

NRC Comments on NEI 96-07, Appendix D, Revision 0g

On October 26, 2018, the Nuclear Energy Institute (NEI) submitted to the U.S. Nuclear Regulatory Commission (NRC), NEI 96-07, Appendix D, Revision 0g (ADAMS Accession No. ML18310A433). The chart below documents the NRC staff's comments on this latest version of NEI 96-07, Appendix D. Below the chart are 4 comments that either: 1) require clarification of a new edit to the guidance; or 2) requests a response to a comment previously provided to NEI in the NRC's action item response document for the draft NEI 96-07, Appendix D, Revision 0g (ADAMS Accession Number ML18282A044).

This document will be used to support a Category 2 public meeting with NEI to discuss these comments on November 14, 2018.

Comment Color Key:

GREEN = NRC has no further comments.

BLUE = Alignment gained on comment at the November 14th meeting

RED = Apparent conflict with regulatory infrastructure; NRC/NEI to gain alignment on what needs to change and why it is necessary.

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1.	General	1	N/A	See Item #1.	The staff does not believe that the RIS is superseded by Appendix D. Therefore, the edit to the executive summary is incorrect.

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					Note from meeting: NEI understands the concern and will further edit this language to ensure that it reflects the RIS 2002-22, Supplement 1 and has been incorporated appropriately.
2.	General	2	N/A	Addressed in Item #7.	No further comments
3.	General	3	N/A	Addressed in Items #13 & #40.	No further comments
4.	General	4	N/A	See Item #28a.	No further comments
5.	General	5	N/A	See Item #70.	This comment was not addressed in Appendix D. The staff will address this comment within its endorsement of Appendix D. Notes from meeting: This general comment is provided is specificity in the comment below. As a result of this meeting, the staff cannot close out this comments and the general concern remains – documentation provided within.

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6.	Executive Summary	A1	C	<p>NRC needs to identify the additional part(s) of the Supplement that need to be incorporated.</p> <p>Supplement 1 to RIS 2002-22 is primarily a guidance document for technical guidance (i.e., the preparation of qualitative assessments and the topics that should be considered therein), not licensing (i.e., 50.59) guidance. Only the guidance in Section 2.2 is related to 50.59, which has already been incorporated into Section 4.3 of Appendix D.</p>	No further comments
7.	1.1	A2	C	To be incorporated	No further comments
8.	1.2	A3	E	To be incorporated	No further comments
9.	1.2	A4	E	Suggested addition not pertinent, but final sentence to be removed.	No further comments
10.	4.2	A5	C	The purpose of the CAUTION is to ensure the user understands that the guidance in the main body	No further comments

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				of NEI 96-07 still applies and/or must be considered. Suggested text will be added.	
11.	4.2	A6	C	To be incorporated	No further comments
12.	4.2	A7	C	The conclusions in the examples will be changed to reflect the phrase "does not screen in for the aspect or topic within the section/subsection" (or equivalent) in place of "not adverse."	No further comments
13.	4.2	A8	C	See Item #28a.	No further comments
14.	4.2.1.1	A9	E	Subject text to be <i>removed</i> , not <i>moved</i> .	No further comments
15.	4.2.1.1	A10	C	Subject text to be removed.	No further comments
16.	4.2.1.1	A11	C	To be incorporated	No further comments
17.	4.2.1.1	A12	C	The suggested language will need to be adjusted to acknowledge that the "engineering evaluation" in this case would be a <i>qualitative assessment</i> (as described in Supplement 1 to RIS 2002-22), which is used in the Evaluation	The parenthetical "(i.e., software CCF likelihood = 0)" is incorrect and needs to be removed from the edits. Otherwise, the edit is acceptable. Notes from meeting: Parenthetical "(i.e., software CCF likelihood = 0)" will be

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				<p>phase, not in the Screen phase.</p> <p>The information in the subsequent paragraph is related and perhaps the paragraphs could be combined.</p>	removed throughout the document.
18.	4.2.1.1	A13	C	In the Screen section, "engineering evaluations" will be changed to "engineering/technical information supporting the change." Note that the term "qualitative assessment" and its process do not apply in the Screen phase, but do apply in the Evaluation phase (as identified in Supplement 1 to RIS 2002-22).	No further comments
19.	4.2.1.1	A14	C	Suggested wording to be slightly modified and added as an example at the end of the sentence.	To be consistent with the deletion of the quoted text in comment A9 and A10, the edited language must also be deleted.

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					Notes from meeting: Parenthetical "(i.e., software CCF likelihood = 0)" will be removed throughout the document.
20.	4.2.1.1	A15	C	Will add "e.g." at the beginning of the items within the parentheses.	No further comments
21.	Example 4-1	A16	C	Parenthetical phrase to be removed.	No further comments
22.	Example 4-1	A17	C	Identified text will be removed and two sentences created.	No further comments
23.	Example 4-1	A18	C	Parenthetical phrase to be removed.	No further comments
24.	Example 4-2	A19	C	Although the observation stated in the NRC comment could be true, this example does not represent an actual plant or an actual licensing basis of a facility. This example simply illustrates the case in which there are "no design functions." Add, " <u>In this case, the licensee has determined</u>	See item A20 Notes from meeting: Example 4-2 will be deleted completely.

