NEI 16-16 [Draft 2]
Staff Comments Resolution Status as of November 2017

The staff has reviewed Nuclear Energy Institute (NEI) 16-16 "Guidance for Addressing Digital Common Cause Failure [Draft 2]" [Agencywide Document Access and Management System (ADAMS) Accession Number ML17135A253] which was submitted on May 12, 2017. The enclosed comments are provided solely on the contents of the as-written document. This document summarizes the state of resolution for all comments on the main body of NEI 16-16 (Appendix A comments are not included). All new content from NRC is contained in the column titled "NRC Follow up). The status is based on results from interactions between NEI and NRC held on September 07, 2017 (ADAMS Accession Number ML17234A026) and November 2, 2017 (ADAMS Accession Number ML17285A944).

The staff intends to review NEI 16-16 for potential use to support 50.59 evaluations under the regulatory requirements of 10 CFR 50.59, with respect to addressing potential common cause failure hazards. The staff will consider the use of this guidance to develop technical conclusions consistent with supporting the draft implementation guidance of NEI Appendix D to NEI 96-07. The staff will also consider use of the guidance to develop technical conclusions for the qualitative assessment in draft RIS-2002-22 Supplement.

The staff also intends to review NEI 16-16 for potential uses to support license amendment requests and new reactor licenses, with respect to addressing potential common cause failure hazards. The staff will consider acceptance criteria in in BTP 7-19 and associated regulatory requirements that address potential CCF hazards. The staff will consider the need for potentially updating BTP 7-19 to reflect NEI 16-16 approaches and any Commission direction as a result of staff's efforts to modernize the policy for CCF (MP #1C). The staff will also consider near-term and long-term implementation needs of industry.

The status of the comments are as follows:

- Resolved: 5 comments (7, 20, 22, 42, and 44).
- Partially resolved: 3 comments (4, 9, and 18).
- Resolution pending Draft 3 implementation: 18 comments (5, 6, 11, 12, 13, 15, 16, 17, 19, 24, 25, 32, 33, 34, 35, 36, 37, 47).
- Not resolved. Discussion necessary: 24 comments (1, 2, 3, 8, 10, 14, 21, 23, 26, 27, 28, 29, 30, 31, 38, 39, 40, 41, 43, 45, 46, 48, 49, 50).

No.	Text Section	NRC Comments	Proposed Action (i.e., addition, deletion or modification)	NEI Discussion Points on Comment	NRC Follow up
1.	General	This guidance proposes using the results from the coping analysis in a comparison to analyses described in the FSAR.	NRC and NEI should continue discussions to determine if results from an FSAR can be compared to results obtained using best estimate methods during upcoming interactions.	NEI agrees.	Not resolved. Discussion necessary.
2.	General	At what level (at the system level or at the plant level) can results be evaluated and compared to analysis in the FSAR?	NRC and NEI should discuss and resolve this difference during upcoming interactions.	NEI agrees that plant level versus system level results should be discussed. The presentation by Pete LeBlond at the 8/1/17 App. D meeting provides a basis for evaluating malfunction results at the plant level.	Not resolved. Discussion necessary. With respect to endorsement of NEI 16-16 as an acceptable means for addressing the regulatory requirements of 50.59, the guidance should be consistent with guidance in Draft Appendix D.
3.	General	Follow-up to comments 3 and 4 from Draft 1. What methodology or deterministic criteria are used for determining the likelihood that a CCF can occur?	Clarify how the qualitative assessments proposed in the document can address deterministic licensing criteria.	NEI would like to discuss this question to gain a better understanding of what type clarification the NRC is seeking. There are two comments in this comment. The question in the cell to the left is	Not resolved. Discussion necessary. Need discussion on how the sources for CCF are determined to be of concern. How will a licensee or applicant a

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				technical and is answered by NEI 16-16 via CCF susceptibility analysis. The comment in the middle cell is about licensing criteria, but not sure which specific criteria	licensee discover and fix faults that are infrequently/rarely triggered? In what kind of time frame would the discovered latent faults be fixed?
4.	General	During NRC-NEI public meetings, NEI representatives have stated that some defensive measures in NEI 16-16 have previously been endorsed by the NRC. No citations to NRC endorsed guidance was found in the document. Citations would facilitate and expedite review of NEI 16-16.	To facilitate this review: If any measures have already been endorsed, please cite the endorsed guidance. Please do not rephrase or change endorsed content if it is included in this document.	There are several examples of where the NRC staff has approved highly integrated digital I&C designs, where design techniques and design attributes (aka Defensive Measures) were used by the designers. These are available to the NRC staff, and NEI has no intention of citing them in NEI 16-16, as much of this material is proprietary. During the public meetings, examples such as the Watts Bar Unit 2	Partially resolved. No discussion necessary at this time. Staff may require additional technical basis information for some defensive measure in Appendix A. NRC will evaluate the defensive measures to determine if there is sufficient basis to deterministically determine that CCF would be sufficiently low, given the safety importance of systems and other

