Process to Address (1) Licensee Proposed Disposition of Peer Review Findings and Observations, and (2) Industry Process to Determine Acceptability of New PRA Methods

Industry is proposing a process to close peer review findings and observations and a process to determine acceptability of new PRA methods. The NRC staff has developed a draft position to communicate their expectations with regard to an acceptable process for these two issues. Since these processes will ultimately be reviewed and endorsed in Regulatory Guide (RG) 1.200, the staff has drafted their expectations as could potentially be documented in RG 1.200.

C. REGULATORY POSITION

1. A Technically Acceptable PRA

This section describes one acceptable approach for defining the technical adequacy of an acceptable base PRA of a commercial light water reactor nuclear power plant. However, the term “PRA” and “base PRA” needs to be defined. For an analysis or approach to be considered a PRA, the analysis/approach must (1) provide a quantitative assessment of the identified risk in terms of scenarios that result in undesired consequences (e.g., core damage or a large early release) and their frequencies, and (2) be comprised of specific technical elements in performing the quantification. A “base PRA” is a PRA that is developed independent of an application; therefore, it is intended to be a technically acceptable PRA for quantifying the risk of a commercial light water reactor nuclear power plant.

For a PRA to have a technically acceptable basis, the PRA needs to have an adequate scope, adequate completion of the technical elements, adequate level of detail, and adequate representation of the as-built and as-operated plant (or as-designed for new reactors).

The scope of the PRA is determined by its intended use. It is envisioned, however, that for currently operating reactors and for reactors at the DC or COL application stage, some applications may require a full-scope Level 1 and some aspects of a Level 2 PRA. Consequently, in this section, the guidance provided is for a full-scope Level 1 and Level 2 PRA. The scope is defined in terms of (1) the metrics used to characterize risk, (2) the plant operating states for which the risk is to be evaluated, and (3) the causes of initiating events (hazard groups) that can potentially challenge and disrupt the normal operation of the plant and, if not prevented or mitigated, would eventually result in core damage and/or a large release.

The technical elements define the needed completeness of the base PRA model. The technical elements have certain technical attributes and characteristics so that the PRA model constructed is both technically sound and defensible. These desired attributes and characteristics can be dependent on the intended use of the PRA; nonetheless, there is a minimal set of technical elements and associated technical attributes and characteristics comprising a base PRA.

The level of detail of the PRA is also determined by its intended use. Nonetheless, a minimal level of detail is necessary to ensure that the impacts of designed-in dependencies (e.g., support system dependencies, functional dependencies, and dependencies on operator actions) are correctly captured. This minimal level of detail is implicit in the technical elements comprising the PRA and their associated characteristics and attributes.

As noted, PRAs used in risk-informed activities may vary in scope and level of detail, depending on the specific application. However, the PRA results used to support an application must be derived from a baseline PRA model that represents the as-built, as-operated plant to the extent needed to support the application. Consequently, the PRA needs to be maintained and upgraded, where necessary, to ensure it represents the as-built and as-operated plant.

This section provides guidance in four areas:
(1) scope of a PRA
(2) technical elements of a full-scope Level 1 and Level 2 PRA and their associated attributes and characteristics
(3) level of detail of a PRA
(4) development, maintenance, and upgrade of a PRA to ensure that the PRA represents the as-built, as-operated plant

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2. Consensus PRA Standards and Industry PRA Programs

One acceptable approach to demonstrate conformance with Regulatory Position 1 is to use a national consensus PRA standard or standards that address the scope of the PRA used in the decisionmaking. ASME and ANS have issued a PRA standard that provides both process and technical requirements for an at-power Level 1 and limited Level 2 PRA for internal events, internal flood, internal fire, seismic, wind, external flood and other external events (Ref. 14). This standard is not prescriptive in that it only establishes what a technically acceptable PRA needs to include, but it does not detail the requirements for performing a technically acceptable PRA. A peer review is needed to determine if the intent of the requirements in the standard is met; and if not met, how these findings are addressed and resolved needs to be determined. Moreover, to meet the requirements specified in the ASME/ANS PRA standard, new methods may be used. A method is considered new if it has not been accepted or endorsed for use in the base PRA (or in a specific risk-informed application) by the NRC (see Section 2.3). These new methods need to be technically evaluated to determine their acceptability.

