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Subject: Comments Concerning Draft Regulatory Guide DG-1226, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (Federal Register Notice 74FR45884, dated September 4, 2009) and Draft Regulatory Guide DG-1227, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications" (Federal Register Notice 74FR45665, dated September 3, 2009)

Exelon Generation Company, LLC (Exelon) is submitting this letter in response to a request from the U.S. Nuclear Regulatory Commission (NRC) for comments concerning the following two draft Regulatory Guides (RGs):

- DG-1226, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," which is proposed Revision 2 to RG 1.174 (same title), dated November 2002
- DG-1227, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications," which is proposed Revision 1 to RG 1.177 (same title), dated August 1998

The NRC's Policy Statement on Probabilistic Risk Assessment (PRA) encourages greater use of PRA analysis techniques to improve safety decisionmaking and improve regulatory efficiency. These draft RGs support this philosophy.

Exelon appreciates the opportunity to comment on DG-1226 and DG-1227 and offers the attached comments for consideration by the NRC.

If you have any questions or require additional information, please do not hesitate to contact Mr. Richard Gropp at 610-765-5557.

Respectfully,

D. P. Helker

David P. Helker
Manager - Licensing

Attachment

SONSI Review Complete
Attachment = ADM-013

E-RIDS = ADM-03
Call = D. Helton (dmh2)

ATTACHMENT

Comments Concerning Draft Regulatory Guides

DG-1226, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis”

and

DG-1227, “An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications,”

Comments on Draft Regulatory Guide DG-1226

1. Page 5, "*Relationship to Other Guidance Documents*"

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-1226, 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.

2. Page 5, "*Relationship to Other Guidance Documents*"

Although NUREG-1855, "*Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making*," is referred to throughout DG-1226, 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-1855, and the expectation for its application in considering risk-informed plant changes.

3. Page 7, Section C, "*Regulatory Analysis*"

The bullet that references NUREG-1855 uses the term "*significant uncertainties*." This term is not defined and Exelon believes that it could be subject to interpretation. Addressing uncertainties and assessing their "significance" merits more discussion in DG-1226. Currently, this is only covered in a NUREG and in the U.S. Nuclear Regulatory Commission's (NRC's) plan on the "phased approach" to PRA quality. Since this draft RG is considered the "umbrella" guidance for all risk-informed activities, Exelon believes that DG-1226 should provide further elaboration on this subject.

4. Page 12, Section 2.2, "*Evaluation of Risk Impact, Including Treatment of Uncertainties*"

Footnote 4 at the end of the last sentence in the top paragraph seems to be attached to the wrong sentence. Exelon believes that it might be more appropriate if the footnote were attached to a sentence that talks about "...in the form of a PRA...", i.e., two sentences earlier in the same paragraph.

5. Page 12, Section 2.2, "*Evaluation of Risk Impact, Including Treatment of Uncertainties*"

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."

6. Page 12, Section 2.2, "*Evaluation of Risk Impact, Including Treatment of Uncertainties*"

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.

7. Page 13, Section 2.3.1, "Scope"

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.

8. Section 2.3.3, "Probabilistic Risk Assessment Technical Adequacy"

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 Category 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-1226 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.

9. Page 32, "References," Item 12

RG 1.200 is referenced without a specific revision number. 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.

10. Appendix A, Page A-3, "Relationship of Importance Measures to Risk Changes"

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.

11. General Comments

There are several new terms/phrases in DG-1226 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.

Comments on Draft Regulatory Guide DG-1227

1. Page 4, "*Scope of this Regulatory Guide*"

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.

2. Page 4, "*Relationship to Other Guidance Documents*"

DG-1227 does not refer to either RG 1.200 or NUREG-1855. 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-1227 to provide additional guidance regarding how the other relevant guidance documents are to be applied.

3. Page 12, Section 2.3.1, "*Technical Acceptability of the PRA*"

Reference is made to RG 1.200 (which includes the term "*technical adequacy*" in its title) while discussing expectations for "*technical acceptability.*" Exelon is requesting clarification whether these two terms are intended to have the same meaning.

4. Page 12, "*Tier 3,*" 1st paragraph, and Page 20, "*Key Component 1,*" Item #3

Section 2.3.7, "*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-à-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-1227?
5. Page 20, Section 2.3.7.2, "*Key Components of the Configuration Risk Management Program*"

"Key Component 1: Implementation of Configuration Risk Management Program"

10 CFR 50.65(a)(3) has been referenced in regard to online risk assessment. The reference should be 10 CFR 50.65(a)(4). This discrepancy comes from the evolution of the Maintenance Rule. Online risk assessment was originally described in paragraph (a)(3). After Revision 0 of RG 1.177 was issued, the Maintenance Rule was revised and online risk assessment moved to its own dedicated paragraph (i.e., paragraph (a)(4)).

6. Page 22, Section 2.4, "*Acceptance Guidelines for Technical Specification Changes*"

Quantitative Acceptance Guidelines

For one-time changes, there are two Incremental Conditional Core Damage Probability (ICCDP) thresholds (i.e., 10^{-6} or 10^{-5} with effective compensatory measures implemented). This is consistent with both NUMARC 93-01, "*Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants,*" 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}), which is in contrast to the fact that ICCDPs up to that threshold are routinely allowed without any risk management actions under licensee 10 CFR 50.65(a)(4) programs. This is inconsistent with both NUMARC 93-01 and RG 1.174 and overly restrictive, especially for AOTs that are expected to be utilized infrequently, since for permanent changes, the Δ CDF/ Δ LERF guidelines are also applied. The Δ CDF/ Δ LERF guidelines, along with risk monitoring, ensure that there is no large change in risk to the public over time and should provide a sufficient backstop to allow for an additional ICCDP/ Incremental Conditional Large Early Release Probability (ICLERP) threshold to be applied for permanent changes, with appropriate considerations of risk management actions that might be applicable above the ICCDP of 10^{-6} or ICLERP of 10^{-7} .