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# Category	Section, Page, Line (Commenter)	Comment	Proposed Resolution (Correction, addition, deletion, future phase activity, etc.)	Status
3 (9/21/16)	General Comment	Ineffective use of vendor technical recommendations can cause or contribute to operational transients, scrams, and component failures per the most recent Generic Communication on the issue; Information Notice (IN) 2012-06, "Ineffective Use of Vendor Recommendations," The guidance does not appear to address this issue.	NEI should include an example where vendor recommendations (i.e., recommended service life) are no longer followed.	
8 Form & Content (9/21/16)	TOC, Page V	It has been stated in the past (by NEI) that Appendix D would follow the same structure as NEI 96-07 so that it would be clear the guidance in Appendix D was an augmentation or supplementation of the main body. The "**CAUTION**" boxes can be retained (Defense in Depth).	For structural consistency: - Delete Section heading 1.1, "Background" - Renumber Section 1.2, "Purpose" as 1.1 - Add a Section 1.2, "Relationship…" Address Issue No. 12 (ADAMS Accession No. ML14255A059) in this section. (See NEI 96-07 Section 1.2.4) - Renumber Section 2, "Definitions" to Section 3. - Add a Section 2, "Defense in Depth…" and summarize the Commission position on D3 for Digital I&C. Include in Section 2: -- Common Cause Failure (CCF) as a concept is only applicable if there are independent redundancies; CCF is not applicable to anything that is not single failure proof. -- CCF is assumed unless a Susceptibility Analysis (e.g., Branch Technical Position (BTP) 7-19 Section 1.9) eliminates it from consideration. -- If there is no documented basis for CCF to be eliminated from further consideration, then the modification screens in (a full evaluation must be performed). -- A Coping Analysis should be performed for every digital upgrade to the Reactor Trip System (RTS) and Engineered Safety Features Actuation System (ESFAS). …	NEI provided a proposed TOC rev. 9/9/2016 with Sec. 2 & 5 as placeholders for content TBD based on evolution of App D during NRC review. TOC discussed and agreed upon at the 9/21/2016 public mtg. To maintain traceability of existing NRC comments, NEI prefers to complete section re-

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				numbering after all current sections have been discussed. The 9/9/16 proposed TOC rev. can be used as a section numbering key for clearer reference back to NEI 96-07, Rev. 1 in the meantime.
9a Previously Expressed Concerns (9/21/16)	Section 1	The evaluation question in 10 CFR 50.59 do not explicitly address the different criteria that are applicable to different SSCs, for example: - Safety-related vs. Non-Safety-Related - System Specific Requirements (e.g., ATWS, ECCS, ...)	NEI should add some introductory text to explain how the questions are addressed for different kinds of SSCs.	
9b Previously Expressed Concerns (9/21/16)	Add Section 1.3	NEI 96-07 Section 1.3 (PDF page 10) states: "After determining that a proposed activity is safe and effective through appropriate engineering and technical evaluations, the 10 CFR 50.59 process is applied to determine if a license amendment is required prior to implementation." [emphasis added] Simply, there are two issues associated with a modification: (1) technical adequacy (i.e., is the change safe and effective), and (2) if a license amendment request (LAR) required. HOWEVER, in order to determine whether a LAR is required, technical evaluations must be performed. It is not clear where the guidance exits for performing	This issue is related to Concern No. 11 as expressed by the NRC on October 9, 2014. NEI should add a Section 1.3 to Appendix D, and provide some text (or a reference) to address the ways in which digital equipment may affect the licensing process. NEI should add words addressing how technical differences between digital and analog	

