

November 30, 2006

MEMORANDUM TO: John D. Monninger, Deputy Director for
Probabilistic Risk and Applications
Division of Risk Assessment and Special Projects
Office of Nuclear Regulatory Research

FROM: Mary T. Drouin */RA/*
Probabilistic Risk and Applications
Division of Risk Assessment and Special Projects
Office of Nuclear Regulatory Research

SUBJECT: STAFF RESPONSE TO PUBLIC COMMENTS ON DRAFT
GUIDE-1161 (REVISION 1 TO REGULATORY GUIDE 1.200,
“AN APPROACH FOR DETERMINING THE TECHNICAL
ADEQUACY OF PROBABILISTIC RISK ASSESSMENT
RESULTS FOR RISK-INFORMED ACTIVITIES”)

Draft Guide (DG) 1161 was issued for public review and comment in September 2006. The review period closed on October 14, 2006. Comments were received from the following stakeholders:

- Nuclear Energy Institute (which also included formal comments for PWR Owner’s group)
- BWR Owner’s Group
- RBR Consultants, Inc.
- ASME Committee on Nuclear Risk Management

The comments from the stakeholder are grouped as follows:

- Comments that the staff is in agreement with, and the DG was revised accordingly.
- Comments that are more observations and do not require any revision to the DG.
- Comments that the staff is not in agreement with and no revision was made to the DG.
- Comments that are format or of a technical edit nature, and where appropriate, the DG was revised.

CONTACT: Mary T. Drouin, RES

J. Monninger

-2-

301-415-6675

The enclosure provides all the stakeholder comments. A staff response is provided for each comment. The staff response describes either (1) how the DG was revised for those comments with staff agreement, or (2) why the DG was not revised for those comments with staff disagreement or the staff did not believe a revision was needed.

Enclosure:

As stated

cc:

F. Eltawila

G. Parry

M. Tschlitz

D. Harrison

J. Monninger

-2-

The enclosure provides all the stakeholder comments. A staff response is provided for each comment. The staff response describes either (1) how the DG was revised for those comments with staff agreement, or (2) why the DG was not revised for those comments with staff disagreement or the staff did not believe a revision was needed.

Enclosure:
As stated

cc:
F. Eltawila
G. Parry
M. Tschlitz
D. Harrison

C:\FileNet\ML070040474.wpd

OAD in ADAMS? (Y or N) Y ADAMS ACCESSION NO.: ML 070040474 TEMPLATE NO. RES-006
Publicly Available? (Y or N) Y DATE OF RELEASE TO PUBLIC _____ SENSITIVE? N

To receive a copy of this document, indicate in the box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

OFFICE	RES/PRA	
NAME	MDrouin	
DATE	11/17/06	

Staff's Response to Public Comments on DG-1161 and SRP 19.1

Listed below are the comments (as actually written) that were submitted by stakeholders on Draft Guide (DG-1161) and Standard Review Plan (SRP) 19.1 (Ref. 1). A staff response is provided below to each individual stakeholder comment.

In the stakeholders comments and the associated staff response, the word "requirement" is used. This term is used with regard to a consensus standard (e.g., ASME PRA standard) which is written in terms of "requirements." The use of this word is standards language (e.g., in a standard, it states the standard "sets forth requirements") and is not meant to imply a regulatory requirement.

A. Comments from NEI (Ref. 2)

1. The regulatory guide needs an implementation period of one year from the date of issuance of the final version. Issuance of Regulatory Guide 1.200 for trial use was necessary to resolve issues of interpretation and to clarify regulatory expectations regarding use of PRA standards. Use of this trial regulatory guide was limited to five pilot plants. Now that the pilot process has been completed and results of that effort communicated, the remaining plants will need time to complete PRA self assessments and make determinations relative to their PRA capability to support future regulatory applications. For regulatory applications submitted to NRC before the one year implementation period, the current process for addressing PRA adequacy should be followed.

Staff Response –

Comment is an observation with regard to the regulatory guide (RG), a revision to the RG was not needed and no change was made to the RG. Implementation of the RG is addressed in the staff's plan for Phased Approach to PRA Quality (SECY-04-0118).¹ (Ref. 3)

2. Appendix B to DG-1161 provides NRC's position on NEI 00-02, the NEI document describing the PRA peer review process. This Appendix notes that "The stated positions are based on the historical use of NEI 00-02 and on the performance of a self-assessment to address those requirements in the ASME PRA Standard ".....that are not included in the NEI subtier criteria." We believe these regulatory positions are confusing and need not address the historical use of NEI 00-02. NEI 00-02 was created as a voluntary industry process to address PRA technical adequacy and its development and use predated the concept of consensus PRA standards. NRC has agreed that the existing (historical) PRA peer reviews, performed to NEI 00-02, may be credited for meeting the peer review requirement of Section 5 of the ASME standard. Thus, it is not logical to provide regulatory "clarifications" and "qualifications" that appear to question the original peer review process. An example is the following:

¹SECY-04-0118 is being updated with a revised schedule for the implementation of RG 1.200, Revision 1.

2.3 PRA Peer Review Team	Clarification	<p>The peer reviewer qualifications do not appear to be consistent with the following requirements specified in Section 6.2 of the ASME PRA Standard:</p> <ul style="list-style-type: none"> • the need for familiarity with the plant design and operation • the need for each person to have knowledge of the specific areas they review • the need for each person to have knowledge of the specific methods, codes, and approaches used in the PRA <p>The NEI self-assessment process needs to address the peer reviewer qualifications with regard to these factors.</p>
--------------------------	---------------	--

The original peer reviews are complete and the peer reviewer qualifications from Section 6.2 of the ASME standard did not exist when these peer reviews were performed. This clarification suggests that credit may not be taken for the original peer reviews because the reviewer qualifications of a standard created years later were not met. This contradicts NRC's overall position that the original peer review process can be credited.

The discussion in the "commentary/resolution" column of DG-1161, Table B-1, relative to Sections 1 through 5 and Appendices A through C of NEI 00-02 adds no value, because the self assessment process described in Appendix D of NEI 00-02 Revision 1 already recognizes the additional steps and actions necessary to use the original peer review results. An example is the following:

1.1 Overview and Purpose	Clarification	<p>The NEI process uses "a set of checklists as a framework within which to evaluate the scope, comprehensiveness, completeness, and fidelity of the PRA being reviewed." The checklists by themselves are insufficient to provide the basis for a peer review since they do not provide the criteria that differentiate the different grades of PRA. The NEI subtier criteria provide a means to differentiate between grades of PRA.</p> <p>The ASME PRA Standard(with the staff's position provided in Appendix A to this regulatory guide) can provide an adequate basis for a peer review of an at-power, internal events PRA (including internal flooding) that would be acceptable to the staff. Since the NEI subtier criteria do not address all of the requirements in the ASME PRA Standard, the staff's position is that a peer review based on these criteria is incomplete. The PRA standard requirements that are not included in the NEI subtier criteria (identified for a Grade 3 PRA in Table B-3) need to be addressed in the NEI self-assessment process as endorsed by the staff in this appendix.</p>
--------------------------	---------------	--

This and other NRC clarifications in Table B-1 are redundant, as the actions to address them are fully enveloped by the process and elements of Appendix D. Industry believes the original peer reviews were a proactive process that added significant value and were a precursor to the standards development activity. There is little value added by NRC critiquing this voluntary industry process with the benefit of hindsight. We thus recommend that Table B-1 (the regulatory positions on Sections 1 through 5 and Appendices A through C of the original NEI 00-02 process) be deleted. The staff need not take a regulatory position on the original peer review process, other than to note that it is acceptable for use in addressing Regulatory Guide 1.200, given the additional actions provided in NEI 00-02 Appendix D (as endorsed by NRC). Following the promulgation of Regulatory Guide 1.200, the original peer review process is not expected to be used, as it is essentially superseded by the Regulatory Guide.

Staff Response –

The ASME standard requires (1) that a peer review process be developed and provides criteria that the process needs to meet, and (2) states that NEI-00-02 provides an acceptable peer review process. It is recognized that peer reviews were performed prior to the development of the standard, and for those peer reviews, the staff objections are not meant to be applied to previous reviews and the RG has been revised to clarify the staff objection. However, there may be users of the standard who use the peer review process in the future (since it is endorsed in the standard); therefore, a staff position on the process is needed.

3. Tables B-2 through B-4 provide the NRC position on Appendix D to NEI 00-02. This new appendix to NEI 00-02 provides the self assessment process, comparison table, and the subtier (grading) criteria. We have reviewed the clarifications and believe that a number of them can be addressed through a simple revision to NEI 00-02 Appendix D. We will provide a revised Appendix D to NRC by October 31 and request that NRC use this version as the basis for Appendix B of the final Regulatory Guide 1.200.

Staff Response –

NEI submitted an updated version to NRC on November 15, 2006 (Ref. 4); the staff's position in Appendix B to RG 1.200, Revision 1, is based on this NEI update.

B. Comments from PWR Owners (Ref. 5)

4. There needs to be an implementation window once DG-1161 is released as RG 1.200, Rev. 1. This implementation period would permit licensees to modify their PRAs to be in compliance with those portions of RG 1.200 (ASME PRA Standard) to support planned risk-informed applications. This implementation period is needed for two reasons:
 - a. For risk-informed applications already submitted or planned to be submitted in a short period of time, there was no requirement to use ASME PRA Standard (as endorsed by RG 1.200, Rev. 1). An implementation period would permit these applications to be “worked off” as licensees are modifying their PRAs.
 - b. Since Rev. 0 was released for trial use, which meant the five pilot RG 1.200 plants, the remaining licensees were reluctant to make changes against a document that had not yet been finalized. With Rev. 1 being issued and lessons learned available from the pilot plants, the licensees can confidently modify their PRA to support their intended risk-informed applications against the final version of the Reg. Guide.

It is recommended that the implementation be at least one calendar year.

Staff Response –

Comment is an observation with regard to the regulatory guide (RG), a revision to the RG was not needed and no change was made to the RG. See staff response to Comment #1.

5. The core damage frequency (CDF) definition provided in Section 1.1 matches the clarification for the definition of CDF in Table A-1 (Appendix A). However, the large early release frequency (LERF) in Section 1.1 does not match the definition in Chapter 2 of the ASME PRA Standard, and there is no clarification in Appendix A of DG-1161,

creating an inconsistency in the definitions.

Staff Response –

The staff agrees with the comment and the RG was revised accordingly.

6. The definition in footnote 5 (Section 1.2.6 of DG-1161) for “key assumption” does not match the definition in Chapter 2 of the ASME PRA Standard and there is no clarification in Appendix A of DG-1161, creating an inconsistency in the definitions. Note that the definition for “key source of uncertainty” (footnote 4 of Section 1.2.6) does match the Chapter 2 definition.

Staff Response –

The staff has included a clarification in Appendix A for both “key assumption” and “key source of uncertainty.” A “key” assumption or source of uncertainty for the base PRA is independent of the application. This clarification has been added to RG 1.200 in Section 3.3.2 and the staff objection in Appendix A for the definitions in the standard.

7. In Section 2.1, on the bottom of page 22 of DG-1161, it is stated that standard “technical requirements address the technical elements of the PRA and what is necessary to adequately perform that element.” This statement does not recognize that some requirements are not necessary to be met (e.g., performed) as a function of the risk-informed application being supported. Further, the ASME PRA Standard permit alternative methods in lieu of “satisfying” a specific requirement.

Staff Response –

The staff disagrees with the comment and no change was made to the RG. For a baseline PRA, all the elements defining a technically acceptable PRA and their associated attributes need to be met. Regulatory Position 1 provides the criteria for a baseline PRA. Regulatory Position 3 recognizes that some parts of the PRA are not needed for an application, and therefore, the criteria for those parts do not need to be met. Further, the standard states that use of alternate methods is outside the scope of the standard.

8. Section 2.2 (first paragraph) states that “a peer review process is provided in the ASME standard and in the industry-developed peer review program (i.e., NEI 00-02).” While NEI 00-02 indeed does provide a peer review process, the ASME PRA Standard only provides requirements for such a process, and not the process itself. This language should be modified.

Staff Response –

The staff agrees with the comment and the RG was revised accordingly.

9. Table 5: “... the interim and final results...” - It is not clear what “interim results” are intended to be documented. It is a challenge to provide adequate documentation for final results. It would be an unnecessary and unproductive burden to ask for documentation of the number of interim results that are produced in the process of performing a risk assessment.

Staff Response –

The staff agrees that the staff position is not clear. The statement is not meant to imply all interim results, only those needed to provide the necessary traceability of the final results. Clarification has been added to the RG.

10. Review of Standard Review Plan Chapter 19.1: There is a factual error in the second paragraph of the Introduction. The American Nuclear Society (ANS), and not the American Society of Mechanical Engineers (ASME), has the lead for the development of the Level 2 PRA and Level 3 PRA Standards. It is expected that the Standards will be published with both society logos.

Staff Response –

The staff agrees with the comment and the SRP was revised accordingly.

11. Appendix A, Table A-1, Global Comment: The comment that the staff provides no position on any reference in the standard is unnecessary. None of the references are part of the requirements in the Standard. They are provided primarily as a help to the user. If the NRC staff identifies references they consider inappropriate (i.e., dated) that are included, those should be specifically identified.

Staff Response –

The staff disagrees with the comment. There are several places in the standard where a reference is provided as an example for an acceptable means of meeting a requirement. That is, if the reference is used, the associated requirement in the standard is met. The staff has not reviewed every reference for its acceptability in meeting the associated requirement in the standard. The staff position remains and no change has been made to the RG.

12. Specific comments on Appendix A, Table A-1:

<u>Section</u>	<u>NRC</u>	<u>Resolution Comment</u>	<u>Staff Response</u>
1.1	Addition of the word current	This clarification is not necessary and could be limiting. The term current is ambiguous. Does it apply only to currently built and operating or include new plants of virtually the same design? Other designs have been using parts of the standard. If NRC wants to limit its endorsement, this should be clarified in the text of the Regulatory Guide.	<i>The staff disagrees with the comment. The staff objection was meant to mean “operating” reactors, the staff objection has been clarified. While parts of the standard are applicable to other reactor designs or for a PRA at the design stage, all the requirements in the standard may not be applicable (i.e., sufficient or adequate) and revisions may be needed. This acknowledgment needs to be in the standard. The staff position remains. However, clarification was added to clearly state the staff position.</i>
2.2			
Core damage	Added parenthetic	Clarification is not acceptable. A fairly small release of fission	<i>The staff disagrees with the comment. An explanation is</i>

<u>Section</u>	<u>NRC</u>	<u>Resolution Comment</u>	<u>Staff Response</u>
	phrase	products from the containment could produce calculated offsite health effects of some magnitude. This definition has not previously been a concern in peer reviews. Typical criteria for core damage have been based on reaching some temperature. See SC-A2.	<i>needed for the word "significant." The staff objection remains and no change was made to the RG.</i>
Extremely rare event	Parenthetic example (1E-6/yr)	Clarification is not acceptable and unnecessary. Referencing world reactors adds confusion to a definition that has been successfully used in the past. If a value is used as an example, it should refer to a specific plant frequency, not worldwide incidence.	<i>The staff agrees with the comment and the RG was revised accordingly.</i>
Internal event	Deleted internal fire	Unacceptable unless the text of the Standard is changed because the text of 1.2 Applicability relies on the current definition. Furthermore, while the existing treatment may not make common sense, NRC has clearly, historically identified "internal fires" as "external events" - see IPEEE (examination of external events). Ultimately, it doesn't matter where fires are classified.	<i>The definition of an internal event has changed over time. Historically, an internal event was defined as an event internal to the component boundary. The definition has changed to be an event internal to the plant boundary. Further, the NRC has not, historically, been consistent in defining internal fire as either an internal or an external event.</i>
Rare event	Parenthetic example. (1E-4/yr)	See comment to Extremely Rare Event	<i>The staff agrees with the comment and the RG was revised accordingly.</i>
3.6	Deletion of the word "safety"	It appears that this is taken from a reference document. If so, the word should be retained. Another reason for retention is that other uses of PRA exist where a component is significant (e.g., economics).	<i>The staff agrees with the comment and the RG was revised accordingly.</i>
4.3.3	Changing "should" to "shall"	This is a qualification not a clarification. The word "should" has appeared in all previous issues of the standard. Unless this change was raised in previous issues of the Regulatory Guide, it is not acceptable to qualify it here.	<i>The staff has had this objection since the initial version of the standard (see RG 1.200 Issued for Trial Use). The staff position remains and no change has been made to the RG. See staff response to Comment #66.</i>

<u>Section</u>	<u>NRC</u>	<u>Resolution Comment</u>	<u>Staff Response</u>
IE-A4	Added words "down to subsystem/train level"	Should be considered a qualification and is a significant change in the requirement. Unless this change was raised in previous issues of the Regulatory Guide, it is not acceptable to qualify it here. Also appears ambiguous -- does the "/" mean "either-or" or "and?"	<i>The staff has had this objection since the initial version of the standard (see RG 1.200 Issued for Trial Use). The staff disagrees that the staff clarification is a significant change. It defines what is meant by "system." The staff clarification has been revised to remove the ambiguity associated with "/."</i>
IE-A4a	Addition of system alignments	Not a clarification and adds to scope of this SR. Unless this change was raised in previous issues of the Regulatory Guide, it is not acceptable to qualify it here.	<i>The staff disagrees with the comment. IE-A4a is a new requirement. The staff disagrees that it adds to the scope; it clarifies what is meant by "system alignment." The staff position remains and no change has been made to the RG.</i>
SY-A22	Added phrase	This clarification assumes that a new SR DA-D8 will be added.	<i>A new SR, DA-D8, needs to be added; see staff position on DA-D8.</i>
SY-B15	Added containment venting or failure	Recommend clarifying the clarification. Add to end "that may occur prior to the onset of core damage." There are very few sequences that would contribute to this category, but it is possible.	<i>The staff agrees with the comment and the RG was revised accordingly.</i>
HR-A1	Added parenthetical "inspection"	Would be better to include inspection in series; it is not a subset of testing or maintenance, i.e., "..... those test, inspection, and maintenance....."	<i>The staff agrees with the comment and the RG was revised accordingly.</i>
HR-E2	Added "diagnose"	Clarification not necessary. Skill of the craft to recover obviously requires diagnosis. Do not see value in adding this since it could imply a separate, documented step in the recovery process increasing response time.	<i>The staff disagrees with the comment. The clarification is needed so that there is no ambiguity or confusion that the action is both diagnosis and recover. The staff position remains and no change has been made to the RG.</i>
HR-G3	Added words	Not clear that the additions help or limit the intent of the performance shaping factors. Clarity of cues could affect more than just meaning, complexity of the required response seems to be the specific objective of this PSF. Determining the need is	<i>The staff disagrees with the comment. The staff still believes that the clarification is needed so that there is no ambiguity that the meaning of the cues is clearly assessed. Other aspects such as the man-machine interface are dealt with in Item #e The staff</i>

<u>Section</u>	<u>NRC</u>	<u>Resolution Comment</u>	<u>Staff Response</u>
		redundant at least for Categories II and III because it is imbedded in the other items, e.g., "clarity of cues."	<i>position remains and no change has been made to the RG.</i>
QU-F2		Recommend clarifying the clarification. The resolution edits this SR to read, "the significant basic events causing accident sequences to be non-significant", but non-significant sequences will not have significant basic events (as defined in the Standard). This should be edited: "the equipment or human actions that are the key factors causing accident sequences to be non-significant."	<i>With regard to the comment specific to the referenced staff objection, the staff agrees and the RG has been changed accordingly. The staff disagrees that non-significant sequences will not have significant basis events (as defined in the Standard). The definition includes both a FV and RAW measures to identify significant basis events.</i>
LE-C1	Removal of word "acceptable"	With the word removed the change appears to be a qualification. The deleted text contained an important word, "acceptable." The Standard needs to be clear here that NUREG/CR-6595 "discussion and examples" provide an acceptable definition(s) of LERF source terms.	<i>The staff disagrees with the comment. NUREG/CR-6595 provides a discussion and examples of different definitions of LERF source terms. The staff objection remains and no change has been made to the RG.</i>
6.3	Changes guidance to requirement	The Standard provides a combination of requirements and recommendations to guide the peer review team. For all elements except Initiating Events, where the entire element is required to be reviewed, a list of typical elements for review is included. However, these are treated as suggestions and "are not intended to be a minimum or comprehensive list of requirements." The Staff proposes to treat these lists of review topics as requirements for the peer review. The PWROG disagrees with this proposed change, believing that it goes beyond the intent of a "peer review" (i.e., is more like a checklist audit) and is too prescriptive an instruction to be mandated for use by a competent team of reviewers. There is concern that this could be counterproductive by forcing	<i>The staff disagrees with the comment. The list provided in the standard is a high level list and is not prescriptive. However, as written in the standard, it is completely open to the reviewer to decide what to review (e.g., a peer reviewer could decide not to review any support system fault trees). There needs to be minimal high level list of the items (or topics) that the peer reviewer must examine. The peer reviewer has the flexibility in determine how to review the minimal list of topics (e.g., which support systems) to review and the level of detail to pursue. The staff objection remains and no change was made to the RG.</i>

<u>Section</u>	<u>NRC</u>	<u>Resolution Comment</u>	<u>Staff Response</u>
		the peer review team to examine and document items that they know through experience are reasonable and at the same time limit the time they can spend on areas appearing questionable.	
6.6.1	Added documentation elements: (k) and (l).	(k) Assessment of key assumptions is essentially covered in item (g) (l) The Standard does not provide for Peer Review Grades. NRC should recognize that grading is outside the scope of this Standard and address it separate from the endorsement of this Standard. This clarification seems to be based on an earlier version of the Standard or a previous NRC recommendation.	<i>The staff agrees with the comments (i.e., on Item #k) and has revised the RG accordingly.</i>

13. DA-C14: The issue raised for this SR does not need a qualification. The issue could be considered as a clarification; however, sufficient requirements already exist to address plant-specific and generic data. Consider, for example, DA-C1 through DA-C4 and DA-D1, DA-D3, and DA-D4. A specific topic on identification and collection of plant-specific or industry data on repair time is sufficiently addressed by other requirements.

