UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 16, 2016

Mr. James E. Slider
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SUBJECT: NUCLEAR REGULATORY COMMISSION RESPONSES TO COMMENTS ON DRAFT APPENDIX O SIGNIFICANCE DETERMINATION PROCESS FOR MITIGATING STRATEGIES

Dear Mr. Slider:

Thank you for the comments you provided by letter dated July 26, 2016, "Comments on Draft Appendix O for Significance Determination Process (SDP) for Mitigating Strategies" (Agencywide Documents Access and Management System Accession Number ML16278A273). The Nuclear Regulatory Commission (NRC) staff considered your comments, revised portions of the document, and has since approved and issued Inspection Manual Chapter (IMC) 0609, Appendix O, "Significance Determination Process for Mitigating Strategies and Spent Fuel Pool Instrumentation (Orders EA-12-049 and EA-12-051)," for use by inspectors. The NRC will also issue the associated technical basis document in the near future. After gaining experience with the use of Appendix O, staff intends to address any lessons learned by modifying the documents as necessary and welcomes future dialogue.

We have provided responses to your comments in the enclosure.

If you have any questions, please contact Russell Gibbs of my staff by telephone at 301-415-8578 or by e-mail at Russell.Gibbs@nrc.gov.

Sincerely,

/RA/

Nathan T. Sanfilippo, Branch Chief
Division of Inspection and Regional Support
Office of Nuclear Reactor Regulation

Enclosure:
NRC Staff Responses to NEI
Comments on Proposed Appendix O SDP
for Mitigating Strategies

Mr. James E. Slider
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NRC Staff Responses to Nuclear Energy Institute (NEI) Comments on Proposed Appendix O Significance Determination Process (SDP) for Mitigating Strategies

The following comments were submitted by the NEI Reactor Oversight Process Task Force on the draft Appendix O SDP[1]. Following each comment, the NRC staff has provided its response.

1. General Comments

a) NEI Comment: SINGLE SDP: The staff originally proposed merging the existing B.5.b SDP (IMC 0609, Appendix L) with the proposed Mitigating Strategies SDP (IMC 0609, Appendix O). Because of the overlap in capabilities utilized in B.5.b and Mitigating Strategies scenarios, NEI believes a single SDP is still the right approach. If NRC insists on retaining separate B.5.b and Mitigating Strategies SDPs, the criteria presented in the Appendix L SDP should be revised downward to better align the B.5.b SDP results with actual low risk significance and with other SDP thresholds.

NRC Response: The staff will consider merging of Inspection Manual Chapter (IMC) 0609, Appendix L, "B.5.b Significance Determination Process," with IMC 0609, Appendix O, "Significance Determination Process for Mitigating Strategies and Spent Fuel Pool Instrumentation (Orders EA-12-049 and EA-12-051)," in the future as more experience is gained. However, the staff believes a more effective and efficient approach for assessing the significance of inspection findings related to B.5.b, mitigating strategies, and spent fuel pool instrumentation is a screening approach similar to that in Appendix O, rather than the deterministic approach as presented in Appendix L.

b) NEI Comment: SCOPE OF INSPECTION: TI 2515/191 includes as an Objective the inspection of implementation of communications and staffing plans. The proposed SDP is silent on the treatment of findings related to communications and staffing. How will NRC handle any such findings?

NRC Response: The now published Appendix O (October 7, 2016) includes a screening question that addresses staffing from a programmatic standpoint (Question 5). The programmatic controls included in Question 5 were taken from NEI-12-06, "Diverse and Flexible Coping Strategies (FLEX) Implementation Guide." Communications could be considered if the issue related to Communications caused a failure of safety function, etc. as captured by the existing questions.

c) NEI Comment: CROSS-REGIONAL PANEL: The Cross-Regional Panel is mentioned on page 2, in the introduction to Section 4.0, "Guidance". The charter for this panel is available in ADAMS and should be included in the references listed in Section 5.0.

NRC Response: ADAMS Accession number ML15093A339 for the Cross-Regional Panel Charter for Temporary Instruction (TI) 2515-191 was added to the references section of Appendix O.