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		these technical evaluations for digital aspects.	technologies could affect the 10 CFR 50.59 process.	
20a (9/21/16)	2.6 Dependability page 11	Multiple definitions are given, rendering the term ambiguous and unsuitable for the purpose of Appendix D. The first definition is too vague to be useable with consistency for the purpose of Section 3.2.1.4. One element, SAFETY, of its broad scope suffices. Given that the SAFETY property is the focus, adding the term "dependability" does not add any specificity. The following notion cannot be translated into practice with consistency: "assurance of adequate quality and low likelihood of failure is derived from a qualitative assessment of the design process and the system design features."	Focus on the SAFETY property. For an example of its decomposition, see Section 2.5.1.1 (esp. Figure 8) in NRC's RIL-1101, "Technical Basis to Review Hazard Analysis of Digital Safety Systems," ADAMS ML14237A359.	Definition removed
25b (9/21/16)	Section 3 Page No. 12	There does not seem to be any criteria to address the complexity of a modification (Assurability, including Verifiability and "Validate-ability" with consistency across different adequately qualified parties). It seems reasonable to assume that the effects of a complex modification cannot be easily determined; therefore, complex modifications should screen in.	NEI to propose guidance to address this concern.	
26 Form & Content (9/21/16)	Section 3, Page No. 12	Sections 3.1, 3.2.1.2, 3.2.1.3, 3.2.1.4, … each address a single aspect, but this fact is not explicitly stated.	NEI should add introductory text that explicitly states that these section only address one aspect (all things not explicitly addressed are not considered).	Complete: 11/16/2016 proposed revision
27 HSI (6/14/16) (9/21/16)	Section 3	It is not clear how the screening process deals with errors of cognitive nature that arise from changes to Human System Interface (HSI) / I&C (such as confusion in operators caused by bottlenecks /delays that occasionally occur in from digitally processed signals). Section 3.2.2.2 deals with properties of the physical interface related to human factors, but there is no such section that deals with cognitive errors. Section 3.2 "Process" refers to the main body Section 3.11 of NEI 96-07. The examples in this document used to consider the human factors associated with changes to HSI do not span the breadth of	NEI should clarify how the screening process looks for potential cognitive issues and/or add a section that addresses this issue.	Complete: 12/20/2016 proposed revision

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		human factors issues that may occur as a result of analog-to-digital or digital-to-digital upgrades.		
29 Adverse Change Internal Consistency Consistency w/ Other Guidance (6/14/16) (9/21/16)	Section 3.1, Page 12	The Screening Introduction paragraph states: "The introduction of software or digital hardware, in and of itself, does not cause the proposed activity to be adverse (i.e., "screen in")." [emphasis added] This statement is not consistent with: - Page 50 which states: "Digital systems are typically prone to failure modes caused by electromagnetic or radiofrequency interference (EMI/RFI)." - RG 1.180 which states: "Existing I&C equipment in nuclear power plants is currently being replaced with computer based digital I&C systems or advanced analog systems. However, these technologies may exhibit greater vulnerability to the nuclear power plant EMI/RFI environment than existing I&C systems."	NEI should provide guidance on the typical ways that analog and digital equipment are different and which ones are potentially adverse. NEI should provide additional guidance to address this concern (e.g., is this a fundamental adversity?). Either a conservative "adverse" assumption should be made, or screening guidance should be provided to determine if new equipment exhibits a greater vulnerability to the nuclear power plant EMI/RFI environment than existing I&C systems.	Discuss 50.59 and EMI/RFI in Evaluation section; EMI/RFI should go to a technical team – MP #3?
30 Consistency w/ NEI 96-07 Adverse Change (6/14/16) (9/21/16)	Section 3.1, Example 3.1, Page No. 12	There appear to be differences between NEI 96-07 and proposed Appendix D guidance on some specific topics, and it is not clear which set of guidance would govern evaluation of a DI&C upgrade. For example: Appendix D Section 3.1 and Specifically Example 3.1 states that a change from analog technology to digital technology is not a fundamental change to how a function is performed, and therefore not inherently adverse. However, NEI 96-07 Section 4.3.2 states: "if failures were previously postulated on a train level because the trains were independent, a proposed activity that introduces a cross-tie or credible common mode failure (e.g., as a result of an analog to digital upgrade) should be evaluated further to see whether the likelihood of malfunction has been increased." This implies that changing more than one redundancy to digital is adverse and requires a 50.59 evaluation. Does one interpret these two sections as conflicting, or complementary (e.g., that a single digital	NEI should resolve inconsistencies, or explicitly state when Appendix D guidance is intended to superseded NEI 96-07 guidance. NEI should explicitly state if examples contain normative guidance (some feel that examples should not be understood to contain normative guidance, others disagree).	What is the intent of comparing the examples cited? Ex. 3.1 in App. D was revised 11/16/16; is NRC comment still valid?

