

August 9, 2016

Mr. Anthony Pietrangelo
Senior Vice President and Chief Nuclear Officer
Nuclear Energy Institute
1201 F Street, NW, Suite 1100
Washington, DC 20004

Dear Mr. Pietrangelo:

On December 3, 2015, the Nuclear Energy Institute (NEI) transmitted two white papers entitled “Qualitative Assessment for Crediting Mitigating Strategies Equipment in Risk-Informed Decision Making” (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15337A103), and “Streamlined Approach for Crediting FLEX in Risk-Informed Decision Making” (ADAMS Accession No. ML15337A105), for U.S. Nuclear Regulatory Commission (NRC) staff consideration. The stated purpose of the first white paper “is to establish the considerations that should be assessed when evaluating the qualitative risk and safety benefit of Mitigating Strategies Equipment in Risk Informed Decision Making (RIDM).” The stated purpose of the second white paper “is to establish a streamlined approach for crediting FLEX in regulatory activities (e.g., SDPs [Significance Determination Processes], NOEDs [Notices of Enforcement Discretion], Recommendation 2.1 SPRAs [Seismic Probabilistic Risk Assessments], etc.). The second white paper also states that “The semi-quantitative treatment described here is intended to provide an initial framework for near-term decision making and is intended to provide a foundation for the longer term solution of developing consensus guidance for direct implementation in PRA [probabilistic risk assessment] models.” After receiving the white papers, NRC staff held a public teleconference on January 21, 2016, to discuss the initial reaction of NRC staff to the white papers (ADAMS Accession No. ML16033A533). During that call, NEI further clarified the scope and intent of the white papers. Specifically, NEI informed the staff that:

- (a) the white papers do not apply to RIDM processes that involve addressing the NRC guidance provided in Regulatory Guide (RG) 1.200, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities” (e.g., quantitative assessments in support of risk-informed licensing actions); and
- (b) the white papers are intended to provide high-level guidance to licensees on how to seek risk-informed credit within a wide spectrum of regulatory processes where NRC uses risk-insights in regulatory decisionmaking.

The Office of Nuclear Reactor Regulation (NRR) staff received comments from NRC staff from the regions, Office of Nuclear Regulatory Research, Office of New Reactors, and various divisions within NRR. The staff updated NEI on the status of NRC staff review of the white papers during a public meeting on February 9, 2016.

On March 16, 2016, NRC staff held a public meeting with stakeholders to discuss comments on the white papers (ADAMS Accession No. ML16104A359). Subsequent to that meeting, on

May 9, 2016, NEI transmitted two revised white papers now entitled “Qualitative Assessment for Crediting Portable Equipment in Risk-Informed Decision Making” (ADAMS Accession No. ML16138A018), and “Streamlined Approach for Crediting Portable Equipment in Risk-Informed Decision Making” (ADAMS Accession No. ML16138A017). The NRC staff has reviewed the revised white papers and concluded that NEI has identified the major areas to be analyzed when seeking credit. This includes topics such as feasibility in the scenario of interest; equipment availability, reliability, and deployment capability; adequacy of time margin; effectiveness of command and control; and environmental conditions. The NRC staff also agrees with NEI that the white paper titled “Streamlined Approach for Crediting Portable Equipment in Risk-Informed Decision Making” would not be applicable to RIDM processes that involve addressing the NRC guidance provided in RG 1.200 (e.g., quantitative assessments in support of risk-informed licensing applications).

We greatly appreciate industry’s efforts to develop quality products to advance the effort to apply appropriate credit for FLEX equipment. As submitted, these documents do not fall within one of the defined processes for NRC endorsement or approval for use. The staff believes that the white papers transmitted on May 9, 2016, provide appropriate high-level guidance to licensees on a process to seek credit in various RIDM processes when they are used in accordance with the application-specific guidance that NRC staff has developed or endorsed. If NEI desires a detailed staff evaluation of these documents, NEI should submit the guidance within the constraints of a defined review process (such as a topical report in accordance with LIC-500, “Processing Requests for Reviews of Topical Reports”). NEI should submit such a request for the review to the document control desk with a reference to an approved charge code for billing purposes. Alternatively, NEI can request an exemption from review fees, in accordance with the appropriate provisions of Title 10 of the *Code of Federal Regulations* paragraph 170.11(a).

As you are aware, the NRC is already allowing credit for mitigating strategies equipment on an ad-hoc basis for certain applications. Therefore, the white papers will help guide licensees to perform more consistent assessments and provide the NRC pertinent information when seeking credit. The following list highlights several areas in which the NRC staff may focus their attention during reviews when licensees utilize the white papers for providing credit in RIDM areas as these are areas that were not fully addressed in the white papers:

- Licensees should ensure that the use of the base failure probability is evaluated, as appropriate, for the applicable scenarios of interest.
- Time margin calculations need to indicate appropriate margin to account for uncertainties in equipment deployment.
- Equipment reliability data and testing protocols should be considered when assessing the equipment availability attribute.
- The effects of possible diagnosis errors need to be analyzed for the applicable scenarios.

NRC is treating the NEI documents submitted as informational and plans to use elements of these documents in support of the development or revision of application-specific guidance for

RIDM areas. Currently, staff is in the process of evaluating revisions to NRC guidance for performing risk assessments for the SDP, Accident Sequence Precursor, and incident evaluation program (NRC Management Directive 8.3, "NRC Incident Investigation Program"). NRC staff is also evaluating program documentation to determine what changes or additional guidance documents are necessary to provide NRC staff appropriate guidance to support crediting of FLEX within the programs of interest (e.g., Inspection Manual Chapter (IMC)-0410 for NOEDs). We plan to continue a high focus on this issue, including continuing efforts through the oversight and direction of the NRC's Risk Informed Steering Committee and our interaction with industry's counterpart committee.

If you or your staff have any questions, please contact Mr. Alexander Schwab at (301) 415-8539 or via e-mail at alexander.schwab@nrc.gov.

Sincerely,

/ra/

William M. Dean, Director
Office of Nuclear Reactor Regulation

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William M. Dean, Director
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