[1] Inspection Manual Chapter 0609, Appendix O, "Post Fukushima Mitigating Strategies Significance Determination Process (Orders EA-12-049 and EA-12-051)", ADAMS Accession No. ML16055A351

2. Title: "Post Fukushima Mitigating Strategies Significance Determination Process (Orders EA-12 -049 and EA-12-051)"

a) NEI Comment: WORDING OF TITLE: To be consistent with TI 2515/191, the title of Appendix O should be written as follows: "Significance Determination Process for Mitigation Strategies and Spent Fuel Pool Instrumentation Orders".

NRC Response: The title of Appendix O was changed to Significance Determination Process for Mitigating Strategies and Spent Fuel Pool Instrumentation (Orders EA-12-049 and EA-12-051), as suggested, while retaining the order numbers.

3. Section 1.0, "Purpose", lines 6 -8: "Entering into this appendix presumes that the performance deficiency is of more than minor significance using the guidance in IMC 0612, Appendix B – Issue Screening."

a) NEI Comment: REFERENCE TO IMC 0612, APP. E: Right after the mention of Appendix B, shouldn't this sentence also mention IMC 0612, Appendix E, "Examples of Minor Issues", as part of the issue screening process?

NRC Response: The reference to IMC 0612, Appendix E, "Examples of Minor Issues," as part of the screening process was added, as suggested.

b) NEI Comment: IMC 0612 EXAMPLES: To support the above, IMC 0612, Appendix E, should be revised to include examples that would apply to a mitigating strategies-related problem.

NRC Response: As stated in the approved Appendix O, the staff intends to add specific examples to IMC 0612, Appendix E, in the future as more experience is gained.

4. Section 4.0, "Guidance", page 3, general comment on the use of screening questions

a) NEI Comment: NEED FOR CRITERIA: Affirmative responses to any one of the five questions in this section direct the user to IMC-0609, Appendix M, for a qualitative SDP. The five screening questions are broadly worded, in effect deferring the hard choices about the significance determination to Appendix M. Thus, Appendix M serves as a catch-all to this draft Appendix O. Yet neither Appendix O nor Appendix M provides specific criteria for making the significance determination. With Appendix M undergoing revision, no one knows what result the Appendix O/Appendix M combination will yield once implemented. Hence, what the draft Appendix O presents is a coarse screen that throws the tough decisions over to a yet-to-be-defined set of criteria for a future revision of Appendix M. The NRC should reconsider this approach.

NRC Response: The staff views that adding specific criteria for each of the five questions is unwarranted, particularly in light of the limited quantity of experience both the staff and industry have with licensee response to Order EA-12-049. In addition, the staff believes that most inspection findings associated with mitigating strategies will likely

screen to very low safety significance (i.e., Green) and therefore considers additional staff resources to develop specific criteria not worthwhile. Moreover, the staff considers the use of IMC 0609, Appendix M, "Significance Determination Process Using Qualitative Criteria," to be appropriate when inspection findings do not screen to Green taking into the relatively high degree of uncertainty associated with mitigating strategies and the lack of more quantitative tools available.

b) NEI Comment: BDB GTG?: What would be the basis on which NRC would screen anything associated with Beyond Design Basis events to a Greater than Green outcome? Based on the improbability of most Beyond Design Basis events, the right SDP should be as simple as a single question: "For all findings related to the Mitigating Strategies, Spent Fuel Pool Instrumentation and BWR Hardened Vent orders, screen to Green."

   NRC Response: The staff does not agree that performance deficiencies and their associated degraded conditions for beyond design basis events are very low safety significance (Green) or less (i.e., minor) by default. There are documented examples in which initiating event frequencies are sufficiently high (e.g., external flooding events) that could result in more important inspection findings (i.e., greater-than-Green) particularly when the associated initiating event has the potential to render multiple mitigating systems unavailable.

c) NEI Comment: CRITERIA IN APP. O: IMC 0609, Appendix L provides B.5.b-specific criteria for screening B.5.b findings without reference to IMC 0609, Appendix M. Why is the Appendix L approach not also suitable for the proposed Appendix O? [The basis for the Appendix L avoidance of Appendix M is provided below.]

