PUBLIC SUBMISSION

SUNI Review Complete
Template=ADM-013
E-RIDS=ADM-03
ADD: Harriet Karagiannis, Stanley Gardocki

Comment (3)
Publication Date: 7/1/2020
CITATION 85 FR 39599

As of: 7/30/20 4:53 AM
Received: July 29, 2020
Status: Pending_Post
Tracking No. 1k4-9i38-gr65
Comments Due: July 31, 2020
Submission Type: Web

Docket: NRC-2012-0110
Issuance and Availability; request for comment (DG-1285, DG-1286, DG-1287, DG-1288)

Comment On: NRC-2012-0110-0022
Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities

Document: NRC-2012-0110-DRAFT-0020
Comment on FR Doc # 2020-14197

Submitter Information

Name: Chad Holderbaum.

General Comment

See attached.

Attachments

OG-20-197

PWROG Comments - RG 1.200 R3 - July 2020

PWROG-19027-NP_Revision_2

Program Management Office
1000 Westinghouse Drive, Suite 172
Cranberry Township, Pennsylvania 16066

Project 694
Docket 99902037

July 28, 2020

OG-20-197

Office of Administration
Mail Stop: TWFN-07-A06
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Program Management, Announcements and Editing Staff

Subject: PWR Owners Group, Risk Management Committee
PWROG Comments on Draft Regulatory Guide 1.200 Revision 3, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities"

The PWR Owners Group has developed on behalf of its members the attached comments on Draft Regulatory Guide 1.200 Revision 3, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities". This letter serves to transmit the PWR Owners Group comments to the NRC. The PWROG appreciates the opportunity to comment on the draft regulatory guidance.

Both enclosures contain suggestions for the staff's consideration. Enclosure 2 has been prepared in collaboration with NRC staff members over the past year and contains the consolidated and final suggestions from the PWROG.

Enclosures to this letter are:
- PWROG Comments on the DRAFT Regulatory Guide 1.200 Revision 3 (Non-Proprietary)
- PWROG-19027-NP Revision 2 (Non-Proprietary)

If you have any questions, please do not hesitate to contact me at (602) 999-2080 or Mr. W. Anthony Nowinowski, Executive Director of the PWR Owners Group, Program Management Office at (412) 374-6855.

Sincerely yours,

Michael Powell
Chairman and COO
PWR Owners Group

Electronically Approved Records are Authenticated in the Electronic Document Management System

DSM:am

Enclosure 1: PWROG Comments – RG 1.200 R3 – July 2020 (Non-Proprietary)
Enclosure 2: PWROG-19027-NP Revision 2

cc: PWROG PMO
PWROG Risk Management Committee
PWROG Licensing Committee
R. Linthicum, PWROG
M. Powell, PWROG
D. Mirizio, PWROG
C. Holderbaum, PWROG
W. Nowinowski, PWROG
L. Fields, US NRC

PWROG Comments on RG 1.200 R3 FRN Questions

Question 1: Prolonged retention of peer review exceptions and deficiencies, which are more commonly referred to as Facts and Observations (F&Os), has the potential to reduce confidence in the implementation of risk-informed programs and increase licensing and potential inspection review resources*. As part of a licensee's base PRA model configuration control process, should licensees periodically close all F&Os using one of the two relevant processes (i.e., a focused-scope peer review or an independent assessment team closure review) in NEI 17-07, Revision 2?*

For clarification, in the peer review process, not all F&Os represent exceptions and deficiencies. There are four types of F&Os: Findings, Suggestions, Best Practices and Unreviewed Analysis Methods (UAM). Of these, only Findings represent exceptions and deficiencies in the PRA model. Unreviewed analysis methods are related to areas where the peer review team either did not have the expertise or enough time to review those technical aspects of the model. As such, only Findings and UAMs have the potential to impact the technical adequacy of the PRA model.

<u>UAM F&Os:</u>
UAM F&Os that are identified as part of a model that is used to support a PRA application should be addressed through an appropriate focused scope peer review (as identified in NEI 17-07), prior to using the model for a PRA application. Any finding F&Os identified during the peer review of the UAM should be addressed as noted below for findings.

<u>Finding F&Os:</u>
As part of a risk informed License Amendment Request, any findings that are open at the time of the application are required to be assessed for their impact on the application. This includes justification that the PRA model remains technical adequate with the open finding. This justification is reviewed by the NRC as part of the License Amendment Request (LAR) review process and any issues regarding PRA technical adequacy are addressed in the safety evaluation, which may include limitations or conditions on the use of the model with the open F&O(s).

Findings from new peer reviews that are performed following a PRA upgrade after a model has been determined to be technical adequate for a regulatory application should be evaluated prior to using the model for that application. If a finding is not closed, a documented justification should be prepared for using the model for regulatory applications with the open finding. In some cases, the finding may be fully addressed, and changes incorporated into the model (including an internal review consistent with the licensees PRA maintenance program prior to implementation) without going through the formal finding closure process. Formal closure of findings is a benefit to the licensee as it eliminates the need to continue to address/evaluate the open finding for future model updates/upgrades and risk informed applications ,But this should be a licensee decision (as opposed to being a regulatory requirement) after considering the costs of the closure process against the benefits of the change based on both a risk and cost perspective. The following examples are cases where a licensee may consider leaving a finding open:

- Peer reviews are typically done against Capability Category (CC) II. For some applications, CC-1 is sufficient and the cost of upgrading the model to CC-II does not provide any significant risk insights
- There are cases where the NRC staff has not accepted the use of a model for low leakage RCP seals for specific applications, as the model was not specifically reviewed by the staff. This can lead to long standing open findings with no clear path to resolution if the licensee has a finding related to not including the model as it without credit, the model does not represent the as-

built, as-operated plant, even though it can be shown that the risk impact of the credit is minimal.

- As additional models are developed (notably for external hazards), the state of the practice may lead to varying expert opinions on the appropriate assumptions, boundary conditions or methods to be used. Determining which opinion is the "best" can be difficult or impossible. In most cases, these differences may be insignificant to the results and/or risk insights and can be dealt with through appropriate sensitively studies.

As RG 1.200 provides guidance for all formal risk informed LARs, regardless of the importance of the PRA model to the application, the impact and needed for finding closures is highly dependent on the specific application that a licensee has implemented. Therefore, any regulatory expectations associated with finding closure should not be a part of RG 1.200 but should be considered in application specific guidance.

What should be the periodicity for completion of these closure processes?

