



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

May 3, 2017

Mr. Greg Krueger,
Director, Risk Regulation
Nuclear Energy Institute
1201 F St. NW, Suite 1100
Washington, DC 20006

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION ACCEPTANCE ON NUCLEAR ENERGY INSTITUTE APPENDIX X TO GUIDANCE 05-04, 07-12, AND 12-13, CLOSE-OUT OF FACTS AND OBSERVATIONS (F&Os)

Dear Mr. Krueger:

By letter dated February 21, 2017 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML17086A431), the Nuclear Energy Institute (NEI) submitted to the Nuclear Regulatory Commission (NRC) Appendix X to NEI 05-04, NEI 07-12 and NEI 12-13, "*Close-out of Facts and Observations*" (F&Os). The letter requested NRC staff review and endorsement of the guidance for a licensee's use to close F&Os that were generated during a peer review process.

NEI transmitted the draft of Appendix X for NRC staff review on February 8, 2016 (ADAMS Accession No. ML16158A032). Since that time, the staff has held several public meetings (ADAMS Accession Nos. ML16082A527, ML16159A027, ML16251A234, ML17018A428, ML16355A051, ML16152A020, and ML17079A036), developed staff expectations (ADAMS Accession No. ML17121A271), performed observations at three industry pilot implementations of the guidance, and audited two of the pilots' final independent assessment reports (ADAMS Accession No. ML17095A252). NEI performed several updates to the draft guidance submitted on February 8, 2016 (ADAMS Accession No. ML16158A032), in response to feedback received from NRC staff during the multiple interactions to prepare the final version of the guidance (ADAMS Accession No. ML17086A431).

The NRC staff finds the process proposed in Appendix X acceptable for the following reasons:

- The NRC staff and a contractor observed three pilot independent assessments performed by two host utilities and audited two of the pilots' final independent assessment reports. The NRC staff assessed the implementation of the process and determined that it supported a systematic, defensible, and documented evaluation for licensee closure of F&Os to support future use in regulatory risk-informed decisionmaking (ADAMS Accession No. ML17095A252).

- The NRC staff determined that the process proposed is consistent with NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants,” Chapter 19.1, “Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities” and the memorandum, “Staff Expectations for an Industry Facts and Observations Independent Assessment Process” (ADAMS Accession No. ML17121A271) for the staff’s determination of the acceptability of a licensee’s probabilistic risk assessment (PRA) for use in regulatory risk-informed decisionmaking.

The NRC has not officially endorsed the guidance in Appendix X, but plans to consider it as part of the upcoming revision to Regulatory Guide 1.200 (estimated notice for public comments 2018 and publication 2019). Licensees may use this guidance on an interim basis. Any aspects of the NRC’s ultimate endorsement of the NEI guidance that were not set forth in this letter do not constitute backfitting. This determination is subject to the licensee’s utilization of the following conditions of acceptance:

- A PRA method is new if it has not been reviewed by the NRC staff. There are two ways new methods are considered accepted by the NRC staff: (1) they have been explicitly accepted by the NRC (i.e., they have been reviewed, and the acceptance has been documented in a safety evaluation, frequently-asked-questions, or other publicly available organizational endorsement), or (2) they have been implicitly accepted by the NRC (i.e., there has been no documented denial) in multiple risk-informed licensing applications. The NRC’s treatment of a new PRA method for closure of F&Os is described in the memorandum “U.S. Nuclear Regulatory Commission Staff Expectations for an Industry Facts and Observations Independent Assessment Process,” dated May 1, 2017 (ADAMS Accession No. ML17121A271).
- In order for the NRC to consider the F&Os closed so that they need not be provided in submissions of future risk-informed licensing applications, the licensee should adhere to the guidance in Appendix X in its entirety. Following the Appendix X guidance will reinforce the NRC staff’s confidence in the F&O closure process and potentially obviate the need for a more in-depth review.

The staff recognizes that the definition of a new PRA method is currently being assessed separately by the industry and NRC staff in development of guidance (i.e., NEI 16-04) which is intended to establish a process for the evaluation of new methods. This definition, once finalized, will supersede the definition provided above. To ensure that the PRA is acceptable for future risk-informed licensing actions, the NRC staff expectations memorandum provides further guidance that the licensee should consider in assessing if closure of an F&O involves either a new method or constitutes a model upgrade.

The NRC also intends to periodically conduct audits of a licensee’s implementation of the Appendix X F&O closure process, as well as review a sampling of the final independent assessment team reports. The purpose of the audits is to further NRC confidence in the independent assessment process for closure of F&Os and to provide continued monitoring and oversight of PRA acceptability.

This F&O closure process is intended to be added as an appendix to the various NEI peer-reviewed guidance documents (i.e., NEI 05-04, 07-12, and 12-13).

The NRC staff recommends that NEI create a single document and incorporate Appendix X into the document. Incorporation of the governing peer review processes into one singular document will improve the effectiveness and efficiency to support future revisions and endorsements requested, reduce confusion on the part of peer reviewers and other document reviewers, and ensure consistent guidance for all types of peer reviews.

The NRC looks forward to continuing to work with the industry on fostering an environment conducive to achieving the full benefit of risk-informed regulation.

Please contact Stacey Rosenberg, Chief of the PRA Licensing Branch, at 301-415-2357 if you have any questions.

Sincerely,

Joseph Giitter, Director */RA/*
Division of Risk Assessment
Office of Nuclear Reactor Regulation

Mary Jane Ross-Lee, Director (Acting) */RA/*
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

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