A staff position is provided below on the acceptability on the use of consensus PRA standard, peer reviews of the PRA model using the standard, technical evaluation for the acceptability of the resolution of peer review findings and observations (F&Os), and the acceptability of new methods.

2.1 Consensus PRA Standards

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Further, the technical requirements may be defined at two different levels: (1) high-level requirements and (2) supporting requirements. High-level requirements are defined for each technical element and capture the objective of the technical element. These high-level requirements are defined in general terms, need to be met regardless of the capability category, and accommodate different approaches. Supporting requirements are defined for each high-

level requirement. These supporting requirements are those minimal requirements needed to satisfy the high-level requirement. Consequently, determination of whether a high-level requirement is met, is based on whether the associated supporting requirements are met. Whether or not every supporting requirement is needed for a high-level requirement is application dependent and is determined by the application process requirements.

The ASME/ANS standard is one example of a national consensus PRA standard; its scope encompasses a PRA for Level 1 and limited Level 2 (LERF) for at-power operation and internal and external hazards. Appendix A to this regulatory guide provides the staff regulatory position regarding this document. If it is demonstrated that the parts of a PRA that are used to support an application comply with the ASME/ANS standard, when supplemented to account for the staff's regulatory positions contained in Appendix A, it is considered that the PRA is considered to be adequate to support that risk-informed regulatory application.

2.2 Industry Review Programs

There are two different reviews that can be performed:

- A PRA standard peer review performed against the PRA standard to determine the technical adequacy of the base PRA model

- An F&O technical review to determine if a finding from the standard peer review has been adequately addressed in the base (or application) PRA model.

2.2.1 PRA Standard Peer Review

A PRA standard peer review of the PRA is performed to determine whether the requirements established in the standard (as endorsed by the NRC in the appendices to this guide) have been met. An acceptable PRA standard peer review approach is one that is performed according to an established process and by qualified personnel and documents the results and identifies both strengths and weaknesses of the PRA.

The **PRA standard peer review process** includes a documented procedure used to direct the team in evaluating the adequacy of a PRA. The review process compares the PRA against established criteria (e.g., technical requirements defined in a PRA standard that conforms to the PRA characteristics and attributes such as those provided in Regulatory Position 1.2). In addition, the peer review evaluate the implementation of the methods used to accomplish the associated SRs. The peer review determines whether the methods were applied correctly for the associated SRs; however, during the peer review, a deficiency may be identified with an accepted method. This deficiency needs to be addressed prior to continued use of the method (see Section 2.3 as a means to propose a new method to address an identified deficiency in a current method). The peer review compares the PRA models against the plant design and procedures to validate that they reflect the as-designed, or the as-built and as operated plant. Assumptions are reviewed to determine if they are appropriate and to assess their impact on the PRA results. The PRA results are checked for fidelity with the model structure and for consistency with the results from PRAs for similar plants based on the peer reviewer's knowledge. Finally, the peer review process examines the procedures or guidelines in place for updating the PRA to reflect changes in plant design, operation, or experience. The process also needs to provide criteria ensuring that the peer review is current. That is, (1) the peer review needs to address the modifications made to the PRA since any previous peer reviews, and (2)

the peer review needs to address modifications made to the standard since any previous peer reviews.

The **team qualifications** determine the credibility and adequacy of the PRA Standard peer reviewers. To avoid any perception of a technical conflict of interest, the PRA Standard peer reviewers will not have performed any actual work on the PRA. Another potential conflict of interest may exist if a peer reviewer (contractor) is assigned an area for review where colleagues or management, from the same organization, performed the actual technical analysis. Although the peer reviewer may not have performed any of the technical analysis, a perception of a conflict could arise from this individual reviewing colleagues or management work. Each member of the PRA Standard peer review team must have technical expertise in the PRA elements assigned for review, including experience in the specific methods that are used to perform the PRA elements. This technical expertise includes experience in performing (not just reviewing) the work in the element assigned for review. Knowledge of the key features specific to the plant design and operation is essential. Finally, each member of the PRA Standard peer review team needs to be knowledgeable about the PRA Standard peer review process, including the desired characteristics and attributes used to assess the adequacy of the PRA including the PRA SRs..

