Public Comments on DG-1227

#	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. 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 1.177 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 staff does not agree with the commenter. Regulatory Guide 1.177 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).
2.	General	NEI, PWROG	Suggest changing "allowed outage time" to "completion time" and "surveillance test interval" to "surveillance frequency" throughout the document to achieve consistency with NUREGs 1430-1434 as noted in the footnote on Page 2.	The requested changes have been made throughout the document.
3.	Page 4, "Purpose of this Regulatory Guide, Last Paragraph	NEI	While the guide at hand focuses on changes to AOTs and STIs, it is understood that other type changes to the Technical Specifications can also utilize the guidance; this should be better emphasized in this section. It is recommended that the second sentence of this paragraph, which deals with other types of TS changes, be moved to the end of the section as a stand-alone paragraph.	The requested change has been made.
4.	Page 4, "Purpose of this Regulatory Guide," Last Paragraph	NEI	The last sentence in this paragraph, which discusses the possibility of additional or revised guidance for plants licensed under 10 CFR 52, should be removed. This issue 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.
5.	Page 4, "Scope of Regulatory Guide," Last Paragraph	NEI	The industry appreciates that the RG has been revised to explicitly address both permanent and one-time changes.	No change requested.

6.	Page 4, “Scope of Regulatory Guide,” Last Paragraph	Exelon	In this section, the word *"permanent"* has been deleted from the phrase, *"proposed permanent TS changes"* in the first sentence and a revised last sentence now states: "... *This regulatory guide provides guidance for both permanent and one time only (AOT)changes to TS."* In the past, this RG has been specifically applicable ONLY to proposed permanent Technical Specifications (TS) changes. One-time TS changes (e.g., Allowed Outage Time (AOT) extensions, Notices of Enforcement Discretion (NOEDs), exigent TS changes), were not formally subject to the guidance of this RG, and expanding the scope provides useful guidance for evaluation of such non-permanent changes. However, in expanding the scope of applicability, does the inclusion of the parenthetical "(AOT)" in the last sentence limit one-time only changes to just AOT changes? Exelon requests clarification whether this draft RG is specifically not applicable to NOEDs or exigent TS changes.	The parenthetical around “AOT” was removed. The staff believes that the existing wording already clarifies that exigent TS changes are included, while NOEDs are not.
7.	Page 4, *"Relationship to Other Guidance Documents"*	Exelon	DG-1 227 does not refer to either RG 1.200 or NUREG-1 855. Both of those documents establish expectations for PRA scope and technical acceptability for risk-informed applications in a broad context. Exelon considers it important for an RG for particular types of applications such as DG-1 227 to provide additional guidance regarding how the other relevant guidance documents are to be applied.	Regulatory Guide 1.200 is in fact referenced in the DG. To augment the existing reference, a paragraph has been added in the “Relationship to Other Guidance Documents” section. A reference to NUREG-1855 has also been added. Also, the pending revision to RG 1.174 addresses the nexus between application-specific RGs (e.g., 1.177) and the guidance provided by RG 1.200 and NUREG-1855.
8.	Page 5, “Risk-Informed Philosophy, ” Third Paragraph	NEI	There appears to be a philosophical difference in approach between DG-1227 and DG-1226 (RG 1.174) when it comes to treatment of the “traditional engineering” aspects of risk-informed decisionmaking. RG 1.174 states that PRA can “provide insights into whether the extent of defense-in-depth is appropriate to ensure protection of public health and safety. However, to address the unknown and unforeseen failure mechanisms or phenomena, traditional defense-in-depth considerations should be used or maintained.” DG-1227, on the other hand, states that “risk analysis techniques can be, and are encouraged to be, used to help ensure and show that these [traditional engineering] principles are met.” This seems inconsistent; further, Section 2.2.1 of DG-1227 appears to actually use the PRA to provide insights, not to “show” that the principles are met, which is more consistent with the RG 1.174 approach.	We do not agree that the two DGs are inconsistent in this respect. In fact, the very sentence quoted from DG-1227 also appears in DG-1226. No change has been made.

