

**Response to Public Comments on Draft Regulatory Guide DG-1285,
 “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific
 Changes to the Licensing Basis”
 Proposed Revision 3 of Regulatory Guide 1.174**

On April 7, 2017, the Nuclear Regulatory Commission (NRC) published a notice in the Federal Register (82 FR 17402) announcing that Draft Regulatory Guide 1285 (DG-1285, proposed Revision 3 of Regulatory Guide (RG) 1.174) was available for public comment. The published version of DG-1285 was made available in the NRC’s Agencywide Document Access and Management System (ADAMS) under accession number ML16358A153. The public comment period ended on May 22, 2017. The NRC received comments from the organization listed below. The bracketed identifiers at the end of each comment relate to annotations the NRC applied to the received comment documents. Annotated versions of the received comment documents are available in ADAMS under the indicated accession numbers below. The following table documents the public comments and NRC staff’s responses.

The NRC received comments from the following:

<p>Ms. Pamela B. Cowan < pbc@nei.org > Nuclear Generation Division Nuclear Energy Institute 1201 F Street, NW., Suite 1100 Washington, DC 20004 Dated: May 22, 2017</p> <p>ADAMS Accession No.: ML17193A299</p>	<p>Mr. James A. Gresham < greshaja@westinghouse.com > Westinghouse Electric Company 1000 Westinghouse Drive Cranberry Township, PA 16066 Dated: May 23, 2017</p> <p>ADAMS Accession No.: ML17193A298</p>	<p>Mr. Justin T. Wheat < jtwheat@southernco.com > Southern Nuclear Operating Company 40 Inverness Center Parkway P.O. Box 1295 Birmingham, AL 35242 Dated: June 1, 2017</p> <p>ADAMS Accession No.: ML17193A297</p>	<p>David P. Helker Exelon Generation Company, LLC 200 Exelon Way Kennett Square, PA 19348 Dated: May 23, 2017</p> <p>ADAMS Accession No.: ML17193A300</p>
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Commenter	Comment Category	Specific Comments	NRC Resolution
Nuclear Energy Institute	General	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. [NEI1-1, NEI1-2]	The NRC agrees that changing the label of the seven defense-in-depth evaluation items from the “factors” to “considerations” is appropriate and the guidance has been revised accordingly.

<p>Nuclear Energy Institute</p>	<p>General</p>	<p>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. [NEI1-3]</p>	<p>The NRC understands the comment. In several NRC guidance documents, the terms “PRA quality” and “technical adequacy” have been used interchangeably in many cases and, in some cases, incorrectly. DPO-2016-001, “Differing Professional Opinion on Probabilistic Risk Assessment Language in Regulatory Guides” (see ADAMS accession No. ML17013A015) raised these issues for consideration and resolution by NRC management. The resolution of DPO-2016-001 directed the staff to adopt the term “PRA acceptability” rather than “PRA quality” and “technical adequacy” in RG 1.174. Consistent with that resolution, the NRC implemented the change in the following manner. In cases where terms such as “PRA adequacy,” “PRA technical adequacy,” or “PRA quality” refer to the acceptability or adequacy of the four PRA aspects of scope, conformance with technical elements, level of detail, and plant representation, the term “PRA acceptability” is now used in place of those terms. In cases where terms such as “technical adequacy” or “PRA quality” refer to conformance with the technical elements in the ASME/ANS PRA standard, the phrasing “conformance with the technical elements” is now used in place of those terms. A Regulatory Information Summary (RIS) is under development to explain the meanings of the terms PRA acceptability, technical adequacy, PRA quality, and PRA applicability; that this is only a change in NRC usage of terms; and the change in terminology does not impact any regulatory processes. It should be noted that the NRC’s change in terminology is intended to be reflected in other relevant guidance documents (e.g., RG 1.200, NUREG-0800, etc.) as they are updated and revised. Additionally, in response to this comment, the NRC has revised the following sentence from page 3 from, “In addition, this revision adopts the term “PRA Acceptability,” including related phrasing variants, in place of the terms “PRA quality” and “technical adequacy” to</p>
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			<p>describe the appropriateness of the PRA used to support risk-informed licensing submittals,” to:</p> <p>“In addition, this revision adopts the term “PRA Acceptability,” including related phrasing variants, in place of terms such as “PRA quality,” “PRA technical adequacy,” and “technical adequacy” to describe the appropriateness of the PRA used to support risk-informed licensing submittals.”</p>

