PRA TECHNICAL ADEQUACY WORKING GROUP
OBJECTIVE 1 - TASK 1 - CONCEPTUAL TASKS

DEFINITION OF NEW METHOD:

A new method is defined in the context of U.S. PRA practice and NRC familiarity in regulatory application, and also represents a fundamentally new approach in addressing a technical aspect of PRA. Therefore, a new method is one that has the following two attributes:

1. It is new to usage in nuclear plant PRAs in the U.S., regardless of the extent of its use in risk assessments outside the U.S. or in other industries (e.g., chemical, telecommunications, defense), AND
2. It is sufficiently different from methods currently in use that it would be considered an "upgrade" in accordance with the definition of upgrade (and the examples of upgrades) in R-G- 1.200 and the ASME/ANS PRA standard.

DEFINITION OF TERMS:

Source: Refers to the "lead" organization in the development of the method. The lead may not be the organization that performed most of the work, but rather the organization whose involvement would give the greatest "credibility" to the method *in the context of regulatory application.* Sources (not in any order) would generally be as follows:

- NRC
- EPRI
- Utility
- Owners Group
- Federal or State Government (method intended for NPP PRA)
- Federal or State Government (method not intended for NPP PRA)
- University or similar non-profit research organization (method intended for NPP PRA)
- University or similar non-profit research organization (method not intended for NPP PRA)
- Non-US organization (method intended for NPP PRA)
- Non-US organization (method not intended for NPP PRA)

Pedigree: Refers to the extent to which the method has been vetted. Pedigree would generally be considered as follows:

- No independent peer review
- Peer reviewed and published
- Formally or implicitly accepted by NRC
- Formally or implicitly accepted by another (i.e., non-US) nuclear regulator
- Formally or implicitly accepted by a non-nuclear regulator or generally accepted in a non-nuclear industry
- Commonly considered by a standards development organization to meet the requirements of its standard(s)

Maturity: Refers to the extent to which the method has been applied. Maturity would generally be considered as follows:

- New. Has not yet been applied.
- Has been piloted only
- Has been used over a few to multiple years

Comment [NRC1]: High level comment – the Objective 1 input will be rolled into the "combined whitepaper" and future comments or outstanding comments will be reserved for the final paper. (Final NRC comments due 12/8/14.)

Industry and NRC WGs will try to hold a public meeting before that time to discuss/clarify comments, as necessary.

The combined whitepaper can use the Problem Statement text to provide background, a description of the tasks/objectives, etc.

Note that some of the comments provided on this draft were previously provided verbally (e.g., at the meeting on 10/24/14) but have not yet been incorporated because this version of the paper is from 9-22-14.

Comment [NRC2]: The application of an existing method in a new a manner or to a new problem (i.e., a change in applicability/scope) may also need to be treated as a new method (even if it is NRC approved) because it may not be approved, or there may be limitations for its use, for the new context.

- Commonly used over some years

Complexity: Refers to the extent to which the method is or is not intuitive or obvious, and the extent to which it is multi disciplinary, as follows:

- Simple, obvious, and intuitive.
- Complex with a narrow field of expertise.
- Complex with interaction/integration of multiple disciplines of expertise.

Process Options (for acceptance of any given method): Refers to possible ways in which new methods could be processed such that they become available for use. These are high level statements of the general approach to the acceptability processes that could be applied based on the source, pedigree, and maturity. For each process options, details would need to be worked out as to the criteria that would be applied to the option and the details of the actual process. Process options include:

1. Usage acceptable immediately upon issuance of draft method. Requires a determination that the draft method has clear support from both NRC and industry.
2. Usage acceptable immediately upon conclusion of comment period on draft method. Requires a determination that the resolution of the comments received
3. Usage acceptable immediately upon resolution of industry/NRC comments?
4. Usage acceptable immediately following gap assessment against requirements of RG 1.200. In a gap assessment, the detailed technical details of the method are considered acceptable, and the only issue is whether the application of the method as described would meet the requirements of R.G. 1.200. The assessment would be against the applicable SRs of the ASME/ANS standard as modified by NRC clarifications and qualifications.
    a. Assessment of NPP Applicability: For methods not originally intended for use for nuclear facilities, the requirement for a gap assessment would include an assessment of whether the method can be applied to a nuclear plant (i.e., that its scope of applicability has an analogy in a nuclear plant.)
5. Usage acceptable immediately following peer review of method. This would be a peer review of the technical aspects of the method against the requirements of R.G. 1.200. The assessment would be against the applicable SRs of the ASME/ANS standard as modified by NRC clarifications and qualifications.
    a. Assessment of NPP Applicability: For methods not originally intended for use for nuclear facilities, the requirement for a peer review would include an assessment of whether the method can be applied to a nuclear plant (i.e., that its scope of applicability has an analogy in a nuclear plant.)
6. Usage acceptable immediately following Industry/NRC methods panel consensus. This refers to the convening and operation of a methods panel that will take the submitted method and, if necessary, revise the method in order to reach a consensus of the panel (i.e., as in the EPRI/NRC MOU methods panel process).

DEFINITION OF NEW METHOD GROUPS:

Below are examples of new method groups that consider a high-level categorization of new methods with an aim towards focusing on the process option that best suits the characteristics of the new method.

Comment [NRC3]: Typical for all discussion on gap assessment.

The scope of RG 1.200 and the PRA Standard is mostly associated with "what to do" or "what should be included in a PRA of a certain capability," while methods (and associated technical bases/guidance) are more in the category of "how to do." A method might meet the "what to do" standard, but be inadequate in the "how it does" that aspect or it might be determined to be acceptable as a simplified approach meeting Capability Category (CC) 1, but not achieve CC 2. The discussion should include language that the expectation of the panels (vetting, peer review, or methods) is to review the technical adequacy of the method (including, potentially, how it might achieve specific CCs); not just that it comports with RG 1.200 and the PRA Standard. The distinction is the level of review of the technical basis c ... [1]

Comment [NRC4]: See previous comment, the NRC does not agree that there is a de facto full acceptance of the technical details for methods that need a gap assessment and that only the RG 1.200 check is needed. However, such methods may only need a high-level review of the technical basis to confirm that the method is technically adequate. It would be acceptable to revise the sentence to reflect this confirmatory review of the technical basis. If the technical basis is found to be lacking at this stage (or anytime a "not accepted" determination is made), then it would need to be documented and sent back to the process originator for reconsideration/revision, etc.

Comment [NRC5]: The text references a "peer review," but in the chart it is "Industry/NRC peer review" in all cases, except under the B path where only "peer review" is used. Through the vetting process the NRC will become aware of a new method, but there needs to be some means of gaining acceptance, of all new methods (see next comment). One approach, which may be reflected in the chart but would need to be added to the text, might be to include the NRC on peer reviews that are addressing new methods, solely for that aspect, to provide some awareness and assurance that the new method has an accepted technical basis and that future applications that use the method won't fa ... [2]

Comment [NRC6]: The purpose of the methods panel should be to evaluate the technical merits/adequacy of the proposed methods; not to develop an acceptable new method. These aspects (review versus development) should be separated activities. If a methods panel determines that a method is not acceptable or that the technical basis has not been adequately presented, it should document that outcome and provide it to the process originator for consideration/revision, etc. If the originator has additional questions regarding the rejection or wants support in further developing the technical basis for the new method, then that should be done outside the panel process; also noting that if pane ... [3]

Group	Description	Available Process Options
A	NRC or NRC-Collaboration: Refers to new methods developed as a result of research performed by NRC or with substantial NRC involvement in collaboration with others (e.g., EPRI, NEI). It is anticipated that these results would enter into the process at the draft 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, 6
C	Peer Reviewed and Published Independent Research for Nuclear Application. Refers to methods that are developed intended for application to nuclear facilities by organizations that are not affiliated with nuclear regulatory agencies or nuclear industry organizations Finding something to be in this category requires a determination that the work was "unbiased" by regulatory or industry interests. Funding from either or both interests would not, a priori, mean that a method could not be in this group, but the extent of influence would need to be considered.	4, 5, 6
D	Peer Reviewed and Published Independent Research for Non-Nuclear Application. Refers to methods that are developed intended for application to other than nuclear facilities. Finding something to be in this category requires a determination that the work was "unbiased" by regulatory or industry interests.	4, 5, 6
E	Peer Reviewed and Published Collaborative Industry Research for Nuclear Application: Refers to methods that are developed in an inclusive way by the industry, involving a broad range of technical contributors and reviewers. Most EPRI and Owners Group research programs would fall into this category.	4, 5, 6
F	Utility research in collaboration with university or EPRI or other NGO (e.g., Underwriters Lab)	6, 7
G	Internal utility research (alone or with contractor)	7

Comment [NRC7]: Table needs to be updated. It is inconsistent with the previous section and the Industry slides (Slide 7) on 10-30-14 (ADAMS Accession No. ML14304A436).

