

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

March 2015

Comment [NRC -Supp1]: This document provides NRC SUPPLEMENTAL Feedback to the March 2015 version of the Industry whitepaper (ML15086A063).

This document does not repeat the more significant NRC feedback provided to the December 2014 version (ML15082A149). Some of those comments were already addressed by the March 2015 version. However, this SUPPLEMENTAL feedback may still note a few of the previous NRC comments that were clarified further at the March 30, 2015 public meeting between the separate NRC and Industry working groups. Changes to those comments are noted in bold font.

This SUPPLEMENTAL feedback also tries to incorporate some of the new feedback from the 3/30/15 public meeting.

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 Standard, and hence RG 1.200, only address the "what" in the PRA, not the "how," or the specifics of methodologies and their use. As a result, 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 aspects of the PRA supporting the licensing applications for which a peer review has identified findings (and sometimes suggestions) and the licensee has identified their disposition of those findings for that application. The current industry guidance and endorsing regulatory guidance does not explicitly identify the process for closing (and documenting the closure of) findings from a peer review.

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 [NRC-Supp2]: Note that NUREG-1855 gives a definition of "consensus model" which is another way of saying "consensus method." Consider referring to that definition.

Comment [NRC-Supp3]: The PRA Standard does provide requirements on "what" is needed for a technically acceptable PRA, but the peer review does not review the methods for their technical acceptability. Rather, the peer review sees if the intent of the SRs were met based on using acceptable methods and ensures the method is implemented correctly.

Comment [NRC-Supp4]: The current writeup states that there have been disagreements regarding the appropriate level of staff review of the PRA supporting the licensing applications and then proceeds to discuss the need to improve the peer review process. However, the scope of the objective statement is related to the documentation and close-out of peer review facts and observations (F&Os) (also referred to as findings and suggestions). The comment in the overview is considerably broader than the actual objective statement. The suggested edit makes the objective match the overview. See suggested edit.

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 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 (and independent, self, or gap assessments) and the licensee's disposition for each risk-informed application 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 licensee's resolution of these F&Os.

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 evaluate other difficulties that the NRC and industry have encountered with the peer review process. This

Comment [NRC-Supp5]: The edit makes it clear that the reported F&Os (and others) currently need to be reported and dispositioned for each application.

Comment [NRC-Supp6]: The edit makes it clear that the focus is the F&Os, not the base PRA. Having the peer review, in itself, to the endorsed Standard with the clarifications and qualifications of the RG, already obviates the need for a detailed review of the base PRA.

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 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 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 Safety Evaluation by the NRC), requesting an Interim Staff Guidance (ISG), or pursuing Standards Developing Organization (SDO) development of a standard followed by NRC endorsement, if they decide that such is their preferred path versus that described below.

At a high level, the process described in this section is intended to provide for rapid resolution and involves:

- Identification of a new method using the provided definition
- Review of the attributes of this method by a joint industry-NRC vetting panel to determine the appropriate review process
- Conduct of the review of the method using the selected process
- Availability of the method for use in regulatory applications

This process is similar to how standards or code case committees are conducted where there is representation by industry and NRC in the process. At the completion of the review of a method, the acceptance or rejection of the method is documented, including any dissenting opinions, and provided to the NRC for formal acceptance and closure.

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 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

Comment [NRC-Supp7]: This is a good addition that addresses a comment raised separately during the internal meeting of the NRC RISC.

Comment [NRC-Supp8]: Reflects a general comment from the internal meeting of the NRC RISC.

Comment [NRC-Supp9]: It is not clear how new usage is any different than being sufficiently different in use of item 2. Suggest deletion of this item and merge into a single definition.

2.1. It is sufficiently different from methods currently in use in nuclear plants PRAs or sufficiently different in application of an existing accepted approach such 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 endorsed ASME/ANS PRA Standard, ~~or 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.~~

Comment [NRC10]: 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.

Suggest discussing on 3/30

As discussed at the public meeting on 3/30, please add the specific reference to the endorsed PRA Standard for where the discussion and examples of updates and upgrades is provided (i.e., refer to the nonmandatory appendix).

Definition of Terms:

In establishing the proper scope of review needed to determine the acceptability of a new method, a number of attributes or characteristics may be considered. The following terms represent some of the significant characteristics to consider.

Comment [NRC-Supp11]: Suggested edit provides an introduction to the section

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
- SDO
- 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 outside the U.S. nuclear industry
- Commonly used over some years outside the U.S. nuclear industry

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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, 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.