Westinghouse Electric Company	Language change	<p>DG-1285 replaces the term PRA "technical adequacy" with "PRA acceptability." This change may result in confusion. On DG-1285, page 36, it notes that limited-scope applications may place a reduced burden on the PRA stating that: "A limited-scope application would lead the staff to conduct a more limited review of the risk results, therefore placing less emphasis on PRA acceptability than would be the case for a broad-scope application." That is appropriate and places the burden of acceptability of the PRA for the application with the regulator. However, DG-1285, page 42 notes that: "An independent peer review (as described in RG 1.200) is important in ensuring PRA acceptability." Thus; the industry peer review team determines the acceptability of the various high level and supporting requirements based on compliance to RG 1.200 (and the ASME Standard) regardless of the application. However, while the peer review can determine the adherence of the PRA to the various supporting requirements for the PRA in general, some applications will require greater detail in the modeling of specific systems, while other applications will require far less to support a specific application. The peer review at that level was intended to establish the technical adequacy of the supporting requirements, and as such, the term was chosen to focus on the PRA general capability. However, the term "PRA acceptability" now being used in DG-1285 implies: (1) the PRA is acceptable for an application, and (2) the PRA is acceptable based on compliance to RG 1.200. While these decisions will frequently be the same, it will not always be so and could result in confusion. Based on this reason, it is recommended that the term "technical adequacy" be retained when referring to the peer review process. [WEC1-1]</p>	<p>The NRC understands the comment. In several NRC guidance documents, the terms "PRA quality" and "technical adequacy" have been used interchangeably in many cases and, in some cases, incorrectly. DPO-2016-001, "Differing Professional Opinion on Probabilistic Risk Assessment Language in Regulatory Guides" (see ADAMS accession No. ML17013A015) raised these issues for consideration and resolution by NRC management. The resolution of DPO-2016-001 directed the staff to adopt the term "PRA acceptability" rather than "PRA quality" and "technical adequacy" in RG 1.174. Consistent with that resolution, the NRC implemented the change in the following manner. In cases where terms such as "PRA adequacy", "PRA technical adequacy," or "PRA quality" refer to the acceptability or adequacy of the four PRA aspects of scope, conformance with technical elements, level of detail, and plant representation, the term "PRA acceptability" is now used in place of those terms. In cases where terms such as "technical adequacy" or "PRA quality" refer to conformance with the technical elements in the ASME/ANS PRA standard, the phrasing "conformance with the technical elements" is now used in place of those terms. A Regulatory Information Summary (RIS) is under development to explain the meanings of the terms PRA acceptability, technical adequacy, PRA quality, and PRA applicability; that this is only a change in NRC usage of terms; and the change in terminology does not impact any regulatory processes. It should be noted that the NRC's change in terminology is intended to be reflected in other relevant guidance documents (e.g., RG 1.200, NUREG-0800, etc.) as they are updated and revised. The NRC has revised the following sentence from page 42 in response to this comment from, "An independent peer review (as described in RG 1.200) is important in ensuring PRA acceptability," to:</p> <p>"An independent peer review (as described in RG 1.200) is an important consideration in risk-informed applications."</p>
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Nuclear Energy Institute	Clarify	<p>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. [NEI1-4]</p> <p>----</p> <p>See page 4, 2nd paragraph</p>	<p>Although this comment is outside the scope considered for Revision 3 of RG 1.174, the NRC does not believe revising the language would impact other parts of the RG, and therefore, would not require any additional consideration. The NRC agrees that the cited phrase is confusing and considers the associated paragraph and the subsequent paragraph on page 4 of DG-1285 to be unnecessary for the narrative in Section B. As such, these two paragraphs have been removed from the guidance.</p>
Nuclear Energy Institute	Clarify	<p>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. [NEI1-5]</p> <p>----</p> <p>See page 4, 3rd paragraph</p>	<p>Although this comment is outside the scope considered for Revision 3 of RG 1.174, the NRC does not believe revising the language would impact other parts of the RG, and therefore, would not require any additional consideration. The NRC agrees that the cited phrase is confusing and considers the associated paragraph and the preceding paragraph on page 4 of DG-1285 to be unnecessary for the narrative in Section B. As such, these two paragraphs have been removed from the guidance.</p>
Nuclear Energy Institute	Language change	<p>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.” [NEI1-6]</p> <p>----</p> <p>See page 4, 3rd paragraph</p>	<p>The NRC agrees that the cited language needs clarification and, based on the resolution of comments NEI1-4 and NEI1-5, the NRC has removed the second and third paragraphs on page 4 of DG-1285 from the guidance.</p>
Nuclear Energy Institute	Editorial	<p>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. [NEI1-7]</p> <p>----</p> <p>See page 5, 1st paragraph</p>	<p>The NRC agrees with the comment and replaced all instances of the acronym “LB” with “licensing basis.”</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Nuclear Energy Institute	Editorial	Section C.2.2.4 is not a sub-section of DG-1285. Suggest using Section C.2.4. [NEI1-8] ---- See page 9, 2 nd bullet	The NRC agrees with the comment and revised the cited language as proposed.