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				SER, and some new plant Design Certifications were used as an example. NEI 16-16 is not a copied and pasted list of endorsed defensive measures. But neither are they made of whole cloth. NEI would like to agreement on the defensive measures via discussions and workshops using the RIS as a backdrop.	diversity & defense-in-depth needs from the regulations. The staff will also consider if the defensive measures provide an equivalent level of protection as the complete testing and internal diversity approaches described in Section 1.9 of BTP 7-19 Revision 6, to eliminate CCF from further consideration. The staff will consider relative consequence significance of a CCF and fundamental independence, diversity, and redundancy requirements for safety critical systems such as RPS and ESFAS I&C systems.
5.	General	The document claims that preventive measures, when applied as a set, provide reasonable assurance that a CCF	Justify why the defensive measures proposed in Appendix A eliminate CCF concerns (i.e., lead to "CCF not credible") from	The NEI position is that reasonable assurance is what is required, not absolute assurance. This	Resolution pending Draft 3 implementation. Discussed during 11/2

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		from a specific I&C failure source is not credible. What is the technical basis for this claim? Appendix A provides preventive measures for various sources of common cause failures but does not provide the technical basis that leads one to conclude that a CCF is "not credible."	further consideration.	concept has been discussed and is addressed in the current version of the RIS 2017-xx. NEI 16-16 provides methods and design techniques and practices to support the reasonable assurance approach. For example, the technical bases for many of the design attributes in Section 3.2.1 of the RIS should be the same technical bases staff is seeking for NEI 16-16.	meeting. Need to see written description of the use of Appendix A and the technical basis for using P measures. The document should focus on reducing the likelihood of common cause failure to a sufficiently low level, consistent with the concepts of the draft RIS supplement to RIS 2002-22 and draft Appendix D, rather than a determination that "CCF is Not Credible"
6.	1.1	Comment 1 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. This section, as well as elsewhere in the document, considers the occurrence of CCF, which does not fully align with the NRC definition and	NRC and NEI should discuss and resolve this difference during upcoming interactions.	NEI requests that the NRC staff please provide the formal NRC position and technical basis for the NRC definition of CCF. This will allow a better understanding of this question.	Resolution pending Draft 3 implementation. Discussed during 11/2 meeting. Alignment was reached between NEI and NRC on the definition of CCF.

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		interpretation of CCF. During the December 2016 meeting NEI and NRC, staff identified the differences on definition of CCF. The meeting summary report summarizes this as: "The NRC staff uses the term to identify an error in software regardless of the consequences of that error. NEI uses the term to identify an error in software that has been triggered to affect multiple instances of the software, and it then focuses attention on the plant effect rather than on the software error itself."			
7.	1.1	Comment 2 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. This section states "there are only two design attributes that may be credited to eliminate the need for further consideration of CCF: diversity within the digital I&C system, or	Since 100% testing and diversity remain viable options for eliminating concerns related to further consideration of CCF, consider mentioning them in the document.	NEI agrees that diversity and 100% testing are viable options. They are included in NEI 16-16 Appendix A, measures A33-P4, A35-P1, A35-P2, A35-P4, A37-P1, and A37-P5.	Resolved.

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		"testability' based on device simplicity." The staff understands that the guidance in this document seeks to expand the use of design attributes and methods beyond diversity and 100% testing.			
8.	1.1	In section 1.1, NEI states: "This guideline is applicable to facility changes done under 10 CFR 50.59 and facility changes that require a license amendment." However, this guidance does not indicate how to use the results or provide a cross-reference to the guidance being developed in Appendix D of NEI 96-07.	Clarify the relationship between NEI 16-16 and NEI 96-07, Appendix D.	The results of NEI 16-16 technical work is used in the same way as other technical analyses that are developed as part of the plant modification process, that are used for input to licensing processes.	Not resolved. Discussion necessary. This was discussed during the 11/2 meeting, but still need to align on the regulatory basis to endorse NEI 16-16 for use on 50.59 and 50.90
9.	1.1	This section states that one of the primary barriers in the current regulation is software common cause failure. However, the guidance addresses more than software CCF.	Clarify the scope of applicability for this guidance.	NEI understands this question to mean that the scope of NEI 16-16 should be clear that it applies to other sources of common cause failure other than software. Please validate this understanding.	Partially Resolved. Resolution pending Draft 3 implementation and agreement to notes related to the CCF definition. Note: The staff would like

