



NRC's Recognition of the American Society of Mechanical Engineer's Conformity Assessment Process

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Agenda

- NRC's Participation on Consensus Codes & Standards
- What is ASME Conformity Assessment?
- Let's Go Back in Time...to the 1980s!
- Information Notice 86-21 and its Supplements
- Summary & Closing Thoughts

NRC's Participation on Consensus Codes & Standards

- The NRC has been an active participant in the development and use of consensus codes and standards since its creation in 1974.
- Consensus codes and standards promote the safe operation of nuclear power plants and improve the effectiveness and efficiency of the regulatory oversight.
- Federal law requires agencies to use technical standards developed by voluntary consensus standards bodies and participate in their development vs. developing their own.

NRC's Participation on Consensus Codes & Standards

- The NRC staff participates on consensus codes and standards development committees along with other stakeholders.
- Codes and standards are developed based on a consensus process with input from all stakeholders.
- The NRC staff reviews codes and standards for possible endorsement in regulatory documents.

ASME Conformity Assessment

- What is ASME's Conformity Assessment?
 - The recognition of a company's or individual's capability to fulfill the requirements of an ASME standard to advance public safety and facilitate international commerce.
- How does conformity assessment relate to Appendix B to 10 CFR Part 50?
 - Licensees issue purchase orders for safety-related components or services that invoke the Quality Assurance (QA) requirements of Appendix B to 10 CFR Part 50.
 - Licensees will then perform an audit of its suppliers to ensure compliance with the QA requirements of Appendix B to 10 CFR Part 50.
- How did the NRC recognize ASME's Conformity Assessment process?

Let's Go Back in Time...to the 1980s!

- March 1981 - The NRC, ASME, and the National Board of Boiler and Pressure Vessel Inspectors (NB) signed an “Exchange of Correspondence.”
- This document outlined an agreement, with conditions, to work toward establishing:
 - A single set of quality requirements; and
 - Recognition by the NRC of ASME’s accreditation program.

Let's Go Back in Time...to the 1980s!

- The NRC had incorporated portions of the ASME Code into 10 CFR 50.55a, “Codes and Standards,” except for complete recognition of ASME’s accreditation program and stamping.
- Several U.S. states had passed laws requiring overall construction of components and systems be performed in accordance with Section III of the ASME Code (Divisions 1 and 2).

Let's Go Back in Time...to the 1980s!

- The overlapping of similar functions resulted in separate audits, surveys, and inspections to the same suppliers of nuclear equipment.
- This caused a duplication of efforts in the evaluation and inspection of the suppliers' QA programs.
- An effort began to develop a program to establish compatible QA requirements in the interest of efficiency and greater effectiveness in assuring the ultimate safety of nuclear power plants.

Let's Go Back in Time...to the 1980s!

- The goal of the program was to establish conditions that would allow for the NRC's recognition and utilization of the ASME/NB system of nuclear accreditation and 3rd party inspection.
- Some of the conditions included:
 - Allow the NRC staff to audit ASME & NB activities;
 - Maintain procedures for conducting and documenting the nuclear accreditation program; and
 - Use of the NQA-1 QA standard, supplemented by NRC positions in Regulatory Guides, as the basis for issuing Certificates of Authorization.

Let's Go Back in Time...to the 1980s!

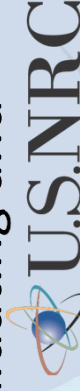
- December 1985 - The NRC, ASME, and NB agreed that based on the requirements contained in the 1986 Edition of the ASME Code, all the conditions in the “Exchange of Correspondence” had been met.
- The NRC’s recognition would allow licensees and applicants to satisfy NRC’s **programmatic QA requirements** related to the evaluation and inspection of a supplier’s QA program.
- The NRC’s recognition was documented in Information Notice (IN) 86-21, “Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders.”

Information Notice 86-21

- March 1986 - IN 86-21 documents the NRC's recognition of ASME's accreditation program as evidence the ASME Certificate Holder has a documented QA program that meets the requirements of Appendix B to 10 CFR Part 50.
- Recognition of ASME's accreditation program **only applies to the programmatic aspects** of the ASME Certificate Holders' QA programs.
- Licensees, applicants, and suppliers are still responsible for ensuring that their sub-suppliers are effectively implementing the approved QA program - Criterion VII of Appendix B to 10 CFR Part 50.