Nuclear Energy Institute	Editorial	In left box on Figure 3 change “Define Change” to read “Define Proposed Change” [NEI1-9] ---- See page 9, Figure 3	The NRC agrees with the comment and has revised the cited Figure as proposed.
Nuclear Energy Institute	Clarify	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. [NEI1-10] ---- See page 10, Section C.1, 3 rd paragraph	The NRC agrees with the comment and has revised the guidance by removing the cited language as proposed.
Nuclear Energy Institute	Editorial	The phrase “...proposed increases in CFR and LERF are small...” should read “...proposed increases in CDF and LERF are small...” [NEI1-11] ---- See page 12, Section C.2, 3 rd paragraph	The NRC agrees with the comment and revised the cited language as proposed.
Nuclear Energy Institute	Editorial	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.) [NEI1-12] ---- See page 12, Section C.2.1, 2 nd paragraph	The NRC agrees with the comment and revised the cited language as proposed.

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Nuclear Energy Institute	Clarify	<p>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. [NEI1-13]</p> <p>----</p> <p>See page 15, Section C.2.1.1.2, 1st paragraph under item 3</p>	<p>The NRC agrees with the comment and revised the cited language as follows:</p> <p>“System redundancy, independence, and diversity result in high availability and reliability of the function and also help ensure that system functions are not reliant on any single feature of the design.”</p>
Nuclear Energy Institute	Editorial	<p>Regarding sentence “Examples include interfacing-system loss-of-coolant accidents (LOCAs)...” should read “Examples include interfacing-system loss-of-coolant accidents (ISLOCAs)...” [NEI1-14]</p> <p>----</p> <p>See page 16, Section C.2.1.1.2, 2nd paragraph under item 5</p>	<p>The NRC agrees with the comment and has revised the cited language as proposed.</p>
Nuclear Energy Institute	Clarify	<p>Regarding the 7th 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 7th 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. [NEI1-15]</p> <p>----</p> <p>See page 17, Section C.2.1.1.2, Item 7</p>	<p>The NRC disagrees with the comment and have not made any related changes to the text. The NRC position is that the licensee should consider whether the proposed licensing basis change meets the intent of the plant’s design criteria in addition to determining whether the proposed changes is in compliance with regulations (i.e., Principle 1 of the risk-informed decisionmaking process). As such, the guidance in Section C.2.1.1.3 states that, “...the licensee should demonstrate a full understanding of any impacts that the proposed licensing basis change might have on the design criteria or severe accident design features of the plant.”</p>

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Nuclear Energy Institute	Clarify	<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. [NEI1-16]</p> <p>----</p> <p>See page 17, Section C.2.1.1.3, 1st paragraph</p>	<p>The NRC agrees that cited language needs clarification. It is possible that small impacts to several of the defense-in-depth evaluation factors (now called considerations as per the resolution of comment NEI1-1) could be considered a significant impact on defense-in-depth overall and therefore could be considered not to maintain consistency with the defense-in-depth philosophy. As such, the NRC has revised the second cited sentence as follows:</p> <p>“The proposed licensing basis change is considered to maintain consistency with the defense-in-depth philosophy if the integrated assessment does not demonstrate a significant impact on a single consideration (i.e., the intent of each defense-in-depth evaluation factor is met) or there is not a significant impact collectively across all seven considerations.”</p>
Nuclear Energy Institute	Language Change	<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.” [NEI1-17]</p> <p>----</p> <p>See page 17, Section C.2.1.1.3, 1st paragraph</p>	<p>The NRC agrees with the comment and revised the cited language as proposed and, consistent with the with the NRC’s resolution of comment NEI1-1, “factors” has been changed to “considerations.”</p>
Nuclear Energy Institute	Editorial	<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.) [NEI1-18]</p> <p>----</p> <p>See page 20, Section C.2.1.1.3, 3rd paragraph under item 3</p>	<p>The NRC agrees with the comment and has revised the cited sentence fragment as follows:</p> <p>“...whether any increase in frequency or decrease in availability or reliability...”</p>

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Nuclear Energy Institute	Clarify	<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. [NEI1-19]</p> <p>----</p> <p>See page 21, Section C.2.1.1.3, last paragraph of item 4</p>	<p>The NRC agrees with the comment and has revised the cited sentence as follows:</p> <p>“However, the licensee should also qualitatively evaluate whether the change has resulted in any of the four impacts above to judge whether this consideration has been met.”</p>