1. Usage of the method is acceptable immediately upon issuance of the interim use method. Requires a determination that the interim use method has clear support from both NRC and industry.
2. Usage of the method is acceptable immediately upon conclusion of the comment period for the interim use 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-vetting panel assessment**. **The vetting panel assessment involves taking 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 (i.e., Capability Category/Category (CC) CC I or CC II) against requirements of RG 1.200. In a gap assessment, the 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.**
 - 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 a favorable **focused-scope peer review** of the method and disposition of review comments. **This methods peer review 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**

Comment [NRC-Supp12]: The edit would distinguish the vetting panel review versus the PRA community understanding of a “gap assessment” and make it clear that it is a review to ensure the bases for the method is technically correct (more than just meets the PRA standard elements). This change should be made throughout the paper.

endorsed ASME/ANS PRA Standard (the “what”) at the appropriate level for its intended use.¹ ~~would be a peer review of the technical aspects of the method against the requirements of R.G. 1.200². The assessment would be against the applicable SRs of the ASME/ANS standard as modified by NRC clarifications and qualifications.~~ This could be an industry peer review, conducted by a team specifically selected for their expertise related to the method in question, done in the same manner as is currently done for PRAs, and NRC observers could be present at the peer review.

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.)

7.6. 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.

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 regulatory uncertainty associated with using the new method at this stage. ~~This also might result in license conditions on these applications to revisit and revise, as appropriate, the application when the final version of the new method is determined accepted or if it is ultimately rejected. For NRC-related methods development, it might also be necessary for the NRC to include an explicit statement if the method is draft for use.~~

Comment [NRC-Supp13]: The industry revised text creates a potentially significant issue. It is not clear how only having NRC as an observer would effectively gain equal participation between the industry and NRC in the review of technical acceptance of a new method. Rather, this methods peer review needs to have guidance developed on how it would function to ensure equal industry and NRC participation or alternatively to incorporate it into Process Option 6 as a smaller version of an Industry/NRC methods panel.

Comment [NRC-Supp14]: In making the prior revision, this appears to have changed from indented a (representing 5a) and the next option should be changed back to 6.

Formatted

Comment [NRC-Supp15]: The edit makes it clear how this might be treated within an application.

¹ Note that this methods peer review is specifically for the evaluation of the method.

² ~~Note that this does not refer to a methods peer review is of a PRA that includes a new method, but rather a peer review constituted specifically for the evaluation of the method.~~

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 recommended 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 U.S. 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, 6
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, 6
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, 6
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

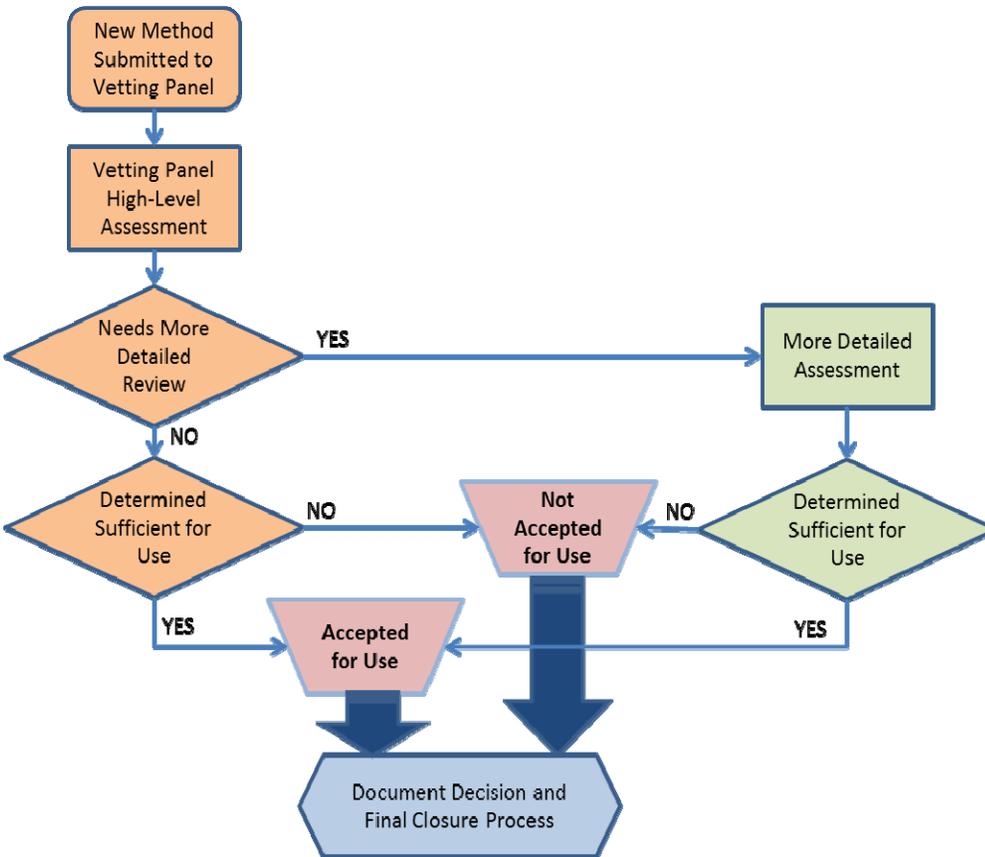
Comment [NRC16]: There may be cases where NRC may need to take a larger role (particularly for process options 4 and 5). Note that there are various levels of scientific peer review and that, as a practical matter, the criteria for publication don't necessarily match those for regulatory acceptance.