As noted above, it is our position that closure of findings should not be required, therefore, there should not be any periodicity required. The important element is to ensure that the impact of open findings on the model and applications is evaluated and documented prior to using the model for a regulatory related application.

PRESSURIZED WATER REACTOR OWNERS GROUP

PWROG-19027-NP
Revision 2

WESTINGHOUSE NON-PROPRIETARY CLASS 3

Newly Developed Method Requirements and Peer Review

Risk Management Committee

PA-RMSC-1647

July 2020

Westinghouse

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

PWROG-19027-NP
Revision 2

Newly Developed Method Requirements and Peer Review

PA-RMSC-1647

Author
Andrea Maioli*
Risk Analysis

Reviewer
N. Reed LaBarge*
Risk and Operations Engineering

July 2020

Approved: Daniel Sadlon*, Manager
Risk and Operations Engineering

Approved: Damian Mirizio*, Program Director
PWR Owners Group PMO

*Electronically approved records are authenticated in the electronic document management system.

Westinghouse Electric Company LLC
1000 Westinghouse Drive
Cranberry Township, PA 16066, USA

© 2020 Westinghouse Electric Company LLC
All Rights Reserved

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

ACKNOWLEDGEMENTS

This report was developed and funded by the PWR Owners Group under the leadership of the participating utility representatives of the Risk Management Committee. The authors would like to thank the following people for the instrumental support provided during a series of dedicated workshops

Roy Linthicum (PWROG Risk Management Committee Chair)

Gary Demoss (BWROG)

Anders Gilbertson (NRC)

Sunil Weerakkody (NRC)

Mehdi Reisi Fard (NRC)

Michael Levine (NRC)

Shilp Vasavada (NRC)

Stephen Dinsmore (NRC)

Victoria Anderson (NEI)

Rick Grantom (ASME/ANS JCNRM)

In memoriam Mary Drouin (NRC)

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

LEGAL NOTICE

This report was prepared as an account of work performed by Westinghouse Electric Company LLC. Neither Westinghouse Electric Company LLC, nor any person acting on its behalf:

1. Makes any warranty or representation, express or implied including the warranties of fitness for a particular purpose or merchantability, with respect to the accuracy, completeness, or usefulness of the information contained in this report, or that the use of any information, apparatus, method, or process disclosed in this report may not infringe privately owned rights; or

2. Assumes any liabilities with respect to the use of, or for damages resulting from the use of, any information, apparatus, method, or process disclosed in this report.

COPYRIGHT NOTICE

This report has been prepared by Westinghouse Electric Company LLC and bears a Westinghouse Electric Company copyright notice. As a member of the PWR Owners Group, you are permitted to copy and redistribute all or portions of the report within your organization; however all copies made by you must include the copyright notice in all instances.

DISTRIBUTION NOTICE

This report was prepared for the PWR Owners Group. This Distribution Notice is intended to establish guidance for access to this information. This report (including proprietary and non-proprietary versions) is not to be provided to any individual or organization outside of the PWR Owners Group program participants without prior written approval of the PWR Owners Group Program Management Office. However, prior written approval is not required for program participants to provide copies of Class 3 Non-Proprietary reports to third parties that are supporting implementation at their plant, and for submittals to the NRC.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

PWR Owners Group
United States Member Participation* for PA-RMSC-1647
Newly Developed Methods Requirements and Peer Review

Utility Member	Plant Site(s)	Participant	
		Yes	No
Ameren Missouri	Callaway (W)	X	
American Electric Power	D.C. Cook 1 & 2 (W)	X	
Arizona Public Service	Palo Verde Unit 1, 2, & 3 (CE)	X	
Dominion Energy	Millstone 2 (CE)	X	
	Millstone 3 (W)	X	
	North Anna 1 & 2 (W)	X	
	Surry 1 & 2 (W)	X	
	V.C. Summer (W)	X	
Duke Energy Carolinas	Catawba 1 & 2 (W)	X	
	McGuire 1 & 2 (W)	X	
	Oconee 1, 2, & 3 (B&W)	X	
Duke Energy Progress	Robinson 2 (W)	X	
	Shearon Harris (W)	X	
Entergy Palisades	Palisades (CE)	X	
Entergy Nuclear Northeast	Indian Point 2 & 3 (W)	X	
Entergy Operations South	Arkansas 1 (B&W)	X	
	Arkansas 2 (CE)	X	
	Waterford 3 (CE)	X	
Exelon Generation Co. LLC	Braidwood 1 & 2 (W)	X	
	Byron 1 & 2 (W)	X	
	Calvert Cliffs 1 & 2 (CE)	X	
	Ginna (W)	X	
FirstEnergy Nuclear Operating Co.	Beaver Valley 1 & 2 (W)	X	
	Davis-Besse (B&W)	X	
Florida Power & Light \ NextEra	St. Lucie 1 & 2 (CE)	X	
	Turkey Point 3 & 4 (W)	X	
	Seabrook (W)	X	
	Pt. Beach 1 & 2 (W)	X	

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

PWR Owners Group
United States Member Participation* for PA-RMSC-1647
Newly Developed Methods Requirements and Peer Review

Utility Member	Plant Site(s)	Participant	
		Yes	No
Luminant Power	Comanche Peak 1 & 2 (W)	X	
Pacific Gas & Electric	Diablo Canyon 1 & 2 (W)	X	
PSEG – Nuclear	Salem 1 & 2 (W)	X	
So. Texas Project Nuclear Operating Co.	South Texas Project 1 & 2 (W)	X	
Southern Nuclear Operating Co.	Farley 1 & 2 (W)	X	
	Vogtle 1 & 2 (W)	X	
Tennessee Valley Authority	Sequoyah 1 & 2 (W)	X	
	Watts Bar 1 & 2 (W)	X	
Wolf Creek Nuclear Operating Co.	Wolf Creek (W)	X	
Xcel Energy	Prairie Island 1 & 2 (W)	X	

*** Project participants as of the date the final deliverable was completed. On occasion, additional members will join a project. Please contact the PWR Owners Group Program Management Office to verify participation before sending this document to participants not listed above.**

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

PWR Owners Group
International Member Participation* for PA-RMSC-1647
Newly Developed Methods Requirements and Peer Review