Nuclear Energy Institute	Language change	<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. [NEI1-20]</p> <p>----</p> <p>See page 25, Section C.2.3, 1st paragraph</p>	<p>The NRC agrees with the comment and revised the cited language as proposed. Additionally, the following related sentence in Section C.2.3.2 was revised from, “In general, a PRA that is performed correctly is one where the methods are implemented correctly and the assumptions and approximations are reasonable,” to:</p> <p>“In general, a PRA that is performed consistent with accepted practices is one where the methods are implemented correctly and the assumptions and approximations are reasonable.”</p>
Nuclear Energy Institute	Language change	<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”. [NEI1-21]</p> <p>----</p> <p>See page 25, Section C.2.3, last paragraph</p>	<p>Although this comment is outside the scope considered for Revision 3 of RG 1.174, the NRC agrees with the comment and does not believe it would impact other parts of the RG, and therefore, would not require any additional consideration. Consequently, the NRC has revised the guidance as proposed.</p>
Nuclear Energy Institute	Editorial	<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. [NEI1-22]</p> <p>----</p> <p>See page 26, Section C.2.3.2, 1st paragraph</p>	<p>The NRC agrees with the comment and revised the cited language as proposed. Similarly, the reference to “Section 2.3.4” of RG 1.200 has been revised to “Section C.2.3.4.”</p>

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Nuclear Energy Institute	Language change	<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. [NEI1-23]</p> <p>----</p> <p>See page 26, Section C.2.3.2, last paragraph</p>	<p>The NRC disagrees that the cited sentence should be deleted; however, the NRC revised the cited sentence as follows to provide additional clarification:</p> <p>“It should be noted that the ASME and ANS Joint Committee on Nuclear Risk Management has successfully balloted to remove Capability Category III and retain Capability Categories I and II in the next edition of the ASME/ANS PRA standard.”</p>
Nuclear Energy Institute	Language change	<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. [NEI1-24]</p> <p>----</p> <p>See page 28, Section C.2.4, Figure 5</p>	<p>The NRC agrees with the comment and has revised the cited figure as proposed.</p>
Nuclear Energy Institute	Clarify	<p>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. [NEI1-25]</p> <p>----</p> <p>See page 34, Section C.2.5.5, 3rd paragraph</p>	<p>The NRC agrees with the comment and revised the cited language from, “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” to:</p> <p>“In addition, if compensatory measures are proposed to counter the impact of the major risk contributors that influence the ability to demonstrate that the acceptance guidelines are met, those compensatory measures should be included in the PRA model that supports the application.”</p>

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Nuclear Energy Institute	Clarify	<p>Regarding sentence “Section C.6 of NUREG-1855 provides acceptable guidance on addressing the SOKC.” Suggest using “Appendix 6-A” of NUREG-1855. [NEI1-26]</p> <p>----</p> <p>See page 34, Section C.2.5.5, 2nd paragraph</p>	<p>The NRC agrees that the cited language needs to be revised, but with respect to changing the reference to “Section C.6” of NUREG-1855 to “Section 6.” The NRC did not make any other changes in response to the comment, as based on the following. The intent of directing the reader to the Section 6 instead of Appendix 6-A is to first expose the reader to the higher-level guidance on the SOKC provided in Section 6 of NUREG-1855, which includes a reference to the related Electric Power Research Institute report that provides guidance on the SOKC, and then direct the reader to Appendix 6-A for more detailed guidance.</p>
Nuclear Energy Institute	Editorial	<p>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”. [NEI1-27]</p> <p>----</p> <p>See page 36, Section C.2.6, 5th paragraph</p>	<p>The NRC agrees with the comment and revised the cited language as proposed.</p>
Nuclear Energy Institute	Language change	<p>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.” [NEI1-28]</p> <p>----</p> <p>See page 36, Section C.2.6, 2nd paragraph</p>	<p>The NRC disagrees with the comment and believes that it is important to retain the existing language on the basis that qualitative risk insights and traditional engineering analysis provide supplemental information that may not be completely addressed by a PRA (e.g., the unknown unknowns). However, the cited language has been revised as follows to provide additional clarity on the context of the statement.</p> <p>“For risk-informed licensing basis changes, 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>

Commenter	Comment Category	Specific Comments	NRC Resolution
Nuclear Energy Institute	Language change	<p>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 .” [NEI1-29]</p> <p>----</p> <p>See page 36, Section C.2.6, 2nd paragraph</p>	<p>The NRC disagrees with the proposed revision of the cited language as it is considered to be complimentary to the proposed resolution of comment NEI1-28. However, the cited language has been revised as follows to provide additional clarity.</p> <p>“Qualitative risk insights may include generic results that have been learned from previous PRAs and from operational experience.”</p>