9.	Page 5, “Risk-Informed Philosophy”	NEI	While this section discusses the five principles, there is no specific reference to Figure 1, which depicts these principles, and the term “Integrated decisionmaking” is never used. It is recommended Figure 1 be specifically referenced, and that “Integrated Decisionmaking” as portrayed in Figure 1 also be mentioned.	A pointer to Figure 1 has been added. Integrated decisionmaking is already mentioned in the second paragraph of this section.
10.	Page 5, “Risk-Informed Philosophy, ” Items 2 and 3	NEI	For items 2 and 3 change “Regulatory Position 2.2” to “Regulatory Position 2.2.1” and “Regulatory Position 2.2.2,” respectively.	The requested change was made.
11.	Page 5, “Risk-Informed Philosophy, ” Item 3	PWROG	Discussion under Risk-Informed Philosophy, item 3: There is slightly inconsistent with other sections by leaving out the words “of this regulatory guide” after “Regulatory Position 2.2.” Revise to be consistent.	The requested change was made.
12.	Page 6, Element 1	NEI	The implied stipulation for the licensee to directly describe how the proposed TS change meets the objectives of the PRA Policy Statement would be more clear if a reference were made to the guidance under Element 1 of Section C, “Regulatory Position.” It is recommended the second to last sentence be revised to read “The licensee should describe the proposed change and how it meets the objectives of the Commission’s PRA Policy Statement, including enhanced decisionmaking, more efficient use of resources, and reduction of unnecessary burden as provided below in Sections 1.1.1, 1.1.2, and 1.1.3.”	The sentence is unchanged from the current active version. The subsequent sentence states "Regulatory Position 1 describes element 1 in more detail." This sentence provides the necessary reference to details in the referenced sections. A similar sentence is used in each of the subsequent elements 2-4, so making this element unique and referring to specific subsections of the regulatory position would introduce inconsistency.
13.	Page 8, Section 2, First Paragraph	NEI	The implied need for the applicant to directly evaluate compliance with the NRC Safety Goal Policy Statement rather than just with the acceptance guidelines of the regulatory guide seems an unnecessary burden for the licensee. The first sentence should be revised to read “The licensee should examine the proposed TS change to verify that it meets existing applicable rules and regulations as expressed through the acceptance guidelines given in this regulatory guide.”	This does not represent a change from the currently published version of the RG. No change has been made to the DG.

14.	Page 9, Element 2, Last Paragraph	NEI	The meaning of “STS” should be defined.	The acronym STS (Standard Technical Specifications) is already defined on page 1.
15.	Page 10, Section 2.2.1, Fourth Bullet	NEI	The fourth bullet should be modified unless it is deemed credible for changes to AOTs to introduce a new CCF mode, as opposed to changing the magnitude of CCF rates.	No change has been made. Technical specification changes could introduce new CCF mechanisms, since AOT changes are not the only changes covered by the Regulatory Guide.
16.	Page 12, Section 2.3, Tier 3 Heading	NEI	To achieve better consistency with established (a)(4) guidance, the industry suggests changing the first sentence of this section such that “evaluated before performing any maintenance activity” is replaced with “assessed and managed.”	The requested change has been made.
17.	Page 12, Section 2.3, Tier 3 Heading	NEI	Add “and demonstration that a licensee meets the (a)(4) requirements is sufficient for Tier 3 assessments” to the end of the first sentence of the first paragraph.	No change has been made. The staff disagrees with the notion that the (a)(4) program alone always satisfies Tier 3.