Suggest discussing on 3/30
As discussed at the public meeting on 3/30, one of the points of this comment was to note that the term “peer review” may have different meanings in different circles (e.g., academia).

Comment [NRC-Supp17]: Process Option 6 is added to make the example clear that Groups B-F can always go to a full methods panel if the Vetting Panel determines that is the appropriate path, especially where acceptance is considered implicit. A similar change needs to be incorporated into the industry flow diagram.

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 standing 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 to which acceptance process option should be used. The panel will consist of an equal number of members appointed by the Director of the Division of Risk Assessment at NRC, **in concert with the Director of the Division of Safety Systems and Risk Assessment at NRC**, and the Director of Risk Assessment at NEI. Note that this panel also may **be called upon to perform a gap determine to perform the technical assessment of the method against RG 1.200, and so should be knowledgeable about the RG and the ASME/ANS standard.**



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

Comment [NRC18]: The narrative about the vetting panel needs to come before or have integrated into it the description of the process options.

Suggest discussing on 3/30
As discussed at the public meeting on 3/30, Industry agreed to this change, but preferred to make this change after completing incorporation of other comments. NRC agrees.

Comment [NRC -Supp19]: Additional NRC staff commented on the NRC proposed flowchart and it has been revised to address these comments.

Comment [NRC20]: Should point out that the (apparent) intent is that there be one Vetting Panel (not one panel for each new method).

Suggest discussing on 3/30
As discussed at the public meeting on 3/30, the NRC agreed that this comment was addressed since the vetting panel can pull on additional expertise to support their review.

Comment [NRC21]: 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?

Suggest discussing on 3/30
As discussed at the public meeting on 3/30, Industry already partially addressed this comment and will add a note about substitutions, etc.

Comment [NRC-Supp22]: There are 2 program offices at the NRC that would need to work together to designate the vetting panel members.

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, **in concert with their technical knowledge and judgment**, 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.

If the vetting panel determines that it has sufficient expertise and the method is simple enough to support their review, then the panel decisions will be based on a holistic assessment of the method. The panel's review would consider the technical bases for the method and make a decision on if the method is acceptable for use. If **there are** technical concerns or sufficient technical justification and information is determined to be lacking, then the vetting panel may determine that the new method is not acceptable for use. The decision and rationale for the decision would be provided to the submitter of the method. This would allow the submitter to consider pursuing modifications and further justification of the method outside this process and potentially enable the submitter to re-submit the enhanced method anew at a later date. If the vetting panel determines that the method is acceptable for use, then the panel will document that decision, the rationale, and any identified limitations, dissenting opinions, or technical considerations to the submitter.

If the vetting panel determines that the proposed new method is too complex or needs a more thorough review, then the panel will refer the method to either a methods peer review or an expert methods panel. These reviews may be similar to a PRA peer review team, augmented

with NRC representation, or a full-blown expert review panel similar to the NRC/EPRI methods panel used for a few fire PRA methods. These panels would conduct a relatively detailed technical review of the method and its technical bases to determine if the proposed method is acceptable for use. Similar to the vetting panel review, if there are technical concerns or sufficient technical justification and information is determined to be lacking, then the expert review panel may determine that the new method is not acceptable for use. The decision and rationale for the decision would be provided to the submitter of the method. This would allow the submitter to consider pursuing modifications and further justification of the method outside this process and potentially enable the submitter to re-submit the enhanced method to the process anew at a later date. If the review panel determines that the method is acceptable for use, then the panel will document that decision, the rationale, and any identified limitations, dissenting opinions, or technical considerations to the submitter.

Regardless of acceptance or non-acceptance of the method, a final closure process would need to be pursued to ensure the status of the proposed method is thoroughly documented within the regulatory structure to support risk-informed applications and NRC reviews.

Comment [NRC-Supp23]: Provides a high-level explanation of the figure.