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					to discuss the implementation of other sources of common cause failure that are defined in the regulation as single failure.
10.	1.1	This section states that "This document provides technical guidance for addressing CCF for compliance to deterministic licensing criteria and NRC policies and positions such as SRM-SECY-93-087 and BTP 7-19." It is not clear how the guidance provided in this draft is consistent with NRC current position, as described in the SRM-SECY 93-087 and BTP 7-19.	NRC and NEI should discuss and resolve this issue during upcoming interactions.	It is not the intent of NEI 16-16 to be consistent with current NRC guidance. The intent of NEI 16-16 is to introduce alternate approaches to address the potential impact of common cause failure for digital I&C designs. NEI agrees that this should be a point of discussion.	Not resolved. Discussion necessary. This was discussed during the 11/2 meeting, but still need to align on the regulatory basis to endorse NEI 16-16 for use on 50.59 and/or 50.90.
11.	1.2 (1)	This item states: "Part 1 determines if a CCF in the target digital equipment is a safety analysis or licensing concern." Not clear what this means. Please provide clarification.	Provide clarifications to the statements and question.	NEI agrees that clarification is required. The intent is to describe the scope of digital SSCs to which NEI 16-16 applies.	Resolution pending Draft 3 implementation.

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		Also, how does this statement relate to the scope defined in the previous paragraph, which states "digital I&C systems or components that can affect a design function described in the FSAR." Please clarify.		NEI proposes to use "design functions described in the FSAR". This is consistent with what the approach is in the current version of RIS 2017-xx. However, NEI 16-16 will still direct the focus on the specific SSCs affected by an I&C failure and how they relate to one or more design functions, because "design functions" may be described nebulously in some FSARs.	
12.	1.2 Flowchart	Comment 6 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. The process and reasoning advocated for determining "Is a CCF Credible?" is not sufficiently articulated. Section 4.2.2.2 states that preventive measures "provide reasonable assurance that a CCF	NRC and NEI should continue discussions on the question "Is a CCF Credible?" and proposed engineering method to answer the question during upcoming interactions. The staff recommends that the discussion focus on the level of uncertainty remaining in a digital system to a CCF vulnerability and that independent parties can	NEI agrees that discussion is needed on this subject. The preventive measures are formulated with sufficient depth and criteria so that any residual uncertainty in CCF likelihood still leaves that likelihood in the range of sufficiently low enough to be considered not credible. This is why	Resolution pending Draft 3 implementation.

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		from a specific I&C failure source is not credible" but does not state why they provide that assurance.	reach the same conclusion after the proposed engineering method is applied.	NEI 16-16 states that a partial P measure from Appendix A is not good enough to conclude that a CCF is not credible.	
13.	1.2 Flowchart	Comment 7 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. During the December 2016 meeting, the staff provided a comment about the question in Part 2 to determine if CCF is beyond design basis. At the time, the staff understood that this document was intended to only address software CCF due to software errors – which is currently considered beyond design basis in SRM-SECY-93-087.	During the February 2017 meeting, NEI clarified that NEI 16-16 considers all type of CCF, not only software, and therefore this question was necessary to address CCF resulting from single failures or AOOs (design basis). The staff recommends that the document be revised to clarify why the question "Is the CCF Beyond Design Basis" is relevant with examples.	NEI agrees that more discussion is required with respect to "beyond design basis", and how that is to be addressed within NEI 16-16.	Resolution pending Draft 3 implementation.
14.	1.2 Flowchart	Comment 8 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. Expansion of the process diagram or an additional diagram that specifically outlines how technical results of the CCF analysis support specific sections of the Draft	NRC and NEI should discuss and resolve this issue during upcoming interactions.	See response to comment #8. NEI and NRC staff should discuss this point further.	Not resolved. Discussion necessary.

