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Ms. Cindy Bladey
Chief, Rules, Announcements, and Directives Branch
Division of Administrative Services
Office of Administration
Washington, DC 20555-0001

Subject: Industry Comments on Draft Regulatory Guide (DG) DG-1285, *An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis* in Response to Federal Register Notice NRC-2012-0110 Released on April 7, 2017

Project Number: 689

Dear Ms. Bladey:

The Nuclear Energy Institute (NEI)¹ is pleased to submit the attached comments regarding DG-1285, *An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis*. Originally released for public comment in May 2012, DG-1285 provides a proposed Revision 3 to RG 1.174. The NRC staff conducted four public meetings in 2016 to solicit public feedback and released an additional draft revision of DG-1285 for public comment on April 7, 2017 (ML16358A153) by re-issuing NRC-2012-0110 in the Federal Register.

The industry appreciates the addition of the guidance on aggregation, and is optimistic that it will improve the review process for future license amendment requests. However, the industry is concerned that Revision 3 to RG 1.174 does not reflect the Commission's direction in the March 9, 2016 Staff Requirements Memoranda in response to SECY-15-0168, *Recommendations on Issues Related to Implementation of a Risk Management Regulatory Framework*, which highlighted that a formal agency-wide definition and criteria for determining the adequacy of defense in depth should not be developed. Specifically, the draft revision includes "factors" of defense in depth, which may be overly prescriptive. The industry believes describing these as "considerations" would be more consistent with Commission direction.

¹ The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

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Ms. Cindy Bladey

May 22, 2017

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Additional detailed comments are provided in Attachment 1 to this letter. We look forward to working with the NRC in the final stages of revising RG 1.174. If you have any questions concerning the industry's comments regarding Attachment 1 to this letter, please contact me.

Sincerely,



Pamela B. Cowan

Attachment 1 - Industry Comments on DG-1285

c: Mr. Michael Johnson, OEDO, NRC
Mr. William Dean, NRR, NRC
Mr. Brian McDermott, NRR, NRC
Mr. Joseph Gitter, NRR/DRA, NRC
Mr. Michael Cheok, RES/DRA, NRC
Mr. John Monninger, NRO/DSRA, NRC
NRC Document Control Desk

Attachment 1

Industry Comments on DG-1285

Section and page from DG-1285	Comment
Overall	The characterization of "factors" of defense in depth is overly prescriptive, and is inconsistent with the Commission direction given in response to SECY 15-0168. Suggest describing these as "considerations" instead.
Overall	Regarding the replacement of the terms "PRA quality" and "PRA technical adequacy" with the new phrase "PRA acceptability." The term "PRA acceptability" causes confusion as the term "acceptability" is used in the PRA context as well as the Regulatory Guide (RG) context in reference to the methods and solutions provided (see Purpose of Regulatory Guides (page 2), Background (page 4, last paragraph; page 5, first paragraph; page 6, second paragraph), and Staff Regulatory Guidance (page 7, second paragraph)). The term "acceptable" is also used in its common English definition sense (e.g., when referring to QHOs in the context of an acceptable level of risk (Background, page 4), treatment of uncertainty (Staff Regulatory Guidance, page 9). Furthermore, in Section B (page 3), the RG states that "PRA acceptability" is replacing the terms "PRA quality" and "technical adequacy"; implying that "quality" and "technical adequacy" are equivalent. The industry perspective is that "quality" is a state of "goodness" for which the industry expects all PRAs to be at a high level of quality. "Technical adequacy" refers to the ability of the PRA to support a risk-informed application based on scope, level of detail, and plant-specificity. Replacing these terms with "acceptability" causes confusion that could negatively impact the ability of a licensee to successfully get a risk-informed application approved. The term "PRA acceptability" and its variants suffer from the same issues as those provided against the use of the term "technical adequacy." RG 1.200 uses the terms "technical adequacy" and "technically acceptable PRA." As an alternative to "PRA acceptability," one could refer to "acceptable technical adequacy." This would allow continued use of the current terminology and still provide for the ability to qualify whether a PRA model's technical adequacy is sufficient to support a specific application. As an example of the confusion introduced by the new terminology, the statement on page 8, "...the staff expects the following:...The plant-specific PRA supporting the licensee's proposals has been demonstrated to be acceptable" is not clear. However, using "...demonstrated to be of acceptable technical adequacy" is more clear as applicants understand how to achieve technical adequacy.
B Page 4	Regarding the phrase "(with variety including both types of models used and the detail of modeling needed)," without proper context, it is difficult for the reader to understand the two types of models being referenced. The examples that follow provide some context; however, it is not enough to fully appreciate the concepts being conveyed. Suggest describing the history of the RPP in more detail for readers not familiar with the program.