Utility Member	Plant Site(s)	Participant	
		Yes	No
Asociación Nuclear Ascó-Vandellòs	Asco 1 & 2 (W)	X	
	Vandellos 2 (W)	X	
Centrales Nucleares Almaraz-Trillo	Almaraz 1 & 2 (W)	X	
EDF Energy	Sizewell B (W)	X	
Electrabel	Doel 1, 2 & 4 (W)	X	
	Tihange 1 & 3 (W)	X	
Electricite de France	58 Units	X	
Elektriciteits Produktiemaatschappij Zuid-Nederland	Borssele 1 (Siemens)	X	
Eletronuclear-Eletrobras	Angra 1 (W)	X	
Emirates Nuclear Energy Corporation	Barakah 1 & 2	X	
Eskom	Koeberg 1 & 2 (W)	X	
Hokkaido	Tomari 1, 2 & 3 (MHI)	X	
Japan Atomic Power Company	Tsuruga 2 (MHI)	X	
Kansai Electric Co., LTD	Mihama 3 (W)	X	
	Ohi 1, 2, 3 & 4 (W & MHI)	X	
	Takahama 1, 2, 3 & 4 (W & MHI)	X	
Korea Hydro & Nuclear Power Corp.	Kori 1, 2, 3 & 4 (W)	X	
	Hanbit 1 & 2 (W)	X	
	Hanbit 3, 4, 5 & 6 (CE)	X	
	Hanul 3, 4 , 5 & 6 (CE)	X	
Kyushu	Genkai 2, 3 & 4 (MHI)	X	
	Sendai 1 & 2 (MHI)	X	
Nuklearna Electrarna KRSKO	Krsko (W)	X	
Ringhals AB	Ringhals 2, 3 & 4 (W)	X	
Shikoku	Ikata 1, 2 & 3 (MHI)	X	
Taiwan Power Co.	Maanshan 1 & 2 (W)	X	

*** Project participants as of the date the final deliverable was completed. On occasion, additional members will join a project. Please contact the PWR Owners Group Program Management Office to verify participation before sending this document to participants not listed above.**

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

TABLE OF CONTENTS

ACRONYMS ix

1 INTRODUCTION 1-1
2 DEFINITION OF NEWLY DEVELOPED METHOD 2-1
3 USE OF NEWLY DEVELOPED METHODS IN PLANT PRA 3-1
4 REQUIREMENTS FOR NEWLY DEVELOPED PRA METHODS 4-1
5 PEER REVIEW FOR NEWLY DEVELOPED METHODS 5-1
5.1 CHANGES TO THE PEER REVIEW SECTION IN THE PRA STANDARD 5-1
5.2 NEWLY DEVELOPED METHOD PEER REVIEW REPORT 5-3
5.2.1 NDM Peer Review Report Structure and Content 5-3
5.2.2 Public Availability of NDM Peer Review Reports 5-5
5.3 PRA METHODS PEER REVIEW OUTCOME 5-6
6 CONCLUSIONS 6-1
7 REFERENCES 7-1

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

ACRONYMS

Acronym	Definition
ANS	American Nuclear Society
ASME	American Society of Mechanical Engineers
BWROG	Boiling Water Reactor Owners Group
CC	Capability Category
F&Os	Facts and Observations
HLR	High Level Requirement
JCNRM	Joint Committee on Nuclear Risk Management
NEI	Nuclear Energy Institute
NDM	Newly Developed Method
PA	Project Authorization
PRA	Probabilistic Risk Assessment
PSA	Probabilistic Safety Assessment
PWR	Pressurized Water Reactor
PWROG	PWR Owners Group
RG	Regulatory Guide
RMSC	Risk Management Committee
SR	Supporting Requirement
USNRC	United States Nuclear Regulatory Commission

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

1 INTRODUCTION

The Pressurized Water Reactor (PWR) Owners Group (PWROG) Project Authorization (PA) RMSC-1647 (Reference 1) supported the interaction between the PWROG Risk Management Committee (RMSC), the United States Nuclear Regulatory Commission (USNRC), the Boiling Water Reactor Owners Group (BWROG) and the Nuclear Energy Institute (NEI) for the development of technical requirements that can be used evaluate the technical adequacy of a Newly Developed Method (NDM) to be adopted in a plant Probabilistic Risk Assessment (PRA).

The objective of this program is to provide clear criteria for the review of NDMs used in support of risk informed applications. This PWROG project develops the definitions, processes and technical requirements necessary to implement NDMs. Concurrent and parallel modification by the NEI of the PRA peer review process documented in NEI 17-07 (Reference 2) accommodates the review of new methods. This report includes the resolution of comments from the USNRC that were discussed at a public meeting on August 21st, 2019 (Reference 3).

Ultimately, the intent is that the requirements for the newly developed method be added in the future edition of the Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications that is being developed by the American Nuclear Society (ANS) and American Society of Mechanical Engineers (ASME) Joint Committee on Nuclear Risk Management (JCNRM).

Revision 2 of this report considers feedback from the JCNRM following the December 2019 ballot for the next edition of the Standard and interaction between the PWROG and commenters of the PRA Standard.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

2 DEFINITION OF NEWLY DEVELOPED METHOD

A number of operating definitions are needed to support the development of the NDM requirements and review process. The following definitions are therefore proposed to be included in the update of Section 1-2.2 of the ASME/ANS PRA Standard. For each definition, multiple sources were used, including the current versions of the PRA Standard (Reference 4), the combined NEI peer review guidance (Reference 2), the USNRC Regulatory Guide (RG) 1.200 (Reference 5), and the ANS glossary (Reference 6). The resulting proposed definitions take into considerations all these sources and modify the definitions as judged to be needed for the purposes of the PRA Standard.

PRA Upgrade: A change in the PRA that results in the applicability of one or more Supporting Requirements (SRs) that were not previously included within the PRA (e.g., performing qualitative screening in Part 4 when this HRL was previously not applicable or the addition of a new hazard model), an implementation of a PRA method in a different context, or the incorporation of a PRA method not previously used.

PRA Method: An analytical approach used to satisfy a supporting requirement or collection thereof in the PRA. An analytical approach is generally a compilation of the analyses, tools, assumptions, and data used to develop a model.

Model: A qualitative and/or quantitative representation that is constructed to portray the inherent characteristics and properties of what is being represented (e.g., a system, component or human performance, theory or phenomenon). A model may be in the form, for example, of a structure, schematic or equation. Method(s) are used to construct the model under consideration.

PRA: A quantitative assessment of the risk, including technical elements for modeled hazards, associated with plant operation and maintenance that is measured in terms of frequency of occurrence of risk metrics, such as core damage or a radioactive material release and its effects on the health of the public [also referred to as a probabilistic safety assessment (PSA)]

PRA Maintenance: A change in the PRA that does not meet the definition of PRA upgrade.