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		upgrade is not inherently adverse, but updating multiple redundancies is)? Furthermore it is not clear how Example 3.1 should be compared to NEI 96-07 Section 4.2.1.2 Example 3. What is the role of the examples in Appendix D? Do the examples illustrate guidance provided in the body of the document, or do they provide additional guidance for the user of Appendix D to consider?		
31 Consistency w/ NEI 96-07 Adverse Change (6/14/16) (9/21/16)	Section 3.1, Page 12	NEI 96-07 Section 4.2.1.2, "Screening of Changes to Procedures [emphasis added] as described in the UFSAR," states (page no. 36) that fundamental changes should screen in. Since Section 3.1 of Appendix D extends the application of the term "fundamental change" from being applied to Procedures and Human System Interface (HIS) (in NEI 96-07) to being applicable to equipment changes; therefore, it should provide guidance and criteria for determining what constitutes a "fundamental change," to equipment. The guidance provided (in Section 3.1) is: (1) "a proposed activity involving a digital modification does not necessarily involve a fundamental change in how a design function is performed." **Note:** This quotation implies that in some cases a proposed activity involving a digital modification does involve a fundamental change in how a design function is performed; however, no digital examples or criteria are included to reach this conclusion. (2) Example 3-1. **Note:** Page 50 states: "Digital systems are typically prone to failure modes caused by electromagnetic or radiofrequency interference (EMI/RFI)." Why is this not considered a fundamental change? More appropriately, when does a proposed activity involving a digital modification involve an adverse change to a design function described in the UFSAR (where adverse means having the potential to degrade the performance of the function)?	NEI should resolve internal inconsistency between Section 3.1 & Page 50. NEI should propose criteria that can be used to determine if an adverse change exists (regarding technology changes). For example, an analog to digital conversion of a non-SR control system may not be adverse if no safety function is dependent on it (or affected by it). However, an analog to digital conversion of more than one redundancy in a safety system that performs a protective action (or is required for the performance of a protective action, i.e., is a required support system) is adverse (i.e., see Example 5.4). NEI should add a specific reference to Example 5.4 in Section 3.1. There needs to be discussion about ~~the appropriate level of~~ quality criteria (that can be validated and verified) applied to the design and incorporated into the licensee's licensing/design bases. For example, with demonstration through V&V~~licensee acceptance and application of appropriate quality standards there is no~~	Discuss 50.59 and EMI/RFI in Evaluation section; EMI/RFI should go to a technical team – MP #3? Discuss how guidance sections will point to Example section Discuss potential use of NEI 96-07, 4.3.2, Ex. 2 to illustrate "not a fundamental change"

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		Note: The screening in Example 5.4 makes a finding of "adverse" based on the fact that identical software is used in both redundancies. Should this example be generalized so that anytime multiple redundancies (or trains) are replaced with digital equipment, the modification should screen in? Furthermore, Example 5.4 (Under the evaluation against Criteria 2) references an evaluation of the EMI/~~E~~RFI ~~susceptibility~~ analysis; why is this not done as part of the screening, rather than as part of the evaluation? It is not clear why NEI 96-07 Section 4.3.2, Example No. 2 on page No 47 was not used or referenced to make the same point as the idea "not a fundamental change."	~~fundamental differences in the analog and digital designs~~.	
32 Consistency w/ NEI 96-07 (6/14/16) ~~(9/21/16)~~	Section 3.1, Page 12, Example 3-1	This example is intended to demonstrate that simply changing from analog to digital does not "fundamentally alter (change) the existing means of performing or controlling" a design function, is not inherently adverse, and therefore, does not inherently screen in (for evaluation). Note: NEI 96-07 Section 4.2.1.2 states: "For purposes of 10 CFR 50.59 screening, changes that fundamentally alter (replace) the existing means of performing or controlling design functions should be conservatively treated as adverse and screened in." A licensee could understand this example as making the implicit argument that if there is no "fundamental" change, then it screens out; however, the adverse question must also be answered. NEI 96-07 also states: "Consistent with historical practice, changes affecting SSCs or functions not described in the UFSAR must be screened for their effects (so-called "indirect effects") on UFSAR-described design functions. ~~A 10 CFR 50.59 evaluation is required when such changes adversely affect a UFSAR-described design function...~~" ~~The SECOND relevant screening question is whether this change has an adverse effect.~~ It is not possible to just change from analog to digital (an abstraction).	NEI should add words in the example to focus the screening on the characteristics of the new equipment, for example, a paragraph could be added that states the new digital equipment performs the intended function as required and does not introduce hazards ~~is at least as good as the old analog equipment in all relevant ways~~ (e.g., See NEI 96-07 Section 4.3.2, Example No. 2). NEI should add a commensurate paragraph to the end of Example 3-1 ~~to direct the performance of an "adversely" determination~~. It is not necessary to discuss whether an analog to digital conversion is a fundamental change or not. The only real question that should be the focus is whether the change is adverse (i.e., has the potential to degrade the function (assuming of course it is a change to a SSC that performs a design function).	Complete: 11/16/2016 proposed revision