B Page 4	Regarding the phrase "reassessing plants with relatively high CDFs for possible backfit," without proper context, it is difficult for the reader to understand the intent. Suggest adding the reactor regulation program for which the activity applies.
B Page 4	Suggest changing the sentence "The principal focus of this RG is on the use of PRA findings and risk insights in decisions on proposed changes to a plant's licensing basis." to read "The principal focus of this RG is to provide guidance to the licensee on an acceptable approach to using PRA findings and risk insights in deciding proposed changes to a plant's licensing basis."
B Page 5	Licensing basis was abbreviated as "LB" but the abbreviation is not used much throughout the document. Consider using the term "licensing basis" or the "LB" abbreviation consistently throughout the document.
C Page 9	Section C.2.2.4 is not a sub-section of DG-1285. Suggest using Section C.2.4.
C Page 9	In left box on Figure 3 change "Define Change" to read "Define Proposed Change"
C.1 Page 10	Regarding the phrase "...with this staff expectation in mind..." it is not clear what the staff expectation actually represents. Suggest removing the phrase or clarifying the staff expectation.
C.2 Page 12	The phrase "...proposed increases in CFR and LERF are small..." should read "...proposed increases in CDF and LERF are small..."
C.2.1 Page 12	Regarding sentence "Sections C.2.1.1 and C.2.1.2 below provide guidance on assessing whether implementation of the proposed licensing basis change maintains adequate safety margins and consistency with the defense-in-depth philosophy." The section references and description are backwards (i.e., the defense-in-depth discussion is first, then safety margin.)
C.2.1.1.2 Page 15	Regarding the sentence "System redundancy, independence, and diversity result in high availability and reliability of SSCs and also help ensure that system safety functions are not reliant on any single feature of the design." System redundancy, independence and diversity help ensure that safety functions are maintained; however, they do not necessarily result in high availability and reliability of SSCs in and of themselves. Suggest focusing on safety functions and not SSCs.
C.2.1.1.2 Page 16	Regarding sentence "Examples include interfacing-system loss-of-coolant accidents (LOCAs)..." should read "Examples include interfacing-system loss-of-coolant accidents (ISLOCAs)..."
C.2.1.1.2 Page 17	Regarding the 7 th factor "Continue to meet the intent of the plant's design criteria," the intent of each plant design criterion is not defined, making the factor particularly subjective. Because current regulations include the plant's design criteria, there is no need to also consider the plant's design criteria as part of an assessment of the impact of the change on defense-in-depth. Suggest deleting the 7 th factor. As an alternative, define and/or clarify the phrase "intent of the plant's design criteria." For example, allowing changes to how the design criteria are met such that it can be demonstrated there is no significant reduction in the effectiveness of one or more layers of defense.

