

# NEI 22-04 Guidance for using ISO-9001 with additional controls to meet 10 CFR Part 50 Appendix B requirements

## NRIC-NEI-EPRI Nuclear Quality Assurance Challenges Workshop

Mark Richter  
Technical Advisor  
Nuclear Energy Institute  
Washington DC



December 5, 2024



# The Nuclear Supply Chain Today

## ■ Problem Statement

- Shrinking base of suppliers with ASME NQA-1 programs
- Growing demand for advanced reactors and supporting the operating fleet
- Seeking a more direct alternative path other than commercial grade dedication

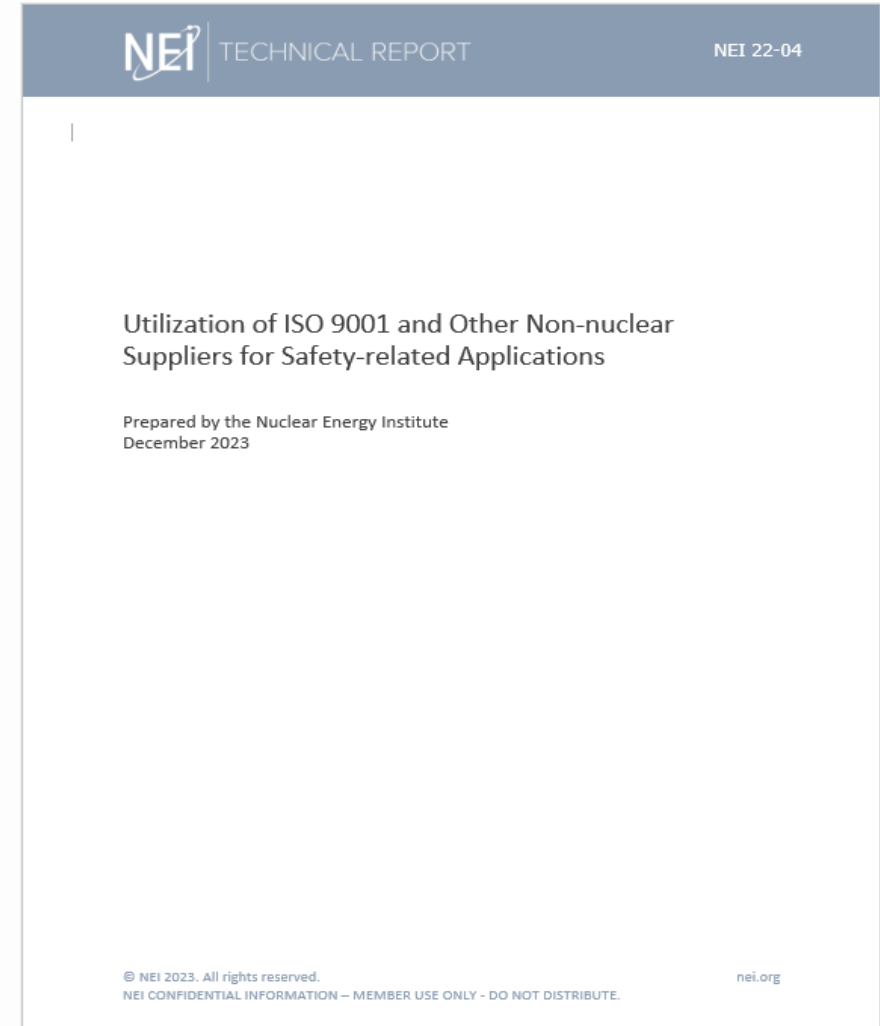
# Why focus on ISO 9001?

- Focus is **meeting customers requirements** (Appendix B)
- Adaptable to any industry with commensurate programmatic rigor
- Global population of suppliers with ISO 9001 programs
- ISO 9001 suppliers with robust QA programs supply reliable products of high quality to other industries
- Nuclear purchasers use ISO 9001 suppliers through commercial grade dedication
- U.S. suppliers competitive qualified to global quality assurance programs

# NEI 22-04



- Builds on SECY-03-0117 conclusion that ISO-9001 offers pathway to meet App. B
- AR Roadmap supply chain action
- Purchaser tool that includes:
  - Implementation process description including screening process for potential suppliers
  - Differences in requirements for ISO-9001 compliance with Appendix B
  - Purchaser identifies supplier controls and requirements for Appendix B compliance
  - Purchaser retains Part 21 compliance



# Benefits and Opportunities

- Risks of shortages, backlogs and higher costs are mitigated by providing market opportunities for new nuclear suppliers
  - Mitigates timeliness and capacity concerns
  - Some developers ready to issue RFPs/RFQs now
- Barriers to entry for new suppliers are minimized by avoiding the burden of developing and maintaining two quality programs
  - Alleviates reluctance to invest in new quality programs absent solid order book
  - Leverages experience base across industries using ISO-9001 with additional controls

# Benefits and Opportunities



- US industry becomes better aligned with the global marketplace in which it operates
  - Nuclear industry operates in a global marketplace. Our members operate in markets dominated by organizations utilizing ISO-9001 based quality programs
  - Prepares industry for future implementation of ISO-19443, the nuclear industry-specific version of ISO-9001 and addresses many of the gaps between ISO-9001 and 10 CFR Part 50 Appendix B.



# Risks and Concerns

- Challenges by nuclear opponents, as well as some in the industry and NRC, that this change could cause a reduction in overall quality
  - NRC accepted or proposed alternative approaches will be developed to ensure compliance with Appendix B
  - Increases competition and options for sourcing components enabling suppliers to differentiate themselves on their ability to deliver quality components. Purchasers often impose supplemental, industry-specific controls tailored to the specific safety requirements, including nuclear supplier applications
- Concerns by NQA-1 suppliers related to their N-Stamp certification based on the belief that NEI 22-04 will allow suppliers with ISO-9001 QA programs to produce N-Stamp components
  - It is a requirement for a Quality Program Certificate that an organization has a documented Quality Program meeting specified requirements in the ASME Section III, Subsection NCA (1), which references ASME NQA-1
  - Regardless of whether the NRC accepts ISO-9001, an N Certificate quality program must meet all requirements of Subsection NCA and all code requirements to be stamped

# Risks and Concerns

- Resistance based on historical practice and commitment to NQA-1, the diminished value of supplier investment in NQA-1, and assertions by some NQA-1 advocates that NEI is competing with ASME
  - NEI 22-04 will not diminish the need for NQA-1 suppliers and in the context of a growing industry, it will result in market benefits for all participants
  - NEI does not have a commercial interest or will derive any financial benefit through industry use of NEI 22-04. The guidance will be available for NEI members to potentially leverage new suppliers to meet their manufacturing and operational needs



# What's Next?

- Implement NEI Policy Process

- NEI is evaluating the potential pathway for using ISO-9001 to meet Appendix B requirements, including NEI 22-04
- NEI members' executive leadership insights inform pathway decisions

- Provides foundation for future options for ISO-9001/other commercial programs which may include:

- Reduced need for audits (e.g., taking credit for ISO, similar to NEI 14-05 for ISO-17025)
- Differences of quality outcomes? (Evaluate component performance by making identical part from NEI 22-04 and NQA-1 App. B programs to validate equivalence)
- Enhancements to NRC requirements to allow more flexibility (based on positive experience with using NEI 22-04)

Questions?  
[mar@nei.org](mailto:mar@nei.org)