   NRC Response: The staff considers the approach used in Appendix O to be more efficient and effective taking into account that most inspection findings will likely be of very low safety significance (Green) or less (i.e., minor). Moreover, the staff may merge Appendix L and Appendix O, but in the form of a risk-informed screening tool, not the deterministic approach used in the current version of Appendix L.

d) NEI Comment: APPLICABILITY OF APP. M: IMC-0308, Attachment 3, Appendix L, says the following: "The staff recognized that Appendix M was not the right significance determination process (SDP) tool to evaluate the significance of B.5.b findings because of "the beyond design basis" nature of the findings. All B.5.b scenarios are initiated by events that are beyond the design basis of the plant. Since these events are outside the baseline risk of the plant, assessing the significance of findings quantitatively would result in an inflated significance. Appendix M, although a qualitative risk tool, is focused on determining if the licensee is operating within its design basis by assessing safety attributes, such as safety margin and defense-in-depth. To deal with the unique nature of the B.5.b inspection finding, the staff recognized the need to develop a specific

qualitative significance determination model based on expert judgment, focused on defense-in-depth, informed by stakeholder input. To ensure a consistent assessment of

findings identified during B.5.b inspections, the staff, with input from industry stakeholders, developed a special SDP for TI 2515/171. This SDP focused on performance deficiencies affecting the feasibility of multiple strategies that have a greater significance than those deficiencies that affect the feasibility of a single strategy. The NRC issued TI 2515/171, Appendix C, on May 16, 2008, and an SDP tailored to B.5.b requirements. The staff incorporated this SDP into Revision 1 of the TI, and issued the TI for use on July 25, 2008." Why doesn't this argument apply equally well to the draft Appendix O?

NRC Response: The staff's thinking has evolved and the information provided in the current version of the Appendix L basis document is no longer viewed by the staff as appropriate. The staff is taking action to remove the language identified for the following reasons:

1) The use of Appendix M may be even more appropriate for beyond basis events due to the inherent uncertainty of circumstances surrounding these events; and
2) The use of Appendix M is not relevant to whether or not licensees operate within the design basis envelope.

5. Section 4.0, "Guidance", page 3, Question 2: "Does the inspection finding involve equipment used for Mitigating Strategies that would result in a complete loss for more than 72 hours of one or more functions to maintain or restore core cooling, containment pressure control/heat removal and/or spent fuel pooling cooling capabilities?"

a) NEI Comment: BASIS: What is the basis for 72 hours?

NRC Response: The 72 hour exposure time for the performance deficiency limit is consistent with guidance in NEI 12-06, "Diverse and Flexible Coping Strategies (FLEX) Implementation Guide," which allows the unavailability of FLEX site capability for a period of 72 hours before alternate compensatory measures are required. The use of the 72 hour exposure time limit was judged to be reasonable to account for shorter term unavailabilities that would be expected to have a very low impact on safety. A similar screening approach is used in other SDP procedures.

b) NEI Comment: COMPARABILITY: A precise limit of 72 hours seems needlessly restrictive in comparison with, for example, technical specification limits that allow 72 hours of unavailability plus time to change plant modes for equipment of greater risk significance than equipment used in Mitigating Strategies.

NRC Response: The staff chose 72 hours as the screening value where all issues of less than 72 hours would automatically screen to Green, recognizing that additional evaluation would be performed in Appendix M in the event the finding does not

automatically screen due to a total loss of function. Requiring an Appendix M evaluation does not imply that the issue is greater-than-Green, only that it doesn't automatically screen to Green.

c) NEI Comment: WOULD: The use of the word "would" ("…that would result in…") is speculative, imprecise and subjective. This appears contrary to the principles of good regulation. How will the NRC minimize or eliminate the problem of defining and interpreting this key term?