<p>C.2.1.1.3 Page 17</p>	<p>Regarding the following excerpt "Although the guidance is presented separately for each factor, the evaluation of the proposed licensing basis change should be performed in an integrated fashion. The proposed licensing basis change is considered to maintain consistency with the defense-in-depth philosophy if the integrated assessment demonstrates no significant impact on a single factor (i.e., the intent of each defense-in-depth evaluation factor is met)." On one hand the guidance suggests an integrated assessment and on the other hand it seems to focus on a significant impact to a single factor. Could small impacts to several of the factors be considered a significant impact on defense-in-depth overall? If so, please clarify.</p>
<p>C.2.1.1.3 Page 17</p>	<p>Regarding the sentence "Such an evaluation of the proposed licensing basis change against the seven factors might be qualitative." Because both quantitative and qualitative methods can be used to support each of the factors suggest changing the sentence to read "Such an evaluation of the proposed licensing basis change against the seven factors might be quantitative and/or qualitative."</p>
<p>C.2.1.1.3 Page 20</p>	<p>Regarding the phrase "...whether any increase in frequency or decrease in dependability..." it is not clear what is meant by the term "dependability." Suggest using commonly understood terms (e.g., availability, reliability.)</p>
<p>C.2.1.1.3 Page 21</p>	<p>Regarding the sentence "However, the licensee should also qualitatively evaluate whether the change has adversely impacted any of the three areas above to judge whether this factor has been met." It is not clear what the "three areas above" are specifically; please clarify.</p>
<p>C.2.3 Page 25</p>	<p>Regarding the sentence "A PRA used in risk-informed regulation should be performed correctly, in a manner that is consistent with accepted practices." Suggest removing the text "correctly," so the sentence reads "A PRA used in risk-informed regulation should be performed in a manner that is consistent with accepted practices." This language also appears twice in Section 2.3.2, first paragraph.</p>
<p>C.2.3 Page 25</p>	<p>Regarding the sentence "The PRA should realistically reflect the actual design, construction, operational practices, and operational experience of the plant and its owner." Although the term "owner" was used in Rev2 of RG 1.174, suggest replacing the term "owner" with "licensee".</p>
<p>C.2.3.2 Page 26</p>	<p>Regarding phrase "...discussed in Section 2.3.1 and 2.3.3, respectively..." the letter "C" should be added to precede the section numbers.</p>
<p>C.2.3.2 Page 26</p>	<p>Regarding the sentence "It should be noted that in the next edition of the ASME/ANS PRA standard the supporting requirements will only include Capability Categories I and II, and Capability Category III will no longer be included." This sentence should be deleted because it is speculating the content of a future revision to the PRA Standard.</p>
<p>C.2.4 Page 28</p>	<p>In Figure 5 "Acceptance guidelines for large early release frequency" suggest changing the reference in Region III from CDF to LERF and removing the Track Cumulative Changes.</p>

C.2.5.5 Page 34	Regarding sentence "In addition, if compensatory measures are proposed to counter the impact of the major risk contributors, such arguments are considered in the decision process quantitatively." It is not clear if quantifying compensatory measures is required for all cases or just in cases where it is appropriate. Suggest adding more guidance to provide clarity.
C.2.5.5 Page 34	Regarding sentence "Section C.6 of NUREG-1855 provides acceptable guidance on addressing the SOKC." Suggest using "Appendix 6-A" of NUREG-1855.
C.2.6 Page 36	Regarding sentence "In many applications, the potential risk can be limited by defining specific measures and criteria that are be monitored subsequent to approval." The word "to" should be added between "are" and "be".
C.2.6 Page 36	Replace the sentence "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." with "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."
C.2.6 Page 36	Replace the sentence "Qualitative risk insights include generic results that have been learned from previous PRAs and from operational experience." with "In addition, qualitative risk insights, including generic results that have been learned from previous PRAs and from operational experience, can be used to supplement plant specific insights."
C.2.6 Page 37	The first bullet ends with a period; however, it should be a comma.
C. Element 4 Page 40	Regarding the sentence "In developing the risk information set forth in this RG, licensees are likely to identify SSCs with high risk significance that are not currently subject to regulatory requirements or are subject to a level of regulation that is not commensurate with their risk significance." This sentence is speculative, and as such, should be deleted or clarified to communicate the intent.
C.6.3 Page 42	Regarding the sentence "The licensee's resolution of the findings of the peer review should also be submitted." The sentence should be clarified to state that F&O resolutions are only submitted if they have not been "Closed Out" per the Peer Review Finding Closure Process (Appendix X of NEI peer review Guidelines). Suggest stating "The licensee's resolution of open peer review findings should also be submitted."
C.6.3.1 Page 43	Regarding the bullet that states "An assessment of the change to CDF and LERF, including a description of the significant contributors to the change and an assessment of the realism with which those contributors have been evaluated." The phrase "an assessment of realism" is vague. Suggest that the phrase is clarified to ensure consistent interpretation.

<p>C.6.3.2 Page 44</p>	<p>Regarding the paragraph "As an option, the submittal could also list (but not submit to the NRC) past changes to the plant that reduced the plant risk, especially those changes that are related to the current application. A discussion of whether these changes are already included in the base PRA model should also be included." This paragraph is vague and unclear. Suggest adding additional language to ensure that the guidance is clear and can be consistently implemented.</p>
<p>D Page 45</p>	<p>Regarding the sentence "The NRC staff does not expect any existing licensee to use or commit to using the guidance in this RG, unless the licensee makes a change to its licensing basis." Suggest changes the sentence to read "The NRC staff does not expect any existing licensee to use or commit to using the guidance in this RG, unless the licensee makes a risk-informed change to its licensing basis."</p>