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New PRA Method Evaluation Process Guidelines

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Nuclear Energy Institute

**New PRA Method
Acceptance Process
Guidelines**

February 2016

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EXECUTIVE SUMMARY

This guidance describes a process that will streamline the process of acceptance of new PRA methods for use in licensing applications. Specifically, this document describes a methods Vetting Panel and provides guidance for conduct of the panel's functions. This Vetting Panel, which consists of an equal number of industry and NRC members, identifies the process to be used to evaluate a new method for use in licensing applications. This process additionally allows for limited use of the method while undergoing the acceptance process.

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ACRONYMS

ANS	American Nuclear Society
ASME	American Society of Mechanical Engineers
CC	Capability Category
EPRI	Electric Power Research Institute
ISG	Interim Staff Guidance
MOU	Memoranda of Understanding
NEI	Nuclear Energy Institute
NPP	Nuclear Power Plant
NRC	Nuclear Regulatory Commission
PRA	Probabilistic Risk Analysis
RG	Regulatory Guide
RISC	Risk-Informed Steering Committee
SDO	Standards Developing Organization

NEW PRA METHODS ACCEPTANCE PROCESS GUIDELINES

1 INTRODUCTION

1.1 OVERVIEW AND PURPOSE

The purpose of this guidance is to provide an efficient process for acceptance of new PRA methods for use in licensing applications, 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.¹

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 standing 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

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 response and closure.

1.2 BACKGROUND

Although the NRC's regulatory position on PRA technical adequacy for licensing applications is documented in Regulatory Guide (RG) 1.200, the RG only addresses the "what" in the PRA, not the "how," or the specifics of methodologies and their use. Therefore, a process for the use of new methods in risk-informed regulatory applications was developed to address this gap.

1.3 PROCESS OVERVIEW

The Vetting Panel will be given the ability to review new methods and determine the process that will be used to determine acceptability of the method for use in licensing applications.

1.4 DOCUMENT ORGANIZATION

Chapter 1 of this document describes the basic overview, purpose and process. In Chapter 2, the document will discuss the definitions and explain the different sets of processes and methods that are undergone. Finally, Chapter 3 will discuss the vetting panel process and associated review processes.

¹ Such existing means include a Frequently Asked Question (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.

2 DEFINITION OF TERMS

2.1 DEFINITION OF A 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*.

2.2 DEFINITIONS OF SOURCE

The 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 has a stake in the method in the context of regulatory applications. 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)

2.3 DEFINITION OF PEDIGREE

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-U.S.) 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)

2.4 DEFINITION OF MATURITY

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

2.5 DEFINITION OF COMPLEXITY

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.

2.6 DEFINITION OF PROCESS OPTIONS (FOR ACCEPTANCE OF ANY GIVEN METHOD FOR USE IN REGULATORY APPLICATIONS)

Process options refer to possible ways in which new methods could be evaluated 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.

2.7 TYPES OF PROCESS OPTIONS

Several different process options exist for the level of the evaluation that should be undertaken. The Vetting Panel may decide which of the following process options best fits a specific model. The following options may be utilized:

1. Usage of the method is acceptable immediately upon issuance of the interim use method. C 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. Calls for 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 Vetting 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 need 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 review of the method and disposition of review comments. This 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 review would also evaluate 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 need 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 methods 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 methods 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.

2.8 DEFINITION OF NEW METHOD GROUPS

Table 2-1 defines 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. For more information on the different process options, refer to section 2.7.

