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Subject: Comments on Draft Regulatory Guide (RG) DG-1285, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (Federal Register 82FR17042, dated April 7, 2017, Docket ID NRC-2012-0110)

This letter is being submitted in response to the U.S. Nuclear Regulatory Commission's (NRC's) request for comments concerning the subject draft Regulatory Guide (RG) DG-1285, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," published in the *Federal Register* (i.e., 82FR17042, dated April 7, 2017).

This draft RG is proposed Revision 3 to RG 1.174 (same title). DG-1285 describes an approach that the NRC considers acceptable for applications for licensing basis changes by considering engineering issues and applying risk insights. The RG provides general guidance concerning analysis of the risk associated with the proposed changes in plant design and operation.

Exelon Generation Company, LLC (Exelon) appreciates the opportunity to comment on the subject draft RG 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 Richard Gropp at (610) 765-5557.

Respectfully,

D. P. Helker

David P. Helker  
Manager, Licensing and Regulatory Affairs  
Exelon Generation Company, LLC

Attachment

**SUNSI Review Complete**

**Template = ADM - 013**

**E-RIDS= ADM-03**

**Add= A. Helker (Anders F. Lickberston)**

H. Karagiannis  
(ChxK)

Comments Concerning Draft Regulatory Guide DG-1285, "An Approach for  
Using Probabilistic Risk Assessment in Risk-Informed Decisions  
on Plant-Specific Changes to the Licensing Basis"

Draft Regulatory Guide (RG) DG-1285, *"An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,"* describes an approach that the NRC considers acceptable for applications for licensing basis changes by considering engineering issues and applying risk insights. The RG provides general guidance concerning analysis of the risk associated with the proposed changes in plant design and operation. This draft RG is proposed Revision 3 to RG 1.174 (same title).

Exelon Generation Company, LLC (Exelon) appreciates the opportunity to comment on DG-1285 and offers the comments in the table on the following pages for consideration by the NRC.

General Comments

Comment No.	Identifier (Section, Page, Paragraph)	Comment	Proposed Resolution
1	<p>Section B, Reason for Revision, Page 3</p> <p>"In addition, this revision adopts the term "PRA Acceptability," including related phrasing variants, in place of the terms "PRA quality" and "technical adequacy" to describe the appropriateness of the PRA used to support risk-informed licensing submittals."</p>	<p>It is not entirely clear why this change is being made. One possibility is that it is a reaction to the following circular sentence in Revision 2: The <b>technical adequacy</b> of a PRA analysis used to support an application is measured in terms of its appropriateness with respect to scope, level of detail, <b>technical adequacy</b>, and plant representation (emphasis added).</p> <p>When the NRC used the term PRA Quality in documents such as SECY-04-0118 (Phased Approach Plan), the intention was to describe what the NRC would find as an acceptable PRA for a licensee to use in an application. To that extent, changing the high-level concept from "PRA quality" or "PRA adequacy" to acceptability is semantically equivalent and should cause no misunderstanding. The intent is to make sure that the PRA has the appropriate scope, level of detail, conformance with the technical elements, and plant representation.</p> <p>In RG 1.200, which is entitled <i>"An Approach for Determining The Technical Adequacy of Probabilistic Risk Assessment Results For Risk-Informed Activities,"</i> conformance with the technical elements is addressed by showing conformance with the requirements of the standard, which demonstrates that, at the technical level, the PRA or the parts that are used to support an application have been performed in a technically correct manner. In this context the term technical adequacy has come to mean conformance with the standard.</p>	<p>Section 2.3.2 Probabilistic Risk Assessment Technical Elements to Support an Application.</p> <p>Suggest changing the title to "Technical Adequacy of the Probabilistic Risk Assessment to Support an Application." This addresses the issue of whether the PRA is technically correct and defensible.</p> <p>The term PRA acceptability is retained for the higher level to replace the old term PRA Quality.</p>

Comment No.	Identifier (Section, Page, Paragraph)	Comment	Proposed Resolution
2	Section 2.3, Page 24, "The PRA analysis used to support an application is measured in terms of its appropriateness with respect to scope, level of detail, <b>conformance with the technical elements</b> , and plant representation."	See above.  The change at the lower level has the potential to be confusing, since the term technical adequacy has come to be understood as conformance with the Standard.	