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		Appendix D to NEI 96-07, with respect to CCF issues, would be helpful. The staff needs this information to determine if endorsement or partial endorsement of the guidance as an acceptable methodology to address CCF concerns for use in Appendix D is possible.			
15.	2	Comment 9 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. The definitions provided in these sections read more like descriptions and approaches rather than formal definitions of the terms. Some definitions are not consistent with how the terms have been used in regulations and regulatory guidance. Endorsement or partial endorsement would be facilitated if the terms are defined consistently with other regulatory guidance documents or that the terms are consistently used in this document and in any	Recommend that formal definitions, similar to those recommended by the staff for use with NEI 96-07 Appendix D, be used.	NEI agrees that definitions should be consistent with other guidance. This should be a topic of discussion going forward.	Resolution pending Draft 3 implementation.

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		documents that may later refer to it.			
16.	2.1	Comment 10 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. The definition for best estimate method in this section implies that relaxed criteria can be used for this method. Rather, best estimate methods use the same acceptance criteria, but apply realistic plant conditions and parameters.	The staff recommends clarification of the definition.	This should be discussed further. Relaxed criteria has been used in the past. For example, the Oconee RPS/ESFAS upgrade applied relaxed acceptance criteria for RCS pressure (ASME Service Level C at 3250 psia) and containment pressure (125 psi, or 98% of ultimate strength).	Resolution pending Draft 3 implementation.
17.	2.4	Comment 11 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. The definition for "CCF Beyond Design Basis" is not clear. The text provided comes across as a description, not a definition and is not consistent with SRM-SECY-93-087.	Clarify that the method proposed in NEI 16-16 refers to all types of CCFs, not only to the CCFs covered in SRM-SECY-93-087.	This point needs to be discussed further.	Resolution pending Draft 3 implementation.
18.	2.5	The relationship of the terminology used in NEI 16-16 to terminology used in NEI 96-07 is not clear. For example,	Clarify relationship between the terminology used in NEI 96-07, Appendix D to the terminology in	NEI agrees that more discussion is needed on key terms.	Partially resolved. Resolution pending Draft 3 implementation for

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		the use of the terms credible and not credible in NEI 16-16 are not consistent with NEI 96-07, Appendix D. The word "bounding" also seems to be inconsistent. Staff reviewing NEI 96-07, Appendix D have also asked about how the words "negligible" and "attributable" (which are used in Appendix D) relate to content in NEI 16-16 (which does not use these words).	NEI 16-16. Where appropriate, ensure alignment of the terms used in both documents.		definition of CCF and sufficiently low. Not resolved: Definitions for other terms, such as bounding, negligible, and attributable. The staff recommends inclusion of the definition of Single Failure.
19.	2.5	The definition provided for "CCF Not Credible" is based on the likelihood of a CCF. This is confusing because the guidance provided requires determination of a credible CCF and how likely the CCF is.	The staff recommends defining what a "Credible CCF" is instead of defining what "CCF not credible" means. NRC and NEI should continue discussions to address CCF credibility and its likelihood. Discussions should include "the proposed graded approach to eliminating the need for further consideration of CCF in safety support systems (such as chillers as have been presented by NEI)"	NEI's view is that a "credible CCF" is the inverse of the definition of "not credible" in 16-16. Credible would then be defined as (emphasis added): "*A CCF can be considered* ***~~not~~*** *credible only if the likelihood of a CCF caused by an I&C failure source is* ***~~no~~*** *greater than the likelihood of a CCF caused by other failure sources that are* ***not*** *considered in*	Resolution pending Draft 3 implementation.

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			as mentioned in comment 12 on Draft 1.	*a deterministic safety analysis described in the FSAR*." This definition of credible is consistent with Figure 4-3 in NEI 01-01.	
20.	2.8	Comment 13 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. It is not clear why this guidance needs to define the role of the Digital Engineer.	Consider eliminating the definition of "Digital Engineer."	The term "digital engineer" was expunged and replaced with "design engineer" in Draft 2.	Resolved.
21.	2.12	Since Section 2.12 defines "mitigating system," consider defining "event initiator."	Include a definition for event initiator.	NEI will consider defining this.	Not resolved. Discussion necessary
22.	3.1	Comment 15 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. This section paraphrases the information in SRM-SECY-93-087 which may lead to confusion.	The staff recommends that NEI use the exact text from SRM-SECY-93-087 where applicable.	This comment needs to be discussed further. Section 3.1 does not refer to the SRM.	Resolved.
23.	3.3, 4.2.2.3	Comment 20 from Draft 1 (originally in section 4.1.2.2.2). The staff did not locate content in Draft 2 that resolves this	Suggest define "preferred malfunction state" or rewording the sentences using this term. Perhaps something like "preferred	NEI would like to discuss this further, and align with the NRC on this term and the "safe state" term	Not resolved. Discussion necessary per NEI response.