Documentation provides the necessary information to ensure that the PRA Standard peer review process and the findings are traceable and the bases of the findings are defensible. Descriptions of the qualifications of the PRA Standard peer review team members and the PRA Standard peer review process are documented. The results of the PRA Standard peer review for each technical element and their respective SRs of the PRA standard are documented. Documentation includes describing where the base PRA does not meet Capability Category II of the standard, the bases for the findings, and determination if Capability Category I is met.. This documentation includes an assessment of the importance of any identified findings on the PRA results and potential uses. In addition, the licensee needs to document how these findings were addressed and resolved (see Section 2.2.2 for acceptability of the licensee's resolutions).

Table 16 summarizes the characteristics and attributes of a PRA Standard peer review. For new reactor designs that have not yet gone into commercial operation, it is recognized that a peer reviewer will not have knowledge of plant operation, and familiarity with some plant features (e.g., passive mitigation systems) may be limited. This lack of knowledge is not to be construed as a limitation for performing a PRA Standard peer review using personnel who are otherwise qualified and generally familiar with the design and operation of similar plant types (e.g., pressurized-water reactors).

Table 16. Summary of the Characteristics and Attributes of a PRA Standard Peer Review

Element	Characteristics And Attributes
Peer Review Process	• Uses documented process • Uses as a basis for review a set of desired PRA characteristics and attributes • Uses a minimum list of review topics to ensure coverage, consistency, and uniformity • Reviews PRA methods • Reviews application of methods • Reviews assumptions and assesses their validity and appropriateness • Determines if PRA represents as-built and as-operated plant • Reviews results of each PRA technical element for reasonableness • Reviews PRA maintenance and update process

	• Reviews PRA modification attributable to use of different model, techniques, or tools • Reviews against modifications to the standard
Team Qualifications	• Independent with no conflicts of interest directly or organizationally (i.e., am not affiliated with or employed by the organization that owns the plant for which the PRA was performed or the entity that developed the PRA, have not performed any work on the PRA, and colleagues or respective management was not involved in performing, reviewing, or overseeing any of the work) • Collectively represent expertise in all the technical elements of a PRA including integration • Expertise in the technical element assigned to review • Knowledge of the plant design and operation • Knowledge of the peer review process
Documentation	• Describes the peer review team qualifications • Describes the peer review process • Documents where PRA does not meet Capability Category II or I of the PRA standard • Assesses and documents significance of findings • Describes the scope of the peer review performed (i.e., what was reviewed by the peer review team)

The ASME/ANS standard requires a peer review to be performed. The peer review, per ASME/ANS, requires that (1) a peer review process be established, and (2) provides requirements for team qualifications and documentation. A peer review methodology (i.e., process) is provided in the industry-developed peer review programs (i.e., Refs. 15–17), and noted in the ASME/ANS standard as an acceptable process. Appendices A, B, C and D to this regulatory guide the staff regulatory position on the peer review requirements in the ASME/ANS PRA standard and the peer review process in NEI 00-02, 05-04, and 07-12 (Refs. 15–17). When the staff's regulatory positions contained in the appendices are taken into account, use of a peer review can be used to demonstrate that the PRA [with regard to an at-power Level 1/LERF PRA for internal events (excluding external hazards)] is adequate to support a risk-informed application.

The implementation of this staff position is intended to provide the needed confidence in the results of the PRA standards peer review such that when used in support of an application, it will obviate the need for an in-depth depth review of the licensee's PRA model by NRC reviewers, allowing them to focus their review on the use of the PRA in the context of the application, the key assumptions, and the areas identified by peer reviewers as being of concern and relevant to the application. Consequently, this staff position will provide for a more focused and efficient review process.

