ASME
SETTING THE STANDARD
STANDARDS & CERTIFICATION

Two Park Avenue
New York, NY
10016-5990 U.S.A.

tel 1.212.591.8500
www.asme.org

September 2, 2025

Mr. Gregory Bowman

Acting Director, Office of Nuclear Reactor Regulation

U.S. Nuclear Regulatory Commission

Washington, DC 20555-0001

Subject: Preserving Nuclear Safety Through Continued Use of ASME NQA-1 for Safety-related Applications: A response to NEI 22-04

Dear Mr. Bowman,

On behalf of the ASME NQA Standards Committee, we are writing to respectfully oppose the endorsement of NEI 22-04, Utilization of ISO 9001 and Other Non-Nuclear Suppliers for Safety-Related Applications, recently submitted to the U.S. Nuclear Regulatory Commission (NRC) by the Nuclear Energy Institute (NEI) (ADAMS Accession number ML25171A135). While we understand and acknowledge the challenges the nuclear industry faces in expanding the supply chain and improving efficiency, NEI 22-04's approach would undermine the foundational safety framework that has long underpinned the nuclear sector's success and public trust.

The ASME NQA-1 standard exists to address the unique, safety-critical nature of nuclear operations. Rooted in 10 CFR 50 Appendix B and 10 CFR Part 21, it is the only consensus-based quality assurance (QA) standard rigorously designed for the nuclear industry and, with its predecessors, has been successfully used for over 50 years. It was developed through a balanced, consensus process with input from diverse stakeholders, ensuring that no single interest dominates its evolution. Unlike ISO 9001, which provides a general framework for quality management across industries, NQA-1 directly links quality processes to nuclear safety and imposes stricter requirements for activities such as design verification, procurement controls, training, audits, and nonconformance resolution.

NEI 22-04 proposes a significant shift from a safety-based QA model to a commercial framework that prioritizes flexibility and efficiency, potentially at the expense of safety. This move could lead to weakened design control, less effective audits, compromised software and materials quality, and decreased personnel qualifications.

Furthermore, NEI 22-04 implies broad consensus and suggests applicability, which may lead to misinterpretation by vendors, licensees, and the public. The proposed use of ISO 9001 as an alternative compliance path to Appendix B overlooks the NRC's own past determination (SECY-03-0117) that ISO 9001 lacks sufficient rigor for safety-related applications unless extensively supplemented.

Nuclear energy is inherently high risk, and quality assurance must remain uncompromising. Endorsing NEI 22-04, or similar alternatives based on ISO 9001, would dilute the safety margins and set a troubling precedent. The solution to supply chain challenges is not to lower the bar, but to support broader adoption of existing high standards by making them more accessible without compromising safety.

We recognize that implementing NQA-1 may seem complex, particularly for new or non-traditional suppliers. However, its rigor reflects the significant consequences of failure in nuclear applications. The Committee recognizes the industry's needs and is actively pursuing: clear language revisions to the Standard, new guidance materials, expanded training resources, streamlined audits, and promotion of the graded approach already embedded in NQA-1.

ASME NQA Standard Committee Position on NEI 22-04

We respectfully urge the NRC to reject NEI 22-04 as an "alternative approach to meeting the requirements of 10 CFR 50 Appendix B".

If you have any questions concerning the contents of this letter, please direct them to Ms. Kathryn Hyam, ASME Director, Nuclear, Clean Energy and Standardization Codes and Standards by telephone at (212) 591-8704 or e-mail at hyamk@asme.org and Abena Dinizulu by telephone (212) 591-8017 or e-mail at dinizulua@asme.org.

Sincerely,

Kathryn Hyam, Director
Nuclear, Clean Energy, and Standardization
Codes and Standards
American Society of Mechanical Engineering
Email: hyamk@asme.org

cc: Officers, ASME Board on Nuclear, Clean Energy, Power, and Facilities Codes and Standards
BNCS Task Group on Regulatory Endorsement
Christina Araguas, NRC
Ms. Kerri Kavanagh, NRC
Mr. Marcus Nichol, NEI