State-of–Practice: Those practices that are widely implemented throughout the commercial nuclear power industry, have been shown to be technically acceptable in documented analyses or engineering assessments, and have been shown to be acceptable in the context of the intended application.

Consensus Method/Model: A method/model that the USNRC has used or accepted for the specific risk-informed application for which it is proposed.

The above definitions allow for the definition of an NDM as follows:

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

Newly Developed Method: A PRA method that has either been developed separately from a state-of-practice method or is one that involves a fundamental change to a state-of-practice method. A newly developed method is not a state-of practice or a consensus method.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

3 USE OF NEWLY DEVELOPED METHODS IN PLANT PRA

A new method can be used to expand or refine an existing PRA but is always envisioned to be an upgrade, which implies a focused scope peer review of an existing PRA. If a new method is used in a PRA, it is necessary to confirm whether the new method that is applied meets the definition of newly developed method.

With the definitions discussed in the previous section, the process described in the following Figure 3-1 can be therefore considered.

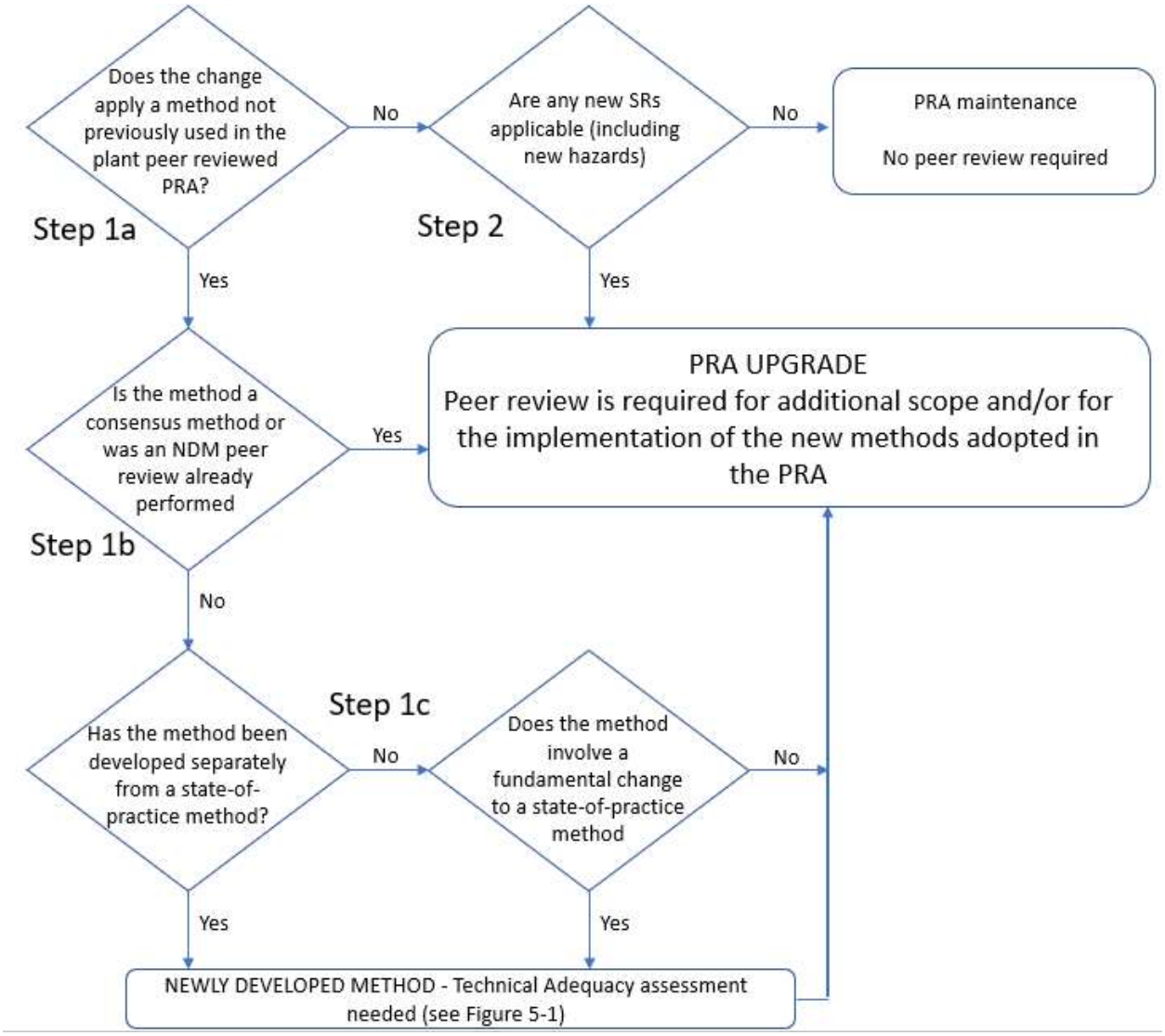

Figure 3-1: Peer Review Determination Process

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

Step 1a: Does the change apply a method not previously used?

Based on the definition of a PRA method that is provided above, in this Step, the analyst should review the change to determine if a new analytical approach was used to meet any SRs.

Step 1b: Does the new method is a consensus method

If the method was already successfully reviewed through the NDM review process or is a consensus method, then there is no need for assessment of its technical adequacy and only a peer review of the application of the method is needed.

Step 1c: Does the change represent a "Newly Developed Method"?

In this step, the analyst should evaluate whether the change would represent a Newly Developed Method as defined above. If the new method simply represents implementation of a state-of-practice method that was not previously implemented in the plant PRA being changed, this would be categorized as a PRA Upgrade.

Step 2: Are any new SRs applicable (including new Hazards)?

This step defines a PRA upgrade as those PRA changes that support any SRs that were previously not reviewed or were previously not applicable (N/A) are now applicable and should be reviewed. It is noted that this includes new hazards or new parts of the ASME/ANS PRA Standards.

If the original PRA Peer review was performed against Capability Category (CC) CC-I of the standard, any PRA changes that were made that support SRs moving from CC-I to CC-II are considered an upgrade.