As stated earlier, the peer review is to be performed against established standards (e.g., the ASME/ANS PRA standard). If different criteria are used than those in the established standard, then it needs to be demonstrated that these different criteria are consistent with the established standards, as endorsed by the NRC.

2.2.2 F&O Technical Review

An F&O technical review of the PRA is performed to determine whether the F&Os identified by the PRA standard peer review have been adequately resolved. That is, the F&O technical review determines whether the resolution of the F&Os have adequately resolved the identified

deficiency such that the impacted PRA standard supporting requirements (SRs) have now been met. An acceptable F&O technical review approach is one that is performed according to an established process and by qualified personnel and documents the results. Moreover, in performing an F&O technical review, the scope of the technical review needs to be identified.

The **F&O technical review process** includes a documented procedure used to direct the team in evaluating the adequacy the F&O resolution. The review process ensures that the F&O resolution is applicable to the F&O, and is defensible and complete. In addition, the F&O resolutions are compared against the plant design and procedures to validate that they reflect the as-designed, or the as-built and as operated plant. That is, the review determines that any proposed plant changes (i.e., design, operational or programmatic) in resolving the F&Os have been implemented. If the proposed changes have not been implemented, then the F&O has not been adequately resolved. Assumptions made as part of the F&O resolution are reviewed to determine if they are appropriate and to assess their impact on the affected SRs. F&Os characterized as documentation shortcomings are examined to ensure that adequate technical substance existed for the PRA standard peer review to have developed F&Os, or make the determination that the impacted SRs are not met because of lack of documentation. Methods applied during the F&O resolution are consistent with accepted methods, or these F&Os cannot be considered resolved until a new technical evaluation has been performed (see Section 2.3) The PRA results, as a result of the F&O resolution, are checked for fidelity with the model structure.

The **F&O technical review scope** identifies whether the F&O resolutions are being reviewed to support a specific application or the base PRA (i.e., independent of applications). If the scope is limited to a specific application, then the F&O is not fully resolved. If the F&O technical review finds the resolution acceptable, it is only acceptable for that application and the F&O is still open for other applications.

The **team qualifications** determine the credibility and adequacy of the F&O technical reviewers. To avoid any perception of a technical conflict of interest, the F&O technical reviewers will not have performed any actual work on the PRA. . Another potential conflict of interest may exist if a reviewer (contractor) is assigned an area for review where colleagues or management, from the same organization, performed the actual technical analysis. Although the reviewer may not have performed any of the technical analysis, a perception of a conflict could arise from this individual reviewing colleagues or management work.Each member of the F&O technical review team must have technical expertise in the general PRA technical element in which the F&O belongs and in the SR which the F&O is written against, and experience in the specific methods that are used in addressing the F&Os. This technical expertise includes experience in performing (not just reviewing) the work in the element assigned for review. Knowledge of the key features specific to the plant design and operation is essential. Finally, each member of the peer review team needs to be knowledgeable about the F&O technical review process, including the desired characteristics and attributes used to assess the adequacy of the F&O resolution.

Documentation provides the necessary information to ensure that the F&O technical review process ensures that the F&O resolutions are applicable, defensible, and complete. Descriptions of the qualifications of the F&O technical review team members and the F&O technical review process are documented. The results of the F&O technical review for F&O are described, including the areas in which the PRA does not meet or exceed the desired characteristics and attributes used in the review process. This documentation includes an assessment of how the F&Os were addressed (e.g., what changes were made to either the

plant or PRA model), why the resolutions were acceptable (e.g., why the impacted SRs are now met), whether the F&O resolutions were limited to a specific application (including identification of the specific application(s)) or to the entire base PRA, and the importance of any remaining deficiencies of the F&Os. Deviations from accepted methods either identified in the resolutions or incorporated in the PRA as a result are identified as an unresolved F&O.

Table 17 summarizes the characteristics and attributes of an F&O technical review. For new reactor designs that have not yet gone into commercial operation, it is recognized that an F&O technical reviewer will not have knowledge of plant operation, and familiarity with some plant features (e.g., passive mitigation systems) may be limited. This lack of knowledge is not to be construed as a limitation for performing an F&O technical review using personnel who are otherwise qualified and generally familiar with the design and operation of similar plant types (e.g., pressurized-water reactors).