18.	Page 12, *'Tier 3,"* **1** st paragraph, and Page 20, *"Key Component* 1,"Item #3 Section 2.3.7,	Exelon	*"Contemporaneous Configuration Control,"* refers to Regulatory Position 2.3, Tier 3, and with the revisions to Regulatory Position 2.3, these discussions imply that the licensee program for compliance with 10 CFR 50.65(a)(4) should provide an adequate approach to meeting Tier 3. The section of DG-1227 that originally specified inclusion of Configuration Risk Management Program (CRMP) in the Administrative Section of the TS has been removed. However, the discussion describing when to invoke the CRMP is still linked to TS AOTs, whereas 10 CFR 50.65(a)(4) does not link the performance of any aspect of risk assessment to TS. Section 2.4 requires implementation of a "risk-informed plant configuration control program" as a prerequisite for AOT changes. In this regard: • Exelon requests clarification whether a licensee program which is in compliance with 10 CFR 50.65(a)(4) meets the total intent of the "risk-informed plant configuration control program" prescribed in Section 2.4. • Exelon requests clarification whether licensee programs for compliance with 10 CFR 50.65(a)(4) are adequate "as-is" for supporting TS changes pursuant to DG-1227. Are there additional requirements vis-a-vis Structures, Systems, or Components (SSCs) with TS AOTs? • Exelon recommends that if additional requirements are intended, then DG-1227 should be clear with respect to the scope of those SSCs. In other words, do those additional requirements apply to all TS SSCs with AOTs, or just the SSCs with AOTs that have been changed pursuant to DG-1 227?	No change has been made. The intent of the minor changes to the Tier 3 program discussion is to identify that the (a)(4) risk assessment is adequate to satisfy that portion of Tier 3. Other existing items in the Regulatory Guide (such as consideration of external events risk, procedural controls, use for risk-informed TS AOTs, etc.) are beyond the (a)(4) requirements and are retained.
19.	Page 12, Section 2.3, Tier 3 Heading	NEI	The last two paragraphs under the Tier 3 heading do not appear to be relevant to Tier 3 exclusively. As such, the information should be relocated to the appropriate sections on Tiers 1, 2, or 3; alternatively, a separate heading could provide additional clarity. Additionally, the discussion should be revised to specify applicability of Regulatory Position 2.3.1 to any tiers. It is suggested that Regulatory Position 2.3.1 applies only to Tier 1.	Several changes were made to address this comment. The two paragraphs in question were moved to the end of the Section 2.3 introduction, the requested change to the first sentence under Tier 3 was made, and a new final sentence was added to the first paragraph under Section 2.3.1.
20.	Page 12, Section 2.3, Tier 3 Heading, Second Paragraph	NEI	In the second sentence, “in general” should be changed to “specifically.”	The requested change was made. Note that the paragraph in question was moved up in response to the previous comment.

21.	Page 12, Section 2.3.1	NEI, PWROG, Exelon	In the heading for Section 2.3.1, the word “acceptability” should be changed to “adequacy” to achieve consistency with other NRC documents, such as RG 1.200. This terminology should be similarly aligned throughout the document.	The requested change has been made.
22.	2.3.1	PWROG	C. Regulatory Position: Note that no revision number to RG 1.200 is identified in the draft document. Add a one-sentence statement or footnote regarding the process by which the appropriate revision can be identified.	No change has been made. The applicable revision of RG 1.200 is the same revision that is germane to the application in question (i.e., the latest revision unless a grace period is in effect).
23.	Page 13, Section 2.3.2, Second Paragraph	NEI	As written, the first sentence could be interpreted as equating Level 2 analysis with LERF. Suggest changing the sentence to read “Evaluations of CDF and LERF should be performed to support any risk-informed changes to TS.”	The requested change has been made.
24.	2.3.1	NEI	In Section 2.3.1, which discusses PRA technical acceptability and the applicability of RG 1.200 to risk-informed technical specifications, the reference to RG 1.200 needs to be specific to the current revision, which will be Revision 2, effective April 2010.	The DG is intended to reference the revision of RG 1.200 appropriate for the application in question (i.e., the current revision unless a grace period is in effect).
25.	Page 13, Section 2.3.1, Last Paragraph	NEI	The discussion on technical adequacy should be enhanced to include guidance on expectations for capability categories for the supporting requirements from RG 1.200. A concise discussion is given in DG-1226 and could be replicated here.	The requested change has been made.
26.	Page 13, Section 2.3.2, Second Paragraph	NEI, PWROG	From cover letter: Section 2.3.2 states that the scope of the analysis should include all hazard groups unless it can be shown that the contribution from the specific hazard group is insignificant. The wording of the commission’s phased approach to PRA scope states that contributors that are significant to the decision should be addressed using an assessment to the PRA standards. The wording in the DG should be revised to be consistent with the commission position. Otherwise, with current definitions relative to “insignificant,” it could be concluded that the risk contributor must be quantified before it can be determined if quantification is unnecessary. From specific comments: For improved clarity, the second sentence should be revised to read “The scope of the analysis should include those hazard groups that have a significant impact on the decision.”	The paragraph has been updated to address the comment.