Nuclear Energy Institute	Editorial	<p>The first bullet ends with a period; however, it should be a comma. [NEI1-30]</p> <p>----</p> <p>See page 37, Section C.2.6, 1st bullet of list</p>	<p>This comment relates to the list of bullets on page 37. The NRC agrees with the comment and revised the cited language as proposed.</p>
Nuclear Energy Institute	Clarify	<p>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. [NEI1-31]</p> <p>----</p> <p>See page 40, Section C.4, last paragraph</p>	<p>The NRC agrees with the comment and has revised the cited language to the following:</p> <p>“In developing the risk information set forth in this RG, licensees may 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.”</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Nuclear Energy Institute	Language change	<p>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.” [NEI1-32]</p> <p>----</p> <p>See page 42, Section C.6.3, last paragraph</p>	<p>Although this comment is outside the scope considered for Revision 3 of RG 1.174, the NRC agrees with the comment and does not believe it would impact other parts of the RG, and therefore, would not require any additional consideration. Consequently, the NRC has revised the guidance to include the following language as a footnote at the end of the sentence in the same paragraph that begins with “For example,”</p> <p>“The NRC has accepted via a letter issued on May 3, 2017, (See ADAMS Accession No. ML17079A427) an industry process entitled “Close-out of Facts and Observations (F&Os)” (See ADAMS Accession No. ML17086A431) that allows a licensee to formally close F&Os that were generated during a peer review process. If a licensee meets the conditions of acceptance as described in the NRC’s letter, a licensee does not need to submit the closed F&Os in any future applications. It should be noted that the NRC position in the May 3rd letter is expected to be incorporated into the next revision of RG 1.200.”</p>
Nuclear Energy Institute	Clarify	<p>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. [NEI1-33]</p> <p>----</p> <p>See page 43, Section C.6.3.1, 2th bullet of second list</p>	<p>The NRC agrees that the phrase “an assessment of realism” in the cited text is unclear. Because an assessment of realism is not considered by the NRC to be necessary for the review of an application, the phrase, “...and an assessment of the realism with which those contributors have been evaluated,” has been deleted from the text.</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Nuclear Energy Institute	Clarify	<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. [NEI1-34]</p> <p>----</p> <p>See page 44, Section C.6.3.2, last paragraph</p>	<p>This comment is outside of the scope considered for Revision 3 of RG 1.174 and addresses language that was not revised and has not had a negative impact on applications. Moreover, the comment may impact other parts of the RG and therefore may need additional consideration. Additionally, it is unclear how the cited language should be expanded to address the concern. Although no changes have been made in response to this comment, the NRC will document this comment for consideration in a subsequent revision to RG 1.174.</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Nuclear Energy Institute	Language change	<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.” [NEI1-35]</p> <p>----</p> <p>See page 45, Section D, 4th paragraph</p>	<p>The NRC disagrees with this comment and has not made any related changes to the text. The language in Section D is generic template text, written in coordination by multiple NRC offices to describe the NRC’s general intent regarding how regulatory guides will be used by the NRC staff, and is used verbatim in most NRC regulatory guides. Although the NRC staff considers this template text’s applicability for each regulatory guide, it is not expected to change except under unusual circumstances, which do not exist for this regulatory guide. As such, the revision proposed by the comment could have significant implications for how this text should be interpreted in other regulatory guides. The following text from Section D explains more specifically when this regulatory guide would be applied, which addresses the concern raised by this commenter:</p> <p>“If an existing licensee voluntarily seeks a license amendment or change and (1) the NRC staff’s consideration of the request involves a regulatory issue directly relevant to this RG and (2) the specific subject matter of this RG is an essential consideration in the staff’s determination of the acceptability of the licensee’s request, then the staff may request that the licensee either follow the guidance in this RG or otherwise demonstrate compliance with the underlying NRC regulatory requirements.”</p>
Westinghouse Electric Company	General	Once RG 1.174, Revision 3 is approved, NUREG-1855 should be revised to reference the appropriate revision number. [WEC1-2]	The NRC agrees with this comment, the NRC will document this comment for consideration in a subsequent revision of NUREG-1855.