Table 17. Summary of the Characteristics and Attributes of an F&O technical review

Elements	Characteristics and Attributes
Technical Review Process	• Uses documented process • Uses as a basis for review a set of desired PRA characteristics and attributes • Uses a minimum list of review topics to ensure coverage, consistency and uniformity • Reviews resolution for applicability, defensibility, and completeness • If methods applied to resolve the F&O are deviations from accepted methods, the F&O is not closed until a new technical evaluation is done (See Section 2.3) • Ensures that PRA is updated for F&O resolution • Assesses F&Os characterized as documentation to determine if adequate information was available for peer review development of F&Os to pertinent SRs • Reviews any assumptions in the resolution and assesses their validity and appropriateness • Determines if PRA represents as-built and as-operated plant after resolution
Team Qualifications	• Independent with no conflicts of interest directly or organizationally (i.e., am not affiliated with or employed by the organization that owns the plant for which the PRA was performed or the entity that developed the PRA, have not performed any work on the PRA, and colleagues or respective management was not involved in performing, reviewing, or overseeing any of the work) • Collectively represent expertise in all the technical elements of a PRA including integration • Expertise in the technical element to which the SR belongs, and the SR • Knowledge of pertinent methods with respect to F&O • Knowledge of the plant design and operation as applied to the F&O • Knowledge of the technical review F&O process
Documentation	• Describes the technical review F&O team qualifications • Describes the scope of the technical review F&O performed (i.e., what was reviewed by the technical review team) • Describes the technical review F&O process • Documents applicability, defensibility, and completeness • Documents if acceptability is based on PRA in general, or application • Documents if resolution is inadequate, including reason and significance • Documents use of deviations from acceptable methods in resolution •

Technical review scope	• Identifies whether applicable to the base PRA application or limited to specific application • Identifies the specific application(s) • Documents resolution is applicable to base PRA or specific applications
Submittal Documentation	• Describes the technical review F&O process • Describes the scope of the technical review F&O performed (i.e., what was reviewed by the technical review team) • Summarizes the F&Os evaluated and the determination of acceptability of their resolutions • Identifies remaining F&Os that are determined to remain open, deviations from accepted methods, and any new F&Os

The ASME/ANS standard requires a PRA Standard peer review to be performed. The Standard, however, does not require the PRA owner to resolve the F&Os resulting from the the PRA standard peer review. An F&O technical review methodology (i.e., process) is provided in the industry-developed peer review programs (i.e., Appendix "x" to NEI-05-04). This guidance needs to be comparable to the peer review guidance provided in the standard for a PRA standard peer review. The staff regulatory position is provided on the peer review requirements in the ASME/ANS PRA standard and the F&O technical review process in Appendix "x" to NEI 05-04. When the staff's regulatory positions on the NEI guidance (i.e., staff endorsement) are taken into account, use of an F&O technical review can be used to demonstrate that the F&Os have been adequately addressed to support a risk-informed application.

The implementation of this staff position is intended to provide added confidence in the resolution of the F&Os from the PRA standards peer review such that when used in support of an application, the review will require fewer RAIs and less resources expended by the staff and licensee, Thus, the staff will be able to focus their review on the use of the PRA in the context of the application, the key assumptions, and the areas identified by the PRA standard peer reviewers as being of concern that are relevant to the application. Consequently, this staff position will provide for a more focused and efficient review process.

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

2.3 Acceptability of New PRA Methods

Developing a PRA model uses various methods to construct the various parts of the model. In the ASME/ANS PRA standard, either (1) requirements are provided for acceptable methods, or (2) requirements actually specify the acceptable methods. For example, the standard may require the analyst to perform quantification using computer codes that have been demonstrated to generate appropriate results when compared to those from accepted algorithms and identify method-specific limitations and features that could impact the results. In the latter case, the standard, for example, may specify that accepted methods for common cause analysis are the Alpha Factor model, Basic Parameter model, Multiple Greek Letter model, or the Binomial Failure Rate model. Moreover, in the former case, there are current state-of-practice methods that meet the standard requirements which have been accepted or endorsed by the NRC. In both cases, the PRA standard peer review evaluates whether the current state-of-practice methods or the specified methods are correctly implemented. There

may be, however, methods, that are not considered state-of-practice or specified in the standard and each have not received NRC acceptance or endorsement.