Staff Response –

The staff does not agree that this topic is addressed in DA-C1, etc. Those SR do not address data on repair. The staff objection remains and no change has been made to the RG.

14. DA-D8: A new requirement is not needed. Quantification is addressed in other requirements, including DA-D1, DA-D3, and DA-D4. An additional requirement would be redundant. Note that requirement LE-C2b needs to be changed to delete the reference to requirement DA-D8, as well as clarification for SY-A22 and DA-C14.

Staff Response –

The staff disagrees with the comment, the new requirement specifies the need for accident sequence specific assessment of failure to repair. See staff response to Comment #13 on DA-C14.

15. IF-C3b: This qualification would create a situation for which data are difficult to obtain. Further, current use of compensatory actions would obviate the concern for any increase in risk contributions. At best, this qualification should be included only in Capability Category III.

Staff Response –

The staff disagrees with the comment and believes that the potential for structural failure from barrier unavailability is a current, good practice, not state-of-the-art. The staff objection remains and no change was made to the RG.

16. Appendix B, NRC position on the NEI peer review process: Table B-5 specifically addresses the NRC regulatory position on NEI 05-04 (Follow-on Peer Review Process), which is completely new to DG-1161.

The clarification of the fifth paragraph of Section 3.0 indicates that a “PRA reviewed against the standard must satisfy all HLRs.” Further, the clarification notes that to meet an HLR, “all SRs under that HLR must meet the requirements of one of the three Capability Categories.” The necessity to meet (or not) individual HLRs and SRs are driven by the supported risk-informed application. There is no requirement in the ASME PRA Standard or for any peer review that **all** HLRs and **all** SRs must be met. The purpose of the peer review is to determine where on the continuum (if at all) the subject PRA is – what is done with that information is to support a particular (or many) risk-informed applications. The staff is offering more than a clarification and obscuring the purpose of a follow-on peer review.

Staff Response –

The staff disagrees with the comment. The original peer review is performed independent of an application; it is a peer review of the base PRA against the standard. The peer reviewer determines whether a supporting requirement is met or it is not met regardless of the application; however, for an application, the analyst will justify whether a specific requirement is needed to support the decision. The peer review performed as part of a PRA upgrade may take into consideration an application in determining the significance of an HLR or an SR that has not been met. The staff objection remains and no change was made to the RG.

C. Comments from H. Specter (Ref. 6)

17. General comments

It is stated that CDF and LERF are surrogates for latent and early fatality risks, respectively. This actually is not the case. There are core damage events, like the accident at TAI, which do not have any substantial release, and therefore do not relate to the latent fatality risk. More appropriate metrics would be the frequency of containment failure or, better, the frequency at which substantial amounts of the reactor's inventory of radioactive cesium is released to the environment. In general, BARS have CDFs that are about an order of magnitude smaller than a typical PWR, but their contribution to the latent fatality risk is about the same. Therefore CDFs alone do not correlate with latent risks.

The situation with LERFs in some ways is even more out of place. The LERF criteria are likely two orders of magnitude smaller than the LERF that would challenge the early fatality safety goal. The delta LERFs that are part of Reg Guide 1.174 are perhaps three orders of magnitude smaller than what which would challenge the early fatality safety goal. It would be instructive if the NRC did an uncertainty analysis of PRA calculated LERFs and then compared the width of the uncertainty band to the acceptable delta

LERFs in Reg. Guide 1.174. Calculated LERFs are subject to uncertainties stemming from operator actions, initiating event frequencies, equipment performance data, numerous assumptions, phenomenological data uncertainties, etc. If the basis for a regulatory decision, such as to accept or reject a proposed change to the licensing basis of an operating power plant, is based on a certain sized delta LERF, yet this delta LERF itself is considerably smaller than the uncertainty in the base LERF value from which it is a departure, then, I believe, the whole regulatory decision making process is in need for a review.

The whole regulatory process might be better served if the staff just said that it wants to use two deterministic metrics as part of its overall sense of defense- in- depth: CDF and cesium release to the environment frequency and just set aside any reference to safety goals or LERF(see below).

Staff Response –

This comment is beyond RG 1.200. It is a comment on the Commission's approved policy of using CDF and LERF as risk surrogates to the Commission's latent and early fatality goals, respectively. As such, this comment is more of an observation and no change has been made to the RG.

18. To be consistent with the definition of core damage frequency on page 7, the LERF definition should start with " Large early release frequency is defined as the sum of the frequencies of those accidents....."

Staff Response –

The staff agrees with the comment and the RG was revised accordingly.

19. The LERF concept traces back to the Early Fatality Safety Goal. If so, the use of the term "early health effects" is too broad because it includes both early fatalities and early injuries. There is no NRC early injury safety goal and any plant that met the early fatality safety goal would easily meet a similar early injury safety goal, if one existed. For Reg, Guide 1.200 purposes it is important not to use the words early health effects as this would be inconsistent with the history of LERF and other regulatory policies.

There are many potential early injury consequences, some of which might require hospitalization and many which do not. For example, there are whole body doses that exceed 50 rem, the threshold for early injuries, that might require some form of medical treatment within a year of exposure. There are also other lesser potential early health effects, such as skin erythema, transepidermal skin effects, hypothyroidism from 200 rems or more of thyroid- H doses, thyroiditis, prodromal vomiting, diarrhea, and pneumonitis from a 500 rem or more lung dose. Not only are there many potential lesser early health effects, they have different thresholds...some of which are controversial..., different geographic ranges over which they might exist... are a function of the emergency response that one assumes is taken, as well as the medical treatment assumed. A further source of potential complexity is whether or not one takes the mean, 90%, 99% or peak consequence numbers in determining if a particular health effect has a non-zero value. Opening the door to evaluations of early injuries as part of the determination of the LERF could invite endless debate.

So for both historical reasons and for practical implementation reasons the words in the draft rev.1 should be narrowed to read "early fatality effects".

Staff Response –

See staff response to Comment #17.

20. A much larger concern is the difficulties with connecting large early releases to offsite responses. If this is done then there is the possibility that much of the calculation of LERFs will shift away from using PRA to determine plant characteristics to offsite consequence analyses. If this occurs then the value of PRA in the regulatory decision making process would be greatly diminished. For example, ongoing emergency planning studies at the Indian Point site show that size and speed of the evacuating population depends on whether or not the release of radioactive material starts at night or during the weekend versus mid-day, mid-week. The night time and weekend population is approximately two thirds of the mid-week population. Not only are fewer people at risk at night or during the weekend, they would evacuate at higher speeds and their early health consequences would be lower. There are also more night time and weekend hours than weekday hours and this should be accounted for. Does the NRC want calculations of LERF to be affected by assumptions of when a release occurs?

Similarly, the present definition of LERF makes reference to the ability of having an effective evacuation in a particular time frame. However, under severe weather conditions, such as snow storms, it might be advisable to shelter until the roads are cleared and then evacuate. Sheltering, particularly accompanied by actions to reduce inhalation doses, can be very effective. One can easily envision a shelter first, evacuate later response that took longer but was more effective than a prompt evacuation into a snow storm that was slower. There is no numerical or verbal definition of what constitutes an effective evacuation. The choice of just an evacuation response in the Reg. guide draft is too narrow and is inconsistent with ongoing emergency planning analyses.

Consider also the situation where there are two identical plants, except that one sits on a site that has essentially no one within one mile of the plant and the other plant has people in this nearby area. As things stand now, one plant would have a different LERF than another, even though they would be otherwise identical. Perhaps this is appropriate, but it means that, in the extreme, low nearby population sites have near zero LERFs independent of plant characteristics or their PRA results. Is this the direction that Reg. Guide 1.200 should lead us to?

Even containment bypass events and loss of containment isolation events have issues that are likely to surface if one goes forward with the present definition of LERF. For example, some source term analyses of particular bypass events that have a pathway through the auxiliary building give a factor of ten credit for source term (assumedly radioactive iodine) reduction in that structure. I assume that this factor of ten is just due to plateout phenomena. Since bypass events themselves, as well as containment isolation events are, in general, quite rare, an additional factor of ten reduction in the iodine would almost certainly make them risk insignificant. Some bypass and loss of isolation sequences might trigger fire protection spray systems as the escaping steam heats up confined areas. If the fire protection sprays are operating then the source terms would be greatly reduced. Are such systems to be credited in a LERF calculation and, if so, are these spray systems to be now considered safety systems, assuming that

they were not so labeled already? Does the NRC staff really want to get into such discussions with the nuclear industry? Personally, I would encourage such discussions.

Some of the issues that I have raised are not new to the regulatory process. In the past extremely artificial offsite responses were assumed to overcome site -to- site differences, such as assuming that someone stays at a prescribed location for a specific period of time before taking a specific protective measure. Such artificial offsite prescriptions can create more problems than they solve.

One of the more important observations to emerge from the ongoing Indian Point emergency planning studies is that, even assuming a conditional large release probability of 1.0, the early fatality risk is near zero for the country's most highly populated site. This is because the consequences, i.e., the number of early fatalities, are near zero. This very small value is principally due to the size and timing of the source term and to offsite emergency actions. Clearly, if the early fatality consequences at this most challenging site are near zero, then its LERF value would be extremely small, likely too small to be an important regulatory tool.

Significant new analyses on emergency planning are now fairly mature and are expected to be under discussion at the NRC over the next several months, including the new emergency planning effort at the Indian Point site, NRC/Sandia emergency planning studies and possibly other studies underway at NEI and EPRI. I suggest that those staff members involved in the further development of Reg. Guide 1.200 track these efforts closely so that the implications of advanced level three analyses on their work are fully understood and well coordinated with the development of Reg. Guide 1.200.

Staff Response –

See staff response to Comment #17.

21. Another approach to defining LERF, also prescriptive but based on observations made in the Indian Point emergency planning analysis, may be somewhat better in that it avoids the potential debates on offsite responses and consequences. One might consider all sequences that might release 5% or more of the core's radioactive iodine into the environment within three hours after the initiation of events that might lead to a core melt. The sum of all such sequences would be the LERF. This is not perfect either, but it would restore the importance of PRA in the regulatory process in terms of calculating the frequency of large early releases. It is also quite conservative in that near zero early fatalities are being calculated at Indian Point for releases of 11% of the reactor's inventory of iodine into the environment within two hours of the start of a core melt sequence.

If this revised definition were accepted, then the definition might read as " The large early release frequency is defined as the sum of the frequencies of those accidents that result in the release of 5 percent or more of the reactor's inventory of iodine into the environment within three hours of the initiation of a core melt sequence."

Staff Response –

See staff response to Comment #17.

D. Comments from ASME (Ref. 7)

22. Section 1: NRC proposed Clarification: No change. Potential users of the Standard may wish to apply portions of it to other reactor types or advanced LWRs until such time as more directly applicable PRA standards are available. Further, the proposed insertion of the word “current” becomes problematic as the Standard is updated.

Staff Response –

The staff disagrees with the comment. See staff response to Comment #12 on 1.1. The staff clarification indicates to potential users that the entire standard, as written, can be used; however, since its focused is for operating light water reactors, the requirements may not be sufficient or adequate for other than operating light-water reactors. The user may need to revise and augment the standard, as appropriate for these other reactors.

23. Section 2.2: Proposed changes to definition of Core Damage: ASME is generally not in favor of the proposed change since it introduces Level 2 PRA considerations. However, it was recommended that this clarification be considered during a future discussion by the ASME CNRM.

Staff Response –

The staff disagrees with the comment. See staff response to Comment #12 on definition of core damage.

24. Section 2.2: Proposed change to definition of Extremely Rare Event: proposed change is acceptable (and should be incorporated into the Standard) if the example is changed to be “/reactor-year” instead of “/yr”. Otherwise it is inconsistent with the requirements.

Staff Response –

The staff agrees with the comment, see staff response to Comment #12 on extremely rare event.

25. Section 2.2: Proposed change (qualification) to definition of Internal Event: No change. The existing wording reflects current common practice. The suggested change could be viewed as implying an inconsistency in the existing version of the Standard.

Staff Response –

See staff response to Comment #12 on internal event definition.

26. Section 2.2: Proposed change to definition of PRA Upgrade: The suggested change would be acceptable with the deletion of the words “have the potential to”. ASME recommends revising the definition in the Standard to read: “The incorporation into a PRA model of a new methodology, or changes in scope or capability that impact the significant sequences. This could”. Additional clarification per the planned Maintenance vs. Upgrade Guidance appendix to RA-S-2002 may also need to be included.

Staff Response –

The staff agrees with the comment and the RG was revised accordingly.

27. Section 2.2: Proposed change to definition of Rare Event: proposed change is acceptable (and should be incorporated into the Standard) if the example is changed to be “/reactor-year” instead of “/yr”. Otherwise it is inconsistent with the requirements.

Staff Response –

The staff agrees with the comment, see staff response to Comment #12 on rare event.

28. Section 2.2: Proposed change to the reference in the definition of Reactor-year: The noted clarification is correct. This change should be incorporated into the Standard.

Staff Response –

The comment agrees with the staff position, no change to the RG is needed.

29. Section 2.2: Proposed change to the reference in the definition of Reactor-operating-state-year: The noted clarification is correct. This change should be incorporated into the Standard.

Staff Response –

The comment agrees with the staff position, no change to the RG is needed.

30. Section 2.2: Proposed change to the definition of Resource Expert: The noted clarification is acceptable, and the change should be made to the Standard.

Staff Response –

The comment agrees with the staff position, no change is needed to the RG.

31. Section 2.2: Proposed new definition for Significant Contributor: ASME recommends that this definition be considered during a future discussion by ASME CRNM.

Staff Response –

The comment agrees with the staff position, no change is needed to the RG.

32. Section 3.5: The proposed clarification to the second paragraph in Section 3.5 is acceptable, and the change should be made to the Standard.

Staff Response –

The comment agrees with the staff position, no change is needed to the RG.

33. Section 3.6: The proposed clarifications should not be implemented in the Standard. Reference to “safety significance” is correct, as this is a reference to terminology used in the code cases that are the examples used in this section.

Staff Response –

The staff agrees with the comment, see staff response to Comment #12 on 3.6.

34. Section 5.4: The proposed change, to delete the clause referring to prioritization, is acceptable and should be made to the Standard.

Staff Response –

The comment agrees with the staff position, no change is needed to the RG.

35. Section 5.8: There was not complete agreement that the proposed changes is needed. However, ASME will consider this further if Section 5 is revised.

Staff Response –

This comment is more an observation and as such, no change was made to the RG.

36. Section 6.1: After substantial discussion, there is no clear consensus within ASME regarding acceptance of the proposed clarification. The ASME CNRM Applications Subcommittee has appointed a working group to consider possible changes to Section 6, and this clarification will be referred to that group for further consideration. The term Key Assumption was not included in the definitions or other requirements when this section was last considered by CNRM.

Staff Response –

This comment is more an observation and as such, no change was made to the RG. In addition, see staff response to Comment #6.

37. Section 6.3: After substantial discussion, there is disagreement regarding acceptance of the proposed clarification. The ASME CNRM Applications Subcommittee has appointed a working group to consider possible changes to Section 6, and this proposed clarification will be referred to that group for further consideration. However, this issue has been considered previously by CNRM, and there do not appear to be new bases provided for overriding the previous decision not to change the requirements.

Staff Response –

The staff disagrees with the comment, see staff response to Comment #12 on 6.3.

38. Section 6.3.9.2: The proposed clarification is consistent with the definitions and this change should be made to the Standard.

Staff Response –

The comment agrees with the staff position, no change is needed to the RG.

39. Section 6.6.1 After substantial discussion, there is no clear consensus regarding acceptance of the proposed clarification. The ASME CNRM Applications Subcommittee has appointed a working group to consider possible changes to Section 6, and this clarification will be referred to that group for further consideration.

Staff Response –

This comment is more an observation and as such, no change was made to the RG. In addition, see staff response to Comment #12 on 6.6.1.

40. Supporting Requirement DA-C14: The issue raised for this SR does not need a qualification. The issue could be considered as a clarification; however, sufficient requirements already exist to address plant-specific and generic data. Consider, for example, DA-C1 through DA-C4, and DA-D1, DA-D3 and DA-D4. A specific topic on identification and collection of plant-specific or industry data on repair time is sufficiently addressed by other requirements.

Staff Response –

The staff disagrees with the comment, see staff response to Comment #13.

41. Supporting Requirement DA-D8: A new requirement is not needed. Quantification is addressed in other requirements, including DA-D1, DA-D3, and DA-D4. An additional requirement would be redundant. Note that requirement LE-C2b needs to be changed to delete the reference to requirement DA-D8, as well as clarification for SY-A22 and DA-C14.

Staff Response –

The staff disagrees with the comment, see staff response to Comment #14.

42. Supporting Requirement IF-C3b: This qualification would create a situation for which data are difficult to obtain. Further, current use of compensatory actions would obviate the concern for any increase in risk contributions. At best, this qualification should be included only in Capability Category III.

Staff Response –

The staff disagree with the comment, see staff response to Comment #15.

E. Comments from BWR Owner’s Group² (Ref. 8)

PART 1 --

43. Clarification of Purpose of Section 1 and Deletion of Section 1.3: This comment deals with the clarity and practical applicability of Section C.1 and has some impact on the structure of the draft guide. The stated purpose of this section is that it “describes one acceptable approach for defining the technical adequacy for an acceptable PRA of a commercial nuclear power plant.” The phrase “one acceptable approach” implies a requirement to be met by the applicant, but none is provided in this section as is done in Sections 2.1 and 2.2 where a specific activity (peer review/self assessment) is required “to demonstrate that the PRA is adequate”.

Moreover, the functional requirements of Section 1 including the associated “technical

² Part 2 of BWR Owner’s Group comments is attached at the end of the comments

characteristics and attributes” of Section C.1.3 are not of sufficient detail to provide practical guidance for reviewing the adequacy of a PRA model for risk-informed submittals to NRC. In particular, the “technical characteristics and attributes” of an internal events PRA are essentially covered by just the High Level Requirements of the ASME Standard. (Note that the nomenclature and grouping of the technical elements differ between the ASME standard and the regulatory guide causing additional unneeded confusion. The difference in placement of the quantification of initiating event events and documentation are examples of such differences.) There are also many Supporting Requirements in the Standard that go into much greater detail and are used (via Appendix A or B) to demonstrate PRA technical adequacy as provided in Section C.2 of the regulatory guide.

Thus, the purpose of Section C.1 is not clear and could cause unnecessary work for an applicant. Most of the content of Section C.1 appears to be based on SECY-00-162, which was issued before the NRC endorsed the ASME Standard. Section C.1 is useful in that it introduces a broad statement of the minimum functional requirements of a PRA as given in SECY-00-162 to provide context for the remaining guidance.

Staff Response –

The staff disagrees with the comment and no change was made to the RG. A RG does not provide requirements, it provides one acceptable approach that can be used. Section C of the RG provides the regulatory positions; Section C.1 provides the regulatory position on what is needed for the base PRA to be technically acceptable. The regulatory position is based, as noted in the RG, on SECY-00-0162. The staff believes it is more efficient, effective, and clearer to restate the needed technical elements and their needed attributes in the RG instead of referring the user to the SECY. In this way, the regulatory position is made very clear. As noted above, a RG does not provide requirements. The licensee can demonstrate conformance with the regulatory position in different ways. One acceptable means is via consensus standards. Consequently, if an applicant chooses to use the ASME standard (as endorsed in Appendix A), Regulatory Position C.1 has been met. This is discussed in Regulatory Position C.2 in the RG. Since Section C provides the regulatory position, it is used to develop the staff positions in Appendices A and B. Further, a licensee may chose not to use the ASME standard, the licensee will then need to demonstrate how the technical elements and their attributes in Regulatory Position C.1 have been met in their base PRA.

44. Delete Section C.1.3 except for the second and third paragraphs (begins “For each given technical element.....”). These should be modified and transferred to the end of Section C.1.2 on page 8 (following “.....Regulatory Position 1.2.7”) as indicated in the markup. Essentially all of the Section C.1.3 material that describes the technical elements for an internal events (including flooding) PRA is covered by the high level requirements of the ASME Standard and is therefore recommended for deletion. As NRC endorses other standards, the requirements of these standards will cover the remaining portions of Section 1.3 that are not under the umbrella of the ASME Standard.

Staff Response –

The staff disagrees with the comment (see staff response to Comment #43), the staff position remains and no change was made to the RG.

45. Modify the first sentence of Section C.1 to more accurately state that only a broad delineation of the minimum functional requirements of a PRA are to follow. This will differentiate their use from the material in Sections C.2.1 and C.2.2 that specify sufficient detailed guidance “to demonstrate that the PRA is adequate to support a risk informed application” for either the consensus standard (Sect. C. 2.1) or industry peer review program (Sect. C.2.2) approach.

Staff Response –

The staff disagrees with the comment (see staff response to Comment #43), the staff position remains and no change was made to the RG.

46. The Part 2 markup includes the Section C.1.3 deletion portion (first bullet) of the recommended changes above. Note that some of the markups resulting from the Section C.1.3 deletion are outside of Section C.1.3 and are obviously contingent on use of the deletions shown for Section C.1.3. (e.g.; change in subsequent section number) Also, there are unrelated markups within Section C.1.3 that will become moot if Section C.1.3 is deleted.

The Part 2 markup also includes the change described above in the second bullet for Section C.1, and should be considered independently of the C.1.3 deletion recommendation since the second bullet change is recommended whether or not Section C.1.3 is deleted.

These modifications will simplify the regulatory guide and reduce confusion on the part of an applicant trying to determine what is required for a risk-informed application.

Staff Response –

The staff disagrees with the comment (see staff response to Comment #43), the staff position remains and no change was made to the RG.

47. Deletion of the Term “Large Late Release.” This comment deals with the incorporation of the term “large late release”. Notwithstanding the inclusion of late releases in SECY-00-162, its use in Draft Regulatory Guide 1161 is unnecessary and inappropriate for the reasons discussed below.

In Section C.1.1 of the regulatory guide under “Risk characterization” (p. 7) core damage frequency (CDF) is introduced as the surrogate for latent fatality risk. This is consistent with the very large margins between latent fatalities allowed by a 10⁻⁴/yr CDF limit and the safety goal latent fatality limit as calculated by Level 3 PRAs for the five plants of NUREG-1150. That is, if the plant’s CDF were controlled to 10⁻⁴/yr, then the expected latent fatality risk would be below the safety goal by the stated margin. The large margins allow for variations among plants in large late release frequency for a given CDF as well as for uncertainties in general. See the summary of margins (stated as ratios) below for the five NUREG-1150 plants.

Latent Fatality Margin Ratios for five NUREG-1150 Plants

Plant	CDF (/yr) (NUREG-1150, Vol. 1,	Margin Ratio Between PRA Plant Margin (PSA Applications Guide, EPRI TR-	Results and Safety Goal Scaled to 10 ⁻⁴ CDF Surrogate Goal
-------	-----------------------------------	---	---

	Dec 1990)	105396, 8-1995, Table C-3, NUREG-1150)	
Surry	4.0E-05	1000	400
Peach Bottom	4.5E-6	4000	180
Sequoyah	5.7E-6	182	104
Grand Gulf	4.0E-6	4444	178
Zion	6.0E-5	182	109

Moreover, by also controlling LERF as provided in DG-1161 and Regulatory Guide 1.174, latent fatalities should also be restricted to values below the Safety Goal based on the observation given in the August 4, 1986 Safety Goal Policy Statement that reads as follows:

“.....if the quantitative objective for prompt fatality is met for individuals in the immediate vicinity of the plant [controlled by LERF in the context of R. G. 1.200], the estimated risk of delayed cancer fatality to persons within 10 miles of the plant and beyond would generally be much lower than the quantitative objective for cancer fatality”.

Consistent with these observations, the ASME Internal Events PRA Standard treats only LERF as the release metric for quantification, and Appendices A and B of DG-1161 do not contradict this approach. Moreover, Regulatory Guide 1.174 (and its associated risk-informed regulatory guides) contains no acceptance guidelines for a large late release, making its quantification moot for applications that follow the associated regulatory guide. Again, in DG-1161 itself, in Section C.1.1 under “Risk characterization”, CDF is named as a surrogate for late fatality risk. (If that were the original intent, it should be stated in the context where the term “large late release” is used.)

Contrary to the above discussion, the term “large late release” is introduced in at least four places in the Regulatory Position portion of DG-1161. Such mention implies that it needs to be incorporated in the PRA model even though it adds little or nothing to the protection of the public in risk-informed decision making. Thus, its mention should be deleted from the text. If it is deemed necessary to include the term as a necessary and expected part of a standard Level 2 PRA, then a footnote to a modified phrase under “Source term analysis” (p. 10) could be added. It would simply state that traditional Level 2/3 PRAs typically characterize all releases (high, low, early, late, etc) as implied in SECY-00-162, but for risk-informed activities covered by this draft regulatory guide, only LERF need be included for the Level 2 risk metric. All other references to the term “large late release” would be deleted (twice on p.10, p. 13, p. 16).

A summary of the rationale for the deletion of the term “large late release” is as follows:

- CDF and LERF limits provide adequate surrogates for controlling latent fatality risk due to their large margins to the latent fatality Safety Goal.
- The term is not included in the NRC endorsed ASME PRA Standard.
- There are no numerical acceptance guidelines for late release in the NRC regulatory guidance for risk-informed changes to a plant’s licensing basis (R.G. 1.174).

Staff Response –

The staff disagrees with the comment. RG 1.200 states that it provides guidance for a full-scope Level 1 and Level 2 PRA. This RG supports both risk-informed activities for operating reactors and for new reactors. The RG also states that CDF and LERF are

the risk metrics generally used. The staff position remains, no change was made to the RG.

48. Self Assessment of Subsequent PRA Improvements

Following demonstration of Capability Category levels for each SR in a PRA model using either the peer review process associated with Appendix A or the self assessment process associated with Appendix B, there likely will be a need to change the PRA model/documentation. This could be due either to a desire to initially improve the Capability Category level of selected SRs or the continuing process of keeping the model current and applicable for given applications (See Section 5.4 of the ASME PRA Standard.) If these model changes do not constitute a “new methodology or significant changes in scope or capability” (See definition of *PRA upgrade*, Section 2.2, ASME PRA standard), then demonstration that the change has been performed adequately and the affected SR(s) meets the given Capability Category can be made by a self-assessment (i.e. peer review not required) likely consisting of a normal structured internal review process. The rationale for this assertion is two-fold:

- In the ASME PRA Standard the definitions for “PRA upgrade” (requires peer review) and “PRA maintenance” (no upgrade required) are not all-inclusive. There are PRA changes that do not meet either the “PRA upgrade” definition nor the “PRA maintenance” definition. Examples include scope of consideration improvement, documentation improvement, additional sensitivity studies to better characterize assumptions, increased model detail using same techniques, and error corrections. These changes and those that resulting from overdue PRA maintenance should not require a follow-on peer review. They could result in an improvement in Capability Category for a given SR.
- Such use of self-assessment is comparable to that specified in Appendix B to demonstrate that grade 2 or 4 sub-elements meet a given Capability Category or the use of self-assessment for all Capability Categories for all SRs of the Internal Flooding technical element.

This provision for the use of self-assessment should be explicitly stated somewhere in Draft Regulatory Guide 1161. A potential technique to accomplish this would be an expanded definition of PRA maintenance in the Section 2.2 portion of Table A-1 to include the changes described above in a category not requiring a peer review. A second technique would be the introduction of a new PRA change category in Section 2.2 to capture changes not requiring a peer review. A third technique would provide recognition in Section 5.4 of Table A-1 (and subsequently in the Standard) that there are some PRA changes that are not PRA maintenance and yet do not require a peer review. To implement this approach, the following sentence is suggested for insertion at the end of the second paragraph of Section 5.4 of the Standard.

“Note that there are some PRA changes that are not *PRA maintenance* and yet do not require peer review since they do not constitute a new methodology nor significant changes in scope or capability (*PRA upgrade*).”

The Chapter 5.4 section of Table A-1 of the regulatory guide should be correspondingly modified to accommodate this change as shown in Part 2.

Suggested wording to accomplish this modification is included in Part 2.

Staff Response –

This comment is taking objection with the language in the standard; as such, the comment is suggesting a change to the standard. This comment is more appropriate for ASME. The staff sees no need to take an objection. The standard only requires a peer review for a PRA change that is an PRA upgrade (i.e., does not require a peer review of a PRA change that is not a PRA maintenance and not a PRA upgrade). Consequently, PRA changes that are not upgrades and that are not PRA maintenance, are not required to be peer reviewed by the standard. No change needed for the RG.

49. Section 1.2.1, Quantification: The sentence beginning “If truncation.....” is awkward and contains a double negative rendering the meaning incorrect. Either delete the word “not” as used the second time or rewrite as shown in Part 2.

Staff Response –

The staff agrees with the comment and the RG was revised accordingly.

50. Section 1.2.3, Quantification, last sentence: The sentence should be clarified or deleted. A partial clarification has been included in Part 2.

Staff Response –

The staff agrees with the comment and the RG was revised accordingly.

51. Fire Analysis: Section 1.2.4 and Table 3 are inconsistent with NUREG/CR-6850 and the draft Fire Standard. In addition, the level for each step does not match the steps listed under internal events in 1.2.1. Finally, Table 3 lists general attributes of Fire PRA, which do not match the attributes in the Fire Standard or NUREG/CR-6850.

Staff Response –

The staff disagrees with the comment, the staff position remains and no change was made to the RG.

52. Section 1.2.5, Hazard Analysis: Use of the very specific uncertainty terms “aleatory” and “epistemic” here for external hazards, but not under “Parameter estimation analysis” in Section C.1.2.1 for internal events, implies a distinction in uncertainty treatments between these two types of PRA types that is artificial.

Staff Response –

The staff disagrees with the comment that there is a artificial distinction in uncertainty treatment with the use of the words “aleatory” and “epistemic.” The staff position remains and no change was made to the RG.

53. Section 1.2.5: While this section treats all relevant external hazards, it probably should be acknowledged that seismic events are the predominant external hazard example of interest.

Staff Response –

The staff disagrees with the comment. Whether seismic is the predominant external hazard of interest is site and plant specific. The staff position remains and no change was made to the RG.

54. Table 8, item 4: Remove the words “thoroughly and completely.” The Standards define the criteria for the PRA, including attributes and high level and supporting criteria, but not what is required.

Table 8, item 5: The emphasis of a PRA standard is not on the methods. As identified in Table 8 item 1, the standard identifies criteria. This is not covered by any bullets in the peer review section of Table 8, which focuses on methods. Please reword appropriately the bullets under Item 5.

Table 8, item 7: This item is not a principle supporting the development of the ASME or any of the ANS standards, and should be removed.

Staff Response –

The staff disagrees with the comment. The principles and objectives, as stated in the table, were developed (i.e., written) by ASME not NRC. The staff agrees with how they are stated. The staff position remains and no change was made to the RG.

55. Section 2.2, first paragraph: The Peer Review Process should also discuss NEI 05-04, Process for Performing Follow-on Peer Reviews. Many utilities are presently performing a “GAP analysis” using 05-04, and the acceptability of this process should be discussed in the regulatory guide. Also, the first paragraph of Section 2.2 indicates the wrong reference for NEI-00-02 (should be Ref. 11 instead of 9).

Staff Response –

NEI-05-04 is discussed in Appendix B as it is referenced in NEI-00-02. Further, the reference to NEI-00-02 has been corrected.

56. Section 2.2, second paragraph, last sentence: The “Appendix B approach” for demonstrating adequate PRA quality for applications includes industry self-assessment for the Technical Element Internal Flooding (Table B-4). Therefore, “internal floods” are part of the appendix B self-assessment process and should not be included in the parentheses with internal fires and external events that provide exclusions to the determination of PRA adequacy.

Staff Response –

The staff agrees with the comment and the RG was revised accordingly.

57. Table 9, Team Qualifications, first bullet: A literal interpretation of “no conflicts of interest” may exclude qualified personnel whose conflict in a practical sense would have no meaningful impact on the integrity of their review. This could likely be the case for obscure organizational connections. Thus, it would seem appropriate to insert a word such as “meaningful” before “conflicts of interest” to allow room for rational interpretation.

Staff Response –

The staff disagrees with the comment. The staff believes that the standard in its requirements appropriately addressed this attribute. No change was made to the RG.

58. Table 9, Documentation, after last bullet: It is helpful to both the PRA owners as well as NRC reviewers to have a rough idea of the scope of the peer review of interest. The addition of a new bullet with the phrase “summarizes scope of review” is meant to assure provision of such information that would include items (d) and (e) specified in Section 6.6 (Documentation) of the ASME PRA Standard.

Staff Response –

The staff agrees with the comment and the RG was revised accordingly.

59. Section 3.3, second and third paragraphs: Most of the material in these two paragraphs is redundant to that contained in the preceding paragraph, Section C.2.1, and Sections C.3.3.1, and C.3.3.2, and can be deleted. The useful reference to Regulatory Guide 1.174 is kept and transferred to the end of Section C.3.3.2 on page 28.

Staff Response –

The staff disagrees with the comment. See staff response to Comment #43.

60. Section 3.3.2: The last sentence is confusing. It seems to indicate the peer review is the basis for sensitivity analysis. Please reword.

Staff Response –

The staff agrees with the comment and the RG was revised accordingly.

61. Section 4.1, fourth bullet: Peer reviews are not required for PRA maintenance. Thus, the word “maintenance” should be deleted. Alternatively, insert the word “associated” before “peer reviews” and end sentence at this point. This would provide inclusion of voluntary review of PRA maintenance for whatever reason.

Staff Response –

The staff agrees with the comment and the RG was revised accordingly.

62. Section 4.2, last bullet: The term “lower capability categories or grades” is confusing. The last sentence could be interpreted to mean that every Supporting Requirement lower than Capability Category III or Sub-element (NEI-00-02) lower than grade 4 should be investigated to see if those grades lead to limitations on the implementation of the licensing change. This could almost be a boundless task. The sense of the requirement should to identify SRM with grades and/or Capability Categories lower than deemed appropriate for the application (i.e. Section 3 of the ASME Standard) to see if they lead to limitations on the implementation of the licensing changes. Thus, the term “the lower” should be deleted and the phrase “lower than deemed required for the given application to determine” should be inserted after “categories or grades.”

Staff Response –

The staff agrees with the comment and the RG was revised accordingly.

63. Table A-1, General Comment: A number of comments suggest removing the recommended changes for various reasons. Basically, since the ASME standard is a consensus standard, the NRC should first propose any changes to the standard in the ASME committee, of which the NRC is a member. Comments 19 through 34 [64 through 793] below provide examples of changes that should be brought in front of the ASME committee.

Staff Response –

The members of the Committee bring their technical expertise; however, the NRC member does bring, when appropriate, NRC views during the development and revisions to the standard. Further, the NRC does provide its official comments to the ASME Committee during the ASME public review and comment period. However, in endorsing the standard, the staff has the obligation to raise objections if it believes the standard does not support the NRC in its statutory responsibility in providing for the protection of the public health and safety.

64. Table A-1, 2.2, Core Damage: The added wording is not accurate. If the radiation from an undamaged core is released from containment, this can cause health effects. Thus the standard, as amended by the table, would mean that any damage at all, even small amounts of localized fuel damage, would be applicable here. This is inconsistent with NRC and industry practice. A significance measure is needed here such that significant offsite consequences are required in order to determine significant core damage. We recommend that until wording can be modified in the standard, the amended wording in the regulatory guide be removed, and proposed wording changes should be brought into the ASME Standard committee for amending the standard.

Staff Response –

The staff disagrees with the comment. See staff response to Comment #12 on core damage.

65. Table A-1, 2.2, Significant Contributor: The definition adds other terms that are not defined in Section 2.2 (e.g., significant basic event, significant sequence). The definition of “significant contributor” does not appear to be in the scope of Section 2.2. We recommend that the item be removed from Table A-1.

Staff Response –

The staff disagrees with the comment. These terms are defined in Section 2 of the standard and are used in the standard. The staff position remains and no change was made to the RG.

66. Table A-1, 4.3.3: The use of outside experts should not be required for any analysis that meets one of the three bullets. If there is an unimportant sequence or model, and expert judgment is used, then inside expert judgment would be acceptable, especially since the additional time and effort to solicit outside support would have no effect on the results. If the NRC would like to require expert judgment in this case, then the significant

contributor aspect should be brought into play here, where external support for expert judgment shall be used for significant accident contributors. We recommend adding: “for all events that are significant contributors” to the requirement.

Staff Response –

The staff disagrees with the comment. Per the standard, outside experts are only needed if a broader perspective is required. The staff noted this objection in RG 1.200 for Trial Use. The staff objection remains and no change was made to the RG.

67. Table A-1, IE-A4: The standard should capture best practices for PRA, especially for Category I/II. However, not all systems are reviewed to the sub-system level as required in the recommended change. Many systems can be reviewed in an IE review at the system level, especially systems that do not result in a plant trip or shutdown. For example, boric acid makeup to the REST would not require sub-system review. Similarly, demineralized water and other support systems can be screened at a system level rather than sub-system level. The NRC-recommended change would deviate from what is typically performed today, and would not meet the guidelines of what the standard should require. Additionally, “sub-system” is not defined in the standard.

Staff Response –

The staff disagrees with the comment. See staff response to Comment #12 on IE-A4.

68. Table A-1, IE-A4a: Temporary alignments for maintenance are considered routine. By changing the requirements to non-routine, the standard would basically require the review of all possible alignments, which is not the practice today, nor is it practical. We recommend defining routine alignments to include scheduled and routine maintenance performed on a system.

Staff Response –

The staff disagrees with the comment. See staff response to Comment #12 on IE-A4a.

69. Table A-1, IE-C10: Adding a specific reference to the standard is not typical unless it is the only acceptable method, and defeats the purpose of a standard as being performance based. In this case, the PRA should include a comparison of the initiating event analysis with the generic initiating events. Adding the reference to an NRC accepted generic database provides no value, but would discourage the use of other initiating event information, such as those provided for specific reactor types by the Owners Group. Additionally, “pertinent” is not defined.

Staff Response –

The staff disagrees with the comment. The standard in many places provides an example (i.e., reference) as an acceptable means of meeting the requirement. Standards are continually being revised and updated. The staff objection remains and no change was made to the RG.

70. Table A-1, SY-B15: In this requirement, the addition of containment failure is open-ended. It is possible to interpret this such that anything within the path of any containment failure (penetration or physical containment boundary failure, such as

during a containment bypass event prior to core damage) needs to include this effect. For example, electrical equipment in the electrical penetration room just outside of containment could be affected by a failed penetration and venting of containment atmosphere into the room. Analysis of all possible break locations is definitely not accepted practice and there is no method for doing this. Please reword the changes to ensure the containment effects are limited to those components aligned to the containment, in the path of a likely break location, or remove the new requirement (h).

Staff Response –

The staff disagrees with the comment. This example is plant design specific. Equipment that could be affected due to harsh environments directly resulting from containment venting or failure need to be identified. The staff objection remains and no change was made to the RG.

70. Table A-1, HR-D3: We recommend changing “potential for confusion” to “clarity”. Clarity or some other positive attribute is better suited for this definition. Also, change “configuration control” to “configuration control process”. Finally, the addition of the wording in bold type here is not recommended. First, we typically don’t review all of the items on the new wording during the performance of an PRA. Second, the additional wording may limit the requirement to only those aspects listed and not require additional aspects to be considered. What if the procedures are in the Shift Manager’s office, and the operator needs to go to the next room just to get a copy? This is not included in the NRC recommended list. However, it may be something we take into account in our analysis.

Staff Response –

The staff agrees with the comment and the RG was changed accordingly.

71. Table A-1, HR-G3: The new wording is confusing. “Degree of clarity of the meaning of cues/indications” does not provide better or clearer direction than the degree of clarity of cues/indications. The use of the term “meaning of cues/indications” is not standard in PRA methods and terminology. Please remove the suggested changes. Similarly, in item g, “determining the need for” is not a standard term. Replace the term with “diagnosing” or other standard terms we typically include in our consideration and analysis.

Staff Response –

The staff partially disagrees with the comment, see staff response to Comment #12 on HR-G3. The staff does agree with the comment on Item #g and the RG was revised accordingly.

72. Table A-1, DA-C14: First, add “data” or “experience” after “plant specific.” Second, the referenced (new) DA-D8 does not have requirements for the acceptability of plant specific data that can be measured. However, the goal here is to use the best data available, and if the plant specific data is limited, then generic data may be more appropriate. The new DA-C14 wording should be revised to either add requirements for when plant specific data is not appropriate or acceptable, or to remove the recommended wording change as listed.

Staff Response –

The staff partially agrees with the comments. The RG has been revised to address the first comment. With regard to DA-D8, the staff disagrees with the comment. See staff response to Comments #13 and 14.

73. Table A-1, DA-D1: By removing the wording listed, the NRC is saying that the Bayesian update process is the only accepted method for updating data, and will remain that way. If for example a new update method were developed that worked better than the Bayesian method for smaller sample sizes, then this new method would not be acceptable. This approach does not seem to meet the goals of the standards as performance-based approaches rather than prescriptive requirements.

Staff Response –

The staff disagrees with the comment. A user can always deviate from a requirement in the standard with appropriate justification. A standard is continually being updated as lessons are learned, new information is obtained, methods are improved, etc. In fact, the ASME standard has undergone two updates. The staff position remains and no change was made to the RG.

74. Table A-1, DA-D6: There is no value added in requiring non-significant CC events to have CC data analysis of a detailed type.

Staff Response –

The staff disagrees with the comment. The supporting requirement for Category III needs to be consistent with the criteria in Table 1.3-1. The staff objection remains and no change was made to the RG.

75. Table A-1, IF-E6A: There is no known method available to adjust common cause for flooding concerns. Please remove the requirements in parenthesis for this method. Again, the standard should document acceptable best practices, and not require new analysis methods not previously performed.

Staff Response –

The staff agrees with the comment and the RG was changed accordingly.

76. Table A-1, QU-A2B: Performing the state-of-knowledge correlations for non-significant events adds no value and is not the accepted best practice for the industry. The recommended wording change should be removed.

Staff Response –

The staff disagrees with the comment. The concern is whether the effect of the state-of-knowledge correlation is significant, not whether the basic events themselves are significant. The staff position remains and no change was made to the RG.

77. Table A-1, QU-E4: As a minimum, the wording should be changed to “key model uncertainties and key assumptions.” However, by adding this requirement, the NRC has now changed the typical analysis performed for I.E. type analysis, and is changing the

typical industry practice. Additionally, for Category 1 analysis, this new analysis provides no benefits. The recommended wording change should be removed.

Staff Response –

The staff disagrees with the comment. Regardless of the category, model uncertainties and assumptions that effect the analysis need to be addressed in some manner (as differentiated by the Capability Category). The staff objection remains, see staff clarification in response to Comment #6.

78. Table B-1, 1.1, Second entry, 2.2 and 3.4: The NRC needs to complete the review of NEI 05-04 that was developed to bridge the gap between NEI 00-02 and Addendum B (note this is done in Table B-5) and include the summary here. Basically, it appears the NRC accepts a combined NEI 00-02 and 05-04 review (with clarifications as stated in the RG 1.200). If this is true, this should be stated here rather than stating that an NEI 00-02 doesn't meet the NRC expectations for Addendum B.

Staff Response –

The staff disagrees with the comment. The staff has completed the review of NEI-05-04 which is referenced later in an Appendix in NEI-00-02. The staff objection remains and no change was made to the RG.

79. Table A-1, 6.6.1, Resolution (I): This "Clarification" to confirm every SR capability category appears to make the peer review scope all encompassing in breath and depth, obviating the need for a minimal set of items to be reviewed as given in Section 6.3 of the ASME Standard. It also minimizes the use of judgment as provided in Standard Section 6.3 by essentially requiring a 100% audit sample of every SR in Section 4 of the ASME Standard. Moreover, items (f) and (g) under Standard Section 6.6.1 should suffice in documenting conformance to SRM through a peer review process and also maintain the flexibility provided through use of reviewer judgement. Therefore, item (I) under 6.6.1 should be deleted.

Staff Response –

The staff disagrees with the comment. The staff does believe it is necessary to sample every SR. Further, the staff position is consistent with Item #g. The staff position remains and no change was made to the RG based on this comment, however, see staff response to Comment #12 on 6.6.1.

80. Table B-1, 2.3, last bullet: The NRC should make clear that all review team members need not have all listed capabilities. The wording is revised in Part 2 to parallel Section 6.2 of the ASME Standard to make this point.

Staff Response –

The staff agrees with the comment and the RG was changed accordingly.

81. Sentence preceding Table B-2, NRC Position on the Self-Assessment Process: The sentence is not clear. There is no Section B.2. Should it be Table B-2? What are "categories"?

Staff Response –

The staff agrees with the comment and the RG was changed accordingly.

82. Table B-2, 7.a: For sub-elements receiving a Grade 4 and where no Table B-4 “Industry Self Assessment Actions” are specified, logic would dictate that the corresponding SR could receive a Capability Category II without further review. If a Capability Category III is considered, a self-assessment against the standard is required to see if Capability Category III requirements are met. This conclusion is consistent with the “Comment/Resolution” given in Table B-5 under Section 4.3 (last sentence) on page B-63. A sentence asserting this position has been added to the “Commentary/Resolution” for Report Section 7.a in Part 2.

Staff Response –

The staff agrees with the comment and the RG was changed accordingly.

83. Introduction to Table B-4: It would be helpful if just prior to the table containing the required self assessment actions (Table B-4) a short summary is provided that describes the product of the use of the table. Such a proposed summary is provided below as a two-sentence insert just prior to Table B-4. (It is repeated in Part 2.)“In summary, following completion of the ‘Industry Self-Assessment Actions’ as augmented by the ‘Regulatory Position’ for all applicable NEI Grade 3 sub-elements (and Grade 4 if no self assessment specified), the corresponding SR may be considered to have met Capability Category II requirements of the Standard. For NEI sub-elements receiving other grades, a self-assessment against the Capability Category requirements of the ASME Standard (with Appendix A modifications) will determine the Capability Category for the corresponding SR.”

Staff Response –

The staff agrees with the comment and the RG was changed accordingly.

PART 2 --

84. Handwritten comments with suggested wording changes to the RG (see Attachment below)

Staff Response --

The staff disagrees with the majority of the suggested wording changes. An NRC regulatory guide has certain criteria for format and language. The majority of the suggested changes are inconsistent with the criteria for a regulatory guide. Many of the suggestions are raised in comments in Part 1. Where the staff agreed with the comment, if suggested wording was provided in Part 2, the staff used the wording where appropriate.

Except for technical editing corrections, the staff agrees with comments on the following pages (see Attachment below) and the RG was changed accordingly.

- *Page 1.200-7, Section 1.1, plant operating states paragraph, second line*
- *Page 1.200-8, Section 1.1.1, paragraph following Table 1*

- *Page 1.200-9, Section 1.2.1, human reliability paragraph*
- *Page 1.200-11, Section 1.2.3, Quantification paragraph*
- *Page 1.200-26, Section 2.2, Table 9, documentation*
- *Page 1.200-28, Section 3.2.2, paragraph proceeding Section 3.3*
- *Page 1.200-30, Section 4.1, last of first set of bullets*
- *Page 1.200-31, Section 4.2, last bullet*
- *Page 1.200-55, 2.3, PRA peer review team*
- *Page 1.200-58, 2nd paragraph*
- *Page 1.200-60, Table B-2, 7.a*
- *Page 1.200-62, paragraph proceeding Table B-4*

Attachment

BWROG Comments on Regulatory Guide 1.200 October 13, 2006 Part 2

This document provides comments on Regulatory Guide 1.200, Revision 1, dated August 2006. The comments in this document are in the form of markups of the original Regulatory Guide, many of which are referred to in the document entitled "BWROG Comments on Regulatory Guide 1.200, October 13, 2006, Part 1." Together these two documents form the BWROG comments on Regulatory Guide 1.200.



U.S. NUCLEAR REGULATORY COMMISSION

August 2006

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 1.200, Revision 1

(Draft was issued as DG-1122)

AN APPROACH FOR DETERMINING THE TECHNICAL ADEQUACY OF PROBABILISTIC RISK ASSESSMENT RESULTS FOR RISK-INFORMED ACTIVITIES

A. INTRODUCTION

In 1995, the NRC issued a Policy Statement (Ref. 1) on the use of probabilistic risk analysis (PRA), encouraging its use in all regulatory matters. The Policy Statement states that "... the use of PRA technology should be increased to the extent supported by the state of the art in PRA methods and data and in a manner that complements the NRC's deterministic approach." Since that time, many uses have been implemented or undertaken, including modification of NRC's reactor safety inspection program and initiation of work to modify reactor safety regulations. Consequently, confidence in the information derived from a PRA is an important issue: the accuracy of the technical content must be sufficient to justify the specific results and insights that are used to support the decision under consideration.

This regulatory guide describes one acceptable approach for determining that the quality of the PRA, in total or the parts that are used to support an application, is sufficient to provide confidence in the results such that the PRA can be used in regulatory decision making for light-water reactors. This guidance is intended to be consistent with the NRC's PRA policy statement and subsequent, more detailed, guidance in Regulatory Guide 1.174 (Ref. 2). It is also intended to reflect and endorse guidance provided by standards-setting and nuclear industry organizations. When used in support of an application, this regulatory guide will obviate the need for an in-depth review of the base PRA by NRC reviewers, allowing them to focus their review on

Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the NRC staff in its review of applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Written comments may be submitted to the Rules and Directives Branch, ADM, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Regulatory guides are issued in ten broad divisions: 1, Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

Single copies of regulatory guides (which may be reproduced) may be obtained free of charge by writing the Distribution Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by fax to (301)415-2289, or by email to DISTRIBUTION@NRC.GOV. Electronic copies of this guide and other recently issued guides are available at NRC's home page at www.nrc.gov through the Electronic Reading Room, Accession Number ML040630078.

On May 19, 2006, NEI issued a revision to the self-assessment guidance incorporated in NEI-00-02, to satisfy the peer review requirement(s) of the ASME PRA Standard (ASME-RA-Sa-2003) as endorsed/modified by the NRC and updated by Addendum B of the ASME PRA Standard. (Ref. 11)

✓ August, 2006, NEI issued NEI-05-04, "Process for Performing Follow-on PRA Peer Reviews Using the ASME PRA Standard." This document provides guidance material for conducting and documenting a follow-on peer review for PRAs using the ASME PRA standard. (Ref. 12)

- SECY-00-0162 (Ref. 13) describes an approach for addressing PRA quality in risk-informed activities, including identification of the scope and minimal functional attributes of a technically acceptable PRA.
- Regulatory Guide 1.201, "Guidelines for Categorizing Structures, Systems and Components in Nuclear Power Plants According to their Safety Significance" (Ref. 14), discusses an approach, along with References 8 and 11, to support the new rule 10 CFR 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors." (Ref. 15)
- SECY-04-0118, "Plan for the Implementation of the Commission's Phased Approach to PRA Quality" (Ref. 16), provides the staff approach in defining the needed PRA quality for current or anticipated applications and the process for achieving this quality, while allowing risk-informed decisions to be made using currently available methods until all the necessary guidance documents are developed and implemented.

PURPOSES OF THIS REGULATORY GUIDE

The purposes of this regulatory guide are to provide guidance to licensees in determining the technical adequacy of a PRA used in a risk-informed regulatory activity and to endorse standards and industry guidance. Guidance is provided in four areas:

- (1) A minimal set of functional requirements of a technically acceptable PRA.
- (2) The NRC position on PRA consensus standards and industry PRA program documents.
- (3) Demonstration that the PRA (in total or specific parts) used in regulatory applications is of sufficient technical adequacy.
- (4) Documentation to support a regulatory submittal.

This regulatory guide provides more detailed guidance, relative to Regulatory Guide 1.174, on PRA technical adequacy in a risk-informed integrated decision-making process. It does not provide guidance on how PRA results are used in the application-specific decision-making processes; that guidance is provided in such documents as References 5 through 8.

[THIS MARKUP MORE CONSISTENT WITH INTENT AND CONTENT OF THIS SECTION]

C. REGULATORY POSITION

1. FUNCTIONAL REQUIREMENTS OF A TECHNICALLY ACCEPTABLE PRA

a minimal set of functional requirements for a technically

This section describes ~~one acceptable approach for defining the technical adequacy for an~~ acceptable PRA of a commercial nuclear power plant. PRAs used in risk-informed activities may vary in scope and level of detail, depending on the specific application. However, the PRA results used to support an application must be derived from a PRA model that represents the as-built, as-operated plant² to the extent needed to support the application

~~In this section, the guidance provided is for a full-scope PRA~~ PRA The scope is defined in terms of (1) the metrics used to characterize risk, (2) the plant operating states for which the risk is to be evaluated, and (3) the types of initiating events that can potentially challenge and disrupt the normal operation of the plant and, if not prevented or mitigated, would eventually result in core damage and/or a large release.

The level of detail required of the PRA model is determined ultimately by the application. However, a minimal level of detail is necessary to ensure that the impact of designed-in dependencies (e.g., support system dependencies, functional dependencies and dependencies on operator actions) are correctly captured and the PRA represents the as-built, as-operated plant. This minimal level of detail is implicit in the technical characteristics and attributes discussed in this section.

This section, consequently, provides guidance in four areas:

- (1) Definition of the scope of a PRA
- (2) Technical elements of a full-scope PRA
- ~~(3) Attributes and characteristics for technical elements of a PRA~~
- (4) Development, maintenance and upgrade for a PRA

attributes and characteristics

[MARKUP CONSISTENT ON DELETION OF SECTION 1.3]

This guidance is in accordance with SECY-00-0162.

1.1 Scope of PRA

The scope of a PRA is defined by the challenges included in the analysis and the level of analysis performed. Specifically, the scope is defined in terms of:

- the metrics used in characterizing the risk,
- the plant operating states for which the risk is to be evaluated, and
- the types of initiating events that can potentially challenge and disrupt the normal operation of the plant.

² Some applications may involve the plant at the design certification or combined operating license stage where the plant is not built or operated. At these stages, the intent is for the PRA model to reflect the as-designed plant.

BOLD

The metrics typically used to characterize risk are

Risk characterization is typically expressed by metrics of core damage frequency (CDF) and large early release frequency (LERF) (as surrogates for latent and early fatality risks, respectively, for light water reactors). These are defined in a functional sense as follows:

[NEED BULLETS TO SHOW THESE ARE SUBHEADINGS TO "THE METRICS"]

Core damage frequency is defined as the sum of the frequencies of those accidents that result in uncover and heatup of the reactor core to the point at which prolonged oxidation and severe fuel damage involving a large fraction of the core (i.e., sufficient, if released from containment, to have the potential for causing offsite health effects) is anticipated.

Large early release frequency is defined as the frequency of those accidents leading to significant, unmitigated releases from containment in a time frame prior to effective evacuation of the close-in population such that there is the potential for early health effects. Such accidents generally include unscrubbed releases associated with early containment failure shortly after vessel breach, containment bypass events, and loss of containment isolation

in risk-informed activities under the purview of this regulatory guide

Issues related to the reliability of barriers, in particular containment integrity and consequence mitigation, are addressed through other parts of the decision-making process, such as consideration of defense in depth. To provide the risk perspective for use in decision making, a Level 1 PRA is required to provide CDF, & limited Level 2 PRA is needed to address LERF. Level 3 PRA is beyond the scope of this guide. End R

Plant operating states (POSs) are used to subdivide the plant operating cycle into unique states such that the plant response can be assumed to be the same for all subsequent accident initiating events. Operational characteristics (such as reactor power level; in-vessel temperature, pressure, and coolant level; equipment operability; and changes in decay heat load or plant conditions that allow new success criteria) are examined to identify those relevant to defining plant operational states. These characteristics are used to define the states, and the fraction of time spent in each state is estimated using plant specific information. The risk perspective is based on the total risk connected with the operation of the reactor, which includes not only full-power operation, but also low-power and shutdown conditions. For some applications, the risk impact may affect some modes of operation, but not others, may affect the risk impact.

[PHRASING WAS REVERSED]

Initiating events are the events that have the ability to challenge the condition of the plant. These events include failure of equipment from either internal plant causes such as hardware faults, operator actions, floods or fires, or external plant causes such as earthquakes or high winds. The risk perspective is based on a consideration of the total risk, which includes events from both internal and external sources.

1.2 Technical Elements of PRA

Table 1 provides the list of general technical elements that are necessary for a PRA. A PRA that is missing one or more of these elements would not be considered a complete PRA. A brief discussion is provided below of the objective of each element.

at any time within the given POS for a given initiating event

Table 1. Technical Elements of a PRA

Scope of Analysis	Technical Element
Level 1	<ul style="list-style-type: none"> • Initiating event analysis • Success criteria analysis • Accident sequence analysis • Systems analysis
Level 2	<ul style="list-style-type: none"> • Plant damage state analysis • Accident progression analysis
Interpretation of results and documentation are elements of both Level 1 and Level 2 PRAs.	

These technical elements are equally applicable to the PRA models constructed to address each of the contributors to risk, i.e., internal and external initiating events, for each of the plant operating states. Because additional analyses are required to characterize their impact on the plant in terms of initiating events caused and mitigating equipment failed, internal floods, internal fires, and external hazards are discussed separately in Regulatory Positions 1.2.3, 1.2.4, and 1.2.5, respectively. Further, to understand the results, it is important to examine the different contributors on both an individual and relative basis. Therefore, this element, interpretation of results, is discussed separately in Regulatory Position 1.2.6. Another major element that is common to all the technical elements is documentation; it is also discussed separately in Regulatory Position 1.2.7.

Positions

the common mode impact initiators due to

INSERT FROM PAGE 15 →

1.2.1 Level 1 Technical Elements

THIS INSERT CONTINGENT ON DELETION OF SECTION 1.3]

Initiating event analysis identifies and characterizes the events that both challenge normal plant operation during power or shutdown conditions and require successful mitigation by plant equipment and personnel to prevent core damage from occurring. Events that have occurred at the plant and those that have a reasonable probability of occurring are identified and characterized. An understanding of the nature of the events is performed such that a grouping of the events into event classes, with the classes defined by similarity of system and plant responses (based on the success criteria), may be performed to manage the large number of potential events that can challenge the plant.

Success criteria analysis determines the minimum requirements for each function (and ultimately the systems used to perform the functions) to prevent core damage (or to mitigate a release) given an initiating event. The requirements defining the success criteria are based on acceptable engineering analyses that represent the design and operation of the plant under consideration. For a function to be successful, the criteria are dependent on the initiator and the conditions created by the initiator. The computer codes used to perform the analyses for developing the success criteria are validated and verified for both technical integrity and suitability to assess plant conditions for the reactor pressure, temperature, and flow range of interest, and they accurately analyze the phenomena of interest. Calculations are performed by personnel who are qualified to perform the types of analyses of interest and are well trained in the use of the codes.

[FOR CONSISTENCY WITH TABLE 1]



mp

Accident sequence-development analysis models, chronologically (to the extent practical), the different possible progression of events (i.e., accident sequences) that can occur from the start of the initiating event to either successful mitigation or to core damage. The accident sequences account for the systems that are used (and available) and operator actions performed to mitigate the initiator based on the defined success criteria and plant operating procedures (e.g., plant emergency and abnormal operating procedures) and training. The availability of a system includes consideration of the functional, phenomenological, and operational dependencies and interfaces between the different systems and operator actions during the course of the accident progression.

Systems analysis identifies the different combinations of failures that can prevent the system from performing its function as defined by the success criteria. The model representing the various failure combinations includes, from an as-built and as-operated perspective, the system hardware and instrumentation (and their associated failure modes) and human failure events that would prevent the system from performing its defined function. The basic events representing equipment and human failures are developed in sufficient detail in the model to account for dependencies between the different systems and to distinguish the specific equipment or human events that have a major impact on the system's ability to perform its function.

Parameter estimation analysis quantifies the frequencies of the initiating events and quantifies the equipment failure probabilities and equipment unavailabilities of the modeled systems. The estimation process includes a mechanism for addressing uncertainties and has the ability to combine different sources of data in a coherent manner, including the actual operating history and experience of the plant when it is of sufficient quality, as well as applicable generic experience.

Human reliability analysis identifies and provides probabilities for the human failure events that can negatively impact normal or emergency plant operations. The human failure events associated with normal plant operation include the events that leave the system (as defined by the success criteria) in an unrevealed, unavailable state. The human failure events associated with emergency plant operation include the events that, if not performed, do not allow the needed system to function. Quantification of the probabilities of these human failure events is based on plant- and accident-specific conditions, where applicable, including any dependencies among actions and conditions.

human actions

in response to the consequences of a given initiating event.

Quantification provides an estimation of the CDF given the design, operation, and maintenance of the plant. This CDF is based on the summation of the estimated CDF from each accident sequence for each initiator class. If truncation of accident sequences and cutsets is applied, truncation limits are set so that the overall model results are not impacted in such a way that significant accident sequences or contributors³ are not eliminated. Therefore, the truncation limit can vary for each accident sequence. Consequently, the truncation value is selected so that the accident sequence CDF is stable with respect to further reduction in the truncation value.

³ **Significant accident sequence:** a significant sequence is one of the set of sequences, defined at the functional or systemic level that, when ranked, compose 95% of the CDF or the LERF, OR that individually contribute more than ~1% to the CDF or LERF. **Significant basic event/contributor:** the basic events (i.e., equipment unavailabilities and human failure events) that have a Fussell-Vesely importance greater than 0.005 OR a risk-achievement worth greater than 2.

[IF LOWER VERSION MAINTAINED, THE SECOND "NOT" NEEDS TO BE DELETED TO BE CORRECT.]

1.2.2 Level 2 Technical Elements

Plant damage state analysis groups similar core damage scenarios together to allow a practical assessment of the severe accident progression and containment response resulting from the full spectrum of core damage accidents identified in the Level 1 analysis. The plant damage state analysis defines the attributes of the core damage scenarios that represent boundary conditions to the assessment of severe accidents progression and containment response that ultimately affect the resulting radionuclide releases. The attributes address the dependencies between the containment systems modeled in the Level 2 analysis with the core damage accident sequence models to fully account for mutual dependencies. Core damage scenarios with similar attributes are grouped together to allow for efficient evaluation of the Level 2 response.

[FOR CONSISTENCY WITH TABLE 1]

Severe Accident progression analysis models the different series of events that challenge containment integrity for the core damage scenarios represented in the plant damage states. The accident progressions account for interactions among severe accident phenomena and system and human responses to identify credible containment failure modes, including failure to isolate the containment. The timing of major accident events and the subsequent loadings produced on the containment are evaluated against the capacity of the containment to withstand the potential challenges. The containment performance during the severe accident is characterized by the timing (e.g., early versus late), size (e.g., catastrophic versus bypass), and location of any containment failures. The codes used to perform the analysis are validated and verified for both technical integrity and suitability. Calculations are performed by personnel qualified to perform the types of analyses of interest and well trained in the use of the codes.

Source term analysis characterizes the radiological release to the environment resulting from each severe accident sequence leading to containment failure or bypass. The characterization includes the time, elevation, and energy of the release and the amount, form, and size of the radioactive material that is released to the environment. The source term analysis is sufficient to determine whether a large early release ~~or a large late release~~ occurs.^{3R} A large early release is one involving the rapid, unmitigated release of airborne fission products from the containment to the environment occurring before the effective implementation of off-site emergency response and protective actions such that there is a potential for early health effects. Such accidents generally include unscrubbed releases associated with early containment failure at or shortly after vessel breach, containment bypass events, and loss of containment isolation. ~~With large late release, unmitigated release from containment occurs in a time frame that allows effective evacuation of the close-in population such that early fatalities are unlikely.~~

Quantification integrates the accident progression models and source term evaluation to provide estimates of the frequency of radionuclide releases that could be expected following the identified core damage accidents. This quantitative evaluation reflects the different magnitudes and timing of radionuclide releases and specifically allows for identification of the LERF ~~and the probability of a large late release.~~

^{3R} Traditional Level 2/Level 3 PRAs typically characterize/quantify all releases (high, low, late, early, etc.). However, for the risk-informed activities covered by this regulatory guide, only LERF need be included as the Level 2 metric. CDF is an adequate surrogate for latent fatality risk. 1.200-10

[SUGGESTED NEW FOOTNOTE IF REFERENCES TO LARGE EARLY RELEASE ARE DELETED AS RECOMMENDED AND SHOWN ELSEWHERE IN MARKUP.]

1.2.3 Internal Floods Technical Elements

PRA models of internal floods are based on the internal events PRA model, modified to include the impact of the identified flood scenarios in terms of causing initiating events, and failing equipment used to respond to initiating events. These flood scenarios are developed during the **flood identification analysis** and the **flood evaluation analysis**. The quantification task specific to internal floods is similar in nature to that for the internal events. Because of its dependence on the internal events model, the flooding analysis incorporates the elements of Sections 1.2.1 and 1.2.2 as necessary.

Flood identification analysis identifies the plant areas where flooding could result in significant accident sequences. Flooding areas are defined on the basis of physical barriers, mitigation features, and propagation pathways. For each flooding area, flood sources that are due to equipment (e.g., piping, valves, pumps) and other sources internal to the plant (e.g., tanks) are identified along with the affected structures, systems, and components (SSCs). Flooding mechanisms are examined that include failure modes of components, human-induced mechanisms, and other water-releasing events. Flooding types (e.g., leak, rupture, spray) and flood sizes are determined. Plant walkdowns are performed to verify the accuracy of the information.

Flood evaluation analysis identifies the potential flooding scenarios for each flood source by identifying flood propagation paths of water from the flood source to its accumulation point (e.g., pipe and cable penetrations, doors, stairwells, failure of doors or walls). Plant design features or operator actions that have the ability to terminate the flood are identified. The susceptibility of each SSC in a flood area to flood-induced mechanisms is examined (e.g., submerge, spray, pipe whip, and jet impingement). Flood scenarios are developed by examining the potential for propagation and giving credit for flood mitigation. Flood scenarios can be eliminated on the basis of screening criteria. The screening criteria used are well defined and justified.

Quantification provides an estimation of the CDF of the plant that includes internal floods. The frequency of flooding-induced initiating events that represent the design, operation, and experience of the plant are quantified. The Level 1 models are modified and the internal flood accident sequences quantified to: (1) modify accident sequence models to address flooding phenomena, (2) perform necessary calculations to determine success criteria for flooding mitigation, (3) perform parameter estimation analysis to include flooding as a failure mode, (4) perform human reliability analysis to account for performance shaping factors (PSFs) that are due to flooding, and (5) quantify internal flood accident sequence CDF. Modifications of the Level 1 models are performed consistent with the appropriate boundary for Level 1 elements for transients and loss of coolant accidents (LOCAs). *to recommendate flooding impacts.*
[THIS LAST SENTENCE SHOULD BE EXPANDED EVEN MORE FOR CLARIFICATION.]

1.2.4 Internal Fire Technical Elements

PRA models of internal fires are based on the internal events PRA model, modified to include the impact of the identified fire scenarios in terms of causing initiating events (plant transients and LOCAs), and failing equipment used to respond to initiating events. These fire scenarios are developed during the **screening analysis**, **fire initiation analysis**, and the **fire damage analysis**. The **plant response and quantification** that is specific to internal fires is

1.2.5 External Hazards Technical Elements

PRA models of external hazards, when required, are based on the internal events PRA model, which are modified to include the impact of the identified external event scenarios in terms of causing initiating events (plant transients and LOCAs), and failing equipment used to respond to initiating events. However, it is prudent to perform a **screening and bounding analysis** to screen out those external events that have an insignificant impact on risk. When external events are modeled in detail, the external event scenarios are developed during the **hazard analysis** and the **fragility analysis** as discussed below. The quantification task specific to external events is similar in nature to that for the internal events. Because of its dependence on the internal events model, the external events analysis incorporates the elements of Sections 1.2.1 and 1.2.2 as necessary.

Screening and bounding analysis identifies external events other than earthquakes (such as river-induced flooding) that may challenge plant operations and require successful mitigation by plant equipment and personnel to prevent core damage from occurring. The term "screening out" is used here for the process whereby an external event is excluded from further consideration in the PRA analysis. There are two fundamental screening criteria embedded here. An event can be screened out if either (1) it meets the design criteria, or (2) it can be shown using an analysis that the mean value of the design-basis hazard used in the plant design is less than 10^{-5} /year and that the conditional core-damage probability is less than 10^{-1} , given the occurrence of the design-basis hazard. An external event that cannot be screened out using either of these criteria is subjected to the detailed analysis.

Hazard analysis characterizes non-screened external events and seismic events, generally, as frequencies of occurrence of different sizes of events (e.g., earthquakes with various peak ground accelerations, hurricanes with various maximum wind speeds) at the site. The external events are site-specific and the hazard characterization addresses both aleatory and epistemic uncertainties. [SOMEWHAT INCONSISTENT TO USE THESE TWO HIGHLY TECHNICAL UNCERTAINTY TERMS

HERE FOR EXTERNAL HAZARDS AND NOT FOR THE CORRESPONDING "PARAMETER ESTIMATION ANALYSIS" ON PAGE 9]

Fragility analysis characterizes conditional probability of failure of SSCs whose failure may lead to unacceptable damage to the plant (e.g., core damage) given occurrence of an external event. For significant contributors (i.e., SSCs), the fragility analysis is realistic and plant-specific. The fragility analysis is based on extensive plant walkdowns reflecting as-built, as-operated conditions.

Plant response analysis and quantification involves the modification of appropriate plant transient and LOCA PRA models to determine the conditional core damage probability, given damage to the sets of components identified. The external events PRA model includes initiating events resulting from the external events, external-event-induced SSC failures, non-external-event-induced failures (random failures), and human errors. The system analysis is well coordinated with the fragility analysis and is based on plant walkdowns. The results of the external event hazard analysis, fragility analysis, and system models are assembled to estimate frequencies of core damage and large early release.

1.2.6 Interpretation of Results

The results of the Level 1 PRA are examined to identify the contributors sorted by initiating events, accident sequences, equipment failures, and human errors. Methods such as importance measure calculations (e.g., Fussell-Vesely Importance, risk achievement worth, risk reduction worth, and Birnbaum Importance) are used to identify the contributions of various events to the estimation of CDF for both individual sequences and the total CDF (i.e., both the contributors to the total CDF (includes the contribution from the different initiators, i.e., internal and external events, and different operating modes, i.e., full and low power and shutdown) and the contributors to each contributing sequence are identified).

The results of the Level 2 PRA are examined to identify the contributions of various events to the model estimation of LERF ~~and large late release probability~~ for both individual sequences and the model as a total, using such tools as importance measure calculations (e.g., Fussell-Vesely Importance, risk achievement worth, risk reduction worth, and Birnbaum Importance).

An important aspect in understanding the PRA results is understanding the associated uncertainties. Key sources of uncertainty⁴ are identified and their impact on the results analyzed. The potential conservatism associated with the successive screening approach used for the analysis of specific scope items such as fire, flooding, or seismic initiating events is assessed. The sensitivity of the model results to model boundary conditions and other key assumptions⁵ is evaluated using sensitivity analyses to look at key assumptions both individually or in logical combinations. The combinations analyzed are chosen to account for interactions among the variables.

1.2.7 Documentation

Traceability and defensibility provide the necessary information such that the results can easily be reproduced and justified. The sources of information used in the PRA are both referenced and retrievable. The methodology used to perform each aspect of the work is described either through documenting the actual process or through reference to existing methodology documents. Key sources of uncertainty are identified and their impact on the results assessed. Key assumptions made in performing the analyses are identified and documented along with their justification to the extent that the context of the assumption is understood. The results (e.g., products and outcomes) from the various analyses are documented. A key source of uncertainty is

⁴ A *key source of uncertainty* is one that is related to an issue in which there is no consensus approach or model and where the choice of approach or model is known to have an impact on the risk profile (e.g., total CDF and total LERF, the set of initiating events and accident sequences that contribute most to CDF and to LERF) or a decision being made using the PRA. Such an impact might occur, for example, by introducing new functional accident sequence or a change to the overall CDF or LERF estimates significant enough to affect insights gained from the PRA. (a)

⁵ A *key assumption* is one that is made in response to a key source of uncertainty in the knowledge that a different reasonable alternative assumption would produce different results, or an assumption that results in an approximation made for modeling convenience in the knowledge that a more detailed model would produce different results. For the base PRA, the term "different results" refers to a change in the risk profile and the associated changes in insights derived from the changes in the risk profile. A "reasonable alternative" assumption is one that has broad acceptance within the technical community and for which the technical basis for consideration is at least as sound as that of the assumption being challenged.

Regardless of the level of detail in the PRA, a minimum set of PRA characteristics and attributes to be included were previously provided in SECY-00-0162. They are now included with more detail in consensus PRA standards (issued or to be issued) that have or will be endorsed by NRC such as described in Appendix A of this regulatory guide. Demonstration of conformance by a PRA with such standards as described in Section 2 is the mechanism by which the technical adequacy of a plant base PRA is demonstrated.

one that is related to an issue where there is no consensus approach or model (e.g., choice of data source, success criteria, reactor coolant pressure (RCP) seal LOCA model, human reliability model) and where the choice of approach or model is known to have an impact on the PRA results in terms of introducing new accident sequences, changing the relative importance of sequences, or affecting the overall CDF or LERF estimates that might have an impact on the use of the PRA in decision making. A key assumption is one that is made in response to a key source of uncertainty.

~~1.3 Attributes and Characteristics of the PRA Technical Elements~~

[THIS INSERT CONTINGENT ON DELETION OF SECTION 1.3]

~~Tables 2 and 3 describe, for each technical element of a PRA, the technical characteristics and attributes that provide one acceptable approach for determining the technical adequacy of the PRA such that the goals and purposes, defined in Regulatory Position 1.2, are accomplished.~~

INSERT ON P. 8

For each given technical element, the level of detail may vary. The detail may vary from the degree to which (1) plant design and operation is modeled, (2) specific plant experience is incorporated into the model, and (3) realism is incorporated into the analyses that reflect the expected plant response. ~~Regardless of the level of detail developed in the PRA, the characteristics and attributes provided below are included. That is, each characteristic and attribute is always included, but the degree to which it is included, as described above, may vary.~~

The level of detail needed is dependent on the application. The application may involve using the PRA during different plant "stages," i.e., design, construction, and operation. Consequently, a PRA used to support a design certification will not have the same level of detail as a PRA of a plant that has years of operating experience. While it is recognized that the same level of detail is not needed, each of the technical elements and its attributes has to be addressed.

~~Table 2. Summary of Technical Characteristics and Attributes of a PRA~~

Element	Technical Characteristics and Attributes
PRA Full Power, Low Power and Shutdown	
Level 1 PRA (internal events -- transients and LOCAs)	
Initiating Event Analysis	<ul style="list-style-type: none"> • sufficiently detailed identification and characterization of initiators • grouping of individual events according to plant response and mitigating requirements • proper screening of any individual or grouped initiating events
Success Criteria Analysis	<ul style="list-style-type: none"> • based on best-estimate engineering analyses applicable to the actual plant design and operation • codes developed, validated, and verified in sufficient detail <ul style="list-style-type: none"> • analyze the phenomena of interest • be applicable in the pressure, temperature, and flow range of interest
Accident Sequence Development Analysis	<ul style="list-style-type: none"> • defined in terms of hardware, operator action, and timing requirements and desired end states (e.g., core damage or plant damage states (PDSSs)) • includes necessary and sufficient equipment (safety and non-safety) reasonably expected to be used to mitigate initiators • includes functional, phenomenological, and operational dependencies and interfaces

[THIS 2 PARAGRAPH TRANSFER IS CONTINGENT ON DELETION OF SECTION 1.3.]

~~Table 2. Summary of Technical Characteristics and Attributes of a PRA~~

Element	Technical Characteristics and Attributes
Systems Analysis	models developed in sufficient detail to: <ul style="list-style-type: none"> • reflect the as built, as operated plant including how it has performed during the plant history • reflect the success criteria for the systems to mitigate each identified accident sequence • capture impact of dependencies, including support systems and harsh environmental impacts • include both active and passive components and failure modes that impact the function of the system • include common cause failures, human errors, unavailability due to test and maintenance, etc.
Parameter Estimation Analysis	<ul style="list-style-type: none"> • estimation of parameters associated with initiating event, basic event probability models, recovery actions, and unavailability events using plant-specific and generic data as applicable • consistent with component boundaries • estimation includes a characterization of the uncertainty
Human Reliability Analysis	<ul style="list-style-type: none"> • identification and definition of the human failure events that would result in initiating events or pre- and post-accident human failure events that would impact the mitigation of initiating events • quantification of the associated human error probabilities taking into account scenario (where applicable) and plant-specific factors and including appropriate dependencies both pre- and post-accident
Quantification	<ul style="list-style-type: none"> • estimation of the CDF for modeled sequences that are not screened due to truncation, given as a mean value • estimation of the accident sequence CDFs for each initiating event group • truncation values set relative to the total plant CDF such that the CDF is stable with respect to further reduction in the truncation value
Level 2 PRA	
Plant Damage State Analysis	<ul style="list-style-type: none"> • identification of the attributes of the core damage scenarios that influence severe accident progression, containment performance, and any subsequent radionuclide releases • grouping of core damage scenarios with similar attributes into plant damage states • carryover of relevant information from Level 1 to Level 2
Severe Accident Progression Analysis	<ul style="list-style-type: none"> • use of verified, validated codes by qualified trained users with an understanding of the code limitations and the means for addressing the limitations • assessment of the credible severe accident phenomena via a structured process • assessment of containment system performance including linkage with failure modes on non-containment systems • establishment of the capacity of the containment to withstand severe accident environments • assessment of accident progression timing, including timing of loss of containment failure integrity
Quantification	<ul style="list-style-type: none"> • estimation of the frequency of different containment failure modes and resulting radionuclide source terms
Source Term Analysis	<ul style="list-style-type: none"> • assessment of radionuclide releases including appreciation of timing, location, amount and form of release • grouping of radionuclide releases into smaller subset of representative source terms with emphasis on large early release (LER) and on large late release (LLR)

[THIS LLR DELETION RECOMMENDED IF TABLE 2 IS MAINTAINED; I.E. SECTION 1.3 NOT DELETED]

In addressing the above elements, because of the nature and impact of internal flood and fire and external hazards, their attributes are discussed separately in Table 3. This is because flood, fire, and external hazards analyses are spatial in nature and have the ability to cause initiating events, but also have the capability to impact the availability of mitigating systems. Therefore, regarding the PRA model, the impact of flood, fire, and external hazards is to be considered in each of the above technical elements.

[DELETION OF THIS PHRASE RECOMMENDED EVEN IF SECTION 1.3 IS NOT DELETED.]

~~Table 3. Summary of Technical Characteristics and Attributes of an Internal Flood and Fire Analysis and External Hazards Analysis~~

Areas of Analysis	Technical Characteristics and Attributes*
Internal Flood Analysis	
Flood Identification Analysis	<ul style="list-style-type: none"> • sufficiently detailed identification and characterization of: <ul style="list-style-type: none"> – flood areas and SSCs located within each area – flood sources and flood mechanisms – type of water release and capacity – structures functioning as drains and sumps • verification of the information through plant walkdowns
Flood Evaluation Analysis	<ul style="list-style-type: none"> • identification and evaluation of <ul style="list-style-type: none"> – flood propagation paths – flood mitigating plant design features and operator actions – the susceptibility of SSCs in each flood area to the different types of floods • elimination of flood scenarios uses well defined and justified screening criteria
Quantification	<ul style="list-style-type: none"> • identification of flooding-induced initiating events on the basis of a structured and systematic process • estimation of flooding initiating event frequencies • estimation of CDF for chosen flood sequences • modification of the Level 1 models to account for flooding effects including uncertainties
Internal Fire Analysis	
Screening Analysis	<ul style="list-style-type: none"> • fire areas are identified and addressed that can result in significant accident sequences • all credited mitigating components and their cables in each fire area are identified. • screening criteria are defined and justified • necessary walkdowns are performed to confirm the screening decisions • screening process and results are documented • unscreened events areas are subjected to appropriate level of evaluations (including detailed fire PRA evaluations as described below)

Table 3. Summary of Technical Characteristics and Attributes of an Internal Flood and Fire Analysis and External Hazards Analysis

Areas of Analysis	Technical Characteristics and Attributes*
Initiation Analysis	<ul style="list-style-type: none"> • fire scenarios in each unscreened area are addressed that can result in a significant accident sequence [ADD "a" IF TABLE 3 MAINTAINED] • fire scenario frequencies reflect plant-specific features • fire scenario physical characteristics are defined • bases are provided for screening fire initiators
Damage Analysis	<ul style="list-style-type: none"> • damage to significant contributors (i.e., components) is addressed; considers all potential component failure modes • all potentially significant contributors (i.e., damage mechanisms) are identified and addressed; damage criteria are specified • analysis addresses scenario-specific factors affecting fire growth, suppression, and component damage • models and data are consistent with experience from actual fire experience as well as experiments • includes evaluation of propagation of fire and fire effects (e.g., smoke) between fire compartments
Plant Response Analysis	<ul style="list-style-type: none"> • fire-induced initiating events that can result in significant accident sequences are addressed so that their bases are included in the model • includes fire scenario impacts on core damage mitigation and containment systems, including fire-induced failures • analysis reflects plant-specific safe shutdown strategy • potential circuit interactions that can interfere with safe shutdown are addressed • human reliability analysis addresses effect of fire scenario-specific conditions on operator performance
Quantification	<ul style="list-style-type: none"> • estimation of fire CDF for chosen fire scenarios • identification of sources of uncertainty and their impact on the results • understanding of the impact of the key assumptions** on the CDF • all fire-significant sequences are traceable and reproducible
External Hazards Analysis	
Screening and Bounding Analysis	<ul style="list-style-type: none"> • credible external events (natural and man-made) that may affect the site are addressed • screening and bounding criteria are defined and results are documented • necessary walkdowns are performed • non-screened events are subjected to an appropriate level of evaluations
Hazard Analysis	<ul style="list-style-type: none"> • the hazard analysis is site- and plant-specific • the hazard analysis addresses uncertainties
Fragility Analysis	<ul style="list-style-type: none"> • fragility estimates are plant-specific for significant contributors (i.e., SSCs) • walkdowns are conducted to identify plant-unique conditions, failure modes, and as-built conditions.

~~Table 3. Summary of Technical Characteristics and Attributes of an Internal Flood and Fire Analysis and External Hazards Analysis~~

Areas of Analysis	Technical Characteristics and Attributes*
Plant response analysis and quantification [LEVEL 3 PRA NOT REQUIRED PER SECTION 1.1 AND SECY-00-0162. ∴ DELETE, REGARDLESS OF FATE OF TABLE 3.]	<ul style="list-style-type: none"> • external event caused initiating events that can lead to significant core damage and large early release sequences are included • external event related unique failures and failure modes are incorporated • equipment failures from other causes and human errors are included. When necessary, human error data are modified to reflect unique circumstances related to the external event under consideration • unique aspects of common causes, correlations, and dependencies are included • the systems model reflects as-built, as-operated plant conditions • the integration/quantification accounts for the uncertainties in each of the inputs (i.e. hazard, fragility, system modeling) and final quantitative results such as CDF and LERF • the integration/quantification accounts for all dependencies and correlations that affect the results; Level 3 Offsite consequence analysis; Assessment of pre-accident inventories of radioactive material; Analysis of the radiation doses received by the exposed populations via direct and indirect pathways; Analysis of the mitigation of these doses by emergency response actions; Calculation of the health effects of the release

In understanding the results from a PRA, the different initiators and operating states need to be considered, in an integrated manner, when examining the results. The attributes for interpretation of the results are discussed separately in Table 4.

~~Table 4. Summary of Technical Characteristics and Attributes for Interpretation of Results~~

Element	Technical Characteristics and Attributes
Level 1 PRA	
Interpretation of Results	<ul style="list-style-type: none"> • identification of the key contributors to CDF: initiating events, accident sequences, equipment failures and human errors • identification of key sources of uncertainty and their impact on the results • understanding of the impact of the key assumptions on the CDF and the identification of the accident sequence and their contributors
Level 2 PRA	
Interpretation of Results	<ul style="list-style-type: none"> • identification of the contributors to containment failure and resulting source terms • identification of key sources of uncertainty and their impact on the results • understanding of the impact of the key assumptions on Level 2 results

~~A significant aspect of the technical acceptability of the PRA is documentation. The attributes for documentation are discussed separately in Table 5.~~

~~Table 5. Summary of Technical Characteristics and Attributes for Documentation~~

Element	Technical Characteristics and Attributes
Traceability and defensibility	 <ul style="list-style-type: none"> the documentation is sufficient to facilitate independent peer reviews the documentation describes the interim and final results, insights, and key sources of uncertainties walkdown process and results are fully described

~~1.3 [CONTINGENT ON DELETION OF SECTION 1.3.]~~
~~1.4 PRA Development, Maintenance and Upgrade~~

The PRA results used to support an application are derived from a PRA model that represents the as-built, as-operated plant to the extent needed to support the application. Therefore, a process for developing, maintaining and upgrading a PRA is established. This process involves identifying and using plant information to develop the original PRA and to modify the PRA. The process is performed such that the plant information identified and used in the PRA reflects the as-built, as-operated plant.⁶ The information sources include the applicable design, operation, maintenance, and engineering characteristics of the plant

For those structures, systems, and components (SSCs) and human actions used in the development of the PRA, the following information is identified, integrated and used in the PRA:

- **plant design information** reflecting the normal and emergency configurations of the plant
- **plant operational information** with regard to plant procedures and practices
- **plant test and maintenance** procedures and practices
- **engineering aspects** of the plant design

Further, plant walkdowns are conducted to ensure that information sources being used actually reflects the plant's as-built, as-operated condition. In some cases, corroborating information obtained from the documented information sources for the plant and other information may only be gained by direct observations.

~~Table 6 describes the characteristics and attributes that need to be included for the above types of information.~~

⁶ It is recognized that at the design certification or combined operating license stage where the plant is not built or operated, the term "as-built, as-operated" is meant to reflect the as-designed plant assuming operational conditions for the given design.

~~Table 6. Summary of Attributes and Characteristics for Information Sources Used in PRA Development~~

Type of Information	Attributes and Characteristics
Design	<ul style="list-style-type: none"> • the safety functions required to maintain the plant in a safe stable state and prevent core or containment damage; • identification of those SSCs that are credited in the PRA to perform the above functions; • the functional relationships among the SSCs including both functional and hardware dependencies; • the normal and emergency configurations of the SSCs; • the automatic and manual (human interface) aspects of equipment initiation, actuation, operation as well as isolation and termination; • the SSC's capabilities (flows, pressures, actuation timing, environmental operating limits); • spatial layout, sizing, and accessibility information related to the credited SSCs; and • other design information needed to support the PRA modeling of the plant.
Operational	<ul style="list-style-type: none"> • that information needed to reflect the actual operating procedures and practices used at the plant including when and how operators interface with plant equipment as well as how plant staff monitor equipment operation and status, and • that information needed to reflect the operating history of the plant as well as any events involving significant human interaction.
Maintenance	<ul style="list-style-type: none"> • that information needed to reflect planned and typical unplanned tests and maintenance activities and their relationship to the status, timing, and duration of the availability of equipment, and • historical information related to the maintenance practices and experience at the plant.
Engineering	<ul style="list-style-type: none"> • the design margins in the capabilities of the SSCs; • operating environmental limits of the equipment; • expected thermal hydraulic plant response to different states of equipment (such as for establishing success criteria); and • other engineering information needed to support the PRA modeling of the plant.

As a plant operates over time, its associated risk may change. This change may occur because of the following:

- The PRA model may change due to improved methods or techniques.
- Operating data may change the availability or reliability of the plant's structures, systems and components.
- Plant design or operation may change.

Therefore, to ensure that the PRA represents the risk of the current as-built and as-operated plant, ,

The NRC endorsed consensus PRA standards contain the the PRA needs to be maintained and upgraded over time. Table 7 provides the attributes and characteristics of an acceptable process.

~~Table 7. Summary of Characteristics and Attributes for PRA Maintenance and Upgrade~~

Characteristics and Attributes
<ul style="list-style-type: none">• Monitor PRA inputs and collects new information• Ensure cumulative impact of pending plant changes are considered• Maintain configuration control of the computer codes used in the PRA• Identify when PRA needs to be updated based on new information or new models/techniques/tools• Ensure peer review is performed on PRA upgrades

2. CONSENSUS PRA STANDARDS AND INDUSTRY PRA PROGRAMS

One acceptable approach to demonstrate conformance with Regulatory Position 1 is to use an industry consensus PRA standard or standards that address the scope of the PRA used in the decision making. An alternative acceptable approach to using an industry consensus PRA standard is to use an industry-developed peer review program.

in developing an internal events PRA standard discussed later in this section.

2.1 Consensus PRA Standards

In general, if a PRA standard is used to demonstrate conformance with Regulatory Position 1, the standard should be based on a set of principles and objectives. Table 3 provides an acceptable set of principles and objectives that were established and used by ASME. Principle 3 recognizes that the various parts of a PRA can be, and are generally, performed to different "capabilities." The different capabilities are distinguished by three attributes. That is, in developing the various models in the PRA, the degree to which:

[TABLE NUMBER CHANGE CONTINGENT ON DELETION OF SECTION 1.3 AND TABLES 6 AND 7.]

- (1) the scope and level of detail that reflects the plant design, operation and maintenance may vary.
- (2) plant-specific information versus generic information is used such that the as-built and as-operated plant is addressed.
- (3) realism is incorporated such that the expected response of the plant is addressed.

It is recognized that the various parts of a PRA will not be to the same capability category. Which part of the PRA meets what capability category is dependent on the specific application.

Table 8. Principles and Objectives of a Standard

1.	The PRA standard provides well-defined criteria against which the strengths and weaknesses of the PRA may be judged so that decision makers can determine the degree of reliance that can be placed on the PRA results of interest.
2.	The standard is based on current good practices ^(see Note below) as reflected in publicly available documents. The need for the documentation to be publicly available follows from the fact that the standard may be used to support safety decisions.
3.	To facilitate the use of the standard for a wide range of applications, categories can be defined to aid in determining the applicability of the PRA for various types of applications.
4.	The standard thoroughly and completely defines what is technically required and should, where appropriate, identify one or more acceptable methods.
5.	The standard requires a peer review process that identifies and assesses where the technical requirements of the standard are not met. The standard needs to ensure that the peer review process: <ul style="list-style-type: none"> - determines whether methods identified in the standard have been used appropriately; - determines that, when acceptable methods are not specified in the standard, or when alternative methods are used in lieu of those identified in the standard, the methods used are adequate to meet the requirements of the standard; - assesses the significance of the results and insights gained from the PRA of not meeting the technical requirements in the standard; - highlights <i>key</i> [emphasis added] assumptions that may significantly [emphasis removed] impact the results and provides an assessment of the reasonableness of the assumptions; - is flexible and accommodates alternative peer review approaches; and - includes a peer review team that is composed of members who are knowledgeable in the technical elements of a PRA, are familiar with the plant design and operation, and are independent with no conflicts of interest <i>that may influence the outcome of the peer review</i> [this clause was not in the ASME definition].
6.	The standard addresses the maintenance and update of the PRA to incorporate changes that can substantially impact the risk profile so that the PRA adequately represents the current as-built and as-operated plant.
7.	The standard is a living document. Consequently, it should not impede research. It is structured so that, when improvements in the state of knowledge occur, the standard can easily be updated.

Note: Current good practices are those practices that are generally accepted throughout the industry and have shown to be technically acceptable in documented analyses or engineering assessments. [No definition was provided for these terms by ASME.]

The standards are written in terms of "requirements." These requirements will be either (1) "process" in nature, or (2) technical in nature. The process type requirements address the process for application, development, maintenance and upgrade, and peer review. The technical requirements address the technical elements of the PRA and what is necessary to adequately perform that element. Therefore, when a standard is used to demonstrate conformance with Regulatory Position 1, the requirements in the standard will need to be met. As a general rule, a requirement of a standard is met when it is demonstrated that there is clear evidence of an intent to meet the requirement. *Note that Principle 5 of Table 2 requires a peer review process be included as a means of assessing that the technical requirements of the Standard are met. See Section 2.2.*

1.200-23 ↑

[TABLE 2 REVERTS TO TABLE 8 IF SECTION 1.3 AND TABLES 6 AND 7 NOT DELETED.]

For process requirements, the intent, is generally straightforward and the requirement is either met or not met. For the technical requirements, it is not always as straightforward. Many of the technical requirements in a standard apply to several parts of the PRA model. For example, the requirements for systems analysis apply to all systems modeled, and certain of the data requirements apply to all parameters for which estimates are provided. *where* If among these systems or parameter estimates there are a few examples a specific requirement has not been met, it is not necessarily indicative that this requirement has not been met. If, for the majority of the systems or parameter estimates the requirement has been met and the few examples can be put down to mistakes or oversight, the requirement would be considered to be met. If, however, there is a systematic failure to address the requirement, e.g., component boundaries have not been defined anywhere, then the requirement has not been complied with. In either case, the examples of noncompliance are to be (1) rectified or demonstrated not to be relevant to the application, and (2) documented.

Further, the technical requirements may be defined at two different levels: (1) high level requirements, and (2) supporting requirements. High level requirements are defined for each technical element and capture the objective of the technical element. These high level requirements are defined in general terms, need to be met regardless of the capability category, and accommodate different approaches. Supporting requirements are defined for each high level requirement. These supporting requirements are those minimal requirements needed to satisfy the high level requirement. Consequently, determination of whether a high level requirement is met, is based on whether the associated supporting requirements are met. Whether or not every supporting requirement is needed for a high level requirement is application dependent and is determined by the application process requirements.

One example of an industry consensus PRA standard is the ASME standard, with a scope for a PRA for Level 1 and limited Level 2 (LERF) for full-power operation and internal events (excluding internal fires). The staff regulatory position regarding this document is provided in Appendix A to this regulatory guide. If it is demonstrated that the parts of a PRA that are used to support an application comply with the ASME standard, when supplemented to account for the staff's regulatory positions contained in Appendix A, it is considered that the PRA is adequate to support that risk-informed regulatory application.

Additional appendices will be added in future updates to this regulatory guide to address PRA standards for other risk contributors, such as accidents caused by external hazards, ~~or~~ internal fire, or caused during the low-power and shutdown modes of operation. *Such as earthquakes*

2.2 Industry Peer Review Program

An acceptable approach that can be used to ensure technical adequacy is to perform a peer review of the PRA. A peer review process can be used to identify the strengths and weaknesses in the PRA and their importance to the confidence in the PRA results. A peer review process is provided in the ASME standard and in the industry-developed peer review program (i.e., NEI-00-02, Ref. 9). The staff regulatory position on the process in the ASME PRA standard and in NEI-00-02 is provided in Appendices A and B, respectively, to this regulatory guide. When the staff's regulatory positions contained in Appendices A and B are taken into account, use of these

processes can be used to demonstrate that the PRA is adequate to support a risk-informed application.

The peer review is to be performed against established standards, e.g., ASME PRA Standard. If different criteria are used than in the established standard, then it needs to be demonstrated that these different criteria are consistent with the established standards, as endorsed by the NRC. NEI-00-02 provides separate criteria for a peer review of a Level 1/LERF PRA at full-power for internal events, excluding internal flood and fire and external events. NEI-00-02 also provides guidance for resolution of the differences between the established standards, as endorsed by the NRC (i.e., ASME PRA standard and Appendix A to this guide) and its peer review criteria. The staff position on this guidance (referred to as the "Licensee Self-Assessment Guidance"), is provided in Appendix B to this guide. When the staff's regulatory positions contained in Appendix B are taken into account, use of the peer reviews performed using NEI-00-02 can be used to demonstrate that the PRA is adequate to support a risk-informed application (with regard to a Level 1/LERF PRA for full-power for internal events (excluding ~~internal floods and fires~~ and external events)).

[APPENDIX B COVERS FLOODS VIA SELF ASSESSMENT]

If a peer review process is used to demonstrate conformance with Regulatory Position 1, an acceptable peer review approach is one that is performed by qualified personnel and, according to an established process that compares the PRA against the characteristics and attributes, documents the results and identifies both strengths and weaknesses of the PRA.

The **team qualifications** determine the credibility and adequacy of the peer reviewers. To avoid any perception of a technical conflict of interest, the peer reviewers will not have performed any actual work on the PRA. Each member of the peer review team must have technical expertise in the PRA elements he or she reviews, including experience in the specific methods that are used to perform the PRA elements. This technical expertise includes experience in performing (not just reviewing) the work in the element assigned for review. Knowledge of the key features specific to the plant design and operation is essential. Finally, each member of the peer review team must be knowledgeable in the peer review process, including the desired characteristics and attributes used to assess the adequacy of the PRA.

The **peer review process** includes a documented procedure used to direct the team in evaluating the adequacy of a PRA. The review process compares the PRA against desired PRA characteristics and attributes such as those provided in Regulatory Position 1.3 and elaborated on in a PRA standard. In addition to reviewing the methods used in the PRA, the peer review determines whether the methods were applied correctly. The PRA models are compared against the plant design and procedures to validate that they reflect the as-built and as-operated plant. Key assumptions are reviewed to determine if they are appropriate and to assess their impact on the PRA results. The PRA results are checked for fidelity with the model structure and for consistency with the results from PRAs for similar plants based on the peer reviewer's knowledge. Finally, the peer review process examines the procedures or guidelines in place for updating the PRA to reflect changes in plant design, operation, or experience. Consequently, over time, additional peer review may be needed (see Regulatory Position 1.3).

1.3 [CONTINGENT ON DELETION OF SECTION 1.3]

Documentation provides the necessary information such that the peer review process and

the findings are both traceable and defensible. Descriptions of the qualifications of the peer review team members and the peer review process are documented. The results of the peer review for each technical element and the PRA update process are described, including the areas in which the PRA does not meet or exceed the desired characteristics and attributes used in the review process. This includes an assessment of the importance of any identified deficiencies on the PRA results and potential uses and how these deficiencies were addressed and resolved.

Table 3 provides a summary of the characteristics and attributes of a peer review.

Table 3. Summary of the Characteristics and Attributes of a Peer Review

Element	Characteristics and Attributes
Team Qualifications [Add .]	<ul style="list-style-type: none"> independent with ^{meaningful} no conflicts of interest collectively represent expertise in all the technical elements of a PRA including integration expertise in the technical element assigned to review knowledge of the plant design and operation knowledge of the peer review process
Peer Review Process	<ul style="list-style-type: none"> uses documented process uses as a basis for review a set of desired PRA characteristics and attributes uses a minimum list of review topics to ensure coverage, consistency, and uniformity reviews PRA methods reviews application of methods reviews key assumptions and assesses their validity and appropriateness determines if PRA represents as-built and as-operated plant reviews results of each PRA technical element for reasonableness reviews PRA maintenance and update process reviews PRA modification due to use of different model, techniques or tools
Documentation	<ul style="list-style-type: none"> describes the peer review team qualifications describes the peer review process documents where PRA does not meet desired characteristics and attributes assesses and documents significance of deficiencies

• SUMMARIZES SCOPE OF REVIEW

3. DEMONSTRATING THE TECHNICAL ADEQUACY OF A PRA USED TO SUPPORT A REGULATORY APPLICATION

This section of the regulatory guide addresses the third purpose identified above, namely, to provide guidance to licensees on an approach acceptable to the NRC staff to demonstrate that the quality of the PRA used, in total or the parts that are used to support a regulatory application, is sufficient to support the analysis.

The application-specific regulatory guides identify the specific PRA results to support the decision making and the analysis needed to provide those results. The parts of the PRA to support

covered by the self assessment / ASME Standard approach of Appendix B to this guide.

The PRA standards and industry PRA programs that have been, or are in the process of being, developed address a specific scope. For example, the ASME PRA standard addresses internal events at full power for a limited Level 2 PRA analysis. Similarly NEI-00-02 is a peer review process for the same scope (with the exception of internal flooding, which is ~~not considered in NEI-00-02~~). Neither addresses external (including internal fire) initiating events nor the low power and shutdown modes of operation. The different PRA standards or industry PRA programs are addressed separately in appendices to this regulatory guide. In using this regulatory guide, the applicant will identify which of these appendices is applicable to the PRA analysis.

3.3 Demonstration of Technical Adequacy of the PRA

There are two aspects to demonstrating the technical adequacy of the parts of the PRA to support an application. The first aspect is the assurance that the parts of the PRA used in the application have been performed in a technically correct manner, and the second aspect is the assurance that the assumptions and approximations used in developing the PRA are appropriate.

~~For the first, assurance that the parts of the PRA used in the application have been performed in a technically correct manner implies that (1) the PRA model, or those parts of the model required to support the application, represents the as-built and as-operated plant, which, in turn, implies that the PRA is up to date and reflects the current design and operating practices, (2) the PRA logic model has been developed in a manner consistent with industry good practice (see footnote to Table 8) and that it correctly reflects the dependencies of systems and components on one another and on operator actions, and (3) the probabilities and frequencies used are estimated consistently with the definitions of the corresponding events of the logic model.~~

~~For the second, the current state of the art in PRA technology is that there are issues for which there is no consensus on methods of analysis. Furthermore, PRAs are models, and in that sense the developers of those models rely on certain approximations to make the models tractable and on certain assumptions to address uncertainties as to how to model specific issues. This is recognized in Regulatory Guide 1.174, which gives guidance on how to address the uncertainties. In accordance with that guidance, the impact of these assumptions and approximations on the results of interest to the application needs to be understood.~~

Table 2
[IF SECTION 1.3
AND TABLES
6 AND 7
DELETED]

3.3.1 Assessment that the PRA Model is Technically Correct [THIS MATERIAL REDUNDANT TO FIRST PR, SECTION 2.1 (TABLE 8) AND SECTIONS 3.2.1 AND 3.2.2]

When using risk insights based on a PRA model, the applicant must ensure that the PRA model, or at least those parts of it needed to provide the results, is technically correct as discussed above.

The licensee is to demonstrate that the model is up to date in that it represents the current plant design and configuration and represents current operating practices to the extent required to support the application. This demonstration can be achieved through a PRA maintenance plan that includes a commitment to update the model periodically to reflect changes that impact the significant accident sequences.

The various consensus PRA standards and industry PRA programs that provide guidance

Sections 2.1 and 2.2 describe two acceptable processes for demonstrating this technical adequacy.

on the performance of, or reviews of, PRAs are addressed individually in the appendices to this regulatory guide. These appendices document the staff's regulatory position on each of these standards or programs.

When the issues raised by the staff are taken into account, the standard or program in question may be interpreted to be adequate for the purpose for which it was intended. If the parts of the PRA can be shown to have met the requirements of these documents, with attention paid to the NRC's clarifications or qualifications, it can be assumed that the analysis is technically correct. Therefore, other than an audit, a detailed review by NRC staff of the base model PRA will not be necessary. When deviations from these documents exist, the applicant must demonstrate either that its approach is equivalent or that the influence on the results used in the application are such that no changes occur in the significant accident sequences or contributors.

3.3.2 Assessment of Assumptions and Approximations

Since the standards and industry PRA programs are not (or are not expected to be) prescriptive, there is some freedom on how to model certain phenomena or processes in the PRA; different analysts may make different assumptions and still be consistent with the requirements of the standard or the assumptions may be acceptable under the guidelines of the peer review process. The choice of a specific assumption or a particular approximation may, however, influence the results of the PRA. For each application that calls upon this regulatory guide, the applicant identifies the key assumptions and approximations relevant to that application. This will be used to identify sensitivity studies as input to the decision making associated with the application. Each of the documents addressed in the appendices either requires, or in the case of the industry peer review program, represents, a peer review. One of the functions of the peer review is to address the assumptions and make judgments as to their appropriateness. This in turn provides a basis for the sensitivity studies. *In addition, Regulatory Guide 1.174 gives guidance on how to address uncertainties that may be attendant with the aforementioned use of assumptions and approximations.*

4. DOCUMENTATION TO SUPPORT A REGULATORY SUBMITTAL [ADD THIS SENTENCE IF PARAGRAPHS DELETED ON PAGE 28]

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

4.1 Archival Documentation

Archival documentation associated with the base PRA include the following:

- A detailed description of the process used to determine the adequacy of the PRA.
- The results of the peer review and/or self-assessment, and a description of the resolution of all the peer review or self-assessment findings and observations. The results are documented in such a manner that it is clear why each requirement is considered to have

been met. This can be done, for example, by providing a reference to the appropriate section of the PRA model documentation.

- The complete documentation of the PRA model. If the staff elects to perform an audit on all or any parts of the PRA used in the risk-informed application, the documentation maintained by the licensee must be legible, retrievable (i.e., traceable), and of sufficient detail that the staff can comprehend the bases supporting the results used in the application. Regulatory Position 1.3 of this guide provides the attributes and characteristics of archival documentation associated with the base PRA. *The consensus PRA standards also provide documentation guidance for the base PRA.*
- A description of the process for maintenance and upgrade of the PRA. The history of the maintenance and upgrade activities are maintained, and include the results of any peer reviews that were performed ~~to~~ as a result of ~~maintenance or~~ ^{PRA} upgrade.

The archival documentation associated with a specific application is expected to include enough information to demonstrate that the scope of the review of the base PRA is sufficient to support the application. This includes:

- The impact of the application on the plant design, configuration, or operational practices,
- The risk assessment, including a description of the methodology used to assess the risk of the application, how the base PRA model was modified to appropriately model the risk impact of the application, and details of quantification and the results.
- The acceptance guidelines and method of comparison,
- The scope of the risk assessment in terms of initiating events and operating modes modeled,
- The parts of the PRA required to provide the results needed to support comparison with the acceptance guidelines,

4.2 Licensee Submittal Documentation

To demonstrate that the technical adequacy of the PRA used in an application is of sufficient quality, the staff expects the following information will be submitted to the NRC. Previously submitted documentation may be referenced if it is adequate for the subject submittal:

- To address the need for the PRA model to represent the as-built, as-operated plant, identification of permanent plant changes (such as design or operational practices) that have an impact on those things modeled in the PRA but have not been incorporated in the baseline PRA model.

If a plant change has not been incorporated, the licensee provides a justification of why the change does not impact the PRA results used to support the application. This justification can be in the form of a sensitivity study that demonstrates the accident sequences or

contributors significant to the application were not impacted (remained the same).

- Documentation that the parts of the PRA required to produce the results used in the decision are performed consistently with the standard as endorsed in the appendices of this regulatory guide.

If a requirement of the standard (as endorsed in the appendix to this guide) has not been met, the licensee is to provide a justification of why it is acceptable that the requirement has not been met. This justification should be in the form of a sensitivity study that demonstrates the accident sequences or contributors significant to the application were not impacted (remained the same).

- A summary of the risk assessment methodology used to assess the risk of the application, including how the base PRA model was modified to appropriately model the risk impact of the application and results. (Note that this is the same as that required in the application specific regulatory guides)
- Identification of the key assumptions and approximations relevant to the results used in the decision-making process. Also include the peer reviewers' assessment of those assumptions. These assessments provide information to the NRC staff in their determination of whether the use of these assumptions and approximations is either appropriate for the application, or whether sensitivity studies performed to support the decision are appropriate.
- A discussion of the resolution of the peer review or self-assessment findings and observations that are applicable to the parts of the PRA required for the application. This may take the form of:
 - a discussion of how the PRA model has been changed, or
 - a justification in the form of a sensitivity study that demonstrates the accident sequences or contributors significant to the application were not impacted (remained the same) by the particular issue.
- The standards or peer review process documents may recognize different capability categories or grades that are related to level of detail, degree of plant specificity, and degree of realism. The licensee's documentation is to identify the use of the parts of the PRA that conform to ~~the lower~~ capability categories or grades, if they lead to limitations on the implementation of the licensing change.

lower than deemed required for the given application (Section 3 ASME PRA Standard) to determine

[LAST SENTENCE WOULD APPEAR TO PRESCRIBE AN ENORMOUS TASK INVOLVING THE EXAMINATION OF THE IMPACT OF EVERY SR WITH A CC LESS THAN III. THE TECHNIQUE SHOULD BE TO DETERMINE THE REVISED GRADE LEVELS USING TECHNIQUES ROUGHLY AKIN TO THOSE IN SECTION 3.1.200-31 OF THE ASME STANDARD AND EXAMINE THE IMPLEMENTATION IMPACT OF ONLY THOSE SRs WHOSE CC IS LOWER THAN THOSE DETERMINED TO BE REQUIRED.]

APPENDIX A NRC REGULATORY POSITION ON ASME PRA STANDARD

INTRODUCTION

ASME has published ASME RA-S-2002, "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications," (April 5, 2002), Addenda A to this standard (ASME RA-Sa-2003, December 5, 2003), and Addendum B to this standard (ASME RA-Sb-2005, December 30, 2005). The standard states that it "sets forth requirements for probabilistic risk assessments (PRAs) used to support risk informed decision for commercial nuclear power plants, and describes a method for applying these requirements for specific applications." The NRC staff has reviewed ASME RA-Sb-2005 against the characteristics and attributes for a technically acceptable PRA as discussed in Regulatory Position 3 of this regulatory guide. The staff's position on each requirement (referred to in the standard as a requirement, a high-level requirement, or a supporting requirement) in ~~ASME RA-Sb-2005~~ is categorized as "no objection," "no objection with clarification," or "no objection subject to the following qualification," and defined as follows:

the ASME Standard

- **No objection:** the staff has no objection to the requirement.
- **No objection with clarification:** the staff has no objection to the requirement. However, certain requirements, as written, are either unclear or ambiguous, and therefore the staff has provided its understanding of these requirements.
- **No objection subject to the following qualification:** the staff has a technical concern with the requirement and has provided a qualification to resolve the concern.

Table A-1 provides the staff's position on each requirement in ASME RA-S-2002, ASME RA-Sa-2003 and ASME RA-Sb-2005. A discussion of the staff's concern (issue) and the staff proposed resolution is provided. In the proposed staff resolution, the staff clarification or qualification to the requirement is indicated either in bolded text (i.e., **bold**) or strikethrough text (i.e., ~~strikethrough~~); that is, the necessary additions or deletions to the requirement (as written in the ASME standard) for the staff to have no objection are provided.

Table A-1 Staff Position on ASME RA-S-2002, ASME RA-Sa-2003, and ASME RA-Sb-2005

Index No	Issue	Position	Resolution
Global			
—	Use of references, the various references, in general may be acceptable, however, there may be aspects that are not applicable or not acceptable	Clarification	For every reference: No staff position is provided on this reference. The staff neither approves or disapproves of information contained in the referenced document.
Chapter 1			

Table A-1 Staff Position on ASME RA-S-2002, ASME RA-Sa-2003, and ASME RA-Sb-2005

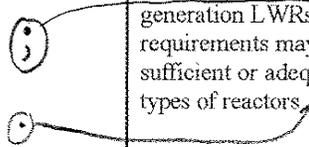
Index No	Issue	Position	Resolution
1.1 	The standard is only for current generation LWRs; the requirements may not be sufficient or adequate for other types of reactors.	Clarification	This Standard sets forth requirements for Probabilistic Risk Assessments (PRAs) used to support risk-informed decisions for current commercial light water reactor nuclear power plants, and prescribes a method for applying these requirements for specific applications (additional or revised requirements may be needed for other reactor designs).
1.2 - 1.7	-----	No objection	-----
Chapter 2			
2.1	-----	No objection	-----
2.2			
Core damage	The use of the term "a large fraction of the core" should be consistent with the definition of "large" used in the LERF definition.	Clarification	<i>core damage</i> : ...involving a large fraction of the core (i.e., sufficient, if released from containment, has the potential to cause offsite health effects) is anticipated.
Extremely rare event	A frequency cutoff should be provided as part of this definition.	Clarification	<i>extremely rare event</i> : one that would not be expected to occur even once throughout the world nuclear industry over many years (e.g., < 1E-6/yr).
Internal event	Internal fire is an internal and not an external event	Qualification	<i>internal event</i> : ...By convention, loss of offsite power is considered to be an internal event, and internal fire is considered to be an external event.
PRA upgrade	See issue discussed on definition of Accident sequence, dominant	Clarification	<i>PRA upgrade</i> : The incorporation into a PRA model of a new methodology or significant changes in scope or capability that have the potential to impact the significant sequences . This could...
Rare event	A frequency cutoff should be provided as part of this definition.	Clarification	rare event: one that might be expected to occur only a few times throughout the world nuclear industry over many years (e.g., < 1E-4/yr).
Reactor-year	This term references the wrong footnote and could more accurately reference the right table in Section 4.5	Clarification	<i>reactor year</i> : a calendar year in the operating life of one reactor, regardless of power level. See Note 2 3 in Table 4.5.1-2 (c).
Reactor-operating-state-year	This term references the wrong footnote and could more accurately reference the right table in Section 4.5	ClarificationSee Note 2 3 in Table 4.5.1-2 (c).

Table A-1 Staff Position on ASME RA-S-2002, ASME RA-Sa-2003, and ASME RA-Sb-2005

Index No	Issue	Position	Resolution
DA-E1 thru DA-E3	-----	No objection	-----
<u>4.5.7 - IF</u>			
4.5.7.1	-----	No objection	-----
Table 4.5.7-1	-----	No objection	-----
<i>Tables 4.5.7-2(a) thru 4.5.7-2(f)</i>			
IF-A1 thru IF-A4	-----	No objection	-----
IF-B1	The list of fluid systems should be expanded to include fire protection systems.	Clarification	For each flood area... INCLUDE: (a) equipment (e.g., piping, valves, pumps) located in the area that are connected to fluid systems (e.g., circulating water system, service water system,... fire protection system...
IF-B1a thru IF-B2	-----	No objection	-----
IF-B3	It is necessary to consider a range of flow rates for identified flooding sources, each having a unique frequency of occurrence. For example, small leaks that only cause spray are more likely than large leaks that may cause equipment submergence.	Clarification	(b) range of flow rates of water
IF-B3a	----- Note: IF-B4 was deleted in Addendum B	No objection	-----
IF-C1	For a given flood source, there may be multiple propagation paths and areas of accumulation.	Clarification	For each defined flood area and each flood source, IDENTIFY the propagation paths from the flood source area to its the areas of accumulation.
IF-C2 thru IF-C2b	-----	No objection	-----

Table A-1 Staff Position on ASME RA-S-2002, ASME RA-Sa-2003, and ASME RA-Sb-2005

Index No	Issue	Position	Resolution
LE-B1 thru LE-B3	-----	No objection	-----
LE-C1	The SR for Capability Category II contains the statement: "NUREG/CR-6595, Appendix A provides an acceptable definition of LERF source terms." In fact, the Appendix contains three possible definitions of LERF.	Clarification	NUREG/CR-6595, Appendix A provides a discussion and examples an acceptable definition of LERF source terms.
LE-C2a thru LE-C10	-----	No objection	-----
LE-D1 thru LE-D6	-----	No objection	-----
LE-E1 thru LE-E4	-----	No objection	-----
LE-F1a thru LE-F3	-----	No objection	-----
LE-G1 thru LE-G6	-----	No objection	-----
Chapter 5			
5.1	-----	No objection	-----
5.2	-----	No objection	-----
5.3	-----	No objection	-----
5.4	See issue discussed on definition of Accident sequence, dominant	Clarification	<u>2nd para</u> : ...Changes that would impact risk-informed decisions should be prioritized to ensure that the most significant changes are incorporated as soon as practical."
5.5, 5.6	-----	No objection	-----
5.7	-----	No objection	-----
5.8 (a)-(d)	-----	No objection	-----
5.8 (e)	It is unclear what is to be documented from the peer review.	Clarification	"(e) record of the performance and results of the appropriated PRA reviews (consistent with the requirements of Section 6.6)"
5.8 (f), 5.8(g)	-----	No objection	-----



5.4	PRA changes that are neither "PRA maintenance" nor "PRA upgrade"	Clarification	Add to end of section: Changes that are neither "PRA maintenance" nor constitute a new methodology or significant changes in scope or capability ("PRA upgrade") do not require a peer review.
-----	--	---------------	--

1.200-49

Table A-1 Staff Position on ASME RA-S-2002, ASME RA-Sa-2003, and ASME RA-Sb-2005

Index No	Issue	Position	Resolution
6.5	-----	No objection	-----
6.6			
6.6.1	As written, It is not clear whether certain essential items are included in the documentation requirements that are necessary to accomplish the goal of the peer review.	Clarification	“ (i) identification of the strengths and weaknesses that have a significant impact on the PRA (k) assessment of the key assumptions (h) an assessment of the capability category of the SRs (or equivalent Peer Review grade)”
6.6.2	-----	No objection	-----

APPENDIX B NRC POSITION ON THE NEI PEER REVIEW PROCESS (NEI 00-02)

INTRODUCTION

2/50

The NEI Peer Review Process is documented in NEI 00-02, Revision 1. It provides guidance for the peer review of PRAs and the grading of the PRA subelements into one of four capability categories. This document includes the NEI subtier criteria which provides the criteria for assigning a grade to each PRA subelement. The NEI subtier criteria for a Grade 3 PRA have been compared by NEI to the requirements in the ASME PRA standard (ASME RA-Sb-2005) listed for a Capability Category II PRA. A comparison of the criteria for other grades/categories of PRAs was not performed since NEI contends that the results of the peer review process generally indicate the reviewed PRAs are consistent with the Grade 3 criteria in NEI 00-02. However, the PRAs reviewed have contained a number of Grade 2, and even Grade 4 elements. The comparison of the NEI subtier criteria with the ASME PRA standard has indicated that some of the Capability Category II ASME PRA standard requirements are not addressed in the NEI Grade 3 PRA subtier criteria. Thus, NEI has provided guidance to the licensees to perform a self-assessment of their PRAs against the criteria in the ASME PRA standard that were not addressed during the NEI peer review of their PRA. A self-assessment is likely to be performed in support of risk-informed applications. This self-assessment guidance is also included in NEI 00-02, Revision 1.

This appendix provides the staff's position on the NEI Peer Review Process (i.e., NEI 00-02), the proposed self-assessment process, and the self-assessment actions. The staff's positions are categorized as following:

- No objection: the staff has no objection to the requirement.
- No objection with clarification: the staff has no objection to the requirement. However, certain requirements, as written, are either unclear or ambiguous, and therefore the staff has provided its understanding of these requirements.
- No objection subject to the following qualification: the staff has a technical concern with the requirement and has provided a qualification to resolve the concern.

In the proposed staff resolution, the staff clarification or qualification that is needed for the staff to have no objection are provided.

NRC POSITION ON NEI 00-02

Table B-1 provides the NRC position on the NEI Peer Review Process documented in NEI 00-02, Revision 1. The stated positions are based on the historical use of NEI 00-02 and on the performance of a self assessment to address those requirements in the ASME PRA standard and Addendums A and B (ASME RA-S-2002, ASME RA-Sa-2003, and ASME RA-Sb-2005) that are not included in the NEI subtier criteria.

Table B-1. NRC Regulatory Position on NEI 00-02.

Report Section	Regulatory Position	Commentary/Resolution
Section 2 PEER REVIEW PROCESS		
2.1 Objectives	Clarification	See comment for Section 1.1.
2.2 Process Description	Clarification	The ASME PRA standard (with the staff's position provided in Appendix A of this regulatory guide) can provide an adequate basis for a peer review of an at-power, internal events PRA (including internal flooding) that would be acceptable to the staff. Since the NEI subtier criteria do not address all of the requirements in the ASME PRA standard, the staff's position is that a peer review based on these criteria is incomplete. The PRA standard requirements that are not included in the NEI subtier criteria (identified for a Grade 3 PRA in Table B-3) need to be addressed in the NEI self-assessment process as endorsed by the staff in this appendix.
Steps 4, 7, & 8	Clarification	See previous comment.
2.3 PRA Peer Review Team	Clarification	The peer reviewer qualifications do not appear to be consistent with the following requirements specified in Section 6.2 of the ASME PRA standard: <ul style="list-style-type: none"> • the need for familiarity with the plant design and operation • the need for each person to have knowledge of the specific areas they review • the need for each person to have knowledge of the specific methods, codes, and approaches used in the PRA <i>Element Assigned For review</i> The NEI self-assessment process needs to address the peer reviewer qualifications with regard to these factors.
2.4 and 2.5	No objection	
Section 3 PRA PEER REVIEW PROCESS ELEMENTS AND GUIDANCE		
3.1	No objection	-----
3.2 Criteria and 3.3 Grading	Clarification	See comment for Section 1.1.
3.3 Grading	Clarification	The NEI peer review process grades each PRA element from 1 to 4, while the ASME PRA standard uses Capability Categories I, II, and III. The staff interpretation of Grades 2, 3, and 4 is that, they correspond broadly to Capability Categories I, II, and III respectively. This statement is not meant to imply that the supporting requirements, for example, for Category I are equally addressed by Grade 2 of NEI-00-02. The review of the supporting requirement for Category II against Grade 3 of NEI-00-02 indicated discrepancies and consequently the need for a self-assessment. The existence of these discrepancies would indicate that it would not be appropriate to assume that there are not discrepancies between Category I and Grade 2. A comparison between the other grades and categories has not been performed. The implications of this are addressed in item 7a on Table B-2.

Table B-1. NRC Regulatory Position on NEI 00-02.

Report Section	Regulatory Position	Commentary/Resolution
Appendix C GUIDANCE FOR THE PEER REVIEW TEAM		
C.1 Purpose	No objection	-----
C.2 Peer Review Team Mode of Operation	No objection	-----
C.3 Recommended Approach to Completing the Review	Clarification	See comment for Section 4.1.
C.4 Grading	Clarification /Qualification	See the two comments on Section 3.3.
C.5 Peer Review Team Good Practice List	No objection	-----
C.6 Output	Qualification	See the comments on Section 4.1.
C.7 Forms	Clarification	The staff does not agree with the use of an overall PRA element grade (documented in Tables C.7-5 & C.7-6) in the assessment of a PRA.

NRC POSITION ON SELF-ASSESSMENT PROCESS

The staff position on the self-assessment process proposed by NEI to address the requirements in the ASME PRA standard and Addendums A and B (ASME RA-S-2002, ASME RA-Sa-2003, and ASME RA-Sb-2005) that are not included in the NEI subtier criteria are addressed in this section. Both the self-assessment process and the specific actions recommended by NEI to address missing ASME standard requirements are addressed.⁸

Table B-2 provides the NRC position on the NEI self-assessment process documented in Appendix D1 of NEI 00-02, Revision 1. The staff's position on specific aspects of this process use the categories provided in Section B.2 of this regulatory guide.

[LAST SENTENCE NOT CLEAR UNLESS "SECTION B.2" IS MEANT TO BE TABLE B-2.]

⁸ The NEI comparison between NEI 00-02 criteria and the ASME requirements utilized the original standard as modified by subsequent Addendums (A and B).

Table B-2. NRC Regulatory Position on NEI Self-Assessment Process.

Report Section	Regulatory Position	Commentary/Resolution
2	Clarification	Certain ASME PRA standard requirements, although not explicitly listed in the NEI subtier criteria, may generally be included as good PRA practice. Credit may be taken for meeting these ASME requirements subject to confirmation in the self-assessment that the requirements were in fact addressed by the peer review. Table B-4 identifies the ASME PRA standard requirements not explicitly addressed in the NEI subtier criteria that the staff believes needs to be addressed in the NEI self-assessment process.
3	Clarification	The staff takes exception to the statement that NEI 00-02 Appendix D2 "is a comparison of the peer review process to the ASME PRA standard Addendum B, as endorsed/modified by NRC in RG 1.200." Since the NRC comments on Addendum B were not published at the time NEI 00-02, Revision 1 was generated, this statement is incorrect. The NEI Self-Assessment document should state that the "Industry has reviewed and compared the technical contents of the peer review process and the ASME PRA Standard (ASME-RA-Sa-2003) as endorsed/modified by the NRC and updated by Addendum B of the ASME Standard." The self-assessment process should consider the clarifications and qualifications on Addendum B that will be provided Appendix A of RG 1.200, Revision 1.
Self Assessment Process Attributes	No objection	-----
Overall Peer Review Process and Decision	No objection	-----
Self Assessment Process Steps		
1. thru 6.	No objection	-----
7.a	Clarification	For the PRA subelements assigned a grade other than a Grade 3 in the NEI peer review (i.e., a Grade 1, 2, or 4), a self-assessment of those PRA subelements required for the application against the Capability Category requirements (of the ASME PRA standard as qualified in Appendix A of this regulatory guide) determined to be applicable for the application needs to be performed and documented. ←
7.b thru 8.	No objection	-----
9	Clarification	The list of items subject to a self assessment action and documentation needs to always include those requirements where "Yes" is listed in the "Addressed by NEI" column and there are actions listed in the "Industry Self-Assessment Actions" column.
10. thru 13.	No objection	-----

However, it is reasonable to assign an SR that requires no Appendix B self assessment that received an NEI grade 4 & Capability Category II without further review.

1.200-60

[THIS INSERT IS CONSISTENT WITH POSITION GIVEN UNDER "COMMENTARY/RESOLUTION FOR REPORT SECTION 4.3 IN TABLE B-5 ON PAGE 110.]

Table B-2. NRC Regulatory Position on NEI Self-Assessment Process.

Report Section	Regulatory Position	Commentary/Resolution
14	Clarification	The staff's comments on which ASME PRA requirements need to be addressed in the self assessment, and on the suggested actions (Appendix D2 of NEI 00-02, Rev. 1) are provided in Table B-3. In addition, the staff's position on the ASME PRA standard, as documented in Appendix A of this regulatory guide, needs to be included in the self assessment of the PRA subelements.

Tables B-3 and B-4 provide the staff position on the NEI comparison of NEI 00-02 (including the subtier criteria) to the ASME PRA standard Addendum B and the self-assessment actions provided in Appendix D2 of NEI 00-02, Revision 1.⁹ The staff's position on the ASME PRA standard (Addendum B) documented in Appendix A of this regulatory guide was considered in the comparison. The review of the NEI comparison and proposed actions was performed under the assumption that all of the requirements in the NEI subtier criteria were treated as mandatory. Thus, the staff position is predicated on the requirement that all of the requirements in the NEI subtier criteria are interpreted as "shall" being required.

Table B-3 provides the staff position of the "explanatory" table preceding the comparison and self assessment actions table provided in Appendix D2. The first two columns are taken directly from the table in Appendix D2.

Table B-3 NRC Regulatory Positions on Actions Utilities Need to Take in Self Assessment Actions.

TEXT	UTILITY ACTIONS	REGULATORY POSITION	COMMENT/RESOLUTION
YES and NONE in Action column	None	No objection	-----
YES and clarifications included in action column	Review comment. It is believed Peer Review Process addressed the requirements. Unless it is suspected a problem exists, no further action required.	Clarification	As written, no action may be taken, which is in conflict with the actions specified in the table providing the industry self assessment actions. It is assumed that the actions provided in that table will be taken.
PARTIAL	Take action(s) specified in comments column	No Objection	-----
NO	Take action(s) specified in comments column	No Objection	-----

ASSESSMENT

In Table B-4, the "NEI Assessment" includes, for each supporting requirement in the ASME

⁹ The NEI self-assessment process was revised to address the requirements in Addendum B of the ASME Standard.

[THESE FIRST 4 CHANGES NEEDED FOR CLARITY AND CONSISTENCY WITH TABLE B-4 HEADINGS]

APPLICABLE

ADDRESSED BY

standard (ASME ^{STD} SR), NEI's assessment if this SR is addressed in NEI 00-02 (NEI 00-02), ~~if it is addressed in NEI 00-02 then~~ where it is addressed is identified (NEI 00-02 ELEMENTS), and whether NEI recommends any self assessment by the licensee (INDUSTRY SELF ASSESSMENT ACTIONS). Table B-4 also includes the staffs position on the suggested industry self assessment action (REGULATORY POSITION).

Table B-4. NRC Regulatory Position on Industry Self Assessment Actions.

NEI ASSESSMENT				REGULATORY POSITION
ASME STD SR	ADDRESSED BY NEI 00-02?	APPLICABLE NEI 00-02 ELEMENTS	INDUSTRY SELF ASSESSMENT ACTIONS	
INITIATING EVENTS				
IE-A1	Yes	IE-7, IE-8, IE-9, IE-10	None	No objection
IE-A2	Yes	IE-5, IE-7, IE-9, IE-10	Confirm that the initiators (including human-induced initiators, and steam generator tube rupture (PWRs)) were included. This can be done by either citing peer review documentation/conclusions or examples from your model. NEI 00-02 does not explicitly mention human-induced initiators but in practice peer reviews have addressed this.	No objection; the definition of active component provided in the Addendum B of the ASME standard needs to be used when verifying ISLOCAs were modeled; IE-7 is the applicable NEI 00-02 element.
IE-A3	Yes	IE-8, IE-9	None	No objection; IE-8 is the applicable NEI 00-02 element.
IE-A3a ⁽¹⁾	Yes	IE-8, IE-9	None	No objection; IE-8 is the applicable NEI 00-02 element.
IE-A4	Partial	IE-5, IE-7, IE-9, IE-10	Check for initiating events that can be caused by a train failure as well as a system failure.	No objection; IE-10 is the applicable NEI 00-02 element.
IE-A4a ⁽¹⁾	Partial	IE-5, IE-7, IE-9, IE-10	Check for initiating events that can be caused by multiple failures, if the equipment failures result from a common cause or from routine system alignments.	No objection

[#] In summary, following completion of the "Industry Self Assessment Actions" as augmented by the "Regulatory Position" for all ^{applicable} NEI grade 3 subelements (and grade 4 if no self assessment specified), the corresponding SR may be considered to have met Capability Category II requirements. For NEI subelements receiving other grades, a self assessment against the Capability Category requirements of the ASME Standard will determine the Capability Category for the corresponding SR.

Table B-4. NRC Regulatory Position on Industry Self Assessment Actions.

NEI ASSESSMENT				REGULATORY POSITION
ASME STD SR	ADDRESSED BY NEI 00-02?	APPLICABLE NEI 00-02 ELEMENTS	INDUSTRY SELF ASSESSMENT ACTIONS	
IF-E3a ⁽³⁾	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
IF-E4	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
IF-E5	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
IF-E5a ⁽⁴⁾	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
IF-E6	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
IF-E6a ⁽⁴⁾	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
IF-E6b ⁽⁴⁾	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
IF-E7	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
IF-E8 ⁽³⁾	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
IF-F1 ⁽²⁾	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
IF-F2 ⁽²⁾	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
IF-F3 ⁽²⁾	No		Use the ASME standard for requirements. NEI 00-02 does not address this supporting requirement.	No objection
QUANTIFICATION ANALYSIS				

↳ NEXT PAGE

Table B-4. NRC Regulatory Position on Industry Self Assessment Actions.

NEI ASSESSMENT				REGULATORY POSITION
ASME STD SR	ADDRESSED BY NEI 00-02?	APPLICABLE NEI 00-02 ELEMENTS	INDUSTRY SELF ASSESSMENT ACTIONS	
QU-F4 ⁽²⁾	No	QU-27, QU-28, QU-32	Use the ASME standard for requirements at the time of doing an application. NEI 00-02 does not address this supporting requirement.	No objection
QU-F5 ⁽²⁾	No		Use the ASME standard for requirements at the time of doing an application. NEI 00-02 does not address this supporting requirement.	No objection
QU-F6 ⁽³⁾	No		Use the ASME standard for requirements at the time of doing an application. NEI 00-02 does not address this supporting requirement.	No objection
LERF ANALYSIS				

↳ NEXT PAGE

References

1. **Draft Regulatory Guide DG-1161** (Proposed Revision 1 of Regulatory Guide 1.200, dated February 2004), "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," September 2006.

Proposed Revision 2 to Standard Review Plan 19.1, "Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," September 2006.
2. **Nuclear Energy Institute**, Letter from Biff Bradley, Manager, Risk Assessment Nuclear Generation Division, to Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC, "Comments on Draft Regulatory Guide DG-1161, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," October 19, 2006.
3. **SECY-04-0118**, "Plan for the Implementation of the Commission's Phased Approach to PRA Quality," U.S. Nuclear Regulatory Commission, Washington, DC, July 13, 2004.
4. **Nuclear Energy Institute**, Letter from Anthony Pietrangelo, Director of Risk- and Performance-Based Regulation Nuclear Generation, Nuclear Energy Institute, to Mary Drouin, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC, "Update to Revision 1 of NEI-00-02, Probabilistic Risk Assessment Peer Review Process Guidance," November 15, 2006.
5. **Nuclear Energy Institute**, Letter from Biff Bradley, Manager, Risk Assessment Nuclear Generation Division, to Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC, "Comments on Draft Regulatory Guide DG-1161, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," Enclosure: PWR Owners Group Comments on DG-1161, October 19, 2006.
6. **Hershel, Specter**, "Dr. Farouk Eltawila / Comments on RG 1.200 - Rev 1," RBR Consultants, Inc., September 11, 2006. (ADAMS # ML063000099)
7. **ASME**, Letter from R. Grantom, Chair, ASME Committee on Nuclear Risk Management, and Kenneth Balkey, PE, ASME, Vice President, Nuclear Codes and Standards, to Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC, "ASME Comments on Draft Regulatory Guide DG-1161 (Proposed Revision 1 of Regulatory Guide 1.200, dated February 2004), "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," November 17, 2006.
8. **BWR Owner's Group**, Letter from Randy Bunt, BWR Owner's Group Chair, to Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC, "Comments on Draft Regulatory Guide DG-1161 (Proposed Revision 1 of Regulatory Guide 1.200, dated February 2004), "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," October 13, 2006.