Commenter	Comment Category	Specific Comments	NRC Resolution
Southern Nuclear Operating Company		<p>The last paragraph of this section only partially supports use of risk-informed methods to modify TS completion times. The problem has been technical branches not allowing changes in risk-informed completion times because they disagree with the redundancy available when in a TS Action. Also, the NRC should consider revising Branch Technical Position (BTP) 8-8 to eliminate conflict with R.G. 1.17 4 and to ensure BTP 8-8 adequately considers risk model insights for one-time or permanent allowable outage time extensions.</p> <p>Proposed Resolution: Add this as the last sentence. "Therefore, if a licensee submits a request for a change to a Technical Specification Completion Time based on risk-informed methods, it is not necessary to show single failure criteria is preserved during the brief allowable outage time if the requested time meets risk-informed criteria. [SNC1-1] ---- See page 20, Section C.2.1.1.3, Item 3</p>	<p>The NRC disagrees with the proposed resolution and has not made any related changes to the text. The NRC does not believe that the level of detail of the proposed resolution is appropriate for this Regulatory Guide and that including such detailed guidance may be considered by the Commission to be too prescriptive. The NRC recognizes that there have been issues related to inconsistent interpretation and implementation of the defense-in-depth philosophy, which is the basis for the development of this revision of RG 1.174. However, the NRC believes that the new guidance provided in Section C.2.1 is sufficient to address the commenter's concern. Regarding the elimination of BTP 8-8, such actions fall outside the scope of effort for the development of RG 1.174, Revision 3; however, this comment will be documented for further consideration by the NRC.</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Southern Nuclear Operating Company		<p>This guidance assumes the failure cause or coupling factor is known. It also does not recognize that protective actions for the redundant (vs. diverse) component can reduce total plant risk.</p> <p>Proposed Resolution: In the third paragraph of this section, add a third approach as follows: “(3) reduce total plant risk by other means”. Add this as the last sentence: “For proposed changes that weaken an existing defense against common cause an acceptable mitigating argument could be based on compensatory measures to reduce the risk such as: reducing the total plant risk by protecting diverse or redundant equipment, reducing the initiating event frequency, etc.” [SNC1-2]</p> <p>----</p> <p>See pages 20 to 21, Section C.2.1.1.3, Item 4</p>	<p>The NRC disagrees with the proposed resolution and has not made any related changes to the text. The NRC does not consider the action of lowering total plant risk as a means of defending against common-cause failures, nor does “reducing the total plant risk by protecting diverse or redundant equipment, reducing the initiating event frequency, etc.” defend against common cause failures. The NRC recognizes that the discussion in the RG implicitly assumes that the failure cause or coupling factor can be (or is) understood with some degree of confidence and thus, the appropriate defense can be implemented. In situations where the failure cause or coupling factor is not understood, the CCF contributor(s) for the associated group of components is (are) typically adjusted to reflect the increased conditional probability that the group of components is susceptible to the same cause or coupling factor. Since the discussion is related to defending against common cause failures and not related to how to model specific situations, the above explanation is not presented in the RG.</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Southern Nuclear Operating Company		<p>Section 2.1.1 lists seven factors to evaluate how the proposed licensing basis change impacts defense-in-depth. Section 2.1.1.3 says it is considered acceptable to use the seven DID evaluation factors described in Section 2.1.1.2 to evaluate the impact of a proposed licensing basis change on DID. Section 2.1.1.3 then says that it is presumed that, prior to the implementation of the proposed licensing basis change, the as-built and as-operated plant is consistent with the DID philosophy. If the as-built and as-operate plant is not consistent with DID philosophy, Section 2.1.1.3 says the licensee and the staff should ensure compliance with existing requirements and implement an appropriate action to address any non-compliances. Section 2.1.1.2 DID evaluation Factor 4 to preserve adequate defense against potential common cause failure maintains the use of diverse components to provide the same safety function to prevent common cause failure from using the same components.</p> <p>Proposed Resolution: The seven DID evaluation factors may not be the ones which were used to determine a plant's compliance in DID philosophy for issuing the operation license for the plant. The seven DID evaluation factors in RG 1.174 should be consistent with the existing DID philosophy, which was used for the licensing of the as-built as-operated plant. [SNC1-3]</p> <p>----</p> <p>See pages 13 to 23, Sections C.2.1.1 to C.2.1.1.3</p>	<p>The NRC disagrees with the proposed resolution and has not made any related changes to the text. The language in the first paragraph of Section C.2.1.1.3 related to non-compliance issues is not intended to imply that, for any given risk-informed licensing basis change, a review of the licensing basis should be performed in order to identify where the licensing basis is inconsistent with the defense-in-depth philosophy. The language is only intended to apply in cases where there is a known non-compliance issue.</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Exelon Generation Company	Language change	<p>This comment relates to the following text, “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.” 