This is all important background/guidance for the vetting panel, but process-wise, the associated flowchart could be simplified because several of the groups can be collapsed based on similar process options.

PROCESS IMPLEMENTATION – THE VETTING PANEL

Figure 1 shows the overall process for achieving acceptance of new methods. The key to this process is the Industry/NRC Vetting Panel. This is a panel of senior technical experts representing industry and NRC that will (1) take a high level look at the proposed method, (2) agree as to the appropriate category the method falls into and, (3) agree to which acceptance process option should be used. ~~The individuals on this panel need to be at a sufficient level of authority that they can bind their interest group to accept the selected process and its results.~~ Note that this panel also may be called upon to perform a gap assessment against RG 1.200, and so should be knowledgeable about the RG and the ASME/ANS standard.

Comment [NRC8]: There are already a number of processes that can be used to approve new methods. It would be useful to clarify that the proposed process under development is intended to provide another option to industry.

Comment [NRC9]: NRC staff on the panel will not be able to have this level of authority (i.e., final endorsement is still the purview of NRR)

The panel's decisions will be based on a holistic look at the method in terms of its source, pedigree, maturity and complexity (terms that were previously defined) and determining from that information the level of review that the method should receive prior to being accepted. Each of these attributes is a continuous distribution, and there are too many possible permutations to make any ~~hard~~ hard ~~and~~ and fast rules. What may be considered sufficient maturity from one source may not be for another. The same could be said about pedigree. This ~~is way the need for~~necessitates a panel that can weigh each attribute and select the appropriate path.

The panel's decisions can take a number of forms, including addressing the following considerations:

a. Is the method controversial? Applied only to NRC or NRC-Collaboration draft 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. The primary considerations would be the pedigree and complexity of the method. It is expected that maturity would have no bearing, since these methods would likely be submitted prior to much application.
b. Is the extent of application sufficient? This refers to whether the method is proven enough in application to provide a level of comfort that it is robust, stable, and valid; that there are unlikely to be hidden traps or snares. The primary considerations would be the pedigree and maturity, the weights of which could be influenced by the source. Complexity may influence the determination of maturity where there have been only a few pilot applications.
c. Is the credibility sufficient? This refers to the overall rigor of the development of the method. It speaks to the inclusiveness of the development process, the quality assurance and checking that was involved, the importance afforded to the development and similar such considerations. The primary considerations would be the source and pedigree, the weights of which could be affected by complexity. Maturity may influence the final decision if the method is submitted to the panel after it has been applied a number of times.

REVIEW PROCESS COMMENTS:

- Size of Review Team - A number of the availability processes presented above involve some type of review. Regardless of the bin a method falls into or the extent of the review required, it is expected that there will be different levels of complexity in the methods to be reviewed. In general, the size of the review team should reflect the complexity of the specific method. The expectation is that the review of a simple method would have no more than 2 people, a complex method with narrow expertise needed might have three or four, and a complex method with multiple disciplines might have as much as six or more (two per discipline).
- Timeframe for Completion of Review and Issuance of Team Consensus - This would also be expected to be a function of the complexity of the method. Keeping with the same complexity concept discussed above, the ~~requirement~~ 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. ~~Exceptions to these timeframes would be permitted only with concurrence of the NRC and NEI RISCs.~~

Comment [NRC10]: This is a consideration for all the methods and is not unique to NRC derived methods. It could be considered under "extent of application" and/or "credibility." As such, recommend incorporating the thought regarding potential controversy with the discussion on extent.

Per the RISC meeting on 10-30-14, may want to use a different word than "controversial."

