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June 14, 2018

Mr. Michael Franovich
Director, Division of Risk Assessment
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Withdrawal of Request for Review of NEI 16-04, *New PRA Method Evaluation Process Guidelines*

Project Number: 689

Dear Mr. Franovich:

On October 20, 2016, NEI¹ requested a fee waiver for the review and pilot of NEI 16-04, *New PRA Method Evaluation Process Guidelines*, which was subsequently granted by the NRC on April 5, 2017. When NEI 16-04 was written, the intention was to address the NRC staff's interest in increasing familiarity with new methods and data that licensees would use in their PRAs, prior to the application of these methods. The goal of this familiarization was to improve efficiency in the licensing and inspection processes associated with risk-informed regulation. Discussions with NRC regarding NEI 16-04, and risk-informed licensing reviews in general, have been inconsistent with this goal; as outlined in this letter, NEI is withdrawing our request for the review of this document.

NEI fully agrees that the NRC has the ability and duty to review information related to licensee PRAs as used to support risk-informed licensing applications, and to subsequently inspect PRA-related information to ensure public health and safety. We take no issue with the established regulatory guidance on the topic, all of which was developed as part of an open and deliberate public process with full stakeholder participation. The existing regulatory guidance on risk-informed licensing applications supports use of the NRC-endorse PRA peer review process to accomplish this, and NEI supports conducting reviews in alignment with existing regulatory guidance to provide for efficient licensing reviews that support NRC's mission.

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¹ The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

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However, over the past several years, practices have departed from the process outlined in existing regulatory guidance, such that the NRC staff has periodically asserted that only PRA methods accepted or approved by the NRC may be used in licensee PRAs supporting risk-informed licensing applications. Further, during public meetings regarding the pilot of NEI 16-04, it became clear that the NRC staff interpreted the purpose of this document to be a means to support NRC staff approval or acceptance of methods and data to be used in licensee PRAs. This interpretation is inconsistent with this guidance document, and is further inconsistent with existing regulations and regulatory guidance. We are therefore withdrawing our request for the review of this document, and suggest that existing regulatory guidance be followed in risk-informed licensing reviews, as outlined below.

Lack of Regulatory Basis for NRC Approval of PRA Methods

There is no stated requirement or expectation that the NRC approve or accept any individual methods used in a licensee's PRA in existing regulatory requirements or regulatory guidance for risk-informed regulation in general. Given that there is no regulatory requirement for reactors operating under 10 CFR 50 to develop, use, or maintain a PRA, there is no regulatory requirement compelling these licensees to seek NRC approval or acceptance of individual methods used in their PRAs.

Regulatory guidance, on the other hand, which addresses voluntary applications, does address expectations for the technical adequacy of PRAs supporting voluntary risk-informed licensing actions. Specifically, Regulatory Guide 1.174, *An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis*, which outlines expectations for risk-informed licensing applications, specifically states "[Regulatory Guide] RG 1.200 is an important related guidance document that describes one acceptable approach for determining whether the base PRA, in total or the parts that are used to support an application, is acceptable for use in regulatory decisionmaking for LWRs." In other words, there is no expectation that the NRC specifically approve individual methods used in licensee PRAs supporting risk-informed licensing applications, rather, application of the guidance in Regulatory Guide 1.200, *An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities*, is sufficient.

Regulatory Guide 1.200 itself gives additional detail regarding the evaluation of PRA technical adequacy. Section 3.3.1 states that "If the pieces of the PRA can be shown to have met the requirements of these documents, with attention paid to the NRC's objections, it can be assumed that the analysis is technically correct. Therefore, other than an audit, a detailed review by NRC staff of the base model PRA will not be necessary." Thus, a peer review against the ASME/ANS PRA Standard, following the industry peer review guidelines as endorsed by the NRC in Regulatory Guide 1.200, is sufficient for demonstrating PRA technical adequacy.

The Standard Review Plan, in 19.3-1, additionally counters the concept that licensees PRA methods need to be approved or accepted by the NRC, stating that, "The PRA elements are assessed to determine whether

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they have been performed in a technically correct manner that conforms to the NRC endorsed PRA standards. This can be determined by an assessment of whether the PRA elements are performed consistent with the standard and peer review process as endorsed in the appendices to RG 1.200." This again reinforces that in reviews of risk-informed licensing applications, a licensee's evaluation using Regulatory Guide 1.200 is sufficient to support a review.

Although regulatory guidance does not support the NRC staff's interpretation of the necessity for approval of individual methods used in licensee PRAs, this misconception has persisted, largely because of misunderstandings associated with the specific requirements for PRA technical adequacy relative to two programs: Risk Informed Tech Spec Completion Times (TSTF-505) and Risk-Informed, Performance-Based Fire Protection (NFPA 805, *Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants*). However, neither of these programs call for NRC approval or acceptance of individual methods or data to be used in a licensee's PRA.

PRA Requirements for NFPA 805

NFPA 805 includes a statement in section 4.4.5.3 that "The PSA [Probabilistic Safety Assessment] approach, methods, and data shall be acceptable to the AHJ [Authority Having Jurisdiction]." In NFPA codes and standards, the concept of a method that is "acceptable to the AHJ" is used to indicate that the relevant regulatory body – in this case, the NRC – approves of the general approach to be used. For example, in permitting occupancy of buildings for federal workers, the regional General Services Administration (GSA) fire protection engineer (the AHJ), may accept the use of NFPA 25, *Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, for sprinkler testing for a given facility. It does not, however, mean that the regional GSA fire protection engineer individually reviews and accepts every action undertaken as part of sprinkler testing in a given facility, simply that the testing is acceptable if done in accordance with NFPA 25.