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 technical adequacy of a PRA analysis used to support an application is measured in terms of its appropriateness with respect to scope, level of detail, technical adequacy, and plant representation (emphasis added). 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. 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>Proposed Resolution: Section 2.3.2 Probabilistic Risk Assessment Technical Elements to Support an Application. 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. The term PRA acceptability is retained for the higher level to replace the old term PRA Quality.</p> <p>[EGC1-1] ---- See page 3, Section B - Reason for Revision</p>	<p>The NRC understands the comment. In several NRC guidance documents, the terms “PRA quality” and “technical adequacy” have been used interchangeably in many cases and, in some cases, incorrectly. DPO-2016-001, “Differing Professional Opinion on Probabilistic Risk Assessment Language in Regulatory Guides” (see ADAMS accession No. ML17013A015) raised these issues for consideration and resolution by NRC management. The resolution of DPO-2016-001 directed the staff to adopt the term “PRA acceptability” rather than “PRA quality” and “technical adequacy” in RG 1.174. Consistent with that resolution, the NRC implemented the change in the following manner. In cases where terms such as “PRA adequacy”, “PRA technical adequacy,” or “PRA quality” refer to the acceptability or adequacy of the four PRA aspects of scope, conformance with technical elements, level of detail, and plant representation, the term “PRA acceptability” is now used in place of those terms. In cases where terms such as “technical adequacy” or “PRA quality” refer to conformance with the technical elements in the ASME/ANS PRA standard, the phrasing “conformance with the technical elements” is now used in place of those terms. A Regulatory Information Summary (RIS) is under development to explain the meanings of the terms PRA acceptability, technical adequacy, PRA quality, and PRA applicability; that this is only a change in NRC usage of terms; and the change in terminology does not impact any regulatory processes. It should be noted that the NRC’s change in terminology is intended to be reflected in other relevant guidance documents (e.g., RG 1.200, NUREG-0800, etc.) as they are updated and revised. As such, no additional changes have been made to the text in response to this comment.</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Exelon Generation Company		<p>This comment relates to the following text: The PRA analysis used to support an application is measured in terms of its appropriateness with respect to scope, level of detail, conformance with the technical elements, and plant representation.” See above (i.e., comment EGC1-1). 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. [EGC1-2]</p> <p>----</p> <p>See page 24, Section C.2.3</p>	<p>The NRC understands the comment; however, as discussed in the resolution to comment EGC1-1, a Regulatory Information Summary (RIS) is under development to explain the meanings of the terms PRA acceptability, technical adequacy, PRA quality, and PRA applicability; that this only represents a change in the NRC’s usage of terms; and the change in terminology does not impact any regulatory processes. As such, no additional changes have been made to the text in response to this comment.</p>
Exelon Generation Company		<p>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.</p> <p>Proposed Resolution: In parallel with the publication of the policy statement, the staff developed an implementation plan to define and 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. [EGC1-3]</p> <p>----</p> <p>See page 4, Section B, 2nd and 3rd paragraphs</p>	<p>Although this comment is outside the scope considered for Revision 3 of RG 1.174, the NRC does not believe revising the language would impact other parts of the RG, and therefore, would not require any additional consideration. The NRC agrees that the second and third paragraphs on page 4 are confusing and considers them to be unnecessary for the narrative in Section B. As such, these two paragraphs have been removed from the guidance.</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Exelon Generation Company		<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. 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>Proposed Resolution: To defend against CCF, one should first understand the cause and then identify potential coupling factors between equipment failures. This parallels the discussion of the demonstration of addressing the factor. Suggest deleting the fourth bullet. [EGC1-4]</p> <p>----</p> <p>See pages 15 and 16, Section C.2.1.1.2, Item 4</p>	<p>The NRC agrees with the intent of the comment and is revising the bullet items under the fourth defense-in-depth consideration of Section C.2.1.1.2 to remove the fourth and fifth bullets and to be consistent with related NRC guidance on common-cause failures. Because the first paragraph of this defense-in-depth consideration speaks to the cause of a common-cause failure, the NRC does not believe it is necessary to address it again in the next paragraph. As such, the NRC is revising the first sentence of the second paragraph under the fourth defense-in-depth consideration in Section C.2.1.1.2 from, "To defend against CCF, one should first identify potential coupling factors between equipment failures," to the following:</p> <p>"Further, to defend against CCF, one should identify potential coupling factors between equipment failures."</p>
