting the decision. This could result in the filing of a Differing Professional Opinion (DPO), which would need to be resolved under a specific NRC process. In such event, since the weight of evidence is in favor of the finding by the consensus panel (whether ~~is~~ **it** be the Vetting Panel or one of the other process panels), the decision of the panel, as endorsed by letter from the Director, Office of Nuclear Reactor Regulation (as needed, per the above) will be effective during the DPO resolution process.

Comment [NRC17]: As written, this appears to be inconsistent with the Appendix 1 figure. This description seems to imply that a method that does not pass a peer review or meet RG 1.200 in a gap assessment can still be used by a licensee in an application so long as the licensee addresses the failings of the method, as identified in the peer review or gap assessment. The Appendix 1 figure implies that such a method would not be accepted for use.

Comment [NRC18]: Suggest using consistent terminology. (Earlier, the paper refers to a “methods panel”.)

Comment [NRC19]: Presumably this refers to the methods panel.

Comment [NRC20]: Both vetting panel and methods panel meetings will need to be public meetings.

Reconsideration of Methods

It is possible, even likely, that following endorsement of a new method (or even for existing methods already in common use) that new evidence becomes available that indicates the method is deficient in some way. ~~In such cases, the original accepted decision and continued use of the subject method can continue until the reconsideration process is completed with a new accepted decision. However, this reconsideration process does not restrict the NRC from fulfilling its regulatory duty and authority in taking actions it deems appropriate. Such actions may include issuance of a generic communication, identifying additional conditions or limitations on the use of the method, up to and including, the rejection of the method for future use. If there are significant concerns with the previous uses of the method, then these past uses would need to be processed consistent with the Backfit Rule and associated guidance. Prior to taking any additional actions the NRC would communicate its concerns and considerations through public meetings, including through the RISCs' public meetings. It can also occur that a previously rejected method is shown to be valid. In such cases, reconsideration can occur by submission of the new evidence to the Vetting Panel with a request to process the methodology anew. In such cases, the original decision (and/or continued use) of the subject method remains unchanged until the reconsideration process is complete and a new decision rendered and closed. The only exception to this is if the NRC determines that the continuation of the status quo with relation to the method in question potentially constitutes a significant immediate threat to the health and safety of the public, in which case the Director, Office of Nuclear Reactor Regulation, will issue a letter to NEI and licensees documenting the basis for this decision and providing appropriate direction, in accordance with NRC regulations.~~

Review Process Comments:

- In order to provide some general expectations for the process as a means of avoiding unbounded expansion of time and resources, this section provides some goals for the process options that require the formation of a technical review team in terms of both the size of a review team and the timeframe for completion of a review given the scope and complexity of a new method. These are not intended as hard and fast limits, but rather as expectations to provoke appropriate planning prior to beginning the review. When deviation from these goals seems needed (for reason such as resource limitations, conflicting priorities, etc.), it should be based on a conscious decision and reasoning as to why and this should be factored into the review plan. For as long as the RISC is in existence, requests for deviations should be brought to their attention in order that they consider whether to alter the constraints. Upon dissolution of the RISC, this responsibility will be delegated to the Vetting Panel.
- Size of Review Team - A number of the available processes presented above involve some type of review. Regardless of the bin a method falls into or the extent of the review required, it is expected that there will be different levels of complexity in the methods to be reviewed. In general, the size of the review team should reflect the complexity of the specific method. The expectation is that the review of a simple method would have no more than 2 people, a complex method with narrow expertise needed might have three or four, and a complex method with multiple disciplines might have as much as six or more (two per discipline).

Comment [NRC21]: Are there any success stories to support the resource commitments and timeframes presented below?

If not we may not want to dictate this information or should make clear that these are just examples.

Comment [NRC22]: Is the expectation that a review team will usually be needed to help the Vetting Panel? If so, the first bullet on the preceding page should point this out. If this is a reference to the Vetting Panel itself, it seems that this implies different Vetting Panels for different new methods.

Comment [NRC23]: Is this statement intended only to apply to the Industry RISC or both RISCs?