NRC Response: The use of the word "would" is consistent with other SDP documents. The word implies that there is strong evidence through inspection that there is a clear nexus between the performance deficiency and the loss of the system function.

d) NEI Comment: NOTE: In the Note below Question 2, the words "there are" can be deleted: "In situations where there are multiple means…"

NRC Response: Agree. The redundant words "there are" were deleted in the approved document.

6. Section 4.0, "Guidance", page 3, Question 3: "Does the inspection finding involve procedures and/or training for Mitigating Strategies that would result in the complete loss of one or more functions needed to maintain or restore core cooling, containment pressure control/heat removal and/or spent fuel pooling cooling capabilities?"

a) NEI Comment: BASIS: What is the basis for this question? If an equipment problem results in loss of function but it can be corrected in less than 72 hours, Appendix O would not direct the user to Appendix M. On the contrary, if a procedure problem results in loss of function, even if it can be corrected in less than 72 hours, Appendix O would direct the user to Appendix M. What is the basis for this differing treatment of equipment problems versus procedure problems corrected within 72 hours?

NRC Response: If the inspection finding is reasonably determined to be the proximate cause of a degraded Mitigating Strategies procedure(s) and/or training condition that could result in the complete loss of one or more functions needed to maintain or restore core cooling, containment pressure control/heat removal, and/or spent fuel pooling cooling capabilities, the finding should not automatically screen to Green and should be further evaluated using Appendix M.

A degraded Mitigating Strategies procedure(s) and/or training finding will screen as very low safety significance (Green) if there is some loss of capability or minor delay in implementation but the inspector determines the function is preserved. For example, if the specific operator training is insufficient, but the procedures are adequate to reasonably ensure that the task could be completed in the required time to provide for

core cooling, containment pressure/heat removal, or spent fuel pool cooling, the finding will screen to Green.

However, due to the complex and fast moving nature of the circumstances surrounding Mitigating Strategies and the high potential for extremely high stressful conditions for the plant staff, the quality of both procedures and training is critical. When evaluating human error probabilities for such complex and stressful conditions, a number of factors are considered. These factors (environment, stress, procedure quality, targeted training, time available to take the actions(s), etc.) weigh significantly towards the successful outcome of both diagnosing the situation and the ensuing actions taken. Therefore, if the inspector concludes that the deficient procedure(s) and training could have a significant impact on the licensee's response to the external hazards potentially resulting in a loss of function to maintain or restore core cooling, containment pressure control/heat removal and/or spent fuel pooling cooling capabilities, it is appropriate to not automatically screen to Green and to further evaluate the significance of the inspection finding using Appendix M.

Retaining Question 3 is important because: (1) it stresses the importance of high quality procedures and training as it relates to a robust defense-in-depth towards Mitigating Strategies; (2) it gives the NRC a focused specific area of regulatory oversight with specificity for assessment; and (3) deficient procedures and training that could cause a loss of the specified functions to cool the core the containment and spent fuel pool could indicate more systemic licensee performance.

Exposure time was excluded from the question since performance deficiencies for procedures and training tend to exist for longer periods and time (i.e., greater than one year).

b) NEI Comment: WOULD: The use of the word "would" ("…that would result in…") is speculative, imprecise and subjective. This appears contrary to the principles of good regulation. How will the NRC minimize or eliminate the problem of defining and interpreting this key term?

NRC Response: The use of the word "would" is consistent with other SDP documents. The word implies that there is strong evidence through inspection that there is a clear nexus between the performance deficiency and the loss of the system function.

7. Section 4.0, "Guidance", page 3, Question 4: "Is the inspection finding associated with a licensee facility that has a documented (e.g., FSAR, IPEEE, or other licensee external hazard analysis paper) external event hazard initiating event frequency greater than 1E-6 per year?"

a) NEI Comment: BASIS FOR 1E-6: What is the basis for the threshold value of 1E-6 per year? At some sites, BDB external event frequencies are greater than the 1E-6 threshold value. For them, this question would throw all findings over to Appendix M.