Information Notice 86-21, Supplement 1

- December 1986 - IN 86-21, Supplement 1, provided clarification for ASME Quality System Certificate (QSC) Holders.
- QSC Holders were excluded from recognition in IN 86-21 as they were not part of the “Exchange of Correspondence” between the NRC, ASME, and the NB.
- Licensees’ misinterpretation of this exclusion resulted in licensees removing QSC Holders from their Approved Suppliers List (ASL).
- If a licensee’s NRC-approved QA program allowed material organizations to be placed in the ASL based on a QSC, then this method for evaluating and selecting vendors is not affected by the issuance of IN 86-21.



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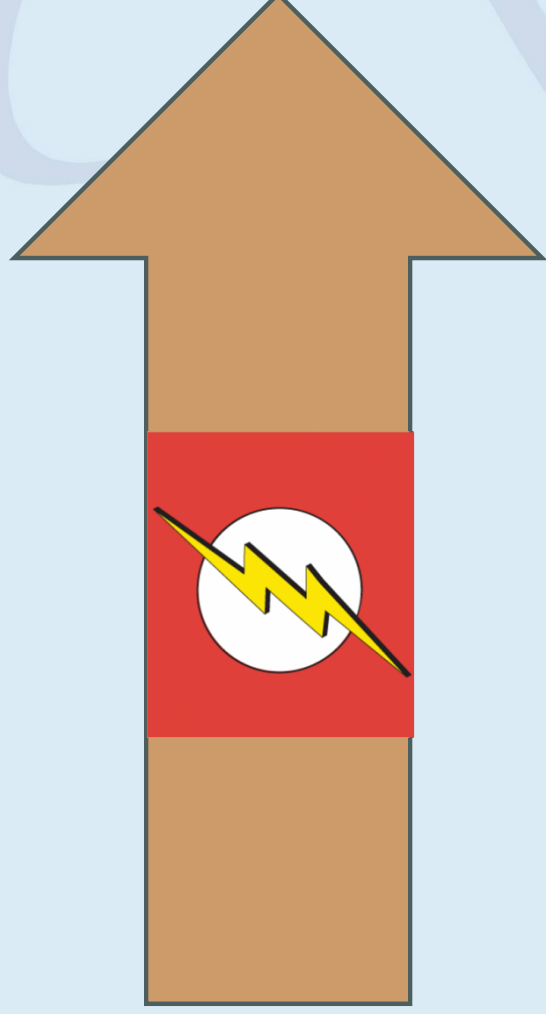
Information Notice 86-21, Supplement 2

- April 1991 - IN 86-21, Supplement 2, provides additional clarification on a licensee, applicant, and suppliers' responsibilities for verifying effective implementation of a sub-supplier's QA program.
- Regulatory Guide (RG) 1.144, " Auditing of Quality Assurance Programs for Nuclear Power Plants," Revision 1, and RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," states that implementation audits are not necessary for procuring items that are:
 - Relatively simple and standard in design, manufacturing, and testing; and
 - Adaptable to standard or automated inspections or tests of the end-product to verify quality characteristics after delivery.

Information Notice 86-21, Supplement 2

- IN 86-21, Supplement 2, clarifies that recognition on ASME's accreditation program only applies to Code items, it does not apply to non-Code items that may be supplied by ASME Certificate Holders.
- IN 88-95, "Inadequate Procurement Requirements Imposed by Licensees on Vendors," provides additional information regarding the procurement of non-pressure boundary parts used on ASME components.

Flash Forward 40 Years...



Summary & Closing Thoughts

- The NRC recognizes that ASME Certificate Holders have a documented QA program that meets the requirements of Appendix B to 10 CFR Part 50.
- This recognition is only for the programmatic aspects of ASME's accreditation program, it does not recognize that it is evidence a supplier is effectively implementing the approved QA program.
- Proper nuclear oversight is essential to ensure the adequate implementation of technical and regulatory requirements for the protection of public health and safety.

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