27.	2.3.2	PWROG	In the second paragraph, there is a requirement for external event analyses unless the issue can be shown insignificant to the decision. There are three changes: 1) Since formal analytical models may not be available, “analysis” should be replaced by “risk-informed assessment.” 2) Change the term “insignificant” to “not significant.” Insignificant can be interpreted as negligible, and not significant can be interpreted as “small.” The use of the phrase “not significant” is more appropriate. 3) It should be acknowledged that while NFPA-805 fire PRA models are conservative, alternate more realistic models are acceptable for other risk informed application, such as risk informed Technical Specification initiatives.	This comment has been addressed, in part, by changes to the paragraph in question. The staff does not agree with other parts of the comment, or they are addressed elsewhere in this DG or RG 1.174.
28.	Page 13, Section 2.3.3.1	NEI	For clarity, in the first sentence, “involved” should be revised to read “involved in the change.”	The requested change has been made.
29.	Page 14, Section 2.3.3.1, First Bullet in Second Bullet List	NEI	For clarity, “AOT” should be revised to read “extended AOT” in the parenthetical phrase.	No change has been made. The use of the term "extended AOT" assumes the proposed change is to extend an existing AOT, which is overly restrictive.
30.	Page 14, Section 2.3.3.1, Third to Last Full Paragraph on Page	NEI	“Section A.1.3.2” should be changed to “Section A-1.3.2.”	The requested change was made.
31.	Page 15, Section 2.3.3.2, Last Paragraph	NEI	“Section A.2” should be changed to “Section A-1.3.2.”	No change has been made. The existing reference is correct.
32.	Page 16, Section 2.3.3.4, Second Paragraph	NEI	This section should refer to the guidance in the ASME/ANS PRA Standard and otherwise discourage the use of pre-solved cutsets.	The staff does not agree with this comment. The DG already invokes the standard through RG 1.200.

33.	Page 16, Section 2.3.4, Item 1	NEI	It is recommended that the last sentence of Item 1 be changed to read “If the risk evaluation is marginal or exceeds the guidelines for a proposed AOT increase and the systems involve those needed for shutdown (e.g. residual heat removal systems, auxiliary feedwater systems, service water systems), the licensee may want to perform comparative risk evaluations of continued power operation versus plant shutdown.”	The requested change was made.
34.	Page 17, Section 2.3.4, Item 2	NEI	For licensees considering the zero maintenance option, it may be helpful to add the following after the second sentence: “Note that the stated acceptance criteria are based on a baseline CDF with ‘nominal expected equipment unavailabilities.’”	No change has been made. This portion of the Regulatory Guide is not being revised, and it is not clear what value this note adds.
35.	Page 17, Section 2.3.4, Item 5	NEI	Change “Regulatory Positions 2.3.7 and 4.1” to “Regulatory Positions 2.3.7 and 4.”	The text has been changed to only cross-reference Section 2.3.7.
36.	Page 18, Section 2.3.5	NEI	Section 2.3.5 of the Regulatory Position should refer to NUREG-1855 and describe how uncertainty analysis should support risk-informed technical specification applications. A hypothetical example of application of NUREG-1855 to a completion time extension was prepared for a joint NRC/EPRI workshop on NUREG-1855 and may be helpful to consult.	A reference to NUREG-1855 has been added. Further guidance has not been added, as it is available in the NUREG itself.