Comment No.	Identifier (Section, Page, Paragraph)	Comment	Proposed Resolution
3	Page 4, 2 <sup>nd</sup> and 3 <sup>rd</sup> Paragraphs	These paragraphs do not seem to flow well – suggest rewording/rewriting the paragraphs to address NRC programs first, then follow on to the purpose of this RG.	In parallel with the publication of the policy statement, the NRC staff developed an implementation plan to define and organize the PRA-related activities being undertaken. This implementation plan is known as the Risk-Informed and Performance-Based Plan, which is abbreviated as RPP. These activities cover a wide range of PRA applications and involve the use of a variety of PRA methods (with variety including both types of models used and the detail of modeling needed). With respect to reactor regulation, activities include for example, developing guidance for NRC inspectors on focusing inspection resources on risk-important equipment and reassessing plants with relatively high CDFs for possible backfit. Another example involves the use of PRA in the assessment of operational events in reactors. The characteristics of these assessments rely on model changes or simplifying assumptions to change the PRA models so that they reflect the conditions experienced during an operational event. In contrast, other applications require the use of detailed performance and design information to provide a more realistic model of the plant.

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4	Pages 15 and 16, discussion of CCF	<p>Second paragraph begins with the sentence "To defend against CCF, one should first identify potential coupling factors between equipment failures." Searching for the cause should logically precede the search for a coupling factor.</p> <p>On Page 16, it is not clear why this is included as a coupling factor. It is a cause of dependency, but not a Common Cause Factor (CCF) as defined in the literature. "Support system dependencies (e.g., common power supplies, ventilation, cooling water, etc.)."</p>	<p>To defend against CCF, one should first understand the cause and then identify potential coupling factors between equipment failures.</p> <p>This parallels the discussion of the demonstration of addressing the factor.</p> <p>Suggest deleting the fourth bullet.</p>
5	Page 16, Item 6	<p>"Human errors include the failure of operators to perform the actions necessary to operate the plant or respond to off-normal conditions and accidents, errors committed during test and maintenance, and other plant staff performing an incorrect action."</p> <p>Even though errors of commission in PRAs are not modeled, there should be some consideration for the potential for creating the conditions under which an Extent of Condition (EOC) might be more likely. Is this what the last phrase is referring to?</p>	<p>Human errors include the failure of operators to perform the actions necessary to operate the plant or respond to off-normal conditions and accidents correctly and in a timely manner, errors committed during test and maintenance, and other plant staff performing an incorrect action.</p>

Comment No.	Identifier (Section, Page, Paragraph)	Comment	Proposed Resolution
6	Page 17, Section 2.1.1.2	<p>The following sentences seem somewhat out of place. It appears that this should be addressed under a different process.</p> <p>"However, there might be situations where a plant is not in compliance with its design basis or licensing basis or new information might arise indicating that the design basis or licensing basis is deficient. In such cases, the as-built and as-operated plant might not be consistent with the defense-in-depth philosophy prior to the implementation of the proposed licensing basis change. When this occurs, the licensee and the staff should ensure compliance with existing requirements (e.g., regulations, license conditions, orders, etc.) and implement appropriate actions to address any non-compliances. When addressing these deficiencies or non-compliances, consideration should be given to the concepts in this document to help achieve consistency with the defense-in-depth philosophy."</p>	Suggest deleting these sentences.