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		Rather the two types of equipment will inherently have different properties, characteristics or failure modes, misbehaviors, and hazards; these differences should be considered in the screening for adverse impacts (e.g., See IN 2007-15, IN 2010-10, IN 2016-01). ~~Effectively NEI is proposing using a concept that was proposed under the NEI 96-07 section for "Procedures as Described in the UFSAR" and applying it to "Changes to the Facility as Described in the UFSAR."~~		
33 Consistency w/ NEI 96-07 Adverse Change (9/21/16)	Example 3.1, Page 12	The use of digital equipment (hardware and software) needs to be addressed during the Screening to determine the impact on the pertinent design functions. 1. The technology used to perform the design function has changed, regardless of whether the method to perform the design function (use of differential pressure signal) remains the same. 2. The digital technology used in the design modification does represent a change in the way that the differential pressure signal is generated, distributed and used for control since the digital upgrade may introduce software, software-based devices, etc. and associated hazards. 3. While the document states in the example that a screening would still need to be addressed, the structure and end conclusion of the example continues to maintain the idea that there is such thing as a 'like for like' replacement when going from analog to digital technology. This would appear to go against the goal of the document as it seems many of the issues regarding 10 CFR 50.59 screenings recently involve screeners not properly taking into account the full range and scope of hazards with digital technology when upgrading the technology of SSCs. If one does consider a digital upgrade a change in how a system and/or components performs a design function, then it should raise more awareness of the hazards when performing any digital upgrade, regardless of whether it fundamentally changes how a design	This may require a discussion with the authors to gain further insight into their thinking on this matter.	Example has changed with 11/16/2016 revision. Still a concern?

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		function is performed.		
34 Coping and Susceptibility Analysis (6/14/16) (9/21/16)	Section 3.2.1, Page 14	The process described in Section 4 of NEI 96-07, has the following steps: 4.1, Determine the Applicability of 10 CFR 50.59 4.2 Screen by determining adversity of the change (or fundamental alterations) 4.3 Evaluate using the eight 10 CFR 50.59 questions Appendix D addresses Screening in Section 3 and has the following aspects: 3.1 "Fundamental" Change evaluation 3.2.1.2 Component Combinations 3.2.1.3 Coping Analysis	NEI should update these screening aspects considering the clarification in its replacement of the term explain why is the guidance for a Coping Analysis not better placed under the 10 CFR 50.59 evaluation questions (as opposed to being screening guidance)?	Complete: 11/16/2016 and 12/20/2016 proposed revisions
36 Form & Content (9/21/16)	Section 3.2.1.2, page 14	Regarding: "If the combination of components and/or functions does not involve SSCs described in the UFSAR (directly or indirectly), or does not involve UFSAR-described design functions, then there cannot be an adverse impact due to the combination aspect of the digital activity." This is a questionable assertion, esp. due to ambiguity in the meaning of "does not involve." If the intended meaning is "does not affect" then there is a circularity in the assertion. How is it determined that "it does not affect …"?	Screening question may need to be layered. That is, one should first address whether the change affects SSCs described in the UFSAR (directly or indirectly), or does not affect UFSAR-described design functions", then (only if it does affect a UFSAR function) address the combination question.	Complete: NEI 96-07, Rev. 1 still applies
38 Consistency w/ NEI 96-07 Adverse Change (9/21/16)	Section 3.2.1.2, Example 3-3	Bullet Number (2) states: "Because the entire feedwater control system is non-safety related, there is no regulatory requirement to provide redundancy. The two control systems existed for operational convenience only, not to satisfy any General Design Criteria requirements." This statement has nothing to do with what is actually written in the SAR, and the regulatory commitments therein. The screening process is used to determine the adverse change to the SAR. Bullet Number (2) seems to be non-pertinent from a screening perspective.	Delete this bullet.	Complete: 11/16/2016 proposed revision
39 Consistency	Section 3.2.1.2, Page 16, Example 3-4	This example does not consider the reliability or probability of failure. For example, if each analog control system had a failure rate of once	This example would appear to be an adverse change because of the increase in the likelihood of	Complete: 11/16/2016