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				there are NO design functions..."	
25.	Example 4-2	A20	C	See response to item #19.	<p>Fails to consider NEI 96-07, Section 3.3, which states, "Design functions may be performed by safety-related SSCs or nonsafety-related SSCs and include functions that, if not performed, would initiate a transient or accident that the plant is required to withstand."</p> <p>Notes from meeting: Example 4-2 will be deleted completely.</p>
26.	Example 4-3	A21	C	Example 4-3 will be reworked to address the new approach proposed in addressing Item #12.	No further comments
27.	4.2.1.1	A22	E	NRC needs to identify a specific type of "combination" not covered by current examples.	Comment not addressed but comment is an enhancement.
28.	4.2.1.1	A23	C	The current sentence will be replaced with the associated guidance from NEI 01-01,	No further comments

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				Section 4.3.3, four bullets at the end of the 1st paragraph.	
29.	Example 4-4	A24	C	Erroneous conclusion basis will be corrected.	No further comments
30.	Example 4-4	A25	C	(1) According to the currently endorsed guidance in NEI 01-01, Section 4.3.3, first bullet at the end of the first paragraph, this type of impact is NOT ADVERSE. Namely, although multiples <i>failures</i> will be created, only one (design) <i>function</i> (i.e., provide feedwater) is affected. The text will be modified to clarify this point.	Resolution on A25b would resolve this comment. Notes from meeting: NEI will change Option 2 to adverse as suggested and edits as appropriate.
31.	Example 4-4	A25	C	(2) "Independence" (in its licensing application) is not applicable to non-safety-related SSCs. In this case, two main feedwater trains are provided for operational convenience and design considerations (e.g., pump sizing).	Was not addressed because Option 2 in the example is counter to the guidance inserted "Reductions in the redundancy, diversity, separation, or independence of a UFSAR-described design function..."

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				<p>The "what if" scenario presented in the comment regarding probability and its impact on reliability does need to be considered, but not as part of this digital specific aspect. Namely, impacts on reliability are addressed in the guidance contained in NEI 96-07, Rev. 1, Section 4.2.1.</p> <p>See note at the beginning of the Screen Response.</p>	<p>An easy fix is to change the conclusion from not adverse to adverse. Reasoning is that reduction in redundancy of the design function is adverse.</p> <p>Notes from meeting: NEI will change Option 2 to adverse as suggested and edits as appropriate.</p>
32.	Example 4-4	A25	C	(3) See response to Item #25b.	<p>See A25b</p> <p>Notes from meeting: NEI will change Option 2 to adverse as suggested and edits as appropriate.</p>
33.	Example 4-5	A26	C	<p>According to the currently endorsed guidance in NEI 01-01, Section 4.3.3, first bullet at the end of the first paragraph, this type of impact is NOT ADVERSE. Namely, although multiple <i>failures</i> will be created, only</p>	<p>Same issue persists as in the previous comment. See comment A25b.</p> <p>Notes from meeting: Clarification is needed on the basis for "not adverse" as the outcome. There is a</p>

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				<p>one (design) <i>function</i> (i.e., control temperature) is affected.</p> <p>The text will be modified to clarify that only one design function is affected.</p>	<p>difference from the previous comment (A25).</p>
34.	Example 4-6	A27	C	<p>"Independence" (in its licensing application) is not applicable to non-safety-related SSCs. There is no design function to maintain physical separation of the multiple control systems that typically exists for most safety-related SSCs.</p> <p>This example (as with other examples) is intended to illustrate a digital specific aspect and is not meant to be inclusive of everything considered in the 10 CFR 50.59 review of an activity.</p>	<p>Based on the inserted quote this example should be revised, "Reductions in the redundancy, diversity, separation, or independence of a UFSAR-described design function..."</p> <p>An easy fix is to change the conclusion from not adverse to adverse. Reasoning is that reduction in independence of the design function is adverse.</p> <p>Notes from meeting: No alignment reached. NEI believes the issue that is raised in this example is addressed in the Evaluation section and as such, there</p>

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					are no additional edits needed. NRC staff believes additional rationale is needed for why this modification screens-in.
35.	4.2.1.2	A28	C	<p>This comment, which gives the option to retain this section, is contrary to General Comment #4 (see Item #D), which recommends the removal of this section.</p> <p>This guidance does not address a generic guidance issue with NEI 96-07, Rev. 1. The purpose of this section is to provide digital-specific application of the related guidance from NEI 96-07, Rev. 1, Section 4.2.1.2.</p> <p>Furthermore, NEI 01-01, Section 4.3.4 contains guidance for HSI. Eliminating this section from</p>	NEI chose to move forward with this section included in the Appendix. Therefore, NRC withdraws this comment.