37.	Page 18, Section 2.3.5, ~~Second to~~ Last Paragraph	NEI PWROG	From cover letter: Section 2.3.5 discusses sensitivity and uncertainty analysis related to assumptions. A final sentence has been added, noting that the "applicant will have to provide substantial justification" relative to tier 2 and tier 3 controls. It is not clear why this sentence was added, and, as a substantial addition to the previous wording, the need for this change should be explained, or it should be removed. Further, regulatory guides are not regulations and should not use requirements language (e.g., "will have to"). From specific comments: The last sentence in this paragraph should be revised to remove the phrase "applicant will have to." The industry suggests revising the sentence to read "Applicant-provided justification may be appropriate." C. Regulatory Position: Section 2.3.5: In the last paragraph, there is an added sentence at the end of Section 2.3.5 (Page 18) that reads "However, the applicant will have to provide substantial justification." In this new sentence, "substantial" justification is versus the deleted wording that said, "may be more difficult to justify." This appears to be changing this requirement. The added sentence is not helpful. The meaning of "substantial" is unclear. The initial portion of the paragraph states that the expectation for the Tier 2 and Tier 3 activity is expected to be robust. This is in the Sensitivity and Uncertainty Section. Tier 2 assessments evaluate the potential for high risk configurations. What is being requested in addition to Tier 2 requirements or (a)(4) of the Maintenance Rule to "assess and manage risk?" Delete final sentence and replace with a clear alternative, such as: "If such circumstances are expected, the utility should provide justification to ensure that the risk consequences of multiple entries into 'longer duration' CTs is properly considered."	The sentence in question has been changed to read: "Therefore, the Tier 2 and Tier 3 aspects of such TS changes should be justified as robust and adequate to control the resulting potential for significant risk increases."
38.	2.3.6	PWROG	C. Regulatory Position, Section 2.2.1: In the second bullet, the following is deleted: "to compensate for weaknesses in design." In the first sentence in Section 2.3.6, second paragraph, the same words were not deleted. Consistency. Remove the words in the second paragraph of Section 2.3.6 and replace them with the words similar to those in Section 2.2.1.	The requested change has been made.
39.	Page 20, Section 2.3.7.2, Key Component 1 Heading	NEI, Exelon	It appears that 10 CFR 50.65(a)(4) is inadvertently mistyped as 10 CFR 50.65(a)(3).	The requested change has been made.

40.	2.3.7.2	PWROG	Item 3 on page 20 refers to “TS action statement,” which is not consistent with the terminology in NUREGs 1430-1434. Revise “TS action statement,” to “TS Action,” to be consistent with the terminology in NUREGs 1430-1434.	The requested change has been made.
41.	2.3.7	NEI	Section 2.3.7 discusses configuration control and the Configuration Risk Management Program (CRMP). As noted in the DG, the CRMP is met though reliance on 10 CFR 50.65(a)(4). This regulatory position has been in effect since shortly after the promulgation of (a)(4). The NRC is currently performing a regulatory analysis to justify expansion of the scope of (a)(4) to include non-internal events initiators. However, this regulatory analysis is not complete. The DG is unclear in its discussion of PRA technical adequacy relative to the applicability of RG 1.200 on the tier 3 process; however, NRC staff has recently stated their intent that RG 1.200 should be applied to tier 3. This is a significant revision to an accepted regulatory position, and is neither justified nor appropriate. We request that the staff clarify the final RG to clearly state that RG 1.200 does not apply to tier 3. 10 CFR 50.65(a)(4) and its NRC-endorsed implementation guidance (RG 1.182) allow quantitative, qualitative or blended approaches to address risk assessment and management. Further, the scope of initiators is limited to internal events. These attributes reflect overt decisions made by the NRC in endorsing the guidance and reflect limits on the state of practice and modeling for configuration control purposes. All plants use their Level 1 internal events PRA in some fashion in their (a)(4) program, and most plants are approaching general conformance with the internal events portion of RG 1.200. However, the PRA is not expected to be compared to RG 1.200 specifically for the purposes of (a)(4) compliance. To invoke RG 1.200, Revision 2, or to make an unspecified reference to RG 1.200 in the context of tier 3 assessments will create substantial problems for the CRMP and (a)(4). The following problems would be created: Rulemaking and Directives Branch November 3, 2009 Page 3 1. The expectations for the CRMP would diverge greatly from the (a)(4) program due to different initiators, and different expectations for quantification. 2. The CRMP expectation would essentially obviate the ongoing (a)(4) regulatory analysis, and is potentially subject to the same regulatory analysis considerations under 10 CFR 109, since it is a new regulatory position. 3. Invoking RG 1.200, Revision 2 into CRMP suggests an expectation for quantification of fire and external events (including seismic) risk. This capability at a level to support (a)(4) is many years away. Significant problems with conservatism in fire PRAs would lead to skewed risk assessments and incorrect risk management actions. The fire PRA will not be usable for decision-making involving comparison to internal events until the existing models are made more realistic. NRC staff involved in the ongoing (a)(4) regulatory analysis have stated that fire can be addressed qualitatively. Further, no plants have external events (seismic) PRAs meeting RG 1.200, Revision 2, and the pilot application is not yet complete.	The staff does not agree with the commenter’s concern. No change has been made with regard to this issue.