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w/ NEI 96-07 Adverse Change (9/21/16)		per thousand hours, and the two analog control system were independent, then the failure of both analog control systems concurrently would occur once in a million hours. The new combined digital system would need to have a failure rate of once in a million hours, for there to be NO increase in the probability of the event (analyzed in the SAR) requiring protective action. However there may be single failures that result in loss of flow from both feedwater trains. If these single failure are more likely than concurrent independent failures of the analog control systems, then the overall reliability of the two train system becomes a criterion for comparison. It is not clear what the failure rate of the new combined digital control system should be for there to be "not more than a minimal increase" in the probability of the event requiring protective action. In addition, this design would seem to increase the likelihood of a malfunction (single failure vs multiple failures). The conclusion of this example is that the change is not adverse based on a new malfunction not being created and, therefore, can be performed under a screening. However, the example does not appear to consider the potential increase in the likelihood of a malfunction of a SSC important to safety.	a malfunction (single failure vs multiple failures) and would require a 10 CFR 50.59 Evaluation, at a minimum. This example should be revised to state that the change is adverse and would require a 10 CFR 50.59 Evaluation. There should be some discussion as to how the Licensee would demonstrate (i.e. what analysis is required) that there is not a more than minimal increase in likelihood of a malfunction. This example could also be deleted, with new examples added that discuss the likelihood of malfunction.	proposed revision
40 Consistency w/ NEI 96-07 Adverse Change (9/21/16)	Section 3.2.1.2 (Ex 3-4)	Combined with 39.		Complete: 11/16/2016 proposed revision
41 Form & Content (9/21/16)	Section 3.2.1.2	The discussion for the Combination of Components/Functions (to address Issue Nos. 5 & 7 in ML13298A787) seems to be centered on the creation of new malfunctions as a result of the activity. The combination of Components/Functions may also increase the likelihood of a malfunction of a SSC ITS. Consider the following scenario: a loop consisting of highly reliable analog cards is being replaced by a single digital controller. Does this result in a not more	Include a discussion of what engineering analysis is required to demonstrate the likelihood of a malfunction is essentially the same or decreased as a result of the digital upgrade.	Discuss with Evaluation section

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		than minimal increase in the likelihood of a malfunction? If so, what analysis is required to demonstrate the likelihood of a malfunction is essentially the same or lower? The combination of components as part of a digital modification has been problematic in the past (see ML14307A765 starting on the bottom of Page No 14 of the enclosure).		
42 Consistency w/ NEI 96-07 Adverse Change (9/21/16)	Section 3.2.1.2	This entire section and its examples concentrates on creating a "new" malfunction or accident initiator. There seems to be an implied conclusion that if nothing "new" is created a digital mod is OK. It neglects the 10 CFR 50.59 question dealing with the likelihood of a malfunction. This may have been purposeful so that the CCF issue could be avoided; however, when certain examples use the combination of two analog trains into one piece of digital equipment and conclude that there is no adverse impact because no new malfunction has been created, it neglects the obvious "likelihood of malfunction" question. Additionally, asking the question about a "new" malfunction or accident initiator during the screening phase is getting the cart before the horse. If you are asking these questions, you should already be past the screening and into the 10 CFR 50.59 evaluation.	Either this section should state up front that the likelihood of malfunction question has been excluded from the examples for the purpose of simplicity, or some of the examples need to be either expounded upon or deleted - example 3-4 comes to mind. However, a better approach might be to perform a wholesale change to this section and stick specifically to guidance and examples that deal with wording in the SAR and potential adverse changes to that wording and SAR defined functions.	Discuss with Evaluation section
43 Consistency w/ NEI 96-07 Adverse Change (9/21/16)	Section 3.2.1.2 Example 3.7	A more realistic example would be where the mechanical governor on the turbine driven auxiliary feedwater pump (SDAFWP) is to be changed to a governor that was based on electricity. This would make both AFWPs dependent on electricity, where previously they were not. How should this be addressed?	NEI should use a more typical/realistic example.	Complete: 11/16/2016 proposed revision
44 Coping and Susceptibility Analysis (9/21/16)	Section 3.2.1.2	WCAP-7306 describes the Westinghouse position (in 1969) in response to ACRS questions regarding CCF, CMF, or Systematic Failures. This position was that the diversity in the equipment provides some protection against CCF. Subsequently, Westinghouse introduced the concept of	NEI should include a representative example.	