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				Appendix D would result in the incomplete inclusion of pertinent guidance when NEI 01-01 is superseded.	
36.	4.2.1.2	A28	C	The acronym HSI is already used in this section. The term "Human Factors Evaluation (HFE)" will be added in a manner similar to that used in Section 4.3 to describe a Qualitative Assessment.	No further comments
37.	4.2.1.2	A29	E	The intent of this guidance is to provide a process for the Screen practitioner to perform the HFE within the Screen if the practitioner is sufficiently knowledgeable to do so. This approach is supported by NEI 96-07, Rev. 1, Section 4.2.1, subsection titled "Screening for Adverse Effects" in the 5th paragraph, 1st sentence.	NRC staff understands NEI's approach.
38.	4.2.1.2	A29	E	NEI 96-07, Rev. 1 contains guidance on how to	No further comments

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				"convert" a technical result into a licensing result (i.e., <i>adverse or not adverse</i>) by "comparing" the new condition with the licensing condition ((refer to the diesel start time example embedded in NEI 96-07, Rev. 1, Section 4.2.1, subsection titled "Screening for Adverse Effects").	
39.	4.2.1.2	A30	E	Detailed technical guidance is provided in the references (e.g., NUREG-0700 and NUREG/CR-6947).	NRC staff understands NEI's approach.
40.	4.2.1.2	A30	E	As with all 50.59 activities, the appropriate subject matter experts are expected to be consulted or participate in developing/creating the technical bases used in the 50.59 process, as necessary.	NRC staff understands NEI's approach. No further comments.
41.	4.2.1.2	A31	C	The word "may" will be deleted.	No further comments
42.	4.2.1.2	A31	C	There is no inconsistency with NEI 96-07 and related	No further comments

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				<p>conclusions in Examples 4-8a and 4-8b.</p> <p>However, use of the word "negative" in the HFE conclusion was inappropriate and will be removed, and the outcomes restated as statements of final conditions, not as "negative" or "positive." Then, as described in NEI 96-07, the Screen uses those final conditions to determine the type of impact (i.e., positive, negative, or none) on design functions (refer to the diesel start time example embedded in NEI 96-07, Rev. 1, Section 4.2.1, subsection titled "Screening for Adverse Effects").</p>	
43.	4.2.1.2	A32	E	<p>Replace the word "final" with "next." However, the first two steps are clearly identified as being the "two-step HSI assessment," so there is NO "third" HSI assessment step.</p>	No further comments

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44.	4.2.1.2	A33	C	<p>The process and examples correctly implement NEI 96-07, Rev. 1 guidance.</p> <p>However, use of the word "negative" in the HFE conclusion was inappropriate and will be removed, and the outcomes restated as statements of final conditions, not as "negative" or "positive." Then, as described in NEI 96-07, the Screen uses those final conditions to determine the type of impact (i.e., positive, negative, or none) on design functions (refer to the diesel start time example embedded in NEI 96-07, Rev. 1, Section 4.2.1, subsection titled "Screening for Adverse Effects").</p>	No further comments
45.	Example 4-8a	A34	C	<p>The HFE outcome is an increase in <i>response time</i>. However, there is no <i>response time</i> element within the identified design functions in this example.</p>	Even though the word "negative" has been removed from this example, the staff does not agree that the remainder of our comments from previous

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				<p>Therefore, although more time will be needed to perform the design function, there is no adverse impact on the ability to actually perform the described design function. The <u>not adverse</u> conclusion is correct in this example.</p> <p>If a <i>response time</i> element was included as part of the design function description, then the new <i>response time</i>, NOT the INCREASE in the <i>response time</i>, would be compared with the <i>response time</i> requirement in the licensing basis to determine the impact.)</p>	<p>discussions have been addressed in example 4-8a.</p> <p>Notes from meeting: NEI agrees to the concept of the language below and will revise Appendix accordingly. “The HFE evaluation determined that the modification impacts the operator’s ability to respond by requiring four actions instead of one action. And the additional actions result in an increase in the operator’s time to respond. However, the actions continues to take place and the HFE professional determined that the operator actions were timely and comparable.”</p>
46.	Example 4-8a	A35	C	The process and example correctly implement NEI 96-07, Rev. 1 guidance.	Even though the word “negative” has been removed from this example, the staff does not agree that

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				<p>However, use of the word "negative" in the HFE conclusion was inappropriate and will be removed, and the outcomes restated as statements of final conditions, not as "negative" or "positive." Then, as described in NEI 96-07, the Screen uses those final conditions to determine the type of impact (i.e., positive, negative, or none) on design functions (refer to the diesel start time example embedded in NEI 96-07, Rev. 1, Section 4.2.1, subsection titled "Screening for Adverse Effects").</p> <p>Propose to change subject sentence to, "The HFE evaluation determined that the modification increased in the operator's time to respond by requiring four actions instead of one action."</p>	<p>the remainder of our comments from previous discussions have been addressed in example 4-8a.</p> <p>Note from the meeting: See comment A34 to resolve this item.</p>