A method is considered a new method when:

> *the NRC has not clearly accepted the identified method's use in the base PRA or for the specific risk-informed application for which it is proposed. If the NRC has accepted for the specific risk-informed application, there is an available published basis summarizing NRC's acceptance.*

Determining the acceptability of a new method can be a lengthy and resource intensive process; however, a more efficient process can be accomplished using an "expert review process," that is, using a "vetting panel" approach. A Vetting Panel approach would be performed to determine whether the proposed new method is acceptable; that is, the new method has a sufficient technical basis for acceptance. An acceptable Vetting Panel approach is one that is performed according to an established process and by qualified personnel, documents the results, and submits for staff acceptance. However, at the last stage of the method approval panel process, NRC may not accept the new method, e.g. due to deficiencies, which may require further work to address NRC comments.

The **Vetting Panel process** includes a documented procedure used to direct the team in evaluating the acceptability of the new method. This process involves the following elements:

- Selection of the panel members including acceptance guidelines
- Identification of whether the new method is associated with a specific application or for the base PRA
- Determination of the level of review needed for the new method including decision guidelines
- Determination if the Vetting Panel members are qualified to perform the review or appoint a technical review team including decision guidelines
- Determine acceptability of the new method including acceptance guidelines
- Determination of whether the new method can be used prior to formal staff acceptance including decision guidelines
- Documentation of the results of the review
- The Vetting Panel or technical review meetings by other experts are public meetings open to all stakeholders
- Evaluation of potential deficiency identified for previously accepted method
- Submittal of new method for staff review and acceptance

The **decision or acceptance guidelines** provide the basis for decisions made by the Vetting Panel or the additional technical experts. Decision or acceptance guidelines need to be established for:

- Accepting method for review
- The level of review needed
- The acceptability of a new method, including limitations and conditions
- Use of the new method prior to formal NRC acceptance
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The **team qualifications** of the Vetting Panel members and any additional technical reviewers determine the credibility and adequacy of the vetting panel process. To avoid any perception of a technical conflict of interest, the Vetting Panel members or additional technical reviewers will not have performed any actual work on developing the new method. Furthermore, the technical reviewer should not represent a licensee who has submitted a risk informed license amendment which includes this new method. The members of the Vetting Panel need to have knowledge and experience in developing PRA models. The Panel collectively must have knowledge of the technical elements of a full-scope Level 1 and Level 2 PRA addressing all hazards and all operating modes. To ensure consistency, there should be a "core group" of members that do not change for each new method evaluated. In addition, the Panel should be comprised of equal number of NRC and industry experts. If the Panel has elected to review the new method for acceptability, each member of the Vetting Panel must have technical expertise in the technical area of the new method and the associated SRs in the PRA standard where the new method is being proposed to be used. This technical expertise includes experience in the work in the element assigned for review which also needs to include knowledge of similar methods.

Documentation provides the necessary information to ensure that the Vetting Panel process and the findings are traceable and the bases of the findings are defensible. Descriptions of the qualifications of the Vetting Panel members, any additional technical review experts, and the review process (including the decision and acceptance guidelines) are documented. The results of the technical review are described including the bases for the review results and which SRs in the PRA standard are impacted by the new method. This documentation also includes whether the technical review was limited to a specific application (including identification of the specific application(s)) or to the entire base PRA. Any deficiencies resulting in rejecting the method are identified, and documented including their importance. For accepted methods, limitations and conditions are also documented. That is, if it is determined that the method is acceptable for use, the basis for acceptability is documented including any necessary limitations or conditions for its use. Moreover, if deficiencies with the new method are identified after the method has been accepted through the vetting panel process, the newly identified deficiency and its importance to the method are documented and the Vetting Panel notified so that the method can be re-evaluated in light of the deficiency and any proposed supporting solution.