The definitions of "state-of-practice", "consensus method", "PRA method", and "newly developed method" are provided in Section 2 and are used to decide whether a PRA method needs to undergo a dedicated peer review against the requirements presented in Section 4.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

4 REQUIREMENTS FOR NEWLY DEVELOPED PRA METHODS

This section summarizes the recommendations to JCNRM pertaining to the definition of a new set of requirements for newly developed PRA methods and specific expectations for the peer reviews of such methods. The generic expectation is that newly developed methods satisfy the set of requirements discussed in this section. This section is to be considered in conjunction with the proposed definitions of state of practice and of newly developed method; based on these definitions (see Section 2) it is clear that there is no expectation to retroactively apply these requirements to every method used in every PRA, however, it is expected that methods used in a PRA will generally meet these requirements in principal.

The requirements have been discussed in dedicated workshops with PWROG, BWROG, NEI, USNRC and JCNRM representatives. Three (3) pilots peer reviews have been performed following an initial drafting of the requirements and of the peer review expectations (see References 7, 8 and 9). The requirements documented in this report incorporate feedback and lessons learned from such pilots as well from a review performed by JCNRM members not involved in the development of the requirements.

It is recommended that requirements for assessing the technical adequacy of a newly developed method used in PRA be documented in a new section (e.g., Section 1-7) of Part 1 of the PRA Standard. The following wording is recommended to be added in the new section.

Section 1-7
Newly Developed Methods

1-7.1 INTRODUCTION

This Section states requirements for newly developed methods explicitly developed for use in PRA to support risk-informed decisions for nuclear power plants. The high level and supporting requirements for the Newly Developed Methods are contained in Tables 1.7.2-1 through 1.7.2-7.

1-7.2 OBJECTIVE

The objective of the newly developed method requirements is to ensure that a newly developed method is technically adequate and are as follows:

a) The newly developed method has clearly defined scope and limitations
b) The newly developed method is based on sound engineering and relevant science
c) The newly developed method has proper treatment of assumptions and uncertainties
d) The newly developed method is based on appropriate and well understood data
e) The newly developed method produces results that are consistent with expectations
f) The newly developed method is clearly documented in such a way that knowledgeable personnel can understand them without ambiguity and that there is enough documentation so that it can be peer reviewed.

The objectives above are intended to be applicable to a large spectrum of methods, although it is understood that not all the supporting requirements could be applicable to all methods. In some cases, depending on the method scope and purpose, some of the SRs may not be applicable. In addition, the SRs are designed to be able to address a stand-alone method (i.e., independent from its implementation on a specific plant PRA). It is recognized that, in some circumstances, a method can be so plant or site specific (especially in the external hazard domain) that a full review of the method can only be performed within its implementation. In such cases, it is envisioned that some of the NM SRs could be overlapping with Part specific SRs (e.g., SRs in Part 8). In such cases, the technical SRs in the appropriate part may take priority to some NM SRs.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

Designator	Requirement
HLR-NM-A	The purpose and scope of the newly developed method shall be clearly stated.
HLR-NM-B	The newly developed method shall be based on sound engineering and science relevant to its purpose and scope.
HLR-NM-C	The data (note that data can be numeric or non-numeric in nature) shall be relevant to the newly developed method, technically sound, and properly analyzed and applied.
HLR-NM-D	Uncertainties in the newly developed method shall be characterized. Sources of model uncertainties and related assumptions shall be identified
HLR-NM-E	The results of the newly developed method shall be reproducible, reasonable and consistent with the assumptions and data, and given the purpose and scope of the newly developed method.
HLR-NM-F	The documentation of the newly developed method shall provide traceability of the work and facilitate incorporation of the newly developed method in a PRA model.

Table 1-7.2-2 Supporting Requirements for HLR-NM-A

The purpose and scope of the newly developed method shall be clearly stated (HLR-NM-A).

Index No. NM-A	Requirement
NM-A1	ENSURE that the stated purpose of the newly developed method (i.e., what is being achieved by the newly developed method) is consistent with the scope (established boundary) of the newly developed method.
NM-A2	ENSURE that the applicability and limitations of the newly developed method are consistent with the purpose and scope in NM-A1.
NM-A3	Based on the limitations and applicability of the newly developed method, IDENTIFY which areas of the PRA for which the newly developed method is intended to be used, and those for which it is specifically not intended for (e.g., hazards, technical elements, plant features, SRs impacted by the newly developed method).

Table 1-7.2-3 Supporting Requirements for HLR-NM-B

The newly developed method shall be based on sound engineering and science relevant to its purpose and scope (HLR-NM-B).

Index No. NM-B	Requirement
NM-B1	ESTABLISH the technical bases for the newly developed method by using approaches founded on established mathematical, engineering and/or scientific principles (e.g., established through operating experience, tests, benchmarking, or acceptance by the scientific community).
NM-B2	If empirical models are used, ENSURE that they are supported by sufficient data which is relevant to the newly developed method and, to the extent possible, that the experimental data are shown to be repeatable.
NM-B3	IDENTIFY assumptions used to develop the technical bases of the newly developed method.
NM-B4	JUSTIFY the rationale for the assumptions identified in NM-B3 (e.g., backed by appropriate operational experience).

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

Table 1-7.2-4 Supporting Requirements for HLR-NM-C

The data (note that data can be numeric or non-numeric in nature) shall be relevant to the newly developed method, technically sound, and properly analyzed and applied (HLR-NM-C).

Index No. NM-C	Requirement
NM-C1	IDENTIFY the data needed to support the development of the newly developed method (e.g., relevant plant-specific data, industry-wide current operating experience and data, or experimental or test data).
NM-C2	COLLECT relevant data consistent with current technical state-of-practice.
NM-C3	DEMONSTRATE that the data used, including experimental data or test data, is relevant to and supports the technical basis of the newly developed method.
NM-C4	SPECIFY the basis for exclusion of data identified in NM-C1.
NM-C5	ANALYZE data (e.g., modifications to the data, use of data in a different context or beyond the original ranges, statistical analysis) using technically sound basis or criteria.
NM-C6	ENSURE that data is applied consistent with the purpose and scope of the newly developed method.

Table 1-7.2-5 Supporting Requirements for HLR-NM-D

Uncertainties in the newly developed method shall be characterized. Sources of model uncertainties and related assumptions shall be identified (HLR-NM-D).

Index No. NM-D	Requirement
NM-D1 Note (1)	CHARACTERIZE the parameter uncertainties associated with the newly developed method consistent with the intended scope and purpose of the method; this characterization could include, for example, specifying the uncertainty range, qualitatively discussing the uncertainty range, or identifying the parameter estimate as conservative or bounding.
NM-D2	IDENTIFY the sources of model uncertainty associated with assumptions identified in NM-B3.
NM-D3	CHARACTERIZE the model uncertainties (identified in NM-D2) associated with the newly developed method; this characterization may be in the form of sensitivity studies.