Exelon Generation Company		<p>"Human errors include the failure of operators to perform the action 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." 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>Proposed Resolution: 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. [EGC1-5]</p> <p>----</p> <p>See page 16, Section C.2.1.1.2, first paragraph</p>	<p>The NRC agrees with the comment and has revised the cited language as proposed.</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Exelon Generation Company		<p>The following sentences seem somewhat out of place. It appears that this should be addressed under a different process. "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> <p>Proposed Resolution: Suggest deleting these sentences. [EGC1-6] ----- See page 17, Section C.2.1.1.3, first paragraph</p>	<p>The NRC disagrees with the comment and has not made any related changes to the text. The NRC position is that the cited language is only applicable in cases where there is a known non-compliance issue.</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Exelon Generation Company		<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. Understanding the drivers of the change in risk (i.e., at the level of initiating events, accident sequences, cut sets, 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>Proposed Resolution: An expansion of the following paragraph providing some examples of how the risk assessment can be used would be helpful: “A comprehensive risk analysis can provide insights into whether the balance among the layers of defense remains appropriate to ensure protection of the 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.” [EGC1-7] ---- See page 18, Section C.2.1.1.3,</p>	<p>The NRC agrees that the paragraph cited in the proposed resolution could be expanded and, as such, the NRC has revise the text to insert the following sentence before the last sentence of the paragraph cited in the proposed resolution.</p> <p>“Understanding the drivers of the change in risk (i.e., at the level of initiating events, accident sequences, cut sets, etc.) can focus attention on which aspect of defense-in-depth is likely to be affected.”</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Exelon Generation Company		<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>Proposed Resolution: 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. [EGC1-8]</p> <p>----</p> <p>See pages 12 through 23, Section C.2.1</p>	<p>The NRC disagrees with the proposed resolution and has not made any related changes to the text. While the NRC recognizes that there are some PRA insights that can be used to inform the evaluation of whether the licensing basis change maintains consistency with the defense-in-depth philosophy, the scope of this portion of the RG is relates to performing that evaluation using the seven defense-in-depth considerations (formerly known as factors). As stated in resolution to EGC1-7, the staff has revised the guidance to include additional information about how PRA insights may be used for the defense-in-depth evaluation. Moreover, as stated in Section B, NUREG/KM-0009, "Historical Review and Observations of Defense-in-Depth" is a recommended resource for gaining a more detailed understanding of defense-in-depth.</p>
Exelon Generation Company		<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>Proposed Resolution: Consider a discussion of License Amendment Requests (LARs) that address changes to programmatic activities as opposed to design changes. [EGC1-9]</p> <p>----</p> <p>See page 19, Section C.2.1.1.3, Item 2</p>	<p>The NRC agrees with the comment and has revised the following text in the second paragraph of the second defense-in-depth consideration from, "The evaluation of the proposed licensing basis change should demonstrate that the change does not result in an excessive reliance on programmatic activities that are used to compensate for an intended reduction in the capability of engineered safety features," to:</p> <p>"The evaluation of the proposed licensing basis change should demonstrate that the change does not result in an excessive reliance on programmatic activities that are used to compensate for an intended reduction in the capability of engineered safety features (or previously approved programmatic activities)."</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Exelon Generation Company		<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." 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. Mental and physical demands are two important PSFs but they are not the only ones.</p> <p>Proposed Resolution: Suggest clarifying the intent. Consider the following: 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"> • Create new human actions that are important to preserving any of the layers of defense for which a high reliability cannot be demonstrated. • 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. [EGC1-10] <p>---- See page 22, Section C.2.1.1.3, Item 6</p>	<p>The NRC agrees with the comment and has revised the text by replacing the three list items under the sixth defense-in-depth consideration (formerly known as a factor) in Section C.2.1.1.3 with the two bulleted list items proposed in the comment.</p>
Exelon Generation Company		<p>There appears to be a typographical discrepancy in the LERF figure (CDF instead of LERF in the Region III annotation) [EGC1-11]</p> <p>---- See page 28, Section C.2.4, Figure 5</p>	<p>The NRC agrees with the comment and revised the cited language in Figure 5 as proposed.</p>

Commenter	Comment Category	Specific Comments	NRC Resolution
Exelon Generation Company		<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>Proposed Resolution: The following is believed to be a more accurate statement: "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." In the third paragraph, suggest adding the words as indicated to link to the use of the PRA. 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. [EGC1-12]</p> <p>----</p> <p>See page 36, Section C.2.6, 2nd paragraph</p>	<p>The NRC agrees that the cited language on quantitative risk results and the subsequent sentence need additional clarification and these sentences have been revised based on similar concerns expressed in comments NEI1-28 and NEI1-29. Additionally, the NRC expanded the guidance under the first defense-in-depth consideration in Section C.2.1.1.3 in response to comment EGC1-7 to emphasize how PRA can be used in evaluating whether the proposed licensing basis change is consistent with the defense-in-depth philosophy. This expansion of the guidance provides similar language to that proposed by the commenter for the third paragraph of Section C.2.6. The NRC believes these changes adequately address this comment and have not made any additional related changes to the text.</p>