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		comment. What is a "preferred malfunction state?"	state when a malfunction occurs.	used in the current version of RIS 2017-xx.	
24.	3.4	Comment 18 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. It appears that this draft guidance is treating 3 possible conditions: (1) "CCF is not credible;" (2) CCF is credible but beyond design basis; or (3) CCF is credible and is within design basis. Review of the document would be aided by specific examples of digital modifications that could fall with the three categories proposed in the document. The staff's review will be aided by a practical understanding on the implications and use of this methodology.	NRC and NEI should continue discussing the appropriate characterization of CCF in terms of credibility, design basis, and beyond design basis during upcoming interactions	The 3 possible conditions are correct. Conditions 2 and 3 may be further "conditioned" as a) bounded by a previous analysis, or b) not bounded by a previous analysis. NEI agrees that examples would be useful. These will be pursued once better alignment between NEI and NRC on the NEI 16-16 content and methods are achieved.	Resolution pending Draft 3 implementation. NRC agrees with the need for examples to provide better context to the technical guidance.
25.	3.4	The description provided in this section does not explain how a credible CCF affects the plant's	Clarify this statement: "a credible CCF is within the plant licensing basis."	NEI agrees to discuss this point with NRC staff and clarify. A credible CCF that	Resolution pending Draft 3 implementation.

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		licensing basis and design basis. It describes the use of preventive measures to determine if a CCF is credible, and then the method to perform a coping analysis.		is considered within the plant licensing basis does not necessarily mean that it is already described as-is in the UFSAR (the converse is that if the CCF is not credible, then it is not considered within the plant licensing basis). In Section 3.4, considering a credible CCF within the plant licensing basis means it must be further addressed using the balance of the guidance in 16-16. The user needs to determine if the credible CCF is previously analyzed, and if the results are bounded by the previous analysis, end the CCF technical evaluation. Otherwise, perform a new analysis.	
26.	3.4	The description from the second paragraph to the end seems to belong to Part 2 in	Add content that describes how a CCF can affect the plant's licensing basis and design basis.	NEI would like to discuss this further with NRC staff to better understand the	Not resolved. Discussion necessary

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		Figure 1. This section, however, does not describe how a CCF can affect the plant's licensing basis and design basis.		exact question. See comment response above.	
27.	4.0	This statement: "The design engineer should document the completed CCF technical evaluation, and preserve the document as a quality record," tells the design engineer what to do with the results of the evaluation. However, this document does not describe how to use the result of this evaluation when performing changes under 10 CFR 50.59 or license amendments.	Clarify how the results of the evaluation will be used.	See response to comment #8.	Not resolved. Discussion necessary An example would be helpful in NEI 16-16 [Draft 3]
28.	4.1	This section lists three criteria. However, it is not clear what that criteria is referring to. It seems that this is to determine if the digital system is an event initiator or credited for event mitigation.	Please clarify what the three criteria in this section are referring to.	NEI agrees to clarify this section. As the comment says, the three criteria are for determining if the digital system is an event initiator or credited for event mitigation.	Not resolved. Discussion necessary NEI should further discuss how the technical evaluation of the potential of the digital system to affect SSCs in this guidance, relates to determining if the digital

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					system is adverse on design functions, as described in the Screening Guidance of Section 4.2 of Draft Appendix D.
29.	4.1	Comment 17 from Draft 1 (content was in Section 3.3 of Draft 1). The staff did not locate content in Draft 2 that resolves this comment. Examples of support systems that result in a "YES" to the question "is the digital equipment an initiator, or credited for event mitigation?" in the flowchart, Part 1 are provided in this section. The staff finds that these examples are useful for clarifying which types of systems result in a "YES" answer.	Consider adding examples that result in a NO answer. Examples would clarify what types of systems result in a "NO" answer.	NEI agrees that these type of examples would be useful. These will be pursued via new Appendices once better alignment between NEI and NRC on the NEI 16-16 content and methods are achieved.	Not resolved. Discussion necessary NRC recommends that NEI includes examples. Staff to review examples in NEI 16-16 [Draft 3]
30.	4.2	This section mostly focuses on using preventive measures, but it does not clearly articulate how the susceptibility analysis is performed. Before using	Provide more information in this section on how to perform and implement the susceptibility analysis.	The purpose of Section 4.2 is to articulate how CCF susceptibility analysis is to be performed. For example, the design	Not resolved. Discussion necessary NRC recommendation is to identify how the design