An analogous interpretation for implementation of NFPA 805 would be use of the ASME/ANS PRA Standard, as endorsed in Regulatory Guide 1.200, to evaluate the acceptability of a licensee's PRA via the peer review process, also endorsed in Regulatory Guide 1.200. In fact, during several ACRS subcommittee meetings regarding the regulatory guidance for NFPA 805, the NRC staff stated such as their interpretation of "acceptable to the AHJ" for methods to be used in PRAs. There is therefore no need for licensees to obtain NRC approval or acceptance of methods to be used in their PRAs supporting NFPA 805 programs.

PRA Requirements for TSTF-505

TSTF-505, based on NEI 06-09, *Risk Managed Technical Specifications (RMTS) Guidelines*, involves use of a licensee's PRA to manage technical specification allowed outage times. The safety evaluation for NEI 06-09 made note of the high expectations for the technical adequacy of PRAs supporting this program, and the

industry fully supports these expectations. In the NEI 06-09 safety evaluation (ML12286A322), the license condition related to the need for a new LAR in light of the use of a new PRA is as follows:

As part of its review and approval of a licensee's application requesting to implement the RMTS, the NRC staff intends to impose a license condition that will explicitly address the scope of the PRA and non-PRA methods approved by the NRC staff for use in the plant-specific RMTS program. If a licensee wishes to change its methods, and the change is outside the bounds of the license condition, the licensee will need NRC approval, via a license amendment, of the implementation of the new method in its RMTS program. The focus of the NRC staff's review and approval will be on the technical adequacy of the methodology and analyses relied upon for the RMTS application.

In stating "PRA and non-PRA methods approved by the NRC staff for use in the plant-specific RMTS program," it is clear that the authors of the safety evaluation intended that, in this context, "method" refers to the analysis approach (PRA or non-PRA) that a licensee uses to evaluate a hazard. The safety evaluation further states:

TR NEI 06-09, Revision 0, permits the use of either PRA or non-PRA type quantitative evaluations, including conservative or bounding methods, to assess risk of these events and conditions. The specific method to be utilized in the RMTS program would be identified and technically justified by the licensee in its plant-specific application to implement the RMTS, and would be reviewed and approved by the NRC staff in a license amendment implementing the RMTS.

The use of the term "conservative or bounding methods" as an example of non-PRA methods also indicates that the intent of the safety evaluation is that "method" in the context of the referenced license condition refers to the analysis approach used to evaluate a hazard.

NEI 06-09 itself offers additional insight into what was intended when the term method is used in the context of the proposed license condition in the safety evaluation, stating in the executive summary that:

Quantification of risk due to internal fire and other significant external events is also necessary for this application, through PRA or bounding methods.

In using the phrase "PRA or bounding methods," the term "methods" means "technical approach to addressing a hazard" – in other words, PRA or non-PRA approaches. NEI 06-09 uses "methods" in this context in several locations, including in Section 2.3.4 on PRA technical adequacy.

The scope of the PRA model shall include Level 1 (CDF) plus large early release frequency (LERF). In addition, RICT and RMAT calculations shall include contributions from external events, internal flooding events, and internal fire events. Inclusion of these factors within the PRA is not explicitly

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required provided alternate methods (e.g., conservative or bounding analyses) are used to accomplish this requirement.

As the staff did not take exception to either of these portions of NEI 06-09, the repeated use of the concept of "PRA and non-PRA methods," as used in the description of the suggested license condition in the safety evaluation, indicates that the intention is that a new LAR would be called for when a new technical approach is used to model a specific hazard (e.g. seismic, high winds).

Path Forward for Treatment of PRA Technical Adequacy in Risk-Informed Licensing Applications

The regulatory guides, safety evaluations, and other staff endorsements referenced above were conducted in a deliberate manner, consistent with the NRC's policies and procedures, and were determined to adequately protect public health and safety in the implementation of these programs. None of this durable regulatory guidance calls for NRC staff approval or acceptance of PRA methods, and instead points to NRC staff review and observation of the results of the NEI PRA peer review process.

NEI continues to welcome NRC staff observation of any portion of the peer review process, and further encourages continued scrutiny of the peer review results themselves. To add an additional regulatory expectation on top of the stated guidelines, specifically, adding a review of PRA methods without regulatory basis, is not the most effective use of the NRC's resources in protecting public health and safety. We are therefore withdrawing NEI 16-04 for endorsement, and additionally request that the NRC work with licensees to establish a mutual understanding of how treatment of PRA technical adequacy will proceed in the future, based on durable regulatory guidance. The upcoming June 18 public meeting on treatment of PRA methods in TSTF-505 applications is one venue for this discussion, and we welcome follow-on public meetings as necessary to achieve this mutual understanding.

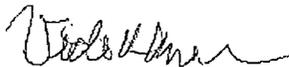
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Should you have any questions regarding this letter, please contact me (202-247-1669, vka@nei.org).

Sincerely,



Victoria K. Anderson

c: Mr. Brian Holian, NRR
Mr. Michael Weber, RES
Mr. Michael Check, RES
Mr. Russell Felts, NRR
Mr. Sunil Weerakkody, NRR
Ms. Stacey Rosenberg, NRR
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