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47.	Example 4-8b	A36 & A37	C	<p>The process and example correctly implement NEI 96-07, Rev. 1 guidance.</p> <p>However, use of the word "negative" in the HFE conclusion was inappropriate and will be removed, and the outcomes restated as statements of final conditions, not as "negative" or "positive." Then, as described in NEI 96-07, the Screen uses those final conditions to determine the type of impact (i.e., positive, negative, or none) on design functions (refer to the diesel start time example embedded in NEI 96-07, Rev. 1, Section 4.2.1, subsection titled "Screening for Adverse Effects").</p> <p>Propose to change [A36] subject sentence to, "The HFE evaluation concluded that this modification could result in the operator</p>	No further comments

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				<p>choosing not to have certain parameters displayed, impacting their ability to monitor the plant and detect changes. In addition, altering the information displayed and the organization of the information will impact the operator's understanding of how the information relates to system performance. This impact on understanding will also impact the operator's ability to assess the situation and plan an appropriate response."</p> <p>Propose to change [A37] subject sentence to, "The HFE evaluation determined that the modification increased in the operator's time to respond by requiring four actions instead of one action."</p>	
48.	Example 4-8b	A38 & A39	C	[A38] This example (as with other examples) is intended	No further comments

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				to illustrate a digital specific aspect and is not meant to be inclusive of everything considered in the 10 CFR 50.59 review of an activity. [A39] Same as response to item 36.	
49.	4.3	A40	C	"Expansion" and "paraphrasing" will be eliminated except for locations where required by digital-specific guidance.	Acceptable with the exception of the parenthetical that states "if such design functions exist" on pages D14 and D15. Notes from meeting: The parenthetical will be deleted throughout the document.
50.	4.3	A40	C	NRC needs to identify the additional part(s) of the Supplement that need to be incorporated. Supplement 1 to RIS 2002-22 is primarily a document for technical guidance (i.e., the preparation of qualitative	Staff provided language from RIS 2002-22, Supplement 1 to be incorporated in Appendix D (ADAMS Accession No. ML18310A203). The following language should be added to the FMEA

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				<p>assessments and the topics that should be considered therein), not licensing (i.e., 50.59) guidance. Only the guidance in Section 2.2 is related to 50.59, which has already been incorporated into Section 4.3 of Appendix D.</p>	<p><u>section under 4.3.6 after the NEI quote:</u></p> <p>“In addition to failures caused by software, other effects of a digital modification could create new results of malfunctions (e.g., combining functions, creating new interactions with other systems, changing response time). For example, if previously separate functions are combined in a single digital device, the failure analysis assessment should consider whether single failures that could previously have affected only individual design functions can now affect multiple design functions.”</p> <p>Notes from meeting: NEI agrees with concept of the language suggested but there will be some changes in the terminology.</p>

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51.	4.3	A41	C	Guidance for how to perform a qualitative assessment (which is a <i>technical</i> assessment) is not pertinent in a licensing-based guidance document. NEI 16-16 (or equivalent) is the appropriate document for inclusion of technical guidance.	No further comments
52.	4.3	A41	C	NRC needs to identify the specific additional part(s) of the Supplement that need to be incorporated. Supplement 1 to RIS 2002-22 is primarily a document for technical guidance (i.e., the preparation of qualitative assessments and the topics that should be considered therein), not licensing (i.e., 50.59) guidance. Only the guidance in Section 2.2 is related to 50.59, which has already been incorporated into Section 4.3 of Appendix D.	No further comments

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53.	4.3	A41	C	Please clarify which restrictions on the applicability of the qualitative assessment so that we consider everything NRC is considering.	No further comments
54.	4.3	A42	C	The phrase "qualitative assessment" will be clarified to reflect its use in Supplement 1 of RIS 2002-22 and made consistent throughout the document.	No further comments
55.	4.3	A43	C	NRC needs to identify the additional part(s) of the Supplement that need to be incorporated. Supplement 1 to RIS 2002-22 is primarily a document for technical guidance (i.e., the preparation of qualitative assessments and the topics that should be considered therein), not licensing (i.e., 50.59) guidance. Only the guidance in Section 2.2 is related to 50.59, which has already been incorporated	No further comments

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				into Appendix D, Sections 4.3.1, 4.3.2, 4.3.5 and 4.3.6.	
56.	4.3.1	A44	C	The Industry agrees the word "initiator" does not exist in the 50.59 Regulation or in NEI 96-07, Rev. 1, Section 4.3.1. However, the NRC comment fails to identify that the word and consideration of "initiator" does exist in NEI 01-01, Section 4.4.1. Since NEI 01-01 is currently endorsed for use in completing 50.59 Evaluations for activities involving digital modifications, the inclusion of guidance in Appendix D, Section 4.3.1 regarding "initiators" is NOT "contrary to 50.59(c)(2)(i)."	No further comments
57.	4.3.1	A44	C	The Industry agrees with the second bullet point that a new initiator of an accident already evaluated in the UFSAR is considered in Evaluation question (i).	No further comments