- Timeframe for Completion of Review and Issuance of Team Consensus - This would also be expected to be a function of the complexity of the method. Keeping with the same complexity concept discussed above, the goal should be that the disposition of a simple method would take no more than one month, a complex method with narrow expertise needed would take no more than three month, and a complex method with multiple disciplines would take no more than six months.

Comment [NRC24]: Rapid dispositioning would be a useful high-level goal.

Continuous Process Improvement:

The performance of this process will be evaluated on a continuing basis and changes made as necessary to maintain effectiveness and efficiency. This will be monitored by the NRC and NEI RISC as long as they remain in existence; after which point such responsibility will devolve to the Vetting Panel.

Comment [NRC25]: Another issue identified during the review of methods is the issue of existing documentation on methods that are determined to be unacceptable. There is not a current means to ensure these rejected methods are identified. (This would also apply to methods rejected through the new process.)

It is proposed that an effort be undertaken to identify, catalogue, and maintain a list of rejected methods (and previously accepted methods) for licensee and NRC reference as part of this effort.

Objective 2: Improve process for documentation and closure of peer review Facts and Observations

Background

There is no explicit guidance on the close-out of peer review F&Os. NRC and industry guidance focus on how peer reviews (and their findings) are used to support an application, not on achieving close-out of the findings. There is discussion of how new peer reviews need to consider previous peer reviews and licensees rely on the most recent, or “latest,” peer review, as augmented by gap assessments if needed⁴. After a peer review, the licensee typically addresses or “dispositions” each F&O per their PRA update processes and procedures. The licensee then identifies their implementation of their proposed resolutions, or “dispositions,” of the peer review findings within each risk-informed application; including justification and application-specific actions performed (e.g., sensitivity analyses) for those findings not fully resolved for the application.

Without a formal close-out process, risk-informed license applications have been required to address all findings from the latest peer review for the hazards relevant to the application, with occasional requests for findings from previous reviews as well, **if the latest peer review was not full-scope**. These peer review results have been augmented by findings from a gap assessment (if needed). However, because there is implicit guidance that peer reviews can be performed to close-out earlier peer reviews and because there have been issues with how the disposition of F&Os are documented (e.g., the finding is not fully characterized, the disposition only notes disagreement with the peer review, the disposition may not address all issues or extent of condition, etc.), the NRC has, in general, previously accepted the performance of a new peer review to close earlier findings.

⁴ Gap assessments are performed if the latest peer review was not against the latest endorsed PRA Standard and latest implemented revision to Regulatory Guide 1.200.

Per the PRA Technical Adequacy Working Group Problem Statement:

The requirement to retain and report all past peer review F&Os until re-evaluated by another peer review is an administrative burden that provides minimal benefit to the licensee. The current process results in additional burden to the licensee due to the effort required for the preparation of the discussion of PRA technical adequacy section in a License Amendment Request (LAR) which is followed by the documentation of the NRC's review of the F&O resolution. The NRC review frequently generates subsequent NRC Requests for Additional Information (RAIs) which increases the effort of the licensee in preparing RAI responses. The only currently accepted F&O closure path is the use of the Peer Review process, which is an additional cost and strain on limited PRA resources. In order to reduce this burden on the licensees to retain, report, and review the previously resolved F&Os, there is a need to provide an additional cost effective, robust process to allow licensees to close F&Os and obviate the need for an in-depth NRC review of the base PRA.

The following sections discuss current difficulties and best practices associated with documentation of peer review findings and their disposition in risk-informed applications, describe approaches considered for close-out of peer review findings, and provide recommendations for resolving the issues discussed.

