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

June 2015

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. 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 ASME/ANS PRA Standard, and hence RG 1.200, only addresses 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 a lack of a clear process for addressing 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 PRA supporting the licensing applications for which a peer review has identified findings and the licensee has identified their disposition of those findings for that application. The current industry guidance and endorsing NRC guidance does not explicitly identify the process for closing, and documenting 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.

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 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 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 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 that used by standards or code case committees that include NRC and industry participation. 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.

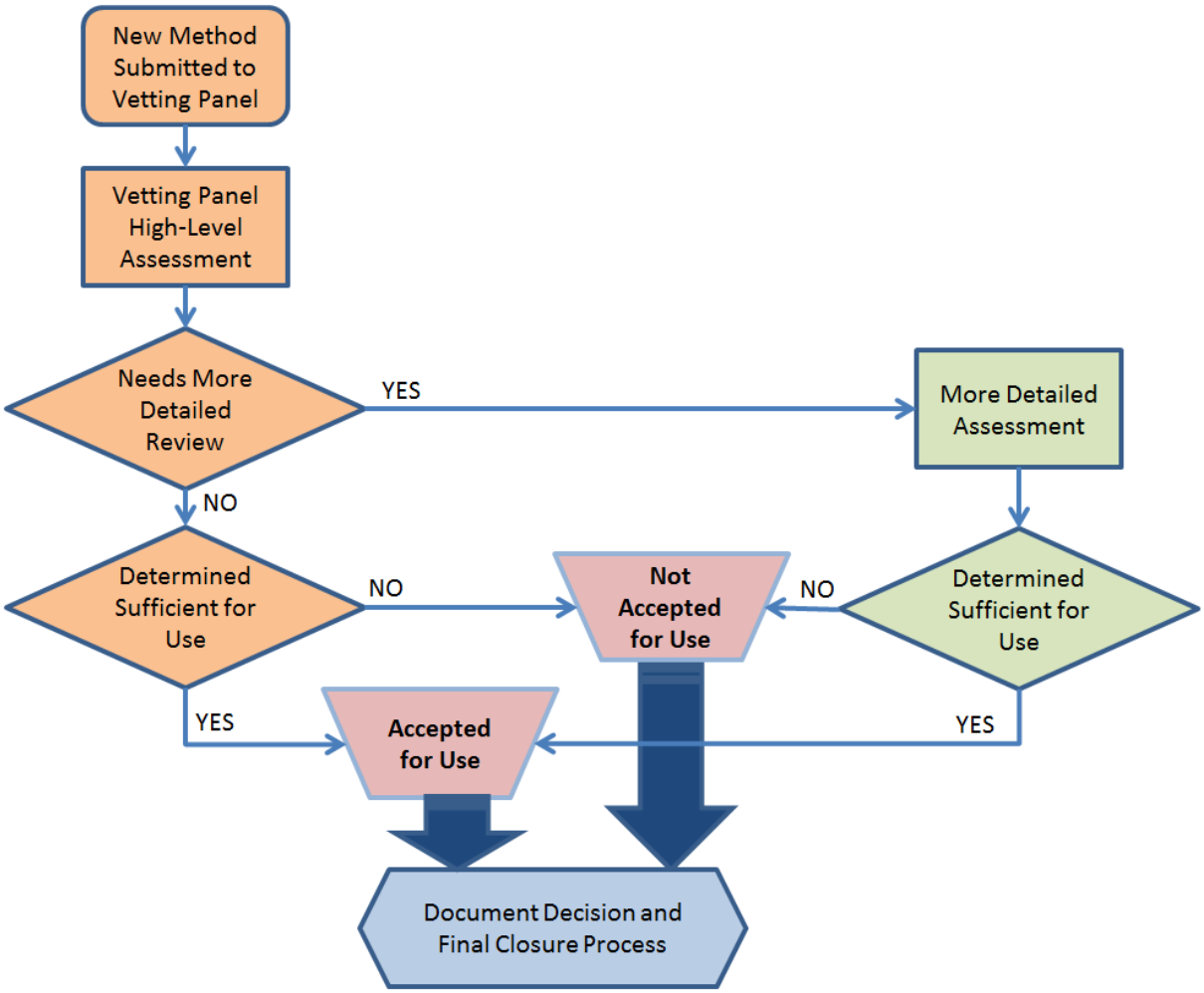
Definition of New Method:

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:

> It is sufficiently different from methods currently in use throughout the U.S. nuclear industry, or sufficiently different in application of an existing approach, such that it would be considered an upgrade in accordance with the definition of upgrade (and the examples of upgrades) in Nonmandatory Appendix 1-A of ASME/ANS RA-S-2008, *Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Applications*.

Vetting Panel

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, all of whom meet the NRC-endorsed NEI peer review guidance document requirements for peer reviewer qualification. These members will be appointed by the Director of the Division of Risk Assessment at NRC and the Director of Risk Assessment at NEI, who will also have responsibility for designating augmented members or substitutes, as necessary. Note that this panel also may be called upon to perform a technical assessment of a given method.



The panel's decisions will be based on a holistic look at the method in terms of its source, pedigree, maturity and complexity (as defined in this paper) 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, in concert with their technical knowledge and judgement, 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 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 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.

Definition of Terms:

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

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
- Standards Development Organization

- 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 in non-nuclear industries

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 vetting panel assessment. The vetting panel assessment involves taking the submitted method under review to determine if there is sufficient documented technical basis 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 at the appropriate level for its intended use (e.g. Capability Category (CC) I or CC II).
    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 method under review to determine if there is sufficient documented technical basis 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 at the appropriate level for its intended use. 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.
    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.

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.

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 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 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

Group	Description	Available Process Options
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

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. Documentation of the Panel decision will be sent from NEI to NRC within one week of the panel decision. 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 vetting panel assessment or a methods peer review, a formal report of the vetting panel assessment or 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 public meetings.
- 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 "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 Division of Risk Assessment Director in NRR and the Division of Safety and Risk Assessment Director in NRO, who shall respond by accepting or rejecting the results, including any kind of additional comments, considerations, or qualifications. A 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 public meetings.
- The final decisions of any review panels will be documented in the public record of the meeting. 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 Division of Risk

Assessment Director in NRR and the Division of Safety and Risk Assessment Director in NRO. The NRC will respond to the letter by accepting or rejecting the results, including any kind of additional comments, considerations, or qualifications.

Reconsideration of Methods

It is possible 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. Prior to taking any additional actions the NRC would communicate its concerns and considerations through public meetings, including through the RISCs' public meetings.

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 (e.g. 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 RISCs, 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 be performed by the vetting panel directly, if the panel has sufficient expertise, or by a methods peer review team, if necessary, may have 2 or 3 people from the NRC and 2 or 3 people from the industry. Similarly, a more complex method that clearly calls for expertise beyond that of the vetting panel will vary in size depending on the disciplines needed for the review.
- 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.

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. Additionally, NEI will maintain a catalogue of the outcome of all panel decisions.

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 needed[1]. 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.

[1] 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.

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 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&Os

- 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 2, 3, and 4 each have a clear role in F&O closure in specific circumstances. It is therefore suggested that Option 5, the Hybrid Approach, be pursued and further developed. Specific considerations related to the role of each approach are discussed below.

Option 2 (New Peer Review): This option may 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 may 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 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.

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.

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.

An additional issue raised relates to the role of peer reviews in the PRA maintenance and upgrade process. This has arisen during reviews of risk-informed licensing applications, and in discussions regarding integration of new data into plant PRAs. It is recommended that the NRC and industry discuss the maintenance and upgrade process, as currently documented in existing regulatory guidance, in a series of public meetings and determine if any guidance changes are warranted.

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, including description of 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 PRA methods available for regulatory application at 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 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 NRC prior to conduct of these pilots.