

October 3, 2016

MEMORANDUM TO: Kevin Hsueh, Chief
Licensing Processes Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

FROM: Joseph J. Holonich, Senior Project Manager /RA/
Licensing Processes Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

SUBJECT: SUMMARY OF JUNE 15, 2016, MEETING ON APPENDIX D OF
NEI 96-07, "GUIDELINES FOR 10 CFR 50.59 EVALUATIONS"

On June 15, 2016, U.S. Nuclear Regulatory Commission (NRC) staff met with representatives from the Nuclear Energy Institute (NEI). The purpose of the meeting was to discuss the NRC staff perspectives on Appendix D of NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluations" Information related to the meeting including presentations and the attendees list can be found in the Agencywide Documents Access and Management System (ADAMS) package accession number ML16166A338. The NEI information presented at the meeting is enclosed to this summary.

Throughout the meeting, the NRC staff and NEI representatives discussed the information contained in their respective presentations. During each presentation, a series of discussions were held to provide clarifications of the information being presented. No regulatory positions or agreements were reached during the meeting.














The following action items were identified at the meeting.

- 1) NEI will provide examples on how NEI 98-03, Guidelines for Updating Final Safety Analysis Reports," can be used to answer questions related to Title 10 of the *Code of Federal Regulations*, Section 50.59.
- 2) NEI will look for more examples of how the guidance in NEI 96-07 can be used.
- 3) NRC staff and NEI will finalize the schedule for biweekly gotomeeting sessions to continue detailed discussions on the topics identified by each organization. The NRC staff will take the lead to coordinate the schedule.

Enclosure:
As stated

Project No. 689

SUMMARY OF CONCERNS DISPOSITION TABLE

NRC CONCERN	NEI 01-01 ISSUE	APPENDIX D	DRAFT TECHNICAL GUIDANCE	OTHER
1	Consistency of Definitions			
2	New and Updated Guidance Documents			
3	Operating Experience (inspections and LAR reviews)			Training/rollout workshops will be critical to success.
4	Best Way to Incorporate Safety Evaluation from RIS 02-22 into NEI 01-01			
5	Diversity and CCF			
6	Draft RIS on Embedded Devices			Inappropriate to address until final. RIS 2016-05 issued 4/29/2016.
7	NEI 01-01 Section 4.3.2 "Software Considerations"			
8	Separate Guidance for Digital Mods vs. 50.59			
9	Erroneous Conclusion Re: No Need for D3 Analysis if Low Likelihood of SCCF			
10	No Guidance to Address Increase in Coupling/Interactions in Non-Safety Systems or Decrease in Independence			
11	Inadequate Guidance for Characterizing Failures (Worst Case, Worst Time, etc.)			

SUMMARY OF CONCERNS DISPOSITION TABLE

12	How does the 50.59 process work for digital upgrades if there is no “digital” licensing basis described in the UFSAR?			Covered in NEI 98-03, <i>Guidelines for Updating FSARs</i> , Rev. 1, as endorsed by RG 1.181
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50.59 DIGITAL GUIDANCE CROSS-REFERENCE TABLE

PHASE	50.59 CONCEPT	NEI 96-07	NEI 01-01	APPENDIX D	COMMENT
Screen	Fundamental Change	Section 4.2.1.2: Identified <i>man-machine interface</i> as an example among changes "that fundamentally alter...the existing means of performing or controlling design functions...." and contained the guidance that this type of change "...should be conservatively treated as adverse..."	1. Section 4.3 states: "The mere fact that a change converts analog equipment or signals to digital does not cause the change to screen in." 2. Section 4.3.4: Supersedes NEI 96-07 guidance by stating "...not all changes to the human-system interface fundamentally alter the means of performing or controlling design functions."	Section 3.1: Expands NEI 01-01 guidance to include ALL aspects of a digital modification (i.e., hardware, software and human-system interface) as not being a fundamental change to the means of performing or controlling design functions.	Determination of adverse is still required, but the requirement to "force" the activity to be adverse is removed. NOTE: No previous guidance exists that forces the hardware or software portions to be adverse.
Screen	Combination of Components or Functions	Section 4.2.1, bullets #2 and #5: Describe some of the effects that may stem from a proposed activity that should be considered in a Screen.	1. Section 4.3.1, bullet #4: Same as NEI 96-07, bullet #2. 2. Section 4.3.3, bullet #1: Addresses "combining previously separate functions."	Section 3.2.1.2: Clarifies NEI 01-01 guidance.	Complies with currently endorsed guidance.
Screen	Coping Analyses	Section 4.2.1: Provides guidance regarding the re-	Not discussed.	Section 3.2.1.3: Clarifies NEI 96-07 guidance.	Complies with currently endorsed guidance.

50.59 DIGITAL GUIDANCE CROSS-REFERENCE TABLE

PHASE	50.59 CONCEPT	NEI 96-07	NEI 01-01	APPENDIX D	COMMENT
		running of safety analyses.			
Screen	Dependability	<p>1. Section 4.2.1, bullet #1: Describes an effect that may stem from a proposed activity that should be considered in a Screen.</p> <p>2. Section 4.2.1, Screening for Adverse Effects: States how reliability is addressed in a Screen, as follows, "...a change that decreases the reliability of a function...would screen in."</p>	Section 4.3.2: Provides guidance regarding software dependability.	Section 3.2.1.4: Clarifies NEI 01-01 guidance.	Complies with currently endorsed guidance.

50.59 DIGITAL GUIDANCE CROSS-REFERENCE TABLE

Screen	Conclusion Justification	<p>1. Section 4.2.1, Screening for Adverse Effects: States how the justification for a conclusion is performed, as follows, "Screening determinations are made based on the engineering/technical information supporting the change."</p> <p>2. Section 4.2.1, Screening for Adverse Effects: States how the justification for a conclusion is performed, as follows, "...design evaluations...may be used as [the] basis for screening out the change."</p> <p>3. Section 4.2.1.1, States how the justification for a conclusion is performed, as follows, "...only proposed changes to SSCs that would, based on supporting engineering and technical information, have adverse effects on design functions require evaluation under 10 CFR 50.59."</p>	Not discussed.	Sections 3.2.1.2 and 3.2.1.3: Conceptually applies NEI 96-07 guidance in the determination of possible impacts. In most cases, qualitative (vs. quantitative) approaches will be used.	Complies with currently endorsed guidance.
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PHASE	50.59 CONCEPT	NEI 96-07	NEI 01-01	APPENDIX D	COMMENT
Screen	Physical Interface	Section 4.2.1.2: Identified <i>man-machine interface</i> as an example among changes "that fundamentally alter...the existing means of performing or controlling design functions..." and contained the guidance that this type of change "...should be conservatively treated as adverse..."	Section 4.3.4: Supersedes NEI 96-07 guidance and provided guidance for determination of possible adverse effects.	Section 3.2.2.2: Clarifies NEI 01-01 guidance.	Complies with currently endorsed guidance.
Screen	Software Common Cause Failure (SCCF)	Not discussed.	Section 4.3.2: Provides guidance regarding SCCF (i.e., "...for some upgrades the likelihood of failure due to software may be judged to be no greater than failure due to other causes...even when it affects redundant systems...").	Not discussed.	SCCF is no longer a topic to be considered in the Screen phase. SCCF will now be addressed in the Evaluation phase since it deals with <i>likelihood of a malfunction</i> , which is addressed in Evaluation criteria 50.59(c)(2)(ii), 50.59(c)(2)(v) and

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PHASE	50.59 CONCEPT	NEI 96-07	NEI 01-01	APPENDIX D	COMMENT
					50.59(c)(2)(vi).
Evaluation	SCCF	Not discussed.	Section 4.4.2: Provides guidance regarding impact of SCCF on malfunction likelihood (i.e., "...[software] developed in accordance with a defined life cycle process, complying with the applicable industry standards and regulatory guidance...should not result in more than a minimal increase in the likelihood of malfunctions."	Sections 4.2.1, 4.5.1 and 4.6.1: Clarifies NEI 01-01 guidance to include Commercial Grade Dedication (CGD).	Complies with currently endorsed guidance.
Evaluation	Hazard Analysis	Section 4.3.2: Not specifically discussed, but how "qualitative engineering judgment and/or industry precedent is typically used to determine if there is more than a minimal increase in the likelihood...of a malfunction" is discussed.	Section 4.4.2: Same as NEI 96-07 guidance, but with specific mention of <i>failure analysis</i> .	Section 4.2.1: Conceptually the same as NEI 01-01, but replaces <i>failure analysis</i> with a broader <i>Hazard Analysis</i> .	Complies with currently endorsed guidance.

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PHASE	50.59 CONCEPT	NEI 96-07	NEI 01-01	APPENDIX D	COMMENT
Evaluation	CCF Susceptibility Analysis	Section 4.3.2: Not specifically discussed, but how "qualitative engineering judgment and/or industry precedent is typically used to determine if there is more than a minimal increase in the likelihood...of a malfunction" is discussed.	Not discussed.	Section 4.2.1: adds <i>CCF Susceptibility Analysis</i> .	Expands the scope of acceptable evaluation techniques to include the use of a <i>CCF Susceptibility Analysis</i> .

50.59 DIGITAL GUIDANCE CROSS-REFERENCE TABLE

PHASE	50.59 CONCEPT	NEI 96-07	NEI 01-01	APPENDIX D	COMMENT
Evaluation	"End Result"	Section 4.3.6: Second bullet after the first paragraph, refers to <u>multiple end results</u> each of which involves a final state of a component.	Section 4.4.6: Supersedes NEI 96-07 guidance by identifying the <i>end result</i> as being a type of accident.	Section 4.6.1: Clarifies NEI 01-01 guidance to distinguish between NEI 96-07 results (i.e., intermediate) and NEI 01-01 results (i.e., end result).	An example in the proposed guidance includes an <i>end result</i> that "crosses over" accident frequency categories to determine if the <i>end result</i> is acceptably bounded (i.e., allows consideration of less frequent accidents and possibly different acceptance criteria). This approach would be an extension of NEI 96-07 guidance on <i>end result</i> for digital modifications only. It does not impact guidance on evaluating frequency of occurrence of accidents.

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