Comment [NRC11]: The timeframe for resolution will likely depend on a number of factors. Complexity is one; others affecting an assessment of "good enough" could include risk significance and cost implications. If an issue is not risk significant (i.e., the new method does not have a significant impact on the applicable risk metrics or insights) it may warrant a lower priority.

A generic review and approval schedule may not be able to be developed based on high-level characteristics. The schedule would be highly dependent on technical specifics. However, it seems reasonable to discuss prioritization (e.g., if a particular proposed new method should be expedited, and what does that mean), and both RISCs could weigh in on this given appropriate information (e.g., about potential risk significance, broad industry impact, potential for establishing a key precedent).

Similarly, it may not be possible to predetermine the number of people on the review team due to resource constraints (for both Industry and NRC).

Comment [NRC12]: Deleted based on feedback from both RISCs at the public meeting on 10-30-14 on Slide 8 (ADAMS Accession No. ML14304A436)

General Comments on Objective 1 Whitepaper

There needs to be some type of formal close-out of the process at the end, which is not currently addressed. After going through this process and ultimately determining that a method is acceptable or not via whatever path, there then needs to be a means of gaining formal acceptance of that result. This could take on the means of a letter from EPRI or NEI to the NRC documenting the results (including any dissenting views of the panel) and then having the NRC respond with accepting the results, including any kind of additional comments, considerations, or qualifications. Such an approach would essentially mirror the PRA Standards process of gaining formal acceptance via RG 1.200, though at a lower level (i.e., exchange of letters).

The general concept that we should be able to leverage past review activities makes sense. However, because past reviews have been performed in a context that differs from ours (for example, the UK regulator thinks in terms of safety cases for periodic safety reviews), we need to be careful that the process doesn't focus exclusively on the summary outcomes of the reviews (e.g., approved for use or not). For important cases, the reviews are needed.

As indicated in the industry paper, there are many possible situations, and many possible gradations of the key attributes. There may need to be multiple panels to ensure both a broad perspective (the vetting panel) and appropriate levels of subject matter expertise on particular topics. (For example, RG 1.200 says that "appropriate fire modeling tools" should be used in fire PRA. Depending on the makeup of the vetting panel, additional experts may be needed to weigh in on what's appropriate.) Given the reliance on panels (who will likely benefit from guidance, but will probably not want to be locked down to rigid processes), perhaps the flow chart could be much simpler.

When making a recommendation to our RISC, we'll need to be mindful of the costs of implementation. In addition to the obvious costs associated with review and evaluation activities, there are potentially hidden costs (e.g., running down whether a method is actually approved and for what, getting the review documents). Note also that the expert panels will, by definition, be involving people who are already fully busy. The RISC may need to be kept abreast of demands and may need to establish priorities.

The paper employs terminology that will need to be further developed. (See, for example, the reference to "simple, obvious, and intuitive" methods. Challenges can arise, for example, when experts in internal events Level 1 PRA consider topics outside this realm.) Note that it would be very useful to have a quick screen to enable timely use of sound, non-controversial methods. However, some of the examples we've discussed (e.g., cabinet HRR) don't fall in this category. It might be useful to have some discussion as to what "success" is for such cases.

The paper should consider and explain the appropriate role of the public in the process. E.g., the vetting panel meetings will be public meetings.

There is no statement regarding what "consensus" means. There are multiple types of consensus, ranging from absolute consensus where everyone on the panel must be in agreement to a simple majority consensus, to all shades in-between. Immediate use of a method that got through a majority consensus that involved a significant dissent by the NRC would not be considered appropriate. This should be addressed directly in the approach. Again, this supports some type of formalized close-out before broad use of a new method.

Additional Comments on the Objective 1 Process Flowchart

The wording in the flow chart may need to be revised. (Refer to comments on Process Options.)

Recommend simplifying the flowchart based on the following:
Paths B, C, and E should all follow essentially the same logic. Path A is more simplistic, which as shown seems appropriate. Path D should probably be more detailed than B, C, and E since it is being brought in from outside the nuclear application field, but maybe that can be accommodated in the extent diamond consideration. Paths F (which is not displayed) and G need to be more restrictive, which as shown for G seems appropriate.

