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May 22, 2025

Michael F. King Acting Director Office of Nuclear Reactor Regulation U.S. Nuclear Regulatory Commission Washington, DC 20555-0001

**Subject**: Request for Endorsement and Fee Exemption for NEI 22-04, Revision 0: "Utilization of ISO 9001 and Other Non-nuclear Suppliers for Safety-related Applications"

## **Project Number: 689**

Dear Mr. King:

On behalf of its members, the Nuclear Energy Institute (NEI)<sup>1</sup> submits for NRC review and endorsement the attached report NEI 22-04, Revision 0, titled *"Utilization of ISO 9001 and Other Non-nuclear Suppliers for Safety-related Applications."* Developed collaboratively with NEI member companies, this document proposes an approach to enable purchasers with Appendix B-compliant quality programs to procure and control nuclear components from suppliers with ISO 9001:2015 quality programs. This guidance also establishes the process that could be applied to other industry-specific non-nuclear QA standards, such as oil, gas, and chemical industries. This guidance is intended to be an additional option alongside the use of ASME NQA-1 and Commercial Grade Dedication (Regulatory Guide 1.164) to ensure a robust and high-quality supply chain for safety-related components.

As the demand for advanced reactors, uprates to the existing fleet, and potential plant restarts continues to grow, the industry faces a critical shortage of ASME NQA-1 qualified suppliers. While the commercial grade dedication (CGD) process has enabled use of ISO 9001 suppliers, the increasing demand for nuclear-grade components needs an option for a more direct and scalable path for suppliers with commercial quality programs to participate.

NEI 22-04 provides such a path. It outlines a structured approach—including supplier screening, gap assessments, and supplemental controls—that enables suppliers with commercial quality programs to meet the requirements of Appendix B. Importantly, this approach aligns with the NRC's prior findings in SECY-03-0117, which recognized that ISO 9001-based programs can meet NRC expectations with targeted enhancements.

<sup>&</sup>lt;sup>1</sup> 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.

NEI respectfully requests that the NRC review and endorse NEI 22-04, Revision 0, and that all associated review activities, including meetings and supplemental submittals, be granted a fee waiver pursuant to 10 CFR 170.11(a)(1)(ii). This guidance supports generic regulatory improvements by enabling consistent application of NRC QA requirements to a broader supplier base and will aid the NRC's efforts to build a robust, future-ready regulatory framework for advanced reactor deployment.

The report also supports the goals of the ADVANCE Act and the 2023 amendments to the National Environmental Policy Act (NEPA), which call for timely and efficient regulatory review and deployment of nuclear technologies. Endorsing NEI 22-04 would:

- Provide a predictable regulatory path for suppliers with commercial quality programs;
- Advance the NRC's objectives for regulatory clarity and efficiency;
- Support the supply chain expansion necessary for new reactor deployment.

NEI and its members stand ready to support NRC staff throughout the review. We are available to provide additional information or revise the document as needed. The report will be made available at no cost.

Please contact me, or Mark Richter at mar@nei.org or 202-439-0954, with any questions.

Thank you for your consideration.

Sincerely,

Marcus Nichol

Executive Director, New Nuclear

## Attachment

c: Mirela Gavrilas, Executive Director for Operations Gregory Bowman, Deputy Director for New Reactor's Michael Franovich, Director, Division of Risk Assessment, NRR Russell Felts, Director, NRR/DRO Jeremy Bowen, Deputy Director Michele Sampson, Director for Division of New and Renewed Licenses