42.	2.4	PWROG	The next to the last paragraph on page 21 discusses “PRA-informed results,” which should be “risk-informed results.’ Revise “PRA-informed results” to “risk informed results.”	In the sentence indicated, “PRA-informed results” has been changed to “PRA results.” An occurrence of “PRA-informed results” in the appendix was also modified.
43.	2.4	PWROG	Item 1 on page 22 refers to “TS AOT entry,” which is not consistent with the terminology in NUREGs 1430-1434. Revise “TS AOT entry,” to “TS Condition entry,” to be consistent with the terminology in NUREGs 1430-1434.	The requested change has been made.
44.	Page 22, Quantitative Acceptance Guidelines	NEI, Exelon	The industry appreciates that, for one-time changes, different acceptance guidelines that are consistent with NUMARC 93-01 have been added. However, for permanent changes, the acceptance guidelines are structured differently. For example, for one-time changes, there are two ICCDP thresholds (i.e., 10-6 and 10-7). This is consistent with both NUMARC 93-01 and the Region 2/Region 3 demarcations from RG 1.174 in that the limit is treated as permeable if additional actions are taken. However, for the permanent changes, only one threshold is specified (i.e., ICCDP of 10-6), even though ICCDPs below that threshold are allowed without any risk management actions under licensee (a)(4) programs. This is inconsistent with both NUMARC 93-01 and RG 1.174, and is overly restrictive, especially for CTs that are expected to be utilized infrequently. Furthermore, for permanent changes, the ΔCDF/ΔLERF guidelines are also applied. The ΔCDF/ΔLERF guidelines, along with risk monitoring, ensure that there is not a large change in risk to the public over time and should provide a sufficient backstop to allow for an additional ICCDP/ICLERP threshold to be applied, with appropriate considerations of risk management actions that might be applicable above an ICCDP of 10-6 or an ICLERP of 10-7	No change has been made. Additional flexibility is provided for one-time changes since compensatory measures may be implemented. For permanent changes, compensatory measures are not typically specified in the TS, and the additional flexibility in risk is not justified.
45.	Page 27, References, Reference 13	NEI	It should be specified that RG 1.200, Revision 2 is the revision referenced throughout this DG.	The revision number has been removed, consistent to the responses on other similar comments on both DG-1226 and DG-1227.
46.	Page A-2, Section A-1.1, Fourth Bullet	NEI	For clarity, insert the word “equipment” after the word “given.”	No change has been made. The requested change is not necessary.

47.	Page A-2, Section A-1.1, Fifth Bullet	NEI	For clarity, insert the words “the plant” after the words “shutting down.”	The requested change has been made.
48.	A-1.3.2.2	PWROG	Typo: Section A-1.3.2.2, paragraph 2, page A-5, “OC” should be “QC.” Revise “OC” to “QC.”	The requested change has been made.