Notes:

(1) Depending on the purpose and scope of the method, uncertainty distributions may need to be explicitly calculated to allow for application of a method for risk significant items to meet Capability Category II of related technical SRs in other parts of the Standard.

Table 1-7.2-6 Supporting Requirements for HLR-NM-E

The results of the newly developed method shall be reproducible, reasonable and consistent with the assumptions and data, and given the purpose and scope of the newly developed method (HLR-NM-E).

Index No. NM-E	Requirement
NM-E1	REVIEW the results from the newly developed method to determine that they are reproducible, reasonable and consistent with assumptions and data addressed in the SRs under HLR-NM-B and HLR-NM-C.
NM-E2	COMPARE the results of the newly developed method with existing methods and, when possible, IDENTIFY causes for substantial differences.
NM-E3	ENSURE uncertainties do not preclude meaningful use of the newly developed method results.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

Table 1-7.2-7 Supporting Requirements for HLR-NM-F

The documentation of the newly developed method shall provide traceability of the work and facilitate incorporation of the newly developed method in a PRA model (HLR-NM-F).

Index No. NM-F	Requirement
NM-F1	DOCUMENT the newly developed method specifying what is used as input, the technical basis and the implementation expectations and limitations by addressing the following, as well as other details needed to fully document how the set of the NM SRs are satisfied: (a) the purpose and scope of the newly developed method (b) the intended use of the newly developed method (c) the limitations of the newly developed method (d) the detailed technical basis for the newly developed method (e) the data source, collection process and data manipulation performed in support of the newly developed method (f) the assumptions and uncertainties associated with the newly developed method (g) the interpretation of the results of the newly developed method in the framework of the intended use and application
NM-F2	DOCUMENT the intended process by which the newly developed method can be applied to a PRA model consistently with the intended use of the newly developed method and taking into account the purpose, scope and limitations.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

5 PEER REVIEW FOR NEWLY DEVELOPED METHODS

This section discusses potential clarifications and modifications of the peer review program to accommodate a peer review of method for which, using the criteria and definition defined above, it is concluded that a peer review is needed. NEI 17-07 (Reference 2) addresses the specifics of the peer review; this section is not presenting updates specific to NEI 17-07 but rather generic clarifications on the process.

5.1 CHANGES TO THE PEER REVIEW SECTION IN THE PRA STANDARD

The following specific changes in Part 1 of the PRA Standard are recommended. Sections not mentioned here below are considered fully applicable (i.e., no recommended changes).

It is recommended that Section 1-6.1.1 (Documentation and Self-Assessment) be removed completely. The documentation of a self-assessment is part of the process and is captured in NEI-17-07. It does not need to be included in the Standard.

It is recommended that Section 1-6.1.4 (Method) be rewritten as follows:

1-6.1.4 Peer Review Process

The review shall be performed using a written process that assesses the requirements of the Technical Requirements section of each respective Part of this Standard and addresses the requirements of the Peer Review Section of each respective Part of this Standard.

The peer review process shall consist of the following elements:

(a) selection of the peer review team
(b) training in the peer review process
(c) an approach to be used by the peer review team for assessing if the PRA meets the supporting requirements of the Technical Requirements section of each respective Part of this Standard
(d) management and resolution of potential differing professional opinions
(e) documentation of the results of the review

When included in the scope of a peer review, a newly developed method shall be reviewed following the dedicated requirements discussed in Section 1-7.

It is recommended that Section 1-6.2.2 (Individual Team Members) be rewritten as follows:

1-6.2.2 Individual Team Members

The peer review team members individually shall be:
(1) knowledgeable of the requirements in this Standard for their area of review
(2) experienced in performing the activities related to the PRA Technical Elements for which the reviewer is assigned
(3) independent from the team that developed the PRA model or the method being peer reviewed.
(4) Subject matter experts should be included to judge the technical adequacy of non-PRA engineering evaluations and to confirm that the applicable envelope defining the limits of the method are identified.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

It is recommended that Section 1-6.2.3 (Review Team Members for PRA Upgrades) be removed completely.

It is recommended that Section 1-6.3 be rewritten as follows:

1-6.3 REVIEW OF PRA TECHNICAL ELEMENTS

The peer review team shall use the requirements of this section, as complemented by hazard specific requirements presented in the Peer Review Section of each respective Part of this Standard for the PRA. These hazard-group–specific requirements are stated in the corresponding peer review section of each Part (e.g., 2-3.3, 3-3.3). The peer review team shall review the technical requirements of the hazard group to determine if the method and the implementation of the method for each PRA Technical Element meet the requirements of this Standard. Additional material for those Elements may be reviewed depending on the results obtained. The judgment of the reviewer shall be used to determine the specific scope and depth of the review in each PRA Technical Element.

The results of the appropriate hazard group PRA, including models and assumptions, and the results of each PRA Technical Element shall be reviewed to determine their reasonableness given the design and operation of the plant (e.g., investigation of cutset or sequence combinations for reasonableness).

The PRA configuration control program is reviewed against the requirements presented in Section 1-5; any newly developed method included in the scope of the peer review is reviewed against the requirements of Section 1-7. It is noted that a newly developed method can be peer reviewed within the scope of a plant PRA (i.e., concurrently with its implementation in a plant PRA) or via a dedicated stand-alone peer reviewed. In this second case the implementation of the method is peer reviewed in a separate peer review.

Even if exceptions to the requirements of Section 1-6.2.4(c) occur, concerning the composition of the peer review team or the duration of the review, all SRs relevant to the scope of the peer review of the PRA are to be reviewed.

The extent of a focused-scope peer review includes all Supporting Requirements (e.g., not just those for which Findings were cited), within the High Level Requirement(s) containing Supporting Requirements with Findings. New Findings may be issued even for Supporting Requirements that did not have previous Findings since a focused-scope peer review encompasses all the Supporting Requirements within an affected High Level Requirement.