Current ~~issues~~ challenges identified with the use of F&Os in risk-informed applications

1. Risk-informed submittals typically include only summaries of the F&Os, including only summaries of the actual dispositions for close-out. This material may be insufficient to ascertain whether the disposition proposed to address the concerns specific to the risk-informed application is appropriate.
2. Different risk-informed applications have different submittal requirements with respect to applicable supporting requirements (SRs) and ~~Capability-capability Category-category (CC)~~ and the associated dispositions. Most risk-informed applications need to assess the impact of F&Os, relevant to the submittal, which did not meet CC II. However, there are some notable exceptions. For example, Containment Type A Integrated Leak Rate Test (ILRT) extension requests need only address F&Os which did not meet CC I. Risk-informed inservice inspection (RI-ISI) applications may need to meet different categories, including some supporting requirements (SRs) at CC III, depending on the type of submittal. Finally, the NRC has set a precedent of asking for all relevant F&Os for certain applications, such as NFPA-805 and Risk-Informed Technical Specification Task Force (RI-TSTF) Initiative 4b (i.e., TSTF-505).
3. The relevance of F&Os and their dispositions to an application has been found to be confusing if the licensee has participated in multiple peer reviews, both full- and focused-scope, on multiple versions of the PRA model. Earlier F&Os and their dispositions may no longer apply to the current model and are essentially sunset. F&Os and dispositions from focused-scope reviews may pre-empt those from more recent full-scope reviews as well.
4. The limitations on available experts from the industry to serve repeatedly as peer reviewers, especially for the non-internal events reviews, remains to be alleviated. While new staff develop the skills to serve in this capacity, the more experienced staff may be retiring or leaving the nuclear arena, such that the overall total of experts remains static and still insufficient. It should be noted that peer reviews are not required to be performed by the Owner's Groups.
5. Disposition of F&Os as "documentation only" is not always appropriate, especially when the concern may have been the unavailability of the required material, at least in some preliminary form, for the team to review. The peer review teams do, however, note the relevant technical SRs associated with such F&Os, and it should therefore be clear when disposition as "documentation only" is and is not appropriate.

Comment [NRC26]: It might be useful to provide an explicit statement of the challenge stemming from this observation.

The overall concern here seems to be that different requirements causes confusion.

Best practices for adequate documentation of F&Os and bases for closure of F&O

- Some licensees provide the full F&O description (including distinguishing between CC I or Not Met) and disposition as well as an additional statement to assess the impact to the specific risk-informed application. Detailed F&Os and dispositions are preferred in order to understand the changes to the PRA model without follow-up questions (and to expedite audits if they are required in the future).
- Some licensees provide a detailed history and description of the peer reviews, gap assessments, and self-assessments. Additionally, some licensees also provide a timeline of PRA model updates and upgrades.
- Only F&Os from the most recent **full-scope and focused-scope** peer review(s) which are applicable to the current model and relevant to the submittal are provided.
- The use of new methods or “Unreviewed Analysis Methods” (UAMs) ~~should be~~ clearly identified.
- If using a Fire PRA or Seismic PRA to address external events, ~~provide similar~~ documentation **similar as-to** that required for the Internal Events F&Os **is provided**.
- Well-maintained, up-to-date PRAs **that are** reviewed to the latest endorsed PRA Standard with thoroughly documented resolutions of findings. **This** greatly expedites the review process, particularly for F&Os associated with external hazards.

Options for F&O Close-out

1. Original Peer Review Team Close-out

~~Licensee~~-The licensee provides a description of the implementation of the proposed resolutions to the peer review F&Os to the original peer review team. ~~Peer~~-The peer review team determines if the proposed resolution resolves the original F&Os. ~~Licensee~~-The licensee may identify proposed resolutions during the actual performance of the peer review, but the peer review team needs to review implementation of the proposed resolution to close-out the F&O. This process has been used on a very limited basis.

PROs

- It ensures continuity and that the individuals most knowledgeable about the F&Os evaluate the dispositions.
- It provides an independent process for establishing closure of previous peer review findings that then do not need to be addressed in new applications.
- The acceptability of the actions by the licensee in closing the finding can be more quickly assessed, as the focus of the team is solely on the prior findings and not against the latest endorsed PRA Standard.
- The costs of this approach should be less than those associated with a new peer review team as the reviewers would already be familiar with the PRA and F&Os and focused only on the close-out of the findings; not on a completely new peer review
- No need for other peer reviews (unless there is a PRA upgrade or additional hazards/modes modeled which would require a focused-scope peer review); only gap assessments to latest PRA Standard would need to be addressed.