Comment No.	Identifier (Section, Page, Paragraph)	Comment	Proposed Resolution
7	Page 18, Bullet Number 1	<p>This discussion essentially provides no new guidance on how to address this item other than to look at each of the four layers in turn. Since this is a RG addressing the use of Probabilistic Risk Assessment (PRA), one might expect some guidance on how to use the PRA to provide insights into how the balance is achieved both prior to and post change.</p> <p>Understanding the drivers of the change in risk (i.e., at the level of initiating events, accident sequences, cutsets, etc.) can focus attention on which aspect of defense-in-depth is likely to be affected. For example, for very low frequency scenarios, such as Large LOCAs, for which the diversity of mitigation methods is reduced, it may be more important to focus on changes that might affect the likelihood of the initiator.</p>	<p>An expansion of the following paragraph providing some examples of how the risk assessment can be used would be helpful:</p> <p>"A comprehensive risk analysis can provide insights into whether the balance among the layers of defense remains appropriate to ensure protection of public health and safety. Such a risk analysis would include the likelihood of challenges to the plant (i.e., initiating event frequencies) from various hazards as well as CDF, containment response, and dose to the public. In addition, qualitative and quantitative insights from the PRA might help justify that the balance across all the layers of defense is preserved."</p>
8	Defense-in-depth factors guidance	<p>There is relatively little concrete guidance on how to demonstrate that these factors are met. Furthermore, some of them are clearly related. For example, the introduction of a compensatory measure is relevant to the assessment of both Items 2 and 6.</p>	<p>Expanding the guidance to focus on using PRA insights to focus the attention on where defense-in-depth is weakest would help. While the PRA can only reflect what is in the model, and does not address the unknowns, the value comes in the presumption that we start with adequate defense-in-depth and what we're looking for is changes. The scenarios that are driving the change will provide the necessary focus.</p>
9	Item 2, Page 19	<p>The discussion focuses on the introduction of new compensatory measures, but one possible change is to the way in which programmatic activities are conducted, which might lessen their effectiveness compared to the base case.</p>	<p>Consider a discussion of License Amendment Requests (LARs) that address changes to programmatic activities as opposed to design changes.</p>

Comment No.	Identifier (Section, Page, Paragraph)	Comment	Proposed Resolution
10	Item 6, Page 22	<p>This first sentence seems superfluous. "The proposed licensing basis change should not significantly increase the potential for or create new human errors that might adversely impact one or more layers of defense."</p> <p>With respect to the bullets, creating new actions is not in itself a demonstration of a loss of defense-in-depth, and in fact could be a compensatory measure. What is important, is whether the response can be performed reliably.</p> <p>Mental and physical demands are two important PSFs but they are not the only ones.</p>	<p>Suggest clarifying the intent. Consider the following:</p> <p>The evaluation of the proposed licensing basis change should demonstrate that the change does not adversely affect the ability of plant staff to perform necessary actions, nor introduce new required actions for which the likelihood of failure is not insignificant.</p> <ul style="list-style-type: none"> <li>• Create new human actions that are important to preserving any of the layers of defense for which a high reliability cannot be demonstrated.</li> <li>• Significantly increase the probability of existing human errors by virtue of significantly affecting PSFs including, for example, mental and physical demands, and level of training.</li> </ul>
11	Figure 5, Page 28	There appears to be a typographical discrepancy in the LERF figure (CDF instead of LERF in the Region III annotation)	

Comment No.	Identifier (Section, Page, Paragraph)	Comment	Proposed Resolution
12	Section 2.6, Page 36	<p>It is becoming commonly accepted that the quantitative results are good indicators but that they must be augmented with an understanding of the contributors. The following sentence is therefore a little misleading: "Quantitative risk results from PRA calculations are typically the most useful and complete characterization of risk, but they should be supplemented by qualitative risk insights and traditional engineering analysis where appropriate."</p>	<p>The following is believed to be a more accurate statement:</p> <p>"The quantitative risk results from PRA models when supplemented by an identification of the contributors and the corresponding risk insights provide the most useful and complete characterization of the risk implications of the proposed licensing basis change."</p> <p>In the third paragraph, suggest adding the words as indicated to link to the use of the PRA.</p> <p>Traditional engineering analysis provides insight into available margins and defense-in-depth. With few exceptions, these assessments are performed without any quantification of risk. However, a PRA can provide insights regarding the strengths and weaknesses of the plant design and operation relative to defense-in-depth by identifying significant contributors (cut-sets) to the relevant metrics and assessing whether the proposed change affects scenarios where the defense-in-depth or safety margins are marginal.</p>