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				Evaluation question (i) considers ONLY those accidents previously evaluated in the UFSAR. Contrast that with Evaluation question (v) which deals with the creation of the possibility of new accidents. The guidance for Evaluation question (v) in NEI 96-07, Rev. 1, Section 4.3.5 contains the following statement: "A new initiator of an accident previously evaluated in the UFSAR is not a different type of accident."	
58.	4.3.1	A45	C	The Industry agrees that an increase in accident frequency can be for a multitude of reasons, including increases from "new" and/or "entirely different" initiators. Refer to the detailed basis provided in the Industry Response to Item #42a & #42b.	No further comments

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				Propose to edit the subject sentence, "After applying the generic guidance in NEI 96-07, Section 4.3.1 to identify any accidents affected by the systems/components involved with the digital modification and, <u>then</u> examining the initiators of those accidents, the impact on the frequency of the initiator (and, hence, the accident itself) due to the digital modification can be assessed."	
59.	4.3.1	A46	E	See response to item #43.	No further comments
60.	Example 4-9	A47 & A48	C	The example will be revised to indicate that there are no accidents related to the chillers.	No further comments
61.	4.3.1	A49	E	Consistent use of "software CCF" (vs. failure, etc.) will be addressed.	No further comments
62.	4.3.1	A50 & A51	C	Clarification of concepts was dispositioned and closed in April 2017 (see <u>Public_Meeting_Items_and_</u>	No further comments

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				Actions (NEI9607AppD_06212017). CCF outcomes of sufficiently low or not sufficiently low were finalized in RIS 2002-22 Supplement 1 and are the only "new" information incorporated.	
63.	4.3.1 and Example 4-12	A52 & A53	C	The Industry agrees that meeting the requirements, etc. is <u>in addition to</u> all other considerations. This statement can be clarified to more clearly identify this fact.	No further comments
64.	4.3.1 and Example 4-12	A52 & A53	C	See response to Item #47.	No further comments
65.	4.3.1 (and other similar locations)	A54	E	Subsection on Human- System Interface Assessment to be deleted.	No further comments
66.	4.3.1 (and other similar locations)	A55	E	Subsection on Human- System Interface Assessment to be deleted.	No further comments
67.	4.3.2	A56	E	The Industry disagrees with the final phrase in the statement: "...reductions in redundancy, diversity and	The wording from the RIS Supplement used to address comment A40 should be included in

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				<p>independence are general technical concerns for digital modifications and <u>not specifically tied to any single evaluation criteria under 10 CFR 50.59</u> [<u>emphasis</u> added to the pertinent phrase].</p> <p>In Supplement 1 to RIS 2002-22, Section 3, 2nd paragraph, near the end of the first sentence (which discussed the four terms) footnote No. 4 is included immediately following the last term.</p> <p>Footnote No. 4 clearly indicates that these terms refer to <u>ONLY</u> NEI 96-07, Section 4.3.2, which provides guidance for <u>ONLY</u> 10 CFR 50.59(c)(2)(ii).</p> <p>The discussion of these terms is located correctly and will not be relocated to</p>	<p>section 4.3.2 of Appendix D, with the exception of the parenthetical added to the first paragraph. See page D14.</p> <p>Notes from meeting: NEI agrees with this comment and will revise accordingly.</p>

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				the beginning of Section 4.3 as suggested.	
68.	4.3.2	A57	C	Agree with the observation; general comment does not provide suggested changes.	No further comments
69.	4.3.2	A58	C	The suggested NRC comment to add the phrase "of the design function" seems inappropriate because the suggested phrase is not in the reference. It is unclear how the second sentence is inconsistent with NEI 96-07, Rev. 1 or RIS 2002-22, Supplement 1.	No further comments
70.	4.3.2	A59	C	Propose to remove discussions of these four terms.	No further comments
71.	4.3.2	A60	C	Propose to remove discussions of these four terms.	No further comments
72.	4.3.2	A61	C	Propose to remove discussions of these four terms.	No further comments
73.	4.3.2	A62	C	Agree to remove paragraph.	No further comments

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74.	4.3.2	A63	C	Propose to remove discussions of these four terms.	No further comments
75.	4.3.2	A64	C	Propose to remove discussions of these four terms.	No further comments
76.	4.3.2	A65	C	(1) This comment is not related to 50.59 guidance. Furthermore, the NRC statement that " <i>Generally, only malfunctions are identified in the UFSAR, not the initiators of the malfunctions</i> " is not representative of most UFSARs. Namely, most UFSARs do identify most, sometimes all, malfunction (and accident) initiators.	No further comments
77.	4.3.2	A65	C	(2) The Industry agrees with the second point that a new initiator of a malfunction already evaluated in the UFSAR is considered in Evaluation question (ii). Evaluation question (ii) considers ONLY those	No further comments

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				<p>malfunctions previously evaluated in the UFSAR.</p> <p>The Industry agrees that an increase in malfunction likelihood can be for a multitude of reasons, including increases from "new" and/or "entirely different" initiators.</p> <p>Propose to replace "If none of the components/systems involved with the digital modification are identified as affecting a malfunction initiator previously identified in the UFSAR, then there is no attributable impact on the likelihood of occurrence of a malfunction." with, "After applying the generic guidance in NEI 96-07, Section 4.3.2 to identify any malfunctions affected by the systems/components involved with the digital modification and, then examining the initiators of</p>	

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				those malfunctions, the impact on the likelihood of the malfunction due to the digital modification can be assessed.”	
78.	4.3.2	A65	C	(3) Evaluation questions (ii) and (vi) address different aspects so their "thresholds" cannot be compared.	This comment has been addressed in the guidance but not addressed in the example. Example 4-13 still uses the term “Malfunction Initiators” throughout the example. Notes from meeting: NEI agrees with this comment and will revise accordingly.
79.	4.3.2	A66 & A67	C	Clarification of concepts was dispositioned and closed in April 2017 (see Public_Meeting_Items_and_Actions (NEI9607AppD_06212017). CCF outcomes of sufficiently low or not sufficiently low were finalized in RIS 2002-22 Supplement 1 and are the	No further comments

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				only "new" information incorporated.	
80.	4.3.5	A68	C	The full text from Supplement 1 to RIS 2002-22, Section 2.2, subsection 10 CFR 50.59(c)(2)(v) will be included. For completeness, the appropriate full text from Supplement 1 to RIS 2002-22, Section 2.2 will be added in 4.3.1, 4.3.2, and 4.3.6.	No further comments
81.	4.3.5	A69	C	"Failure likelihood" will be used throughout Appendix D in lieu of "software CCF" for consistency with RIS 2002-22, Supplement 1.	No further comments
82.	4.3.5	A70	E	Delete phrase.	No further comments
83.	4.3.5	A71	E	To be incorporated	No further comments
84.	4.3.5	A72	C	Note will be removed.	No further comments
85.	Example 4-16	A73	C	Example will be reworked to match the guidance.	No further comments
86.	Example 4-16	A74	C	Use of the phrase "qualitative assessment" will be clarified and made consistent.	No further comments

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87.	Example 4-17	A75	C	Example will be reworked to match the guidance.	No further comments
88.	4.3.6	A76	C	Section 4.3.6 will be retained and is critical to the application of 10 CFR 50.59 to digital activities. NRC comments do not identify specific conflicts with 10 CFR 50.59 or associated regulatory basis and guidance documents.	No further comments, as NEI has chosen to keep this section in Appendix D.
89.	4.3.6	A77	C	In the "review" subsection, add the scope of "supporting UFSAR analyses..." from NEI 96-07, Rev. 1, Definition 3.12, Discussion section, first bullet, in the discussion of <i>safety analyses</i> .	<p>Page D-55, the sentence below needs to be deleted or revised to meet 50.59 (c)(2)(vi) as follows:</p> <p>For these cases, this Evaluation criterion also needs to consider the impact this potential failure creates on a "...malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report"</p> <p>Notes from meeting: Alignment has not been reached for this comment.</p>

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90.	4.3.6	A78	C	Comment does not provide specific evidence of misplaced context or specific misinterpretation. While it would be ideal to refer to NEI 96-07, Rev.1, the importance of the quoted definitions and discussion highlights is critical to the proper application of 10 CFR 50.59 to digital activities. Specific conclusions of concern to the staff have not been identified.	No further comments
91.	4.3.6	A79	C	This concern is addressed in the preceding discussions and in Steps 2 and 5 of Section 4.3.6, in which all Design Functions are considered.	The staff will need to address this item in their endorsement of Appendix D. As written, the guidance does not indicate that this Appendix should only be used for digital modifications due to the uniqueness aspects of digital technology. Notes from meeting:

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					NEI understands the NRC staff's position and will take no action.
92.	4.3.6	A80	C	Yes, 10 CFR 50.59(c)(2)(vi) states "Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report (as updated)." The "results" in the UFSAR are presented in the safety analyses as defined in NEI 96-07, Rev. 1, Sec. 3.12. This is distinct from the broader descriptive material contained in the balance of the UFSAR, e.g. descriptions of a component's failure. NEI 96-07, Rev. 1, Sec. 4.3.6 begins with, "Malfunctions of SSCs are generally postulated as potential single failures to evaluate plant performance with the focus being on the result of the malfunction rather than the cause or type of	The staff provided language to address this comment (ADAMS Accession No. ML18282A044). This language was not included in the Introduction to the "Determination of Safety Analysis Result Impact" section of the revision to Appendix D. The staff will note this issue as an exception in its endorsement of Appendix D. Notes from meeting: NEI will take no action.

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				malfunction.” [emphasis added] An SSC’s functional level is generally too low to independently represent a malfunction result as discussed in NEI 96-07.	
93.	4.3.6	A81	C	See response to item #73.	<p>PDC and GDC provides incomplete consideration of design basis function. Design Basis function is defined in NEI 96-07.</p> <p>Notes from meeting:</p> <ol style="list-style-type: none"> 1. Agreed language change to the first sentence of the paragraph – “One means to determine if a <i>design function</i> is a <i>design basis function</i> would be aided by identifying the associated General Design Criteria (GDC) to which a <i>design bases function</i> applies.....” 2. The paragraph that starts – “If no <i>design basis functions</i>....”<i>will be moved and will become as the last paragraph of Step 2.</i>

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					<p>3. The underline sentence will be added to the new second to last paragraph of Step 2. “However, safety analyses do not typically identify all of the SSCs that are relied upon to perform their design functions. <u>Thus, certain design functions, while not specifically identified, in the safety analysis, are credited in an indirect sense.</u>”</p> <p>4. editorial change in the third to last paragraph of step 2 – the underline word were misspelled <i>bases function</i> should include both direct and indirect <u>effects</u> on the design functions</p>
94.	4.3.6	A82	C	The referenced text relates to Section 4.3.2 in NEI 96-07, Rev. 1 and would not be considered as part of Section 4.3.6.	No further comments
95.	4.3.6	A83	C	The interdependent activities being discussed are not "compensatory actions." The actions being discussed are actions	No further comments

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				<p>associated with the as-designed SSC. For example, a new digital system could be equipped with a "reset" button. If the operating procedure contains steps for manipulation of the reset button, then those instructions are NOT compensatory actions. However, if after utilizing the reset button, the SSC still does not function properly and OTHER actions NOT COVERED by any other procedure are developed in response to or to address the degraded condition of the SSC, then those newly-developed actions would be <i>compensatory actions</i>.</p> <p>These types of activities (i.e., compensatory actions) are not unique to digital and would be addressed in accordance with the guidance in NEI 96-07, Rev.</p>	

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				1 (e.g., Section 4.3.2, Example 4, and Section 4.4).	
96.	4.3.6	A84	C	<p>Section 4.3.6.2 does not exist in NEI 96-07, Rev. 1. The quote is from NEI 96-07, Rev. 1, Section 4.3.2, which is not pertinent in Section 4.3.6 (of NEI 96-07 or Appendix D).</p> <p>Clarification/explanation of the comment/concern is needed.</p>	<p>The staff provided language to address this comment (ADAMS Accession No. ML18282A044). This language was not included in the following sections of the revision to Appendix D. The staff will note this issue as an exception in its endorsement of Appendix D.</p> <p>This is also applicable for Step 6 and associated examples.</p> <p>Notes from meeting: See A80 corrections 3. The language will be added to Step 2.</p>
97.	4.3.6	A85	C	[First Paragraph] The Industry agrees that "...there will never be any 'pre-existing safety analysis' for new types of events created by a change." That specific condition is not the subject	The staff provided language to address this comment (ADAMS Accession No. ML18282A044). This language was not included in the following sections of the revision to Appendix D.

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				<p>of Evaluation question (vi), but would be addressed using Evaluation question (v).</p> <p>The guidance in Section 4.3.6 is correct for the cases in which a pre-existing safety analysis does exist. The statement regarding "no safety analysis involved" is to remind the 50.59 practitioner of the limitations of this particular question.</p>	<p>The staff will note this issue as an exception in its endorsement of Appendix D. This is also applicable for Step 6 and associated examples.</p> <p>Notes from meeting: NEI will take no action.</p>
98.	4.3.6	A85	C	[Second Paragraph] The Industry agrees with statements made in this paragraph, but no suggested changes are identified.	<p>The staff provided language to address this comment (ADAMS Accession No. ML18282A044). This language was not included in the following sections of the revision to Appendix D. The staff will note this issue as an exception in its endorsement of Appendix D. This is also applicable for Step 6 and associated examples.</p> <p>Notes from meeting: NEI will take no action.</p>

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99.	4.3.6	A85	C	[Third Paragraph] The Industry agrees with statements made in this paragraph, but no suggested changes are identified.	The staff provided language to address this comment (ADAMS Accession No. ML18282A044). This language was not included in the following sections of the revision to Appendix D. The staff will note this issue as an exception in its endorsement of Appendix D. This is also applicable for Step 6 and associated examples. Notes from meeting: NEI will take no action.
100.	4.3.6	A85	C	[Fourth Paragraph] Consequences (i.e., radiological dose) are addressed in two separate Evaluation questions: (iii) and (iv). ALL 50.59 questions must be addressed for any proposed activity (with the exception of activities involving Methods of Evaluation). If there is an impact on the radiological dose result,	The staff provided language to address this comment (ADAMS Accession No. ML18282A044). This language was not included in the following sections of the revision to Appendix D. The staff will note this issue as an exception in its endorsement of Appendix D. This is also applicable for Step 6 and associated examples.

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				either question (iii) or (iv) will be the appropriate location, not question (vi).	Notes from meeting: NEI will take no action.
101.	4.3.6	A86	C	The statement will be changed from "meeting the acceptance criteria" to "being bounded."	No further comments
102.	4.3.6 Example 4-19	A87	C	See Industry Responses in Items #79a and #79d.	This comment is applicable to the revised version of Example 4-19, which states that "Although the software CCF likelihood was determined to be not sufficiently low , there are no safety analyses that directly or indirectly credit the design basis function or contain expected responses of the radiation monitors." This is inconsistent with NEI 96-07, Section 4.3.2, "The safety analysis assumes certain design functions of SSCs in demonstrating the adequacy of design. Thus, certain design functions, while not specifically identified in the safety

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					<p>analysis, are credited in an indirect sense.”</p> <p>This guidance should be added to Appendix D.</p> <p>Note from meeting:</p> <p>The first sentence in this example will be revised as follows:</p> <p>“A complete upgrade of the area radiation monitors that monitor a variety of areas (e.g. small rooms, hallways, etc.) for high radiation is proposed. “</p> <p>The example will be revised to conform to this sentence. However, this revision will not remedy the comment provided by the NRC staff.</p>
103.	4.3.6	A88	C	<p>See Industry Response in Item #77.</p> <p>There are no partial quotations.</p>	No further comments
104.	4.3.6	A89	C	The effect of the increased feedwater flow was	No further comments

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				incorporated into the example, as illustrated in the second paragraph for the response to Step #6. Consistent with the Six Step Process, a Design Function that is not associated with a Design Basis Function is identified as part of Step #2. That Design Function is then addressed as part of Step #s 5 and 6.	
105.	4.3.6	A90	C	The Industry agrees with the technical content of the comment. However, ONLY the impact on malfunction results is addressed in Evaluation question (vi), for which the stated conclusion is correct. The other valid concerns identified in the comment would be addressed in other pertinent Evaluation questions, such as (i), (ii) and (v).	In this example, previously separate functions are combined in a single digital device, then the evaluation needs to consider whether single failures that could previously have disabled only individual functions can now disable multiple functions. NEI 96-07 illustrates this concern when it states: An example of a change that would create the possibility for a malfunction with a different result is a

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					<p>substantial modification or upgrade to control station alarms, controls, or displays that are associated with SSCs important to safety that creates a new or common cause failure that is not bounded by previous analyses or evaluations.</p> <p>Notes from the meeting: NEI will revise the second sentence in step 6 of this example to read as such with the underline wording as new addition to sentence:</p> <p>In the proposed design, all four SBCS turbine bypass valves could also fail open <u>concurrent with the failure of the pressurizer control system</u> due to a software CCF in the</p>

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					digital control system. This revision does not resolve NRC's comment.
106.	4.3.6	A91	C	The statement will be changed from "meeting the acceptance criteria" to "being bounded."	Edit required – Accident Analysis Acceptance Criteria was removed to satisfy this comment, but replace with the language below that needs to be revised: “maximum allowed peak RCS pressure, maximum allowed secondary pressure, minimum allowed DNBR, maximum allowed peak linear heat rate and the dose consequences” Notes from the meeting: NEI agrees to remove “allowed.”

Below are comments that either: 1) require clarification of a new edit to the guidance; or 2) requests a response to a comment previously provided to NEI in the NRC's action item response document for the draft NEI 96-07, Appendix D, Revision 0g (ADAMS Accession Number ML18282A044).

1. In section 4.2.1, the unsolicited revision (shown below) was submitted. Please clarify the need for this revision.

~~A 10 CFR 50.59 Evaluation is required for digital modifications that adversely affect design functions, or the methods used to perform or control design functions.~~ There is no regulatory requirement for a proposed activity involving a digital modification to *default* (i.e., be mandatorily "forced") to an adverse conclusion.

Notes from meeting: NEI believes this sentence was generic and redundant and therefore not needed. NRC agrees that the paragraph is clear without the deleted sentence.

2. In the Screening section, specifically in Example 4-4, reductions and redundancy should be considered in the examples to be consistent with the revision to the guidance. Otherwise, change option 2 to adverse.

Notes from meeting: Resolved per comment A25.

3. In section 4.3.6, page D-60, the unsolicited revision (shown below) was submitted. The new text is underlined. Please clarify why this additional language was added.

If all *design basis functions* continue to be performed/satisfied, and there are no other *design functions* involved, then the proposed activity does NOT create the possibility for a malfunction of an SSC important to safety with a different result because no malfunction occurs. With no malfunction occurring, there cannot be a different result.

Notes from meeting: No action. NEI added this language for completeness. NRC will document accordingly in response letter.

4. On Page D47, the staff noted that the referenced 63 FR 56106 is a proposed rule and not the final rule. NEI should reference final rules in its guidance, as there are differences between the proposed rule and final rule. Comment previously provided (ADAMS Accession Number ML18282A044).

Notes from meeting: NEI will take no action on this comment. NRC believes this is an error in the document.