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		preventive measures, the design engineer should assess the hazards, vulnerabilities or susceptibilities.		engineer can determine if available P or L will address susceptibility of CCF caused by various I&C failure sources.	engineer will determine the CCF failure source is a concern (e.g., hazard analysis, FMEA, etc.)
31.	4.2	Comment 23 from Draft 1. The staff did not locate content in Draft 2 that resolves this comment. This section does not describe how to perform an analysis of the CCF malfunction.	The staff recommends adding a description on what constitutes an analysis of the CCF malfunction, methods, and acceptance criteria.	NEI would like to discuss this point further with the NRC staff. Section 4.2 only covers Part 2 of the CCF Technical Evaluation. However, an overview of CCF malfunction, methods and acceptance criteria is provided In Section 4.2.1, on page 14. Detailed guidance on these issues is provided in Section 4.3.	Not resolved. Discussion necessary (related to comment 30).
32.	4.2	This section states: "Note that the CCF susceptibility analysis can make use of a wide range of potentially applicable preventive or limiting measures provided in Appendix A" but does not elaborate on how preventive or limiting measures can be used nor what they can	Explain/describe how the use of preventive or limiting measures can be used and what they can accomplish (in terms of eliminating CCF from further consideration).	NEI would like to discuss this point further with the NRC staff. The purpose of the paragraph from which the sentence is quoted is simply to point out that one cannot read the title of a defensive measure and apply it. The details	Resolution pending Draft 3 implementation.

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		accomplish.		matter. In addition, the remainder of Section 4.2 explains/describes how the use of preventive or limiting measures can be used and what they can accomplish (in terms of eliminating CCF from further consideration).	
33.	4.2.1	This section is labeled as an overview but is fairly detailed. This section provides a detailed description of the CCF susceptibility analysis, including steps that are performed later in the process.	Consider moving specific details to the subsections in which these details are addressed? For example, any description related to the use of preventive measures should be part of Section 4.2.2.2	NEI will review the content in this section and consider moving detailed content to other sections. However, Section 4.2.1 provides guidance for addressing issues not addressed in later sections, such as what to do with a new, previously unidentified failure source, or an incomplete defensive measure. NEI feels that it is necessary to summarize these issues in an overview, before the user gets involved in a detailed	Resolution pending Draft 3 implementation.

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				analysis.	
34.	4.2.1	Comment 19 from Draft 1 (content was in Section 4.1.1 of Draft 1). The staff did not locate content in Draft 2 that resolves this comment. This section states that the digital engineer confirms the applicability of <u>at least one</u> P measure, L measure, or LR measure from Appendix A. If an alternate P, L, or LR measure is credited, the digital engineer is responsible for providing documented justification for each alternate measure. The section, in part, later states that a CCF that is not credible requires no further assessment.	The technical basis provided should be strengthened by additional information that includes design rationale, analyses, data, or operational experience to justify a "credibility" determination.	NEI proposes to discuss adding some of these key points to NEI 16-16, in a way that is consistent with the information in the current version of RIS 2017-xx. For example, the technical bases for many of the design attributes in Section 3.2.1 of the RIS should be the same technical bases staff is seeking for NEI 16-16.	Resolution pending Draft 3 implementation.
35.	4.2.1	This section should require that any preventive, limiting or likelihood reduction measure, described or not in the Appendices, used should be documented in the CCF susceptibility analysis.	Require that any preventive, limiting or likelihood reduction measure, described or not in the Appendices, used should be documented in the CCF susceptibility analysis.	The executive summary and section 1.2 already state that CCF technical evaluations shall be documented. To improve clarity regarding CCF susceptibility analysis, NEI	Resolution pending Draft 3 implementation.