It is recommended that Section 1-6.6.1 be rewritten as follows:

1-6.6.1 Peer Review Team Documentation

The peer review team's documentation shall demonstrate that the review process appropriately implemented the review requirements.
Specifically, the peer review documentation shall include the following:

(a) identification of the version of the PRA reviewed
(b) a statement of the scope of the peer review
(c) the names of the peer review team members
(d) a brief resume on each team member describing the individual's employer, education, PRA training, and PRA and PRA Technical Element experience and expertise
(e) the elements of the PRA reviewed by each team member
(f) a discussion of the extent to which each PRA Technical Element was reviewed, including justification for any supporting requirements within the peer review scope that were not reviewed

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

(g) results of the review identifying any differences between the requirements in the Technical Requirements section of each respective Part of this Standard and Section 1-5 and the method implemented, defined to a sufficient level of detail that will allow the resolution of the differences
(h) identification and significance of exceptions and gaps relative to the Standard's requirements, in sufficient detail to allow the resolution of the gaps that the peer reviewers have determined to be material to the PRA
(i) an assessment of PRA assumptions that the peer reviewers have determined to be material to the PRA
(j) differences or dissenting views among peer reviewers
(k) recommended alternatives for resolution of any differences
(l) an assessment of the CC of the SRs (i.e., identification of what CC is met for the SRs)

It is recommended that Section 1-6.6.2 be rewritten as follows:

1-6.6.2 Resolution of Peer Review Team Comments

Resolution of Peer Review Team comments (Facts and Observations (F&Os) shall be documented. The resolution of the F&Os findings shall describe how the deficiency was addressed such that the associated SR can now be demonstrated to be met.

Emphasis is given on whether an F&O is resolved via a PRA maintenance or a PRA upgrade.

A focused scope peer review is performed to address any PRA upgrade.

It is recommended that Section 1-6.6.3 be removed completely as it is now addressed by Section 1-7.

There is no need to make any change in the hazard specific peer review sections (e.g., Section 2-3), as there is nothing hazard-specific that needs to be addressed in the review of a method.

5.2 NEWLY DEVELOPED METHOD PEER REVIEW REPORT

This section discusses the structure and content of a NDM peer review report.

If the NDM is peer reviewed in conjunction with a plant PRA and is documented as part of the plant PRA peer review, dedicated sections in the reports need to be created for the NDM review portion of the review, including the same content discussed below.

5.2.1 NDM Peer Review Report Structure and Content

The following is the recommended content of the report for a NDM peer review.

Introduction

Purpose

A short description of the purpose of the report.

Scope

The method that is being peer reviewed needs to be uniquely identified.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

Also, it should be clarified which technical supporting requirements should be peer reviewed when the NDM is applied to a plant PRA

Peer Review Process

Overview of Review Process

A short summary of the process used needs to be presented, mainly with reference to the NEI peer review guidance and to the PRA Standard (or to the document that contains the review requirements).

Peer Review Schedule and Reviewer Assignments

A short summary of the steps followed during the review process.
A very short biography of all the peer review team members that confirms the reviewer's qualifications and pre-requisites should be provided.

Reviewed Information

All the documentation reviewed in support of the NDM review should be listed.

Summary of Review Results and Observations

Method Characterization

The reviewer's understanding of how the method that was reviewed qualifies as a newly developed method, based on the NDM definition.

If a NDM is an evolution of existing methods, it would be helpful to provide indications of whether the original methods were already peer reviewed (or being part of a plant PRA that was peer reviewed)

Technical Adequacy

A summary of each SRs in the NDM section of the Standard is met, not met, not reviewed or not applicable. A short rationale needs to be provided for each SR that is judged not applicable.

For each applicable SRs, facts and observations linked to the SR should be provided (this is a summary, although all detailed F&O wording needs also to be provided).

Assessment of the Requirements

Documentation of the reviewer assessment for each SR that is judged applicable. The assessment should explicitly indicate the basis for the SR assessment as met or not met.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

Facts and Observations

F&Os written against the method.

Conclusions

A summary of the overall report. A positive statement on the technical adequacy of the method needs to be repeated for clarity in the conclusions.

Reviewer Resumes and Qualification Review

Documentation of the reviewer pre-requisites along with each review team members resume.

The judgment of the review lead about the review team meeting the reviewer qualification requirements.

The method owner acceptance of the review team and concurrence on the qualification.

Non-Proprietary Summary for Public Use

An appendix has to be provided that includes a short summary of the overall review with no proprietary information. The minimum information needed in this section is:

a. Unique identification of the method reviewed
b. Process followed for the review (i.e., reference to NEI guidance)
c. Review team composition (full resume not required)
d. Method characterization and technical adequacy summary
e. SR assessments and associated basis
f. F&Os wording and/or basis for closure of F&Os.
g. List of SRs to be peer reviewed in a focused scope review applying the method

Alternatively, if the full NDM peer review report is determined to be non-proprietary, the full report can be made publicly available; in this case the non-proprietary summary would not be needed.

5.2.2 Public Availability of NDM Peer Review Reports

While there is no expectation that the full NDM peer review report is made publicly available, the non-proprietary Appendix of the peer review report is expected to be made available to the public so that both the NRC and any utility applying in the future for the method can reference the fact that the method has been peer reviewed.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

There is no mandatory vehicle to be used to ensure public availability of the non-proprietary appendix of the peer review report but the following mechanisms can be considered as examples:

a. The non-proprietary appendix of the peer review report can be made available on the web site of the method developer and owner organization (e.g., EPRI, PWROG, etc.)
b. The appendix can be added in an Appendix to the method primary report (e.g., EPRI report)
c. The appendix can be made available to the NRC to be loaded on ADAMS (no formal request of review or endorsement would be needed).

Note that “publicly available” is not necessarily to be intended as “for free”.

5.3 PRA METHODS PEER REVIEW OUTCOME

The following Figure 5-1 summarizes the possible outcomes from an NDM peer review and the repercussion on the use of the method in a plant PRA model. Beyond the proposed peer review process, submittal of the method to the NRC for a direct assessment remains a valid option.

If the suggested peer review process is used to assess the technical adequacy of the method, then two main possible outcomes from a newly developed method peer review are:

a. If all the NM SRs are MET and there are no open findings, the method is considered technically adequate and can be implemented in a plant PRA. Following implementation, the plant will undergo a focused scope peer review where the review team will assess if the method is adequately applied to the plant PRA and is performed against the technical supporting requirements in the relevant Part(s) of the PRA Standard.
b. If there are NM SRs that are NOT MET or there are open finding against some NM SRs, the conclusion will be that the newly developed method is NOT technically adequate. In this situation, it would not be recommended for a plant to apply the method in the plant PRA. It is possible to envision that some of the open findings may be easy to disposition (e.g., a minor documentation finding or related to a portion of a method that is not used by the plant). It becomes the plant responsibility to address those findings in the application of the method in the plant PRA.