Also, for Paths B, C, D, and E there is the potential to need a methods panel (i.e., detailed technical bases review) and that is not reflected in the diagram. It should likely be a third potential outcome of the extent diamond consideration.

One possible simplification: Show Path A, Combine Paths B, C, D, and E into one common path, and Combine Paths F and G into one common more restrictive path.

An example of another possible simplification is attached.

Additional (Preliminary) NRC comments for Final Combined Whitepaper

The final paper should recommend a pilot of the new vetting panel process as a follow-up activity. (A pilot is more likely to identify practical challenges, e.g., in collecting the information needed by the vetting committee.)

The final paper may need a disclaimer about the NRC Differing Professional Opinion (DPO) and Non-concurrence processes and how this new process does not affect those programs. Methods that once were accepted might be shown to be incorrect and unacceptable when considered/reviewed by a broader audience than the few staff that evaluated the original method, and these processes address that concern.

The final paper should also mention some of the alternative processes (submitting a Topical Report, the FAQ process, ISG documents, consensus standards with RG endorsement, a letter from NRR to NEI, etc.) and that the vetting panel can recommend using these processes (if it will result in a faster outcome). We may also want to note that NUREGs and NUREG/CRs provide good information, but don't necessarily represent an approved NRR regulatory position.

Similarly, there might need to be a reminder that the NRC is obligated to review what a licensee submits as part of an application, this new supplementary process in no way limits what/how licensees can submit information to the NRC.

The NRC has the responsibility for approving the use of all new methods that provide input to decisions that have the potential to affect public health and safety. Depending on the circumstances, the NRC may exercise this responsibility in various ways, but the principle remains. This may need to be clarified in the final document so that the public does not get the wrong impression.

Page 2: [1] Comment [NRC3] **NRC** **11/12/2014 11:23:00 AM**

Typical for all discussion on gap assessment.

The scope of RG 1.200 and the PRA Standard is mostly associated with “what to do” or “what should be included in a PRA of a certain capability,” while methods (and associated technical bases/guidance) are more in the category of “how to do.” A method might meet the “what to do” standard, but be inadequate in the “how it does” that aspect or it might be determined to be acceptable as a simplified approach meeting Capability Category (CC) 1, but not achieve CC 2. The discussion should include language that the expectation of the panels (vetting, peer review, or methods) is to review the technical adequacy of the method (including, potentially, how it might achieve specific CCs); not just that it comports with RG 1.200 and the PRA Standard. The distinction is the level of review of the technical basis of the method and detail needed for each type of review (vetting – high-level [more a confirmatory check], peer review – more detail considering the technical basis, methods panel – much more detailed looking intently at the technical basis).

Page 2: [2] Comment [NRC5] **NRC** **11/12/2014 11:26:00 AM**

The text references a “peer review,” but in the chart it is “Industry/NRC peer review” in all cases, except under the B path where only “peer review” is used. Through the vetting process the NRC will become aware of a new method, but there needs to be some means of gaining acceptance, of all new methods (see next comment). One approach, which may be reflected in the chart but would need to be added to the text, might be to include the NRC on peer reviews that are addressing new methods, solely for that aspect, to provide some awareness and assurance that the new method has an accepted technical basis and that future applications that use the method won’t fall into question since the NRC may not be fully aware of the outcome of the peer review without such an interaction. Further, the peer review would need to specifically identify the new method and the results of its review as part of their documentation.

Page 2: [3] Comment [NRC6] **NRC** **11/12/2014 11:19:00 AM**

The purpose of the methods panel should be to evaluate the technical merits/adequacy of the proposed methods; not to develop an acceptable new method. These aspects (review versus development) should be separated activities. If a methods panel determines that a method is not acceptable or that the technical basis has not been adequately presented, it should document that outcome and provide it to the process originator for consideration/revision, etc. If the originator has additional questions regarding the rejection or wants support in further developing the technical basis for the new method, then that should be done outside the panel process; also noting that if panel members subsequently work on the refinement, they then would be excluded from a future panel review of that method due to a conflict of interest (note that this independence is not stated and should be in the context of all the method pathways). This was the major lesson learned of the initial EPRI/NRC methods panel process; instead of making relatively quick decisions on the adequacy of new methods and their technical bases, they turned into developmental panels that lasted more than a year.