The **submittal guidance** describes what is to be included in the submittal and identifies what method is being submitted for acceptance and the basis for acceptance. Moreover, any dissenting views by either Vetting Panel members, technical experts or public comments are identified and resolution described. The schedule of staff review and acceptance is also provided.

Table 18 summarizes the characteristics and attributes of an acceptable Vetting Panel approach for determining the acceptability of new methods to be used in a PRA

Table 18. Summary of the Characteristics and Attributes of a Vetting Panel Approach for New PRA Methods

Element	Characteristics and Attributes
Vetting Panel Process	• Uses documented process • Uses as a basis for review a set of desired technical characteristics and attributes • Uses a minimum list of review topics to ensure coverage, consistency and uniformity • Reviews the submitted methods • Reviews application of methods • Reviews assumptions and assesses their validity and appropriateness • Determines if PRA method represents as-built and as-operated plant • Reviews results of PRA technical element representing method for reasonableness • Uses facilitator for Vetting Panel process • Vetting Panel or expert review team meetings are noticed and open to the public and the public's input solicited.
Team Qualifications	• Equal number and participation of NRC and industry members • Identification of core group of NRC and industry members • Independent with no conflicts of interest (i.e., have not performed any work in developing the new method or submitted to NRC in risk informed application) • Collectively represent expertise in all the technical elements of a PRA impacted by the new method • Expertise in the technical aspect of the new method assigned to review • Knowledge of the technical evaluation process • Knowledge of associated SRs in the PRA standard
Vetting Panel Decision guidelines on accepting method for review	• Determine if adequate information is available for review • Determine if the proposed method is needed (justify invoking the panel) — Consider existing methods/approaches and need for new method — Consider the resources and time needed for the review — Consider the significance of the issues of the current methods relative to the new proposed method — Determine if adequate information on the new method is available to perform a review
Vetting Panel Decision guidelines on the level of review needed	• Identify the scope of review (e.g., technical areas) • Panel members have the necessary qualifications to perform the review • Extent of any previous application • Extent of previous technical reviews • Identify review team; e.g., — Vetting Panel — Separate expert panel — Augmented Vetting Panel with additional expert advise/support • Determine the level of review needed; e.g., — Analytical review — Phenomenological review — Perform test cases
Acceptance guidelines on the acceptability of a new method	• Separate achieved consensus by both NRC members and industry members • Method has been "benchmarked" and piloted including results • Method has been applied in similar applications including results • Level of "quality assurance," that is, previous technical reviews and qualifications of the various reviewers; e.g., — Internal self-assessment — Internal technical review

	— External expert review • Identification and treatment of uncertainties or sensitivities including results • Incorporation of latest "scientific knowledge" • Technical bases, justification or merits on method acceptability provided by the method developer • to enable use of the method • Identification of method limitations and conditions of use, and relative importance of these limitations/conditions
Vetting Panel acceptance guidelines on the use of a new method prior to staff acceptance	• Identification of acceptance conditions for use in specific applications and their bases, which may include — Potential limitations have been demonstrated to have negligible impact on the results for the application (including the bases and justification), — Use of conservative or bounding parameters or assumptions appropriate for the application — Additional sensitivity studies required and must be addressed
Documentation	• Describes the technical team qualifications • Describes the evaluation process • Describes the scope of the technical evaluation performed (i.e., what was reviewed by the team) • Describes the technical bases for acceptance or rejection • Deficiencies resulting in rejection are identified • Conditions of use and limitations described • Documents the Vetting Panel and review team decisions; e.g., — Acceptance for review — Determination of expertise needed — Determination of acceptability for use (generally or for specific application(s)) with specific conditions or limitations in use — Determination of deficiencies resulting in rejection of method — Determination for interim use — Dissenting views presented
Submittal Guidance for Formal NRC acceptance	• Description of process used • Description of actual method reviewed • Description of limitation or conditions of method for use, including any additional limitations/conditions for interim useIdentification of specific application for use • Identification of dissenting views, including potential impact of views • Description of public input and resolution • Submit to NRC RES/DRA for staff review coordination and staff acceptance

When the staff's regulatory positions on the NEI guidance (i.e., staff endorsement) are taken into account, use of a vetting panel process can be used to demonstrate that the method is adequate to support a risk-informed application. However, per the NRC-endorsed PRA Standard, when a new method is used in the base PRA it would constitute a PRA "upgrade," which would require a focused-scope peer review to ensure that the new method is properly implemented.