   The F&O closure process (see Appendix E of Reference 2) can be used to close findings associated with an NDM. It is to be noted that the F&O closure process requires the developer of the method (and the independent assessment team) to evaluate whether a finding is closed through a maintenance or an upgrade activity (which would result in the need for a follow up NDM peer review to be performed). Note that the operating definitions of PRA upgrade and PRA maintenance may not be directly applicable to a PRA method. However, the concept remains valid when considering that a PRA method maintenance activity would be:

   - a correction of an error that does not change the intent or the conclusions for the method;
   - the processing of more input data with the same process that does not change in the intent of the conclusion of the method;

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

- the expansion of documentation for data and assumptions already used (but not appropriately documented in origin);
- performance of more sensitivities to discuss uncertainties and or to confirm the applicability of the method within the original intended range of application;
- clarification of the documentation in support to implementation of the method.

A PRA method upgrade activity would be an action that changes the intent of the method, such as:

- extension/change of the scope/applicability of the method;
- a fundamentally different way to process input/output data (beyond usage of a different tool to perform the same process function)

Following an F&O closure review and/or a focused scope peer review for the NDM, an update of the summary information needs to be made again available to the public to document the new technical adequacy assessment.

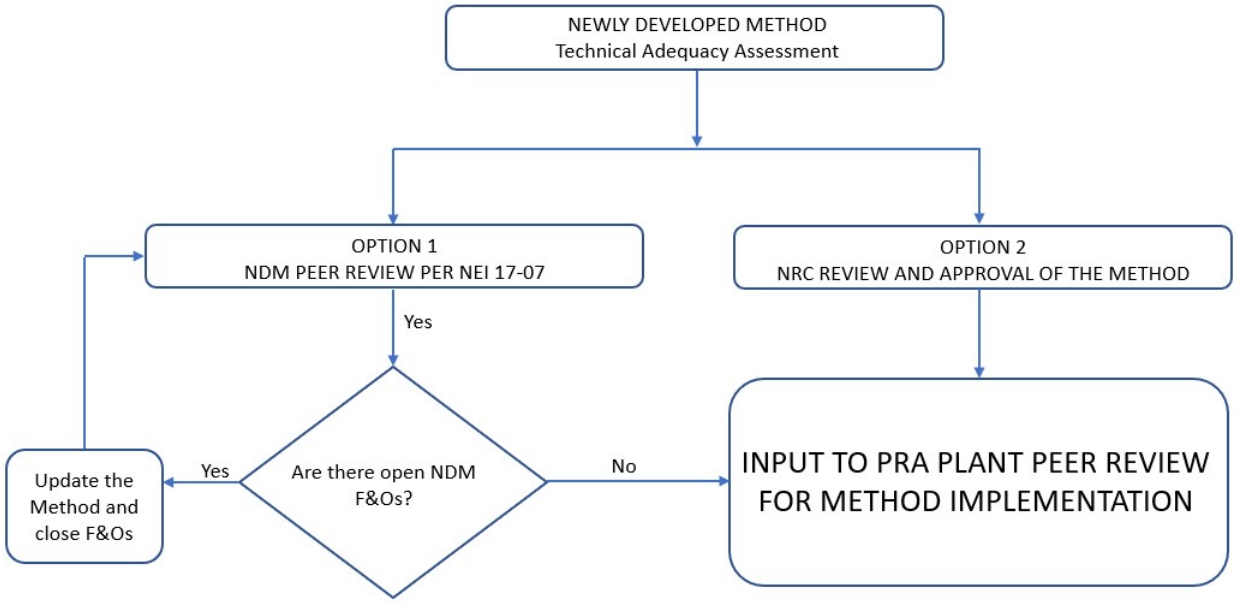

Figure 5-1: Newly Developed Method Peer Review Flow Chart

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

6 CONCLUSIONS

The PWROG worked with a number of stakeholders to define a set of technical requirements to be associated to a method used in PRA for a plant. A number of definitions were also proposed that would support a process for which newly developed methods could be explicitly peer reviewed within the PRA peer review program to ascertain the technical adequacy of the method.

Specific changes to the upcoming edition of the ANS/ASME PRA Standard are proposed in this report to support the NDM definition, technical requirements and per review process. This document would enable the upcoming NEI peer review guidance to support and manage the review of NDMs concurrently or before their implementation in a plant PRA.

An efficient process for the review of NDMs would support a more streamlined acceptance by the USNRC of PRA changes in support to risk-informed application and license amendments.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

7 REFERENCES

1. PA-RMSC-1647, R1 Model Maintenance vs Upgrade Workshop.

2. NEI 17-07, Performance of PRA Peer Reviews Using the ASME/ANS PRA Standard. Revision 2, August 2019. (ADAM ML19228A242).

3. Public Meeting with the Nuclear Energy Institute to Discuss the Use of New Probabilistic Risk Assessment Methods Following the Issuance of an Amendment to Utilize a Risk-Informed Process. August 21st, 2019. (ADAM ML19207A443).

4. ASME/ANS RA-Sb-2013, Addenda to ASME/ANS RA-S-2008, Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications.

5. USNRC Regulatory Guide 1.200, Revision 2, An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities. March 2009. (ADAM ML090410014).

6. American Nuclear Society, Standard Committee. Glossary of Definitions and Terminology (as of April 2019). Available on the ANS web site: http://www.ans.org/standards/toolkit/

7. PWROG-19019-NP, Revision 0-A, *Newly Developed Method Peer Review Pilot – EDG Component Reliability Data Development* – PA-RMSC-1647. June 2019.

8. PWROG-19020-NP, Revision 1, *Newly Developed Method Peer Review Pilot – General Screening Criteria for Loss of Room Cooling in PRA Modeling* – PA-RMSC-1647. April 2020.

9. Draft Jensen Hughes report BD000000.000-RPT-01 – Newly Developed Method Peer Review Pilot – fraction of Complete Fire Damage to a NUREG-2178 Vol 1 Group 4 Electrical Cabinet. Draft 0a as of June 2019.

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)

This page was added to the quality record by the PRIME system upon its validation and shall not be considered in the page numbering of this document.

Approval Information

Author Approval Maioli Andrea Jul-10-2020 18:01:02
Reviewer Approval Labarge Nathan R Jul-13-2020 13:01:32
Manager Approval Sadlon Dan Jul-13-2020 14:35:15
Manager Approval Mirizio Damian S Jul-27-2020 12:57:50

Files approved on Jul-27-2020

*** This record was final approved on 7/27/2020 12:57:50 PM. (This statement was added by the PRIME system upon its validation)