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 regarding the review path 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~~vetting panel assessment or a methods peer review, a formal report of the ~~gap-vetting panel assessment or methods peer review team~~ will be developed, including dissenting opinions. Consensus will consist of a majority of both the NRC-appointed members and the industry-appointed members. The vetting panel and methods peer review meetings will be Category 2 public meetings. ~~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.i.e., a ~~Methods 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 by accepting or rejecting the results, including any kind of additional comments, considerations, or qualifications. Methods 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. Vetting and Methods 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 under their existing processes. ~~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 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 [NRC-Supp24]: In determining the appropriate review path, it is not necessary to obtain NRC Office Director approval, since it would be part of an endorsed process. However, regarding the final acceptance or rejection of a method through this process would need to be submitted and formally accepted by the NRC program offices (i.e., Division Directors for NRR/DRA and NRO/DSRA) as identified in the new last bullet. In addition,

Comment [NRC-Supp25]: This is redundant with the earlier text and not needed here.

Comment [NRC26]: Suggest using consistent terminology. (Earlier, the paper refers to a "methods panel".)
Additional language has been proposed as part of the SUPPLEMENTAL feedback to gain consistency and clarity.

Comment [NRC-Supp27]: As discussed at the 3/30 public meeting, this text is not necessary and can be more generally addressed by suggested replacement text.

- The final decision regarding the acceptance or rejection of a new method by any of the review panels (i.e., vetting, methods peer review, or methods 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 month of the panel decision) from NEI to the DRA Director in NRR and the DSRA Director in NRO. The NRC will respond to the letter accepting or rejecting the results of the process.

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.

Comment [NRC-Supp28]: As discussed at the 3/30 public meeting, this reference to the Backfit Rule is not necessary.

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 those process options that require the formation of a technical review team (i.e., **methods peer review team or methods panel**) for the review of a given method 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 industry and NRC RISCs are 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 be performed by the vetting panel directly if it has sufficient expertise or if a methods peer review team is deemed necessary it may have no more than 2 or 3 people from the industry and 2 or 3 people from the NRC (i.e., a total team size of 4 or 6). Similarly, a more complex method that clearly needs expertise beyond the vetting panel will vary in size depending on the disciplines needed for the review. 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).~~
- **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

Comment [NRC-Supp29]: To add clarity on size of teams.

needed would take no more than three month, and a complex method with multiple disciplines would take no more than six months.

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 [NRC30]: 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.

Suggest discussing on 3/30
Per the discussions at the 3/30 public meeting, both NRC and industry agreed that this would be a worthwhile endeavor.

The development of this guidance will be a follow-on activity.

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 needed³. 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.

³ 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 ~~licensee's resolution of these F&Os 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.

Comment [NRC-Supp31]: To be consistent with edit in overview.

Current 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. Confusion may arise because different risk-informed applications have different submittal requirements with respect to applicable supporting requirements and capability category -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 (RI-TS) 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.

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) are clearly identified.
- If using a Fire PRA or Seismic PRA to address external events, documentation similar 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

The licensee provides a description of the implementation of the proposed resolutions to the peer review F&Os to the original peer review team. The peer review team determines if the proposed resolution resolves the original F&Os. 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. 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.

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 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.
- The review would be focused on what was implemented to close out the finding.

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 All Options

Given the advantages and disadvantages outlined above, ~~Options 1, 2, 3, and 4 each~~ have a clear role in F&O closure in specific circumstances. ~~as described below~~ Therefore, it is recommended that the Hybrid Approach (Option 5) be pursued and further developed.

~~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.~~

~~Option 1 (Original Peer Review Team): Similar to Option 2, a licensee is free to conduct a follow-on peer review using the previous team; however, it is not anticipated that this will be a practical option in many, if any, cases given personnel turnover.~~

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 [NRC-Supp32]: As discussed at the 3/30 public meeting, it is recommended that the recommended approach be Option 5 (Hybrid Option) with the need to develop high-level guidance on implementation/selection of the appropriate path for closure of findings (both inclusion and exclusion of paths for different types of findings); recognizing the significance of the finding and the potential role of the peer review team in making this determination.

The development of this guidance will be a follow-on activity.

Objective 3: Address Additional Gaps in the Peer Review Process

The industry and NRC working groups conducted a 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.

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 **and associated guidance, such as qualifications of the vetting panel members**
- 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 **consistent with Option 5 (Hybrid Approach)** and detailing timeline and process for verification of reviewer qualifications
- **Development of a catalogue of formally or informally accepted and rejected (or flawed) PRA methods for U.S. nuclear power plants**
- New NRC 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 (and the Standard Review Plan, Inspection Procedures and Regulatory Guide 1.174, as applicable) 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. **A list of items that need to be explicitly addressed within the pilots needs to be identified through interactions between the industry and the NRC prior to conducting these pilots.**