The implementation of this staff position is intended to provide added confidence in the new method such that when used in support of an application, the review will require fewer RAIs and less resources expended by the staff and licensee. Thus, the staff will be able to focus their review on the use of the PRA in the context of the application, the key assumptions, and the areas identified by the vetting panel and PRA standard peer reviewers as being of concern and

relevant to the application. Consequently, this staff position will provide for a more focused and efficient review process.

As stated earlier, the technical review is to be performed against established process as endorsed by the NRC. If a different process is used than the endorsed process, then it needs to be demonstrated that this different process is consistent with the process, as endorsed by the NRC.

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4. Documentation to Support a Regulatory Submittal

The licensee develops documentation of the PRA model and the analyses performed to support the risk-informed regulatory activity. This documentation comprises both archival (i.e., available for audit) and submittal (i.e., submitted as part of the risk-informed request) documentation. The former may be required on an as needed basis to facilitate the NRC staff's review of the risk-informed submittal.

4.1 Archival Documentation

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4.2 Licensee Submittal Documentation

To demonstrate that the technical adequacy of the PRA used in an application is technically adequate, the staff expects the following information will be submitted to the NRC:.

- To address the need for the PRA model to represent the as-designed or as-built, as-operated plant,

- Identification of permanent plant changes (such as design or operational practices) that have an impact on those things modeled in the PRA but have not been incorporated in the baseline PRA model. If a plant change has not been incorporated, the licensee provides a justification of why the change does not impact the PRA results used to support the application. This justification should be in the form of a sensitivity study that demonstrates the accident sequences or contributors significant to the application decision were not adversely impacted (remained the same).

- Documentation that the parts of the PRA required to produce the results used in the decision are performed consistently with the standard as endorsed in the appendices of this regulatory guide. If a requirement of the standard (as endorsed in the appendix to this guide) has not been met, the licensee is to provide a justification of why it is acceptable that the requirement has not been met. This justification should be in the form of a sensitivity study that demonstrates the accident sequences or contributors significant to the application were not impacted (remained the same).

- A summary of the risk assessment methodology used to assess the risk of the application, including how the base PRA model was modified to appropriately model the risk impact of the application and results. (Note that this is the same as that required in the application-specific regulatory guides.)

- Identification of the key assumptions and approximations relevant to the results used in the decision-making process. Also, include the peer reviewers' assessment of those assumptions. These assessments provide information to the NRC staff in their determination of whether the use of these assumptions and approximations is appropriate for the application, or whether sensitivity studies performed to support the decision are appropriate.

- A discussion of the resolution of the peer review ~~(or self-assessment, for peer reviews performed using the criteria in NEI 00-02)~~ findings and observations that are applicable to the parts of the PRA required for the application. This decision should, in addition, provide the following information:

  – a discussion of how the PRA model has been changed
  – a justification in the form of a sensitivity study that demonstrates the accident sequences or contributors significant to the application decision were not adversely impacted (remained the same) by the particular issue

- A discussion of new methods should be provided with the following additional information:
    - Identification of method replaced
    - Discussion of new method applied
    - Reference for acceptability of new method
    - Applicability of new method, identifying why limitations don't impact application and why conditions are appropriate

- The standards or peer review process documents may recognize different capability categories or grades that are related to level of detail, degree of plant specificity, and degree of realism. The licensee's documentation is to identify the use of the parts of the PRA that conform to capability categories or grades lower than deemed required for the given application (Section 1-3 of ASME/ANS RA-Sa-2009).

Previously submitted documentation may be referenced if it is adequate for the subject submittal: