Response to Public Comments on Draft Regulatory Guide (DG) -1226 "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decision on Plant-Specific Changes to the Licensing Basis" Proposed Revision 2 of RG 1.174

A notice that Draft Regulatory Guide, DG-1226 (Proposed Revision 2 of RG 1.174) was available for public comment was published in the *Federal Register* on September 4, 2009 on page 74 FR 45884. The Public Comment period ended November 3, 2009. Comments were received from the organizations listed below. The NRC has combined the comments and NRC staff disposition in the following table.

#	Section/ Reference	Comment Source	Comment	NRC Response
1.	General	NEI	A key companion document, RG 1.200, "An Approach for determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," is listed in the references without a revision number; this should be corrected to specifically reference Revision 2, which would be consistent with the citations on pages 13 and 14 of DG-1226. Referencing RG 1.200 without a revision number is not conducive to maintaining regulatory stability, as issuance of future revisions of RG 1.200 could appreciably alter the implications of portions of RG 1.174 without any prior NRC or public review. The lack of a specific revision number in the reference could also lead to ambiguity in the guidance during the implementation period for any future revisions to RG 1.200, as during this time, it would not be clear which revision is intended in the reference.	The commenter is correct that the draft guide was inconsistent in whether or not a specific revision number was provided. It has been updated such that there are no references to a specific revision of Regulatory Guide 1.200. Regulatory Guide 1.174 references the revision of RG 1.200 appropriate for the application in question (i.e., the current revision unless a grace period is in effect).
	Page 32, Ref. 12		It should be specified that RG 1.200, Revision 2 is the revision referenced throughout this DG.	
		Exelon	Exelon is requesting further clarification regarding whether the NRC plans to reference a specific revision of RG 1.200. Not referencing a specific revision to RG 1.200 implies that once issued RG 1.174 endorses the most current revision of RG 1.200.	

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2.	General	NEI	The discussions on expectations for PRA scope and technical adequacy need to better emphasize that quantitative bounding and margins analysis may be sufficient to demonstrate that the impact of a specific hazard group is minimal or bounded, and that a complete PRA is not necessary. These discussions should also clarify that it is not necessary for the licensee to quantify risk contributors that would not affect the decision to demonstrate the lack of significance. This comment is significant in light of industry's finite resource capability, current issues with inaccuracy in fire PRA, current state of piloting of the external events portion of the combined standard, and our desire to continue implementing risk-informed applications that use the best available information to assess risk impacts commensurate with their significance. Applications provide the best method to enhance risk understanding and use of risk concepts.	The staff does not believe that this concern warrants modification of the guide.
3.	General	Exelon	There are several new terms/phrases in DG-1 226 that contain more than a nominal reference to concepts defined elsewhere. For example: * *"Hazard Groups"* in Section 2.3.1. * *"Capability Category"in* Section 2.3.3. • "Key sources of model uncertainty" in Section 2.5.5, Footnote 8 and "Key assumption" in, Section 6.3, Footnote 9, which are worded somewhat differently. * The definition of "reasonable" relative to "Key modeling assumption" in Section 6.3.1, Footnote 10, is worded differently than in the American Society of Mechanical Engineers (ASME)/American Nuclear Society (ANS) PRA standard. In some instances, there are inconsistencies between the usage in DG-1226 and in the referenced source. This creates the potential for misunderstanding and misapplication. Exelon suggests that some of these discussions be replaced with reference to the source documents for definitions.	The hazard group list (Section 2.3.1) and the Capability Category description (Section 2.3.3) have been modified to be entirely consistent with the ASME/ANS PRA standard. The test associated with key sources of model uncertainty and key assumption are already verbatim from the PRA standard. Minor edits were made to the footnote on reasonable modeling assumptions to also make it identical to the PRA standard.

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4.	Throughout document Page, 14, Section 2.3.3	NEI PWROG	The term “technical acceptability” should be changed to “technical adequacy” to better align with the ASME/ANS PRA Standard and RG 1.200. The title of this Section is changed to “*Probabilistic Risk Assessment Technical Adequacy,*” but the text in the first paragraph (first sentence) states “In the current context, technical acceptability will be understood as being determined by the adequacy of the actual modeling and the reasonableness of the assumptions and approximations.” “Technical acceptability” in the first sentence should be replaced with “technical adequacy.”	The DG has been updated to be more consistent with RG 1.200 with regard to the use of the terms adequate and acceptable.
5.	Page 4, “Background,” Last Paragraph of Section	NEI	“Section 2.2.4” should be changed to “Section 2.4.”	This change was made.
6.	Pg. 4, “Purpose of This Regulatory Guide”	NEI	One proposed revision references the possibility of additional or revised guidance for reactors licensed under 10 CFR Part 52. Discussions on this topic are taking place in a process separate from this RG revision, and a commission-level decision may be forthcoming. Inclusion of a discussion on this process in RG 1.174, Revision 2 prior to completion of the decisionmaking process does not enhance the clarity of the guidance, and the reference to this potential additional or revised guidance should be removed. Re-stated in the specific comments: The last sentence of this section [pg. 4 “Purpose of This Regulatory Guide”] should be removed. The issue of risk metrics for reactors licensed under 10 CFR 52 is being addressed in separate venues, and a Commission-level decision may be forthcoming. The industry suggests that such statements not be incorporated into regulatory guides until the decisionmaking process is complete.	The staff does not agree with the commenter’s concern. No change has been made.
7.	Page 5	Exelon	Although Regulatory Guide 1.200, *"An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities,"* is referred to throughout DG-1 226, it is not mentioned in this section. Exelon believes that it is important to explain the relationship between the considerations for risk-informed plant changes and the consideration of Probabilistic Risk Assessment (PRA) capability to support risk-informed plant changes.	The section in question has been modified to address this concern.

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8.	Page 5	Exelon	Although NUREG-1855, *"Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making,"* is referred to throughout DG-1 226, it is not mentioned in this section. Exelon believes that it is important to explain the relationship between the process for addressing uncertainties, per NUREG-1 855, and the expectation for its application in considering risk-informed plant changes.	This concern has been implicitly addressed by the additions made to address the prior comment regarding RG 1.200.
9.	Page 7, "Regulatory Position," Third Bullet on Page	NEI, Exelon	This bullet references NUREG-1855 and uses the term "significant uncertainties." This term is not defined and could be subject to interpretation. Addressing uncertainties and assessing their "significance" merits more discussion in this RG. It should not be solely deferred to a NUREG, which has no regulatory standing. Currently, this is only covered in a NUREG and in the staff's plan on the Phased Approach to PRA Quality. As the umbrella RG for all risk-informed activities, RG 1.174 should give this subject more elaboration.	The sentence has been revised to use the terminology "key sources of uncertainty" to better align with the supporting guidance.
10.	Page 7, "Regulatory Position," Sixth Bullet on Page	NEI	It would seem appropriate and consistent with NRC philosophy to also include in the "cumulative effect" any changes that decrease risk in the decision process. It is suggested that the second sentence of bullet 6 be revised to read "The cumulative effect of such changes, risk increase and risk decrease (if available), should be tracked and considered in the decision process."	The requested change has been made.
11.	Page 8, Section 1, Figure 2	NEI	Figure 2 should be moved to just after the last paragraph on page 7, which is where it is referenced.	The requested change has been made.
12.	Page 11, 2.1.1	PWROG, NEI	Defense-in-depth (last bullet) states "The intent of the general design criteria is maintained…" This bullet should be replaced with "The intent of the plant's design criteria is maintained…" to maintain consistency with the change made in Regulatory Guide (RG) 1.177.	The requested change has been made.
13.	Page 11, 2.1.2	PWROG	The Draft Regulatory Guide (DG) states (Ref. 5-9). This should be replaced with (Refs. 5, 7-9) since Reference 6 has been withdrawn and Reference 9 replaced Reference 6.	The requested change has been made.

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14.	Page 12, Section 2.2, Second to Last Sentence in Top Paragraph	Exelon NEI	In the top paragraph, in the sentence that includes the phrase "...or *bounding estimates will be adequate...,"* Exelon believes that it may be beneficial to add the word "risk" to the phrase so that it reads: *"...or bounding risk estimates will be adequate."* This sentence should be revised to clarify that "bounding risk estimates" will be adequate for some applications by explicitly using that term rather than simply stating that "bounding estimates" will be adequate.	The requested change has been made.
15.	Page 12, Section 2.2, footnote (4)	PWROG	"In still others, a qualitative assessment of the impact of the LB change on the plant's risk may be sufficient.[4]" Footnote 4 quotes RG 1.200's definition of probabilistic risk assessment (PRA) (which limits a PRA to a quantitative assessment). Footnote 4 seems to be out of place in this paragraph. The sentence in which the footnote appears is one that discusses the use of a qualitative assessment. The definition in RG 1.200 limits PRA to quantitative assessments. The first paragraph of Section 2.2 notes that the "level of sophistication of the evaluation, including the scope of the risk assessment ..., depends on the contribution the risk assessment makes to the integrated decisionmaking …" While it is recognized that an in-depth and comprehensive risk assessment will be necessary to support some risk-informed applications, it is also noted that for other (less risk-significant) applications, or for contributors that are not significant to an application, "calculated risk-importance measures **or bounding estimates will be adequate**." (emphasis added) The concept of using bounding analyses is also discussed in Section 2.5.5: "if the estimated value of a particular metric is very small compared to the acceptance goal, a simple bounding analysis may suffice …" Also, the ASME/ANS PRA Standard allows quantitative and qualitative assessments in the definition of PRA. Accordingly, to support flexibility for simplified or bounding methods, the footnote should be deleted.	The footnote has been moved to address the first part of this concern. The staff does not agree with the second part of the concern as stated, and no change has been made to address this aspect of the comment.
16.	Page 12, Section 2.2, First Full Paragraph on Page	NEI	The second sentence should be revised to remove the references to latent cancer fatalities and land contamination to maintain the clear, concise point that long-term containment performance is an important consideration.	The paragraph in question was deleted because the concern it was attempting to address is already covered by defense-in-depth, and the paragraph itself was clearly causing confusion.

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17.	Page 12, Section 2.2, First Full Paragraph on Page	NEI	While CDF and LERF have historically been the risk metrics used to support risk-informed applications, the draft revision to this RG suggests that licensees should also qualitatively address "the impact of the proposed change on those aspects of containment function not addressed in the evaluation of LERF." However, as there is no information on the expectations for such assessments available in this RG or elsewhere, the statement should be removed.	The paragraph in question was deleted because the concern it was attempting to address is already covered by defense-in-depth, and the paragraph itself was clearly causing confusion.
		Exelon	The second paragraph refers to potential risk impacts not reflected in changes in Core Damage Frequency (CDF) and Large Early Release Frequency (LERF). While this is a valid point, specific risk metrics and acceptance criteria have not been established. Therefore, Exelon believes that the guidance that the impacts of the proposed change on aspects of containment function be qualitatively addressed must be based on a non-risk evaluation (e.g., relative to maintaining defense-in-depth and safety margins). Further, the proposed language in DG-1226 begs the question, if long-term containment performance is one example, are there others which should be addressed? Exelon is concerned that this could result in a series of questions and answers within the NRC's Request for Additional Information (RAI) process, under the framework of addressing additional examples of: *"issues for which the risk impact is not reflected, or inadequately reflected, by changes to CDF and LERF."* This could result in an evolving list of unexpected new factors to be qualitatively addressed in a risk context, creating inefficiency and uncertainty in the regulatory change request process. Exelon recommends that the sentence beginning, ***"...For** example, changes affecting long-term* ...,. be deleted since it is speculative and not measurable.	
		PWROG	The DG seems to suggest the potential addition of a new risk metric when it states that "Recognizing that the containment function is an important factor in maintaining the defense-in-depth philosophy, the impact of the proposed change on those aspects of containment function not addressed in the evaluation of LERF should be addressed qualitatively …" Historically, Core Damage Frequency (CDF) and Large Early Release Frequency (LERF) have been the only risk metrics used to support risk-informed applications. These metrics are well understood and quantifiable by the industry. While the DG addresses this potential qualitative metric as a permissive (the word "should" is used), the DG's language should ensure that no new risk metrics are required/expected by the staff in the review of a risk-informed application.	

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18.	Page 12, Section 2.2, Item 3	NEI	Since the title of the cited "Section 2.5" does not mention uncertainty, it would be clearer if the word "provides" were replaced with the word "includes" in the last sentence of Item 3.	No change has been made. Whether uncertainty appears in the title of Section 2.5 or not, that section does provide the specified information.
19.	Page 12, Section 2.2, Footnote 4	NEI, Exelon	This footnote appears to be improperly associated with the last sentence in the paragraph. It seems more appropriate that the footnote be placed at the end of the third to last sentence, which ends with "…to provide adequate justification."	The requested change has been made.
20.	Page 13, Section 2.3.1	PWROG	This paragraph defines hazard groups using the definition from the ASME/ANS PRA Standard. However, the typical hazard groups discussed in the DG are not consistent with those in the ASME/ANS PRA Standard. The DG uses "Typical hazard groups considered in a nuclear power plant PRA include: internal hardware faults (internal events), internal floods, internal fires, seismic events, high winds, external floods, and transportation accidents." This should be consistent with the ASME/ANS PRA Standard which uses "Typical hazard groups considered in a nuclear power plant PRA include: internal events, seismic events, internal fires, high winds, external floods, etc… In some cases it may be appropriate to treat internal flooding as a separate hazard group." It is not necessary to redefine "hazard groups" in the DG. The ASME/ANS PRA Standard has defined the term and RG 1.200 takes no exception to the definitions in ASME/ANS RA-Sa-2009. This paragraph should be revised to be consistent with the ASME/ANS PRA Standard.	The paragraph has been revised to be consistent with the PRA standard.

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21.	Page 13, Section 2.3.1	NEI	The discussion on hazard groups states that “when the risk associated with a particular hazard group or operating mode is significant to the decision being made, it is the Commission’s policy that, if a staff-endorsed PRA standard exists for the hazard group or operating mode, then the risk will be assessed using a PRA that meets that standard,” and also allows qualitative treatment of modes and hazard groups “when the licensee can demonstrate that those risk contributors would not affect the decision.” This language needs to be clarified that quantitative bounding and margins analysis may still be sufficient to demonstrate that the impact of a specific hazard group is minimal or bounded, and that a complete PRA is not necessary. Further, it should be clarified that it is not necessary for the licensee to quantify risk contributors that would not affect the decision to demonstrate the lack of significance. The intent would be more clear if the beginning of the last sentence were revised to read “However, when the risk associated with a particular hazard group or operating mode is significant to the decision (i.e., if quantitatively accounted for, would affect the decision)…”	The commenter appears to have re-stated the intent of the paragraph in different, but not clearer, terms. The existing paragraph already addresses the concerns expressed. No change has been made.
		Exelon	This section discusses the extent to which a PRA must be capable of quantitatively evaluating the risk from different hazard groups or operating modes associated with the proposed change. The discussion indicates that a qualitative evaluation is adequate when the associated risk contribution "... *would not affect the decision...,"* but then states that a quantitative model that meets available staff-endorsed PRA standards must be used for hazard groups or operating modes *"...significant to the decision* ....." Exelon recommends that the terminology used in these two places be consistent. Exelon suggests that the phrase *"would affect the decision"* be used in place of phrase *"is significant to the decision"* in the last sentence of this section.	The requested change has been made.
22.	Page 13, Section 2.3.2, Last Paragraph	NEI	The reference to Regulatory Position C.3 of RG 1.200 does not appear to address the subject of the paragraph. This reference may more appropriately belong prior to section 2.3.1 since that regulatory position address scope, level of detail, and technical adequacy. If not, then the subsection of C.3 related to accounting for changes in the PRA model should be referenced.	The reference was incorrect, and has been corrected to Section C.1.3.

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23.	Page 14, Section 2.3.3, Fourth Bullet	NEI	The bullet would be more clear if worded as “documentation of the technical adequacy of the PRA to support a regulatory submittal.”	The requested change has been made.

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24.	Page 14, Section 2.3.3, Last Paragraph	NEI	The second sentence should be re-worded, as the use of the term “strive” is not consistent with conveying a regulatory expectation. A more appropriate statement would be “In general, meeting Capability Category II is expected to be sufficient for most applications.”	The staff does not agree with all of the stated concerns. However, the staff does see that the proposed wording unnecessarily varied from the already published analogous wording in RG 1.200. Therefore, the wording here has been updated to match that in RG 1.200 (Section C.2.1).
		Exelon	This section discusses.NRC expectations regarding PRA Standard Capability Categories, and states that: *"It is the staff's general expectation that licensees should strive to meet at least Capability Categoiy II for all supporting requirements, since that represents current good practice."* Exelon requests clarification regarding how licensee efforts to *"strive to meet"* any particular Capability Category would be measured. Further, DG-1 226 describes regulatory expectations for a quantitative tool for risk assessment, with extensive use within this draft RG of terminology and concepts from RG 1.200. In those portions of DG-1226 which rely on concepts from RG 1.200, such as and especially Section 2.3.3, Exelon believes that the discussion should be very clear that it is adherence to the concepts that is required, not necessarily adherence to the specific framework described in RG 1.200.	
		PWROG	“It is the staff’s general expectation that licensees should strive to meet at least Capability Category II for all supporting requirements, since that represents current good practice[6]. However, a supporting requirement that meets Capability Category I is acceptable if it can be shown that it is sufficient to support the application. In addition, for some applications, a specific supporting requirement may need to meet Capability Category III.” It is the PWROG’s position (and general industry position) that not all ASME/ANS PRA Standard supporting requirements (SRs) need to be satisfied at least Capability Category (CC) II to support all risk-informed applications. As the DG states, CC I are acceptable if that is sufficient to support the application. The DG should not make statements about meeting SRs at any particular CC level. The PRA Standard SRs provide a minimum requirement that may or may not support the application. It is up to the licensee to determine which SRs are needed for the application and then what level of PRA technical adequacy is needed to support the application. Further, the PRA Standard also permits supplementary analysis when SRs are not met or assessed before the required level. The current DG language does not really provide any guidance on what CC is necessary for a given risk-informed application.	

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25.	Page 14, Section 2.3.3, Footnote 5	NEI	This footnote does not appear to be grammatically correct, and would be better stated as "The American Nuclear Society (ANS) is developing a draft standard for low-power and shutdown modes of operation (to be incorporated into the ASME/ANS PRA standard (Ref. 14)), and for Level 2 and Level 3 PRAs."	No change has been made. The existing wording conveys the point. The suggested revised wording suggests that the Level 2 and Level 3 PRA standards are one effort, which they are not.
26.	Page 14, Section 2.3.4, Last Paragraph	NEI	Consistent with other footnotes in this DG, it seems appropriate that the text from footnote 9 of RG 1.200 be included here in the description of the as-built, as-operated plant. Suggest adding the following before the last sentence of the paragraph "As-built, as-operated is a conceptual term that reflects the degree to which the PRA matches the current plant design, plant procedures, and plant performance data, relative to a specific point in time."	The suggested footnote has been added. Regarding the PWROG concern, the existing text already contains the caveat "to the extent needed to support the application." Between this existing text and the added footnote, the concern seems to be adequately addressed.
	Multiple instances	PWROG	DG-1226 adds a new section (2.3.4) which states "The PRA results used to support an application are derived from a PRA model that represents the as-built and as-operated plant to the extent needed to support the application. At the time of the application, the PRA should realistically reflect the risk associated with the plant." The terminology "as-built, as-operated" also appears in Sections 2.2 and 2.3. While the PWROG agrees that a PRA based on the "as-built, as-operated" plant is the goal for each plant's PRA, there are changes in equipment and/or operation that may not yet be explicitly included in the PRA model. To support a risk-informed application, such changes should only have to be considered qualitatively if they could impact the change. The DG's language should not suggest that to support risk-informed applications, the PRA must always reflect the most current plant/operational configuration. There is obviously a time period needed between PRA updates that should not restrict the use of the PRA to support a risk-informed application. The DG should be clear on this point.	

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27.	Page 18, Section 2.5.2	NEI	The description of a “parameter” in the context of this section would be more clear if a more specific example were given. Additionally, the last sentence of the section needs clarification.	This paragraph has not been changed from the current active RG. As indicated in the sentence that precedes this section, more information on this subject is available in NUREG-1855. Regarding the last sentence, an additional reference is already provided.
28.	Page 20, Section 2.5.4, Last Paragraph	NEI	The last sentence of this paragraph implies that Section 2.5.5 is going to discuss approaches to deal with incompleteness. In reality, Section 2.5.5 is more broad, dealing with comparison of PRA analysis results with acceptance guidelines in general. Thus, it is recommended that the word “discusses” be changed to “includes” in the last sentence of Section 2.5.4.	The requested change has been made.
29.	Page 20, Section 2.5.5, Fourth Paragraph	NEI	The second sentence of the cited paragraph implies that the need for additional detail in Region III of Figure 3 is the same as that needed for Region II if the calculated risk change is near the region boundary. This implies the same accuracy need for a two order of magnitude spread in the calculated risk change. If the change is in Region III, it is already classified as “very small.” In fact, if the maximum CDF risk change of Region III is assumed (i.e. 10-6 or “near the region boundary”), this change is only about 1% of the maximum allowed base CDF (and surrogate safety goal), allowing significant margin to accommodate uncertainty. This additional burden on Region III assessments also seems inconsistent with the philosophy implied in paragraph 2, where it is stated that if the calculated value of delta CDF is very small as defined by Region III, “a detailed quantitative assessment of the baseline value of CDF --- will not be necessary.” A similar argument holds for LERF. It is recommended that the second sentence of the fourth paragraph of Section 2.5.5, which begins with “In Region III of Figures 3 and 4,” be deleted, and for grammatical consistency, the word “Similarly” be deleted from the next sentence.	The commenter is over-stating what exists in the DG. The DG simply says that if the estimates are close to the region boundaries “more detail will be required.” This piece of the DG is the same as the currently published RG (revision 1). No change is made.

#	Section/ Reference	Comment Source	Comment	NRC Response
30.	Page 21, Section 2.5.5, ~~Second~~ Seventh Paragraph	NEI	The discussion of "reasonable" is not entirely consistent with the definitions given in footnote 10 of this DG and in the ASME/ANS PRA Standard as endorsed by RG 1.200. To avoid unnecessary hypotheses being postulated, the fourth sentence should be revised to read "In this context, "reasonable" means that the hypotheses, adjustment factors, or modeling approximations or methods have broad acceptance within the technical community and that the technical bases for consideration are at least as sound as that of the hypotheses, adjustment factors, or modeling approximations or methods."	The sentence in question has been removed, and a footnote has been added to align the definition of reasonable with that from the ASME/ANS PRA standard.
31.	Page 21, Section 2.5.5, ~~Last~~ First Full Paragraph on Page	NEI	The second to last sentence in this paragraph could be interpreted to say that the only approach to be taken when a sensitivity study exceeds an acceptance guideline is to identify compensatory actions or increase monitoring. However, NUREG-1855 says that those are two alternatives, but it may also be the case that the analyst can explain that the analysis result is unduly conservative or the alternative assumption is not applicable to the application case. It is the analyst's responsibility to provide a clear assessment of the credibility of the assumption. Specifically, on Page 116, the NUREG states that, "When one or more of the sensitivity results demonstrate that the acceptance guidelines are not met and the recommendation is for rejection of the proposed change, the analyst should provide the decisionmaker with a clear assessment of the credibility of the sensitivity study as a reasonable alternative to the proposed base case analysis." This sentence should be revised to be consistent with NUREG-1855, both to prevent confusion and to avoid unnecessary and unsound rejection of applications.	A parenthetical was added to remind the reader that NUREG-1855 provides additional guidance on treating PRA uncertainty in the decisionmaking process.
32.	Page 21, Section 2.5.5 footnote 8	PWROG	The footnote reads "In the ASME/ANS PRA standard (Ref. 14) a source of model uncertainty is labeled 'key' when it could impact the PRA results that are being used in a decision, and consequently, may influence the decision being made." This definition quotes RG 1.200 (Ref. 12) footnote 13 in Section 3.3.2. RG 1.200 states that "a different reasonable alternative assumption would produce different results." The DG footnote (8) definition of key assumption is not consistent with the definition of key assumption in footnote 9 of Section 6.3 of the DG. Both definitions (and footnotes) should reference RG 1.200.	The staff disagrees, and believes that the text in question is consistent with both RG 1.200 and the PRA standard.

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33.	Page 22, Section 2.6, Fifth Paragraph	NEI	In the first sentence, the term “scope of implementation” should be defined, perhaps with an example. It would seem that many proposed changes to the LB would be either disallowed or permitted in their entirety. An example of a change that is only partly implemented could provide clarification.	While this sentence is unchanged from the current active version of the RG, we agree with the confusion and have changed the sentence accordingly.
34.	Page 23, Section 2.6, Eight Paragraph	NEI	This paragraph implies that the 7 bulleted items that follow are required for a submittal only “when the calculated values of the changes in the risk metrics, and their baseline values, when appropriate, approach the guidelines.” If this condition is true, it is recommended that it be reinforced by inserting the phrase “if the risk metrics approach the guidelines” after the word “Therefore” in the sentence preceding the bulleted items.	The requested change has been made.
35.	Page 23, Section 3, First Paragraph	NEI	The last sentence of the first paragraph includes a reference to Reference 6 (cited as “Refs. 5-9”) which is RG 1.176. The section titled “Relationship to Other Guidance Documents” states that RG 1.176 has been superseded by RG 1.201 (Ref. 9). It is recommended that Reference 6 (cited in Refs. 5-9) in the reference on page 23 be deleted, and that other references to RG 1.176 in DG-1226 be corrected as well.	The requested change has been made.
36.	Page 25, Section 3, Last Paragraph in Section	NEI	It is not clear why the need for a corrective action program is stated since it should already be part of the QA program whether or not changes are being made to the LB. Moreover, DG-1226 is not where one would expect characteristics of the corrective action program to be specified. Its inclusion may imply some sort of new requirement related to the LB change when that is not the case. It is recommended that the last paragraph of Section 3 be deleted.	The staff does not agree with the commenter’s concern, and this passage has not been changed from the active version of the RG.
37.	Page 26, Section 5, Third Bullet	NEI	“Section 3” should be replaced with “Section 6.”	The requested correction was made.

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38.	Page 27-28, Section 6.3, Last Bullet and Following Paragraph	NEI	This stipulation could be interpreted to require the PRA to be subject to the QA provisions of Appendix B to 10CFR50 if it is used in part to enhance or modify safety-related functions. Depending on the interpretation of "enhance or modify safety related functions," this requirement has the potential for severely restricting risk-informed changes to the LB for a number of utilities and appears unnecessary with normal QA coverage of the non-risk portion of the submittal for safety related functions, and PRA technical adequacy covered by RG 1.200. Very few, if any, utilities have placed their PRAs under the umbrella of Appendix B to 10CFR50. It is recommended that the last bullet and the paragraph that follows in Section 6.3 be deleted, and that the following sentence be used as a conclusion to Section 6.3: "The licensee would be expected to control PRA activity in a manner commensurate with its impact on the facility's design and licensing basis and in accordance with all applicable regulations."	The staff does not agree with the commenter's concern, and this passage has not been changed from the active version of the RG, other than changing it from 1 large bullet to a concise bullet and supporting paragraph.
39.	Page 28, Section 6.3, Second to Last Paragraph	NEI	The second sentence would seem to require that a peer review report on the base PRA include statements relative to a specific PRA application. The only way this could occur is if a peer review were done for each application, which is an untenable requirement. (Alternately, if the intent is that the peer review and its report specify the Capability Categories for the supporting requirements of the PRA standard that relate to the application, then the intent of the cited paragraph is appropriate. However, that intent would need to be more clearly stated.) Moreover, the third sentence implies that a peer review report of the base model specify limitations for a specific application which is impossible absent a peer review for each application. It is the licensee that should identify such limitations at the time of the specific application. It is recommended to replace the second sentence of the second to last paragraph with the following: "The licensee's submittal should discuss measures to ensure technical adequacy such as a report of a peer review and discuss the appropriateness of the PRA model for supporting a risk assessment of the LB change under consideration." Also, in the following sentence, the word "report" should be replaced with "submittal."	The paragraph has been updated to address the commenter's concern.

#	Section/ Reference	Comment Source	Comment	NRC Response
40.	Page 28, Section 6.3, Last paragraph, first sentence	PWROG	Last paragraph, first sentence: changed "peer review, certification, or cross comparison when performed" to "peer review." The DG should be clear that "certifications," as performed in accordance with NEI 00-02 are peer reviews. Further, some licensees have extended their NEI 00-02 reviews with a self-assessment (gap analysis) as defined in Appendix D of NEI 00-02 and endorsed by RG 1.200. The language of the DG should not limit licenses to "peer reviews" performed in accordance with the latest versions of the ASME/ANS PRA Standard.	No change has been made. A peer review is what is required.
41.	Page 28, Section 6.3, Last Paragraph	NEI	To clarify intent, it is recommended that in the second sentence, the phrase "following the peer review" be inserted after "PRA was modified" in the second sentence of the last paragraph	The requested change was made.
42.	Page 28, Section 6.3.1	PWROG	In the first paragraph, second sentence, the DG changed "deemed proprietary and justified as such" to "properly identified as proprietary." This seems to indicate that the justification for proprietary classification is no longer needed. The term "properly identified" is not defined. If justification is provided when the proprietary status is determined, the language should be revised in the DG.	The phrase "in accordance with the regulations" was added to the sentence in question. The revision from the previous version of the RG is not intended to suggest a change in process, only to clarify the meaning.
43.	Page 28, Section 6.3.1, Fifth Bullet	NEI	As stated, it is difficult to discern which fault and event trees are required for submittal. If CDF is calculated as part of the analysis, essentially all such trees are in scope. If the intent is to include only those trees that are modified for the application (by structure or failure rate/initiating event data) then the language of the fifth bullet be revised to state this. It is recommended that bullet 5 be revised to read as follows: "The event and fault trees that require modification to support analyses of the proposed change with a description of their modification."	The requested change has been made.
44.	Page 28, Section 6.3.1	PWROG	Seventh bullet: "dominant sequences" has been replaced with "significant sequences." This is acceptable, but to be consistent, the word "dominant" should also be replaced with "significant" in the Appendix A-2 Section "Sensitivity Analysis for Recovery Actions."	The requested change was made.

#	Section/ Reference	Comment Source	Comment	NRC Response
45.	Page 28, Section 6.3.1, Footnote 10	NEI PWROG	This footnote should include the definition of "key," as it is associated with the term "key modeling assumption." "In the ASME/ANS PRA standard, a modeling assumption is one that is related to a model uncertainty where the uncertainty is made with the knowledge that a different reasonable alternative assumption exists…" This is intended to be the definition of "key modeling assumption." However, the referenced text from the ASME/ANS PRA Standard is for the term "assumption" (not key). "Key assumption" is defined by the PRA Standard as when the assumption "may influence … the decision being made." Reconcile what definition is desired, e.g., "assumption" versus "key assumption," and use the appropriate definition.	The footnote has been augmented as requested.
46.	Page 29, Section 6.3.1	PWROG	Ninth bullet: The description of what quantitative information could consist of is not consistent with the revised tenth bullet: "The information could include quantitative (e.g., IPE or PRA results for internal initiating events, external event PRA results if available)…" vs. "The information could include quantitative (e.g., IPE or PRA results for internal and external hazards)." Bullets 9 and 10 should be consistent with each other. The language in bullet 10 is consistent with the ASME/ANS PRA Standard.	The sentence in question was removed as part of the response to the comment below.
47.	Page 29, Section 6.3.1, Ninth and Tenth Bullets	NEI	The term "total plant PRA" should be more precisely defined, or replaced with the term "baseline PRA" if appropriate. Additionally, in the last sentences of these bullets the stated need for "results of margin analyses and outage configuration studies" as related to the baseline PRA is not clear.	"Total plant" has been replaced with "full-scope, baseline." In addition, the 2nd paragraph of each bullet has been removed, on the basis that now that standards exist there is no need for these types of qualifications.
48.	Page 29, Section 6.3.1	PWROG	Tenth bullet: removal of words "if available" indicates that the external events PRA must be available. The words "if available" should be retained in both bullets 9 and 10. Seismic PRA (and other external events) may not be necessary to support a risk-informed application if that PRA scope is not significant to the risk profile. The need and the resources required to develop seismic PRAs are being identified. The DG should not suggest that a PRA that includes seismic and other external events is a requirement for all risk-informed submittals.	This concern has been addressed by the edits made in the response to the comment above.

#	Section/ Reference	Comment Source	Comment	NRC Response
49.	Page 29, Section 6.3.2, Last Paragraph	NEI	As stated, the guidance is confusing in that it specifies “that the submittal could list (not submit to the NRC) past changes...”	The comment is not sufficiently articulated to allow understanding of the commenter’s specific concern. Note that the phrase in question has not been changed since the last issuance of this RG.
50.	Page A-1 to A-3, Section A-2	NEI	Under Section A-2, Technical Issues Associated with the Use of Importance Measures, the impact of the use of conservative methods in fire PRA should be added as an issue to consider. A major issue right now is the mandated use of conservative fire PRA methods. Conservative biases can undermine the validity and utility of importance measures.	The staff disagrees with the comment. There is no mandated use of conservative fire PRA methods. The second paragraph of this section already identifies that risk ranking may be affected by assumptions, techniques, and data, and that the burden is on the licensee to assure the technical adequacy of the PRA, including its fire PRA if conservative assumptions, methods, or data are applied.
51.	Page A-3, Appendix A	Exelon	The discussion in this section does not provide guidance or discuss NRC expectations relative to determining importance measures for a PRA that addresses multiple hazard groups at different levels of refinement (i.e., for some hazard groups the PRA contains significantly greater conservative biases than for other hazard groups). Exelon recommends that additional guidance be included in this Appendix to address this issue.	The issue raised is not specific to different hazard groups. The same issue exists within a particular hazard group. The commenter is referred to RG 1.200 (Section 1.2.10) for additional information about how to consider the effect that assumptions have on the results (for which importance measures are one type of result).