NRC Response: If the inspection finding is reasonably determined to be (1) the proximate cause of a degraded Mitigating Strategies, and (2) there is prior knowledge that an associated initiating event frequency (IEF) is larger than one in a million (1E-6) per year, and (3) the product of the IEF and the performance deficiency's exposure time

is greater than one in a million (1E-6), then the finding should not automatically screen to Green and instead should be evaluated using Appendix M.

With an IEF greater than 1E-6, there is the potential that a quantitative evaluation will calculate a delta core damage frequency of greater than 1E-6 and thus yield a greater-than-Green result. This question requires multiplying the IEF by the performance deficiency's exposure time. The exposure time is defined as the duration period of the failed or degraded structure, system, or component (SSC) being assessed that is reasonably known to have existed (see the RASP Handbook Volume 1 for a detailed discussion of the exposure time).

Though it is expected that most beyond design basis external events (BDBEE) for which the Mitigating Strategies are intended to protect against are rare, this is not always the case. For example, there are documented cases of design basis floods with frequencies as high as about 1.3E-4 per year. Thus, an inspection finding pertaining to a beyond design basis flood could easily have a frequency of 1E-4 per year. With a frequency larger than 1.E-6 per year, a performance deficiency which degrades a plant's capability but not defeat the entire capability to perform a safety function could possibly lead to a greater-than-Green finding.

8. Section 4.0, "Guidance", page 3, Question 5: "Does the finding involve significant programmatic issues in two or more of the following areas such that implementation of the Mitigating Strategies Program would be unsuccessful: (1) equipment monitoring and/or reliability; (2) procedures used for Mitigating Strategies; (3) training developed/implemented for Mitigating Strategies?"

a) NEI Comment: BASIS: What is the basis for this question? Why is two programmatic areas the right threshold?

NRC Response: The evaluation of the "programmatic" aspects of licensee response to Mitigating Strategies is appropriate, particularly in the very early stages of licensee response to Mitigating Strategies while implementation lessons are being learned. The chosen areas of focus were selected from NEI 12-06. Two or more areas was chosen as a reasonable indication of a reduction of the effectiveness of the overall program.

Note – the use of the term "program" does not refer to a specific program, per se, that is required for Mitigating Strategies. Rather, consistent with NEI 12-06, it indicates that response to Order EA-12-049 involves a large number of areas that need to be considered for a successful and robust response to the Order.

b) NEI Comment: QUESTIONS 5 vs. 2 & 3: In practice, what would Question 5 capture that Questions 2 and 3 would not?

NRC Response: The screening significance threshold for Questions 2 and 3 is higher than for Question 5 since Questions 2 and 3 address specifics areas (i.e., FLEX

equipment, procedures, and training). Questions 5 is intended to capture lower level programmatic issues that collectively reduce the effectiveness of the licensee response to Order EA-12-049.

c) NEI Comment: PROGRAM: To what does the proper noun "Mitigating Strategies Program" refer? Is this intended to apply to the Final Integrated Plan, just Mitigating Strategies, or something else that comprises a recognizable "program"? Or is the word "programmatic" intended to be a synonym of "systematic" or "pervasive" without reference to a specific plant program?

NRC Response: The term "programmatic" is used more loosely referring to the programmatic controls of the licensee response to the Order EA-12-049, consistent with NEI 12-06. The mention of programmatic issues is not intended to mean that a specific program is in place.

d) NEI Comment: WOULD: The use of the word "would" ("…that would result in…") is speculative, imprecise and subjective. This appears contrary to the principles of good regulation. How will the NRC minimize or eliminate the problem of defining and interpreting this key term?

NRC Response: The use of the word "would" is consistent with other SDP documents. The word implies that there is strong evidence through inspection that there is a clear nexus between the performance deficiency and the loss of the system function.

e) NEI Comment: EXPOSURE: The wording of Question 5 makes no mention of exposure time. Why not?

NRC Response: Exposure time was judged by the staff as being unwarranted since typically programmatic control issues tend to be long standing (i.e., over a year).