**Table 2-1
New Method Groups**

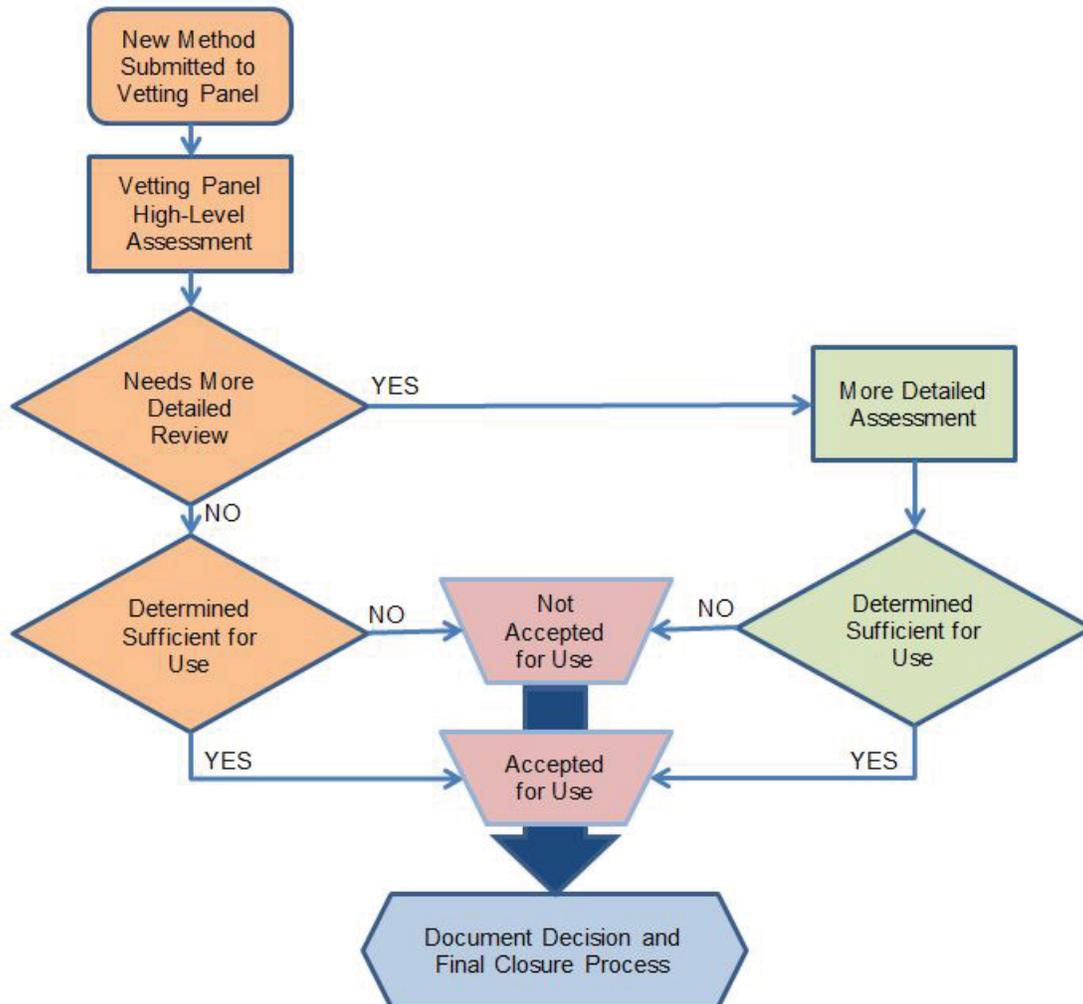
Group	Description	Anticipated Process Options
A	NRC or NRC-Collaboration: Refers to new methods developed as a result of research performed by NRC or with substantial NRC involvement in collaboration with others (e.g., EPRI, NEI). It is anticipated that these results would enter into the process at the 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 calls for 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 calls for a determination that the work was “unbiased” by regulatory or industry interests.	4a, 5a
E	Peer Reviewed and Published Collaborative Industry Research for Nuclear Application: Refers to methods that are developed in an inclusive way by the industry, involving a broad range of technical contributors and reviewers. Most EPRI and Owners Group research programs would fall into this category.	4, 6
F	Non-Collaborative Industry Research for Nuclear Application: Refers to methods that are developed by a single utility, consultant, vendor, etc., and therefore not involving a broad range of technical contributors and reviewers.	6

3 REVIEW OF NEW METHODS

3.1 OVERVIEW OF THE VETTING PANEL

Figure Error! Reference source not found.-1 visually depicts the overall process for achieving acceptance of new methods. The key to this process is the standing Industry/NRC Vetting Panel. The Vetting Panel consists 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 Vetting Panel will consist of an equal number of members, all of whom meet the NRC-endorsed NEI peer review guidance document expectations 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 the Vetting Panel also may be called upon to perform a technical assessment of a given method.

Figure Error! Reference source not found.-1
Process for Acceptance of New Methods for Use in Regulatory Applications



3.2 OVERVIEW OF REVIEW PROCESS

After a new method is submitted to the Vetting Panel, the Vetting Panel will make a high-level assessment decision determining the validity of the new method and the process option and respective category the method should fall into. After that decision is made, based on the process option and respective category of that process option, it is determined if a more detailed analysis is called for. If a more detailed analysis is called for, the vetting panel may choose to either undertake it themselves or direct a technical review team (e.g. methods peer review team or methods panel) to undergo the review. After the technical review team determines the results, the final decision is made by the Vetting Panel. Additionally, based on the respective category the new method is determined to be in, it could be utilized prior to final acceptance of the method.

3.3 VETTING PANEL DECISION-MAKING CONSIDERATIONS

The Vetting 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 chapter 2) and determined from the information of 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. This necessitates that the Vetting Panel weighs each attribute, in concert with their technical knowledge and judgement, and select the appropriate path.

The Vetting 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 Vetting 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.

3.4 REVIEW PROCESS OF A GIVEN METHOD BY A TECHNICAL REVIEW TEAM

The Vetting Panel is may form a technical review team when necessary to implement a certain process option. When implementing this departure from a typical process option is deemed necessary, for reason such as resource limitations, conflicting priorities, etc., this should be based on a conscious decision.

3.5 SIZE OF REVIEW TEAM

A number of the available processes presented in section 2.7 involve some type of review. Regardless of the group a method falls into or the extent of the review called for, 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 Vetting Panel has sufficient expertise, or by an augmented review team, if necessary, including 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.

3.6 TIMEFRAME FOR COMPLETION OF REVIEW AND ISSUANCE OF THE TEAM CONSENSUS

The timeframe for completion of a review and issuance of the team consensus would also be expected to be a function of the complexity of the method. Keeping with the same complexity concept discussed in other portions of this guidance, 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.

3.7 RECONSIDERATION OF METHODS

It is possible that following acceptance 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..

3.8 OPEN MEETINGS AND DOCUMENTATION

The Vetting Panel and the process for accepting new methods for use in licensing applications will take place during public interactions, and there will be formal closure. Specifically:

- 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 vetting 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 members AND a majority of Industry members are in agreement. Documentation of the Vetting Panel's decision will be sent from NEI to NRC within one week of the vetting 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 calls for the Vetting Panel assessment or a methods review, a formal report of the vetting panel assessment or focused-scope review team will be developed, and will include dissenting opinions. Consensus will consist of a majority of both the NRC-appointed members and the industry-appointed members. The Vetting Panel and focused-scope review meetings will be public meetings.
- Where the decision of the Vetting Panel is to follow a process that calls for 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 methods 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.

3.9 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.

4 REFERENCES

1. ASME/ANS RA-S-2008, “Standard for level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Applications,” April, 2008.