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		microprocessor based Protection Systems in the early 1970's on the Integrated Protection System (IPS) which was part of the RESAR 414 standard plant design; the NRC staff documented its evaluation of this design in NUREG-0493 (1979). Subsequently the NRC staff wrote SECY-91-292, which expressed the staff concerns regarding the combining of previously diverse functions. Subsequently the staff published SECY-93-087 and BTP 7-19. In summary, the combination of formerly diverse analog protective function onto a common digital platform lead to the requirement for a D3 analysis; however, the examples in this section do not include such an example.		
45 HSI (9/21/16)	Section 3.2.1.2	It is unclear if the screening process includes factors that may cause operator error, confusion, decreased situation awareness, increase in operator workload, etc. caused by combining SSC as part of the modification.	Clarify how the process addresses how HSI may contribute to human error.	Complete: 11/16/2016 proposed revision
46 Coping and Susceptibility Analysis (9/21/16)	Section 3.2.1.3, Page 19	This section addresses "Coping Analysis," but there is no section to address "Susceptibility Analysis." One could change this section to address "Susceptibility Analysis," since susceptibility analysis is more similar to the "adversity" question of the screening process, while "coping is more similar to the "how adverse" questions in the evaluation.	NEI should address "Coping Analysis," and "Susceptibility Analysis," with the same level of detail and abstraction.	Section removed: 11/16/2016 proposed revision
48 Internal Consistency (9/21/16)	Section 3.2.1.3, Page 19	The examples in Section 5 do not include a subsection on "Coping Analysis," (i.e., to address 3.2.1.3) as they do on "Combinations of Components and Functions," (i.e., to address 3.2.1.2)	NEI should address guidance of Section 3.2.1.3 in the examples in Section 5.	Section removed: 11/16/2016 proposed revision
49 Coping and Susceptibility Analysis (9/21/16)	Section 3.2.1.3, Page 19	This section talks about a "Coping Analysis." There are few specifics in this section explaining criteria and methodology for the Coping Analysis. If this type of analysis is to be relied upon, more specifics need to be added. Generally, the NRC expects that a CCF Coping Analysis is performed	In the public meeting on April 28, 2016, NEI stated that Appendix D would not contain or reference technical guidance; however, it was also identified that a mapping was required to direct users to the appropriate technical guidance. This mapping would not be in Appendix D.	Section removed: 11/16/2016 proposed revision

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		in accordance with NUREG-0800 (SRP) Chapter 7, I&C, BTP 7-19. This analysis can have several outcomes: - CCF is not a problem (no changes needed) - CCF can be addressed by manual means(Already in Procedures) - CCF can be addressed by manual means(Not yet in Procedures) - CCF must be addressed by diverse automatic means	Please consider adding criteria and examples for each category of analysis outcomes.	
50 Coping and Susceptibility Analysis (9/21/16)	Section 3.2.1.3	This section states: "The coping analysis evaluates the plant-level effect of a failure that causes a malfunction of one or more SSCs, with the objective of demonstrating additional assurance that the plant remains safe, despite the malfunction." The Licensee must demonstrate that the change does not meet any of the criteria in 10 CFR 50.59 (c)(2). Even if a modification results in a plant remaining safe, it may still require a LAR for implementation. In addition, this section does not describe how the Coping Analysis would support a screening or evaluation.	Additional information should be included that describes how this Analysis supports the overall 10 CFR 50.59 Process. Please add guidance with respect to analysis and evaluation question No. (viii).	Section removed: 11/16/2016 proposed revision Discuss additional guidance with Evaluation section
51 Form & Content Consistency w/ NEI 96-07 (9/21/16)	Section 3.2.2.3	Appendix D Section 3, "Screen Guidance" presumably contains guidance for doing 10 CFR 50.59 screenings; therefore, Subsection 3.2.1.3, "Coping Analysis," is an analysis that is done as part of a screening assessment. Subsection 3.2.1.3 directs the reader to NEI 96-07 Section 4.2.1, which states: "If the effect of a change is such that existing safety analyses would no longer be bounding and therefore UFSAR safety analyses must be re-run to demonstrate that all required safety functions and design requirements are met, the change is considered to be adverse and must be screened in." Based on the guidance in NEI 96-07 Section 4.2.1, just the fact that a Coping Analysis is performed would cause the modification to screen in. NEI 96-07 does not address the specific outcomes of a Coping Analysis, and the SAR probably does not include a Coping Analysis	NEI should provide criteria and examples that address the possible outcomes of the Analysis.	Section removed: 11/16/2016 proposed revision