CONs

- Close-out of the F&Os may require considerable time, and repeatedly re-assembling even part of the original team, especially with the team leader, may quickly become prohibitive.
- The review would not be against the latest endorsed PRA Standard, but only focused on what was implemented to close the finding.
- Limited resources for conducting peer reviews results in potential scheduling issues; these impacts are more significant as licensee PRAs are upgraded to address other hazards (e.g., seismic), and thus need peer reviews in these areas too.
- Original reviewers may no longer be available or reassembling the original Peer Review team may not be practical.

- Delay between this “Close-out F&O Peer Review” and report being completed can be extensive (6+ weeks).

2. New Peer Review Used for Close-out

This process involves a focused-scope peer review of one element and the close-out of findings within that element (with findings on remaining elements still having to be addressed) or a completely new peer review that re-addresses how the PRA addresses PRA technical adequacy relative to RG 1.200 and the Standard. In this approach, the licensee has a new peer review performed (total or focused-scope) that includes consideration of previous peer review findings and the licensee’s implementation of their resolutions of those findings. Original findings of the newly peer reviewed elements are sunset/eliminated and replaced by any new findings of the new peer review. New peer reviews often result in new findings that have to be addressed in applications. Currently, the licensees decide when to perform a new peer review based on criteria from the ASME/ANS PRA Standard regarding PRA upgrades.

PROs

- A new peer review allows an independent consideration and review of how prior findings were addressed by the licensee.
- It provides an independent process for establishing closure of previous peer review findings that do not need to be addressed in new applications
- It updates peer reviewed elements to the latest endorsed PRA Standard and encourages PRAs to be kept relatively contemporary as methods, plant configurations, etc., evolve.
- Need not secure availability from original peer review team members

CONs

- Limited resources for conducting peer reviews results in potential scheduling issues; these impacts are more significant as licensee PRAs are upgraded to address other hazards (e.g., seismic), and thus need peer reviews in these areas too.
- Non-trivial burden associated with assembling a full peer review team.
- The new team will be likely to generate new F&Os, which will need to be closed out in some manner.
- Delay between this “Close-out F&O Peer Review” and report being completed can be extensive (6+ weeks).

3. NRC Review and Close-out

Licensee submits information to NRC identifying the implementation of their proposed resolution of findings either in conjunction with or independent of any risk-informed applications. NRC determines if the proposed resolution resolves the original findings or if additional information/action is needed. This process is informally being applied, on a very limited basis, for licensees with both NFPA-805 and other risk-informed LARs being reviewed concurrently in order to improve schedule and reduce regulatory burden.

Comment [NRC27]: These are 2 very different cases and the Pros & Cons should address them accordingly.

PROs

- It provides a regulatory process for establishing closure of previous peer review findings that do not need to be addressed in new applications.
- No need for other peer reviews (unless there is a PRA upgrade or additional hazards/modes modeled which would require a focused-scope peer review); only gap assessments to latest PRA Standard would need to be addressed.

CONs

- If performed outside of an application review, there may be significant up-front resource and time investment for both the licensee and the NRC as this is essentially effectively an application review, though only focused on resolution of findings, and involves schedule, resources, and associated costs typical of a regulatory review. Similarly, this process will likely require RAIs in order to come to agreement on the closure of some findings, which will extend such reviews well beyond the length of other approaches that would typically be less than two months. This process will primarily benefit licensees that plan on submitting multiple risk-informed applications.
- ~~It would not necessarily be against the latest endorsed PRA Standard if the peer review was conducted using an earlier version of the standard.~~ The review would be only focused on what was implemented to close out the finding, unless a gap assessment is required.
- This could give the appearance that the NRC is formally approving the PRA and the Peer Review F&O closure, since the NRC will have to docket the NRC Audit.

Comment [NRC28]: This is a factual comment, not really a con. It is particularly beneficial if applied to a broad-scope application initially.

Comment [NRC29]: Per NRC policy (as discussed in RIS 2007-06), the review would be against the latest endorsed version of the standard and currently implemented version of RG 1.200, so the gaps would need to be evaluated.

Comment [NRC30]: This is not really a con. Every review (which results in acceptance of a license amendment request) must conclude that the PRA is technically adequate for the given application.

