February 24, 2014

MEMORANDUM TO:	Anthony J. Mendiola, 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 NOVEMBER 14, 2013, MEETING ON NUCLEAR ENERGY INSTITUTE GUIDANCE DOCUMENT NEI-01-01, "GUIDELINE ON LICENSING DIGITAL UPGRADES: EPRI [ELECTRICAL POWER RESEARCH INSTITUTE] TR-102348, REVISION 1, NEI 01-01: A REVISION OF EPRI TR-102348 TO REFLECT CHANGES TO THE 10 CFR 50.59 RULE"

On November 14, 2013, staff from the U.S. Nuclear Regulatory Commission (NRC) held a meeting with representatives from the Nuclear Energy Institute (NEI) and industry representatives. The purpose of the meeting was to discuss NRC staff concerns with NEI-01-01, "Guideline on Licensing Digital Upgrades: EPRI TR [Technical Report]-102348, Revision 1, NEI 01-01: A Revision of EPRI TR-102348 to Reflect Changes to the 10 CFR [Title 10 of the *Code of Federal Regulations*] 50.59 Rule" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML020860169).

Regulatory Information Summary (RIS) 2002-22, "Use of EPRI/NEI Joint Task Force Report, 'Guideline on Licensing Digital Upgrades: EPRI TR-102348, Revision 1, NEI01-01: a Revision of EPRI TR-102348 to Reflect Changes to the 10 CFR 50.59 Rule'" (ADAMS Accession No. ML023160044) conditionally endorsed NEI 01-01.

Prior to the meeting, the NRC staff provided a sample listing of concerns to NEI by letter dated November 5, 2013 (ADAMS Accession No. ML13298A787). Enclosed is a list of the meeting attendees.

Meeting presentations can be found in the ADAMS package for the meeting (ADAMS Accession No. ML13308A004). A copy of the notice and agenda can be found in ADAMS Accession No. ML13261A094.

In its opening remarks, the NRC staff noted that it had attended a recent NEI/industry meeting as a drop-in opportunity to learn more about what was being done to address the NRC staff concerns with NEI-01-01. Then the NRC staff said that it had sent NEI a letter (ADAMS Accession No.: ML13298A787) presenting examples of NRC concerns with NEI-01-01.

NEI opened by expressing thanks for holding the meeting and noting that the good exchanges in previous meetings helps the industry know what to do to improve safety.

Further, NEI said that the letter provided by the NRC staff was good in identifying topics to start discussions and focus the meeting.

Following the introductory remarks, the meeting participants began to discuss each item in the NRC letter. Numbers below correspond to the item in the November 5, 2013, NRC staff letter (ADAMS Accession No. ML13298A787).

1. Consistency in definitions/revision of definitions in NEI 01-01

The NRC staff opened the discussion on this item by noting that, although the NEI definitions were initially consistent, over time, the definitions used by the industry have evolved. Continuing, the NRC staff said that it recognized that different documents have different levels of authority.

As an example it was noted that 10 CFR 50.59 was a requirement while a regulatory guide (RG) was guidance on how to meet a requirement. To help NEI gain a clear understanding of the extent of the inconsistencies, the NRC staff recommended that NEI identify where the inconsistencies could be found. Although the NRC staff had identified some inconsistencies, having NEI develop a complete list would be helpful.

Responding to the NRC staff comments, the NEI representatives stated that NEI concurs that definitions need to be consistent and properly applied. Where agreements have been reached on definitions between the NRC and industry, these need to be captured. The NEI representatives stated that NEIs position is that the screening criteria need to be kept consistent with 10 CFR 50.59 and NEI 96-07, Rev. 1, "Guidelines for 10 CFR 50.59 Evaluations," and RG 1.187, "Guidance for Implementation of 10 CFR 50.59 Changes, Test, and Experiments" (ADAMS Accession No. ML00375910) conditionally endorsed NEI 96-07, Rev. 1.

As the discussion continued, it was suggested that a Diversity and Defense-In-Depth (D3) analysis should be done regardless of whether a license amendment request (LAR) is being submitted or a change is being made under 10 CFR 50.59. In response, the industry questioned why a D3 analysis was needed in some circumstances. The NRC staff stated that the Staff Requirements Memorandum (SRM) to SECY 93-087, "Policy, Technical, And Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs," cited within Branch Technical Position (BTP) 7-19, "Guidance for Evaluation of Diversity and Defense-In-Depth in Digital Computer-Based Instrumentation and Control Systems," articulates when a common-cause failure (CCF) needs to be evaluated, that is when a D3 analysis is needed.¹

Industry stated that if a CCF is credible, and it can result in unanalyzed fault condition (high likelihood of a fault condition with a different result), then a D3 analysis (or other analysis demonstrating design adequacy) is necessary for safety systems. The NRC staff articulated that BTP 7-19 states:

¹ Note: SECY-91-292, "Digital Computer Systems for Advanced Light Water reactors," dated September 16, 1991, contains additional material describing the development of the Diversity and Defense-In-Depth policy articulated in SECY-93-087 Item II.Q and the associated SRM.

"In summary, while the NRC considers (software) CCF in digital systems to be beyond design basis, NPPs should be protected against the effects of anticipated operational occurrences (AOOs) and postulated accidents with a concurrent CCF in the digital protection system.

The purpose of this BTP is to provide guidance for evaluating an applicant's D3 assessment. design, and the design of manual controls and displays to ensure conformance with the NRC position on D3 for I&C systems incorporating digital, software-based or software-logicbased RTS or ESF, auxiliary supporting features, and other auxiliary features as appropriate. This BTP has the objective of confirming that vulnerabilities to CCF have been addressed in accordance with the guidance of the SRM on SECY-93-087 and clarification provided in this staff guidance, specifically" (emphasis added)²

It was suggested by industry that NEI 96-07 be reviewed by the NRC staff because it describes the consequence of an overly conservative D3 study for CCF for a software design. The NRC staff stated that the SECY 93-087 addressed "Defense Against Common Mode Failures in Digital Instrumentation and Control Systems" and referenced the methodology of NUREG-0493, "A Defense-In-Depth Assessment of the RESAR-414 Integrated Protection System." which only addressed the reactor trip system or emergency safety features actuation systems (RTS/ESFAS), but the current applicability includes other safety equipment (as described above).3

Continuing on the topic, the NRC staff stated that there is a disconnect between 10 CFR 50.59 and NEI 01-01. As a result of that statement, the NEI representatives requested that NRC provide examples where this "disconnect" exists. It was then stated by industry representatives that while they agree that issues with definitions can lead to ambiguity in applying licensing criteria, they do not agree that there is a "disconnect" between licensing criteria and 10 CFR 50.59.

The industry representatives stated that the tools in place (NEI 01-01, BTP 7-19, and NEI 96-07 Rev. 1) provide acceptable guidance to assess digital upgrades per 10 CFR 50.59. Refining the definitions in NEI 01-01 and providing more examples of proper application of the above tools can close the gaps that are causing the issues cited by the NRC staff with digital instrumentation and control (DI&C) upgrades.

Further, the industry representatives indicated that it does not at this time subscribe that if software is involved in a safety system design that a CCF probability of 1 should be assumed and a D3 analysis required. It was stated that other assessment techniques may be used to address a CCF.

² IEEE 603-1991 Contains definitions of "Auxiliary Supporting Features" and "Other Auxiliary Features" as well specific requirements for each. ³ A D3 assessment is performed at the plant level, and assess the plants overall vulnerability; therefore, other

equipment must necessarily be considered.

The NRC staff stated that it would like to see these other proposed assessment techniques as part of a dialog with industry to resolve this issue. In addition, the NRC staff emphasized that it wanted licensees to have a level of confidence licensees can use 10 CFR 50.59 and submit only those items needed to be addressed in an LAR. This then, would help ensure that the NRC staff kept its focus on activities and reviews needed for safety.

2. Consider having NEI 01-01 reference currently endorsed industry standards and include guidance provided for by precedence.

The NRC staff would like the revision of NEI 01-01 to reference currently endorsed industry standards and include guidance provided for by precedence (e.g., Wolf Creek field-programmable gate array (FPGA) application – ADAMS Accession No.: ML090610317) and other guidance documents (e.g., DI&C-ISG-04 Rev. 1, "Interim Staff Guidance Highly-Integrated Control Rooms-Communications Issues (HICRc)" ADAMS Accession No.: ML083310185)). That is, NEI 01-01 should consider new positions and new guidance.

There was no further clarification on this item at the meeting.

3. NEI 01-01 is not clear to all implementers as demonstrated at LaSalle and Shearon Harris. It needs to be clarified to prevent misinterpretation.

The NRC staff stated that the industry should solicit input from parties involved at LaSalle and Shearon Harris to garner lessons learned. The NEI representatives stated that this input has been explicitly solicited as part of this effort. They further stated there were errors made in implementation of NEI 01-01 at Shearon Harris for solid-state protection system (SSPS). In response, the NRC staff stated that while this may be true, another aspect of the Shearon Harris example is that multiple instances of these types of errors have occurred and, because the Pressurized Water Reactor Owners Group (PWROG) agreed with a Westinghouse position, this indicates a multi-person breakdown in understanding, pointing to a problem with the NEI 01-01 guidance. The NEI representatives agreed that NEI 01-01 could be clarified to help preclude implementation errors in the future.

The NRC staff stated that when NEI 01-01 is revised, the NRC staff positions such as in the Wolf Creek Safety Evaluation Report (that the definition of "digital" devices includes FPGA logic developed with software tools) be considered for incorporation into the definition of digital devices.

4. Document Relationships

There are some positions in the safety evaluation (SE) included in RIS 2002-22, "Guidance for Licensing Digital Upgrades," that could be incorporated into NEI 01-01. This item (as presented in the NRC letter) is not an exhaustive list of the positions that should be evaluated for incorporation into NEI 01-01.

The NEI representatives stated that the industry will consider the positions incorporated in the SE for revision of NEI 01-01.

5. Diversity and Common Cause Failures

The Atomic Energy Handbook as cited in the letter provides a lot of the basis captured in the General Design Criteria and the NRC recommended industry review the particular sections cited to understand these bases.

The NRC staff feels that NEI 01-01 confuses the ideas of Defense-in-Depth, diversity, and single failures when it comes to software CCF. The NRC staff acknowledged that CCF is beyond design basis for single failure, but stated that CCF is not beyond design basis for everything. In other words, meeting single-failure criteria does not equal Defense-in-Depth.

The NRC's policy statement is to always assume a CCF and show coping capability.⁴ However, NEI believes that per NEI 01-01 that's a BTP 7-19 issue – not a 50.59 issue. The NEI representatives asserted that NEI 01-01, NEI 96-07, and 10 CFR 50.59 allow for CCF to not be a malfunction with a different result if the likelihood is sufficiently low (or to demonstrate coping - that the results are bounded). Disconnects between the NRC's policies and industry's interpretation of NEI 01-01 are part of the reason that the NRC staff believes that NEI 01-01 must be revised.

6. Draft RIS on Embedded Devices

Industry will consider information provided in the Draft RIS on Embedded Devices in the Revision to NEI 01-01.

7. NEI 01-01 Section 4.3.2, "Software Considerations"

The NRC discussions centered on the position that the cited statement cannot be justified by quantitative means. If this cannot be done, the NRC stated that the bar of this justification may be very high. Industry responded that there are modern analysis techniques that can provide persuasive (although not specifically calculated) justifications with regard to judgment of failure likelihood.

The NRC staff also had an issue with NEI 01-01 making an analogy/comparison of software failures being "judged to be no greater than the failure due to other causes, i.e., comparable to hardware common cause failure." The NRC stated that this judgment will need to be very persuasive to withstand regulatory scrutiny.

For the specific quote, industry cited examples about how this statement was intended for use (a simple digital transmitter). The example (as given in NEI 01-01) is intended to be very limited in scope and should not be extrapolated to larger digital systems/implementations.

8. Guidance for Digital Modifications as a topic separate from Guidance for Implementing 10 CFR 50.59.

⁴ SRM to SECY-93-087 Item No. II.Q does not contain guidance or direction for conditions under which a D3 analysis does not need to be performed; however, BTP 7-19 does contain criteria for not performing a D3 analysis.

The NRC staff stated that the topic presented is self-explanatory. The NEI representatives stated that industry will consider separating the guidance.

9. D3 Analysis

This item was discussed in detail under item #1. The NEI representatives believe that there is confusion within the staff regarding its concept of this issue (#9). The industry representatives stated that Section 4.1 and 4.2 of NEI 01-01 do not relate to the unlikely nature of a CCF and a D3 analysis. Instead, Section 4.1 and 4.2 relate to whether a CCF results in a condition with a different result. The NRC staff agreed to re-evaluate this item.

10. Coupling/Interaction Or Decreases In Independence

In its letter, the NRC staff noted that NEI 01-01 should provide guidance with regard to non-safety digital system failure modes and how they challenge the assumptions of the accident analysis. To help focus the discussion on this topic, the NRC staff provided an example.

For a non-safety-related system whose failure has been analyzed in the Final Safety Analysis Report, if a digital aspect is added, how have we evaluated any change in failure that would affect the Chapter 15 accident analysis? It was suggested that the NRC staff propose criteria to address this issue.⁵ NEI 01-01 does not specify what is sufficient to answer the 10 CFR 50.59 questions for non-safety systems that are transient initiators and whether the transients that can result from a software CCF are "a different result." The NEI representatives agreed to consider this issue.

In closing the NRC staff noted that a path forward with milestones was needed to address its concerns. To address the NRC staff issues, the NEI representatives discussed how NEI has broken the activity up into multiple areas which are more manageable pieces that may progress at different rates.

The NEI representatives also stated they are interested in working through the issues in these areas with the NRC staff in a workshop format. It is expected that this effort would be iterative. The NRC was amenable to this approach and an action item was to coordinate the development of a schedule for these workshops with the first meeting in January (and bimonthly after that).

At the end of the meeting, an industry user of NEI 01-01 suggested that a bounding definition of software "common cause failure" be established. Does it fail high? Low? As is? Worst possible? NUREG/CR-6303 was suggested as a starting point to help in this definition effort.

⁵ ADAMS Accession No. ML13318A217 already describes the beginnings of NRC efforts in this area.

Action Items

- A. Industry will consider the following items in revising NEI 01-01
 - 1. Positions incorporated in the Wolf Creek SE for inclusion in NEI 01-01.
 - 2. Information provided in the Draft RIS on Embedded Devices in any proposed revision of NEI 01-01.
- B. Separating the guidance discussed in Item 8 will be considered by the industry
- C. The NRC staff agreed to re-evaluate Item 9.
- D. Industry will consider providing guidance with regard to non-safety digital system failure modes and how they challenge the assumptions of the accident analysis.
- E. NEI and the NRC staff will work to schedule the next meeting for mid-January to early February.

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