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		(especially for an analog to digital modification); however, coping analyses should be treated like safety analyses.		
52a	Section 3.2.1.4	See comment 20a above on Section 2.6 Dependability definition - the term "dependability," including its components, reliability, availability, maintainability, is neither necessary nor helpful for the engineering-dependent aspects of the modification. V&V would suffice. Extrapolation from operating history is not valid because neither the item nor its environment are seldom identical or sufficiently similar to allow valid aggregation. The relationship between the quality of the development process and the quality of the work product is not repeatable because of the large variable space (e.g., see in NRC's RIL-1101 Tables 4, 10, 12, 14, 16, 18, 3) ADAMS ML14237A359. The process-product quality relationship can be used asymmetrically, i.e., "If the process is not good, don't expect the product to be good." Similarly "design measures" may reduce the potential defect space, but, by themselves, are not sufficient. V&V is the element that can provide the information necessary and sufficient to reach the conclusion. There is a fallacy in the assertion "… more reliable … (equipment) …preserving the system-level design function. See comment #28. Effects of engineering deficiencies cannot be measured in terms of a reliability performance measure (the probability that an item can perform a required function under given conditions for a given time interval). The term "tools" does not match the items referred to by the term. It seems that the collection of these items is the evidence to support the satisfaction of the targeted property of the system. If the targeted property is "SAFETY" (no hazard remaining), then the itemized list should be revised accordingly.	See comment added above on Section 2.6. In the second bullet, instead of "testability" use "verifiability"; the latter broadens the scope to include various kinds of analysis and combination of the various verification techniques. Analysis can be performed at various phases of the development cycle – even at the concept phase, providing valuable evidence early in the lifecycle (e.g., "non-verifiability").	Definition removed
53 Form & Content	Section 3.2.4	**Hazard Analysis**	In the public meeting on April 28, 2016, NEI stated that Appendix D would not contain or reference	

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(9/21/16)		Similar to the comment on the Coping Analysis. There are few specifics in this section explaining criteria and methodology for the Hazard Analysis. **Note:** RIL-1101 (ML14237A359). Appendix C in RIL-1101 includes a comparative survey of methods used elsewhere.	technical guidance; however, it was also identified that a mapping was required to direct users to the appropriate technical guidance. This mapping would not be in Appendix D.	
54 HSI (9/21/16)	Section 3.2.2.2	The section excludes items identified in NEI 96-07 such as "equipment manipulations, actions taken or options available, manipulation sequences or operator response times." The bases for this exclusion is not clear. Consideration of operator responses and other excluded elements can be greatly affected by changes to HSI and may, in some cases, be adverse.	Clarify the bases for this exclusion.	Complete: 11/16/2016 proposed revision
55 Form & Content (5/31/16) (9/21/16)	Section 3.2.2.2	The examples in this section illustrate principles, but these principles and associated criteria are not explicitly stated in this section.	Provide criteria for screening the adversity of interface changes.	
56 HSI (6/14/16) (9/21/16)	Section 3.2.2.2, Page 21	This section states "The digital aspect is concerned with the interaction itself, not how the physical component is operated and controlled." It is not clear what is meant by "operated and controlled" in this context. This section is focusing on the interaction between the human and the machine. It does not make sense to separate the control function for manually controlled operations when discussing the man machine interface.	NEI should revise and clarify what is meant by this statement.	Complete: 11/16/2016 proposed revision
57 HSI (9/21/16)	Section 3.2.2.2, Example 3-8, Page 21	This example is misleading. If this example was supposed to address only analog to digital aspects, then an analog knob could be replaced by a digital knob. The real concern is switching the type of interface device; not all devices are equally good. Some interface types are sufficiently similar to screen out, which ones? This example states that switching from a knob to a touch screen does not adversely impact the ability of the operator to control the device. There is no explanation of the rational or basis for this conclusion.	Please provide a rational or basis for the conclusion reached. Is any touch screen implementation as good as a knob?	Discuss scope of examples
58 HSI (9/21/16)	Section 3.2.2.2, Example 3-8 Page 21	Example 3-8 provides a description of a reasonable design that considers human factors by using a button labeled with an up arrow to	Clarify how cognitive issues caused by HSI are addressed.	Discuss scope of