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				can add a paragraph at the front of Section 4.2.1 that states the analysis shall be documented per the worksheet in Appendix C.	
36.	4.2.1	This section does not provide guidance to determine if a CCF is credible or not.	NRC and NEI should discuss the use of these terms.	Section 4.2.1 is only an overview. To improve clarity, NEI can add a sentence in an appropriate paragraph that points the reader to Section 4.2.2.2, which provides guidance for determining CCF credibility.	Resolution pending Draft 3 implementation.
37.	4.2.1	This section does not describe what the design operator should do if the result of that malfunction is similar to the system level or component level malfunction results included in a previous deterministic analysis. The guidance only addresses what to do if they are different.	Describe what one should do if the malfunction result is similar to the one described.	Section 4.2.1 is only an overview. However, to improve clarity, NEI can add a sentence that says if the system or component level results are the same as previously analyzed, then the CCF technical evaluation ends here (as already illustrated in	Resolution pending Draft 3 implementation.

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				Figure 1).	
38.	4.2.1	This section states: "If the FSAR identifies a malfunction result at the plant system level, with or without a description of component level malfunctions that can lead to this plant system level malfunction result, only the plant system level malfunction result is pertinent to the CCF malfunction assessment."	NRC and NEI should discuss at what level the malfunction result can be evaluated and compared with existing results (at the plant or system level).	NEI agrees that further discussion is required on this point. The presentation by Pete LeBlond at the 8/1/17 App. D meeting provides a basis for evaluating malfunction results at the plant level.	Not resolved. Discussion necessary per NEI response. The staff anticipates that resolution of this issue will be dependent on the resolution to proposed Section 4.3.6 of draft Appendix D. NEI should also clarify if this specific guidance regarding malfunction levels has any relevance to license amendment requests and associated guidance for safety review of affected equipment.
39.	4.2.1	This section states: "the design engineer assesses the likelihood of the CCF based on available likelihood reduction measures to determine the appropriate method and acceptance criteria for the analysis of the plant-	Provide guidance to describe how to assess the CCF likelihood using the likelihood reduction measures.	Section 4.2.1 is on overview. NEI can add a sentence in the last paragraph of Section 4.2.1 that will point the reader to Sections 4.2.2.3 and 4.2.2.4 where LR	Not resolved. Discussion necessary

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		level CCF malfunction result." This guidance does not describe how to assess the CCF likelihood using the likelihood reduction measures.		measures are used, if applicable, to determine that a credible CCF is BDB. Otherwise, a credible CCF is DB.	
40.	4.2.1	This section states: "The plant-level analysis uses analytical methods and related acceptance criteria commensurate with the CCF likelihood." However, it is not clear how the CCF likelihood can be used to perform plant-level analysis.	Explain how to use CCF likelihood to perform a plant-level analysis and the acceptance criteria.	Section 4.2.1 is an overview. In the last paragraph, it states: "*The plant-level analysis uses analytical methods and related acceptance criteria commensurate with the CCF likelihood. Therefore, if a CCF is credible and the subsequent malfunction result is different at the system or component level, the design engineer assesses the likelihood of the CCF based on available likelihood reduction measures to determine the appropriate method and acceptance criteria for the analysis of the plant-level*	Not resolved. Discussion necessary.

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				CCF malfunction result, which follows, using the guidance in Section 4.3."	
41.	4.2.2	For consistency, use the same text in Figure 1 for this section title.	This section title should be consistent with the terminology used in Figure 1.	4.2.2 does not appear in the flow chart, please clarify the comment. It would probably be too busy, but NEI could add a box to Figure 1 that encapsulates 4.2.2.2, 4.2.2.3 and 4.2.2.4, and label the new box as 4.2.2.	Not resolved. NEI requests clarification. NRC recommendation: Change "Assess CCF Sources 4.2.1.1" to "4.2.2.1 Determine Applicability of I&C Failure Sources"
42.	4.2.2	Are the CCF sources listed in Appendix A the only potential CCF sources?	Clarify that Appendix A describes potential CCF sources, but that there could be others not described in the Appendix.	NEI agrees that a note in Section 4.2.2 to this effect would be helpful, to reiterate what Section 4.2.1 states: "… *the design engineer identifies any other potential sources of CCF not listed in Appendix A that may be unique to a specific application*."	Resolved with Comment. NRC suggests that section 4.2.1 state: " … the design engineer must identify any other potential sources not listed in Appendix A …"
43.	4.2.2	If this section is describing the sources, why does it include determination of CCF credibility and likelihood? These	Edit Figure 1 or the content in this section to ensure consistency within the document.	Further discussion is needed with the staff to better understand this comment. Section 4.2.2 is	Not resolved. Discussion necessary