4. Licensee Close-out

This would call for a licensee to document implementation of proposed resolution of findings to close-out peer review findings, by using independent resources (internal, contracted, or through a utility-to-utility exchange). This process has relatively minimal additional costs or impacts beyond the already established need to document closure of findings and should be part of the existing licensee processes for updating the PRA. Documentation is retained for NRC audit in context of risk-informed application reviews and is provided to future peer reviews for consideration.

PROs

- It provides a process for establishing closure of previous peer review findings without conducting a new peer review.
- Existing industry guidance documents, currently endorsed by the NRC, include language supporting such a process. Specifically, the peer review teams can include “non-involved utility personnel from other sites for multi-site utilities [or] use of current contractors (on-site or otherwise) involved in other work,” and a similar set of criteria could be applied to personnel conducting F&O close-outs. Further, Section 1-6.2.2 of the ASME/ANS PRA Standard states, as criteria for peer reviewer independence, that “the peer review team members shall have neither performed nor directly supervised any work on the portions of the PRA being reviewed,” which allows for a utility to use resources independent from the specific PRA being reviewed for F&O close-out.
- No need for other peer reviews (unless there is a PRA upgrade or additional hazards/modes modeled which would require a focused-scope peer review); only gap assessments to latest PRA Standard would need to be addressed.
- Would allow closing some straightforward F&Os where the parameters of the F&Os are easily understood.
- Most timely closure method for F&Os at minimal expense, which allows resources to be applied to other important activities.

CONs

- It would not necessarily be against the latest endorsed PRA Standard if the peer review was conducted using an earlier version of the standard. The review would be only focused on what was implemented to close out the finding, unless a gap assessment is required.
- **There may be the potential for the perception of a conflict of interest.**

5. Hybrid Approach

This process is a merger of multiple aspects of the above approaches within some hierarchical framework. This will involve the identification of attributes of findings for grouping into types of findings and then the determination of which of the above approaches are appropriate for close-out of specific types of findings.

PROs

- Provides process, with varying levels of NRC review, for establishing closure of previous peer review findings that do not need to be addressed in new applications.
- Allows a graded approach to the closure process for peer review findings.
- In resolving most findings, there will be no need for other peer reviews (unless there is a PRA upgrade or additional hazards/modes modeled which would require a focused-scope peer review); only gap assessments to latest PRA Standard would need to be addressed.
- Would allow closing some straightforward F&Os where the parameters of the F&Os are easily understood.
- Most timely closure method for F&Os at minimal expense, which allows resources to be applied to other important activities.

CONs

- Requires establishing a hierarchical framework for how to close out findings; including identifying the attributes of findings that can be addressed by various approaches.
- It would not necessarily be against the latest endorsed PRA Standard if the peer review was conducted using an earlier version of the standard. The review would be only focused on what was implemented to close out the finding, unless a gap assessment is required.
- A tracking program may be required for F&O close-out, particularly if some F&Os are closed out via NRC reviews of risk-informed applications or if the licensee closes out F&Os without third party review.

Recommended Approach: Combination of Options 2, 3, and 4

Given the advantages and disadvantages outlined above, Options 2, 3, and 4 each have a clear role in F&O closure in specific circumstances, as described below.

Option 4 (Licensee Close-Out): This option is envisioned as the most efficient option for most situations. In this process, a licensee would use individuals who meet the qualification and independence criteria of NRC-endorsed industry peer review guidance documents and the ASME/ANS PRA Standard to conduct a review of open F&Os. The individuals used in the close out, as well as their qualifications and independence, would be provided in a report documenting the verification of close-out on an F&O-by-F&O basis. Those F&Os deemed “closed” in this report would no longer need to be reported in risk-informed application submittals.

Option 2 (New Peer Review): This option would be applied in cases where licensees perform follow-on peer reviews. For the areas which are covered by a given follow-on peer review, a licensee need not report F&Os from previous peer reviews in risk-informed application submittals. In other words, only the most recent F&Os, not otherwise closed out by another process, would need to be reported in risk-informed application submittals, as the peer review process calls for review of F&Os from previous relevant peer reviews.