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		increase the parameter and a down arrow to decrease the same parameter. This example is used because it shows one way in which the new design can achieve the goal described in the UFSAR of "increase and decrease the control room functions using manual controls located in the Main Control Room." However designers could also achieve this same goal using a different design. Instead they could have designed a system where the operator presses his finger to a touch screen and swipes right to increase and left to increase. Lifting the finger from the screen would send the signal and initiate actions in the plant. In this case, the UFSAR function is maintained therefore the modification would not have screened in, however operators could very easily accidentally swipe left instead of right for a variety of reasons (confusion about mapping left/right to increase/decrease, tremor in the hand, getting bumped by another operator, etc.) creating an undesired effect on system operation. This could be captured by the screening element for Physical Interaction in some cases if the potential error is assessed to something like a hand tremor or the operator getting bumped by another operator, however it is not clear that the issue would be screened in due to the cognitive mapping issues associated with swiping left/right to increase/decrease the value.		examples
59 HIS Form & Content (9/21/16)	Section 3.2.2.2, Example 3-9, Page 22	Based on the example, one could conclude that all changes from a "tactile feedback" knob to a touch screen require a 10 CFR 50.59 evaluation. Is this the intent? The criteria and rational are missing from the example.	NEI should provide a rationale or basis for the conclusion reached.	Complete: 11/16/2016 proposed revision
60 HIS Form & Content (9/21/16)	Section 3.2.2.2, Page 23	There are generally two types of problems with the amount of information provided to the operators: (1) Too Little, or (2) Too Much. This page only provides criteria for reducing the information to the operator, it does not address too much information.	NEI should provide criteria. (e.g., Move the "too much"-information guidance from Page 24 to this sub-section.)	Complete: 11/16/2016 proposed revision
61 HSI	Section 3.2.2.2, Pages 23 & 24	Subsections: - "Number and/or Type of Parameter"	Consider adding additional examples to illustrate this concept.	Complete: 11/16/2016

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(9/21/16)		- "Information Presentation" There are no examples provided for when these element cause adverse impacts on UFSAR described design functions.		proposed revision
62 HSI (9/21/16)	Page 24 "Information Presentation"	This description has a list of three bullets that explain how information presentation may cause potential impacts. A comprehensive list may not be desirable in this document, however an expanded list should be considered. This is screening guidance and I assume there may not always be a human factors expert conducting the screening. A more complete list of the ways in which information presentation may cause safety impacts could be useful while screening these issues.	Consider adding items to the list.	Complete: 11/16/2016 proposed revision
63 Form & Content (9/21/16)	Section 3.2.3	If an analog protection system is replaced with a digital one, and as part of that replacement, and D3 analysis is performed in accordance with BTP 7-19, and the acceptability of the modification is based on this analysis, why would not this be a change in the methods described in the FSAR?	Provide criteria and examples to address D3 analyses.	
64 Form & Content (9/21/16)	Section 3.2.3	**Common Cause Failure Considerations** Similar to the comment on the Coping Analysis. There are few specifics in this section explaining criteria and methodology for the CCF Considerations.	NEI should provide a cross reference to the appropriate criteria.	
65 Consistency w/ NEI 96-07 (9/21/16)	Section 4, Page No. 26	The numbering in Appendix D does not match that in NEI 96-07.	NEI should renumber to be Section 4.3.	NEI provided a proposed TOC rev. 9/9/2016 with Sec. 2 & 5 as placeholders for content TBD based on evolution of App D during NRC review. TOC

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				discussed and agreed upon at the 9/21/2016 public mtg. To maintain traceability of existing NRC comments, NEI prefers to complete section re-numbering after all current sections have been discussed. The 9/9/16 proposed TOC rev. can be used as a section numbering key for clearer reference back to NEI 96-07, Rev. 1 in the meantime.