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		determinations seem to belong in other sections to be consistent with Figure 1.		not just about failure sources. It describes how defensive measures can be used to determine likelihood (aka credibility) of a CCF, and depending on likelihood of a credible CCF, whether or not its DB or BDB.	
44.	4.2.2.1	This section states that fire, smoke, and operations or maintenance human errors are also sources of CCF but that they are addressed in other industry guidance and that the defensive measures on fire, smoke, and human error are included for interested users. No note to reflect this is placed in Appendix A (Sections A.2.5 and A.4).	Remove the defensive measures in sections A.2.5and A.4 and reference the appropriate guidance.	NEI feels that the clarifying information in the body of NEI 16-16 is sufficient to cover this point.	Resolved. If NEI 16-16 is endorsed, NRC will state that these methods were not considered in endorsement and that licensees should look elsewhere for endorsed defensive measures listed in A.2.5 and A.4.
45.	4.2.2.1	This section states: "If a proposed I&C system or component design has a failure source that is not on the list provided above, it should be identified and addressed using	Please provide a reference to a section in the guidance that explains how it should be addressed.	NEI agrees that an expanded discussion on this point is needed in the document. The idea here is that a new failure source may or may not be	Not resolved. Discussion necessary

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		this guide." It is unclear how this guide should be used for a failure source not on the list in this section.		"prevented" per se; if it's not, then the CCF is credible and should be analyzed using the remaining guidance. In other words, just because a new failure source is identified doesn't mean NEI 16-16 is N/A.	
46.	4.2.2.4	This section seems to cover two different subjects: likelihood reduction and determination of analysis.	Recommend dividing this section in two: (1) likelihood reduction and (2) determination of analysis.	NEI will consider this in the next update to NEI 16-16. Simply put, if an LR measure is applied, the CCF results are BDB; if not, the CCF results are DB.	Not resolved. Discussion necessary
47.	4.2.2.4	What is the justification or basis for this text: "A likelihood reduction measure allows a credible CCF to be considered beyond design basis."	Provide justification or technical basis for the statement. Why does a likelihood reduction method allow this?	NEI would like to have further discussion with the NRC staff on this point. Industry believes staff views quality and independence as the bases for treating SCCF as BDB per SECY/SRM 93-087. Conversely, without quality and independence, SCCF must	Resolution pending Draft 3 implementation.

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				be treated as DB.	
48.	4.2.2.4	This section should refer to other sections in the guidance if likelihood reductions cannot be used.	Provide appropriate references to other sections.	NEI agrees that an expanded discussion on this point is needed in the document. If an LR cannot be used for a credible CCF, then the CCF results are to be analyzed using conservative DB methods.	Not resolved. Discussion necessary
49.	4.2.2.4	Comment 21 from Draft 1 (content was in Section 4.1.2.2.3 of Draft 1). The staff did not locate content in Draft 2 that resolves this comment The document partially describes the use of "Conservative Methods" and "Best Estimate Methods." The staff's review would be facilitated by incorporating and referencing NRC guidance on acceptable implementation of these methods.	The staff recommends that NEI incorporate or reference NRC guidance on acceptable implementation of conservative and best estimate methods. Otherwise, provide justification for using alternate methods.	NEI requests that the NRC staff provide the NRC documents that address implementation of conservative methods and best estimate methods. These will be considered for incorporation into NEI 16-16.	Not resolved. Action item for NRC
50.	4.2.2.5 and 4.2.2.6	This comment is a follow up to comment 22 from Draft 1 (content was in Section	NRC and NEI should discuss this comment during upcoming interactions to increase	NEI agrees that further discussion is needed with the staff to better	Not resolved. Discussion necessary. The staff believes that the rigor of

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		4.1.2.2.4 of Draft 1) which stated that the staff is willing to consider the use of risk insights in this document or future revisions. The purpose and key takeaways of sections 4.2.2.5 and 4.2.2.6 are not clear. Do some defensive measures apply only to non-safety equipment?	understanding on the purpose and key takeaways of these two sections.	understand these points. The purpose of 4.2.2.5 is to explain that some defensive measures, not all, provide a graded approach based on safety classification (for example, a measure to protect against high temperature requires formal EQ for 1E, good practice for non-1E). The purpose of 4.2.2.6 is to explain that the PRA can be used to provide risk insights to influence system design.	defensive measures to reduce CCF likelihood and analysis of failure consequences (e.g. D3 and coping assessments to address uncertainties) should be commensurate with risk significance.