Option 3 (NRC Review and Close-Out): This option would be available to licensees with a substantial application, such as NFPA 805, already under review. In a new application submittal, for F&Os not already closed by licensee close-out or a new peer review, a licensee may reference a previous NRC application review as the basis for close-out of an F&O. However, the other options are preferable, as it is recognized that the NRC review is application-specific, and that some level of additional NRC review will be necessary to confirm that the F&O was adequately addressed for the current application under consideration.

In addition to the above process for closure of F&Os, industry and/or NRC should develop guidance on documenting F&Os in risk-informed applications, following the best practices identified above.

Comment [NRC31]: It should be noted that Option 1 is a subset of Option 2. Therefore, this effectively recommends a combination of all other options which would suggest that a hybrid approach (i.e., Option 5) should be developed further and considered as the recommended approach.

Objective 3: Address Additional Gaps in the Peer Review Process

The industry and NRC working groups ~~each~~ conducted ~~an exhaustive~~ review of current issues with the peer review process to determine if there were any additional issues associated with PRA technical adequacy and the peer review process that the working groups could address. One such topic, process for assuring peer reviewer is technically qualified for the technical area being reviewed, was identified and discussed by the working group. The term “qualified” means that the individual peer reviewer has adequate technical depth and breadth of experience for the PRA areas being reviewed.

Currently, the NRC-endorsed industry peer review guidance, as well as the ASME/ANS PRA Standard, gives clear qualification standards for peer reviewers. The industry peer review guidance documents further call for reviewers to provide resumes documenting their qualifications for inclusion in the final peer review report.

However, questions have still occasionally arisen regarding reviewer qualifications for completed reviews, which is problematic for both the NRC and the licensee. Although the industry has worked to ensure that peer review teams are qualified for all technical elements under review, documentation of this qualification needs to reflect this effort. In some cases, reviewer resumes may not fully reflect relevant experience and expertise, resulting in questions during risk informed license application reviews. **In other cases, observers or individuals being trained on the process are identified as part of the peer review team without clarifying their role, again resulting in questions during risk informed license application reviews.**

In order to prevent this in the future, the process outlined in the industry peer review guidance documents should be updated to give the host utility for a peer review the responsibility to review documentation of peer review team qualification in advance of the review **and request new members, as necessary**. Specifically, reviewer resumes should be provided when the team is identified to the host utility. This will allow the host utility sufficient time to **review the team and ensure adequate documentation of qualification** prior to conduct of the on-site peer review.

Comment [NRC32]: Current guidance emphasizes application experience. A different level of expertise may be needed when assessing if a new (or non-mainstream) approach meets the intent of standards and guidance.

Summary and Path Forward

The recommendations in this paper, if fully implemented, will substantially improve the regulatory processes associated with verification of PRA technical adequacy for risk-informed licensing applications. Addressing technical adequacy of methods in advance of peer reviews and more clearly defining expectations for F&O closeout, in particular, will reduce burden to licensees and the NRC, and facilitate improved efficiency in the review of risk-informed licensing applications.

Implementation of these recommendations will require updates to existing industry guidance documents and NRC regulatory guides, as well as development of new supporting documents. Documents to be developed or updated are as follows:

- New industry guidance document describing the process for making new methods available for regulatory application
- Revisions to industry peer review guidance documents (NEI 05-04, NEI 07-12, ~~NEI 12--13~~) to include description of process for closure of peer review F&Os and detailing timeline and process for verification of reviewer qualifications
- New NRC ~~Interim Staff Guidance~~ ISG document(s) endorsing the above

In the long term, these changes should be incorporated into the next scheduled revision of Regulatory Guide 1.200 to consolidate the guidance associated with PRA technical adequacy for risk-informed licensing applications.

Additionally, given the number of new steps associated with the proposed process proposed for making new methods available for regulatory application, the process should be piloted following drafting of the new industry guidance document to ensure that the process, as described, is effective.

Comment [NRC33]: Relevant NRC Standard Review Plan sections, Inspection Procedures, RG 1.174, etc. may also need to be revised as part of the implementation to address changes in the ISG and RG 1.200.