



# ASME vs. Appendix B: Ensuring Compliance with the Regulatory Requirements

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- Appendix B vs. ASME Section III
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  - Qualification of Sub-Suppliers
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# 10 CFR 50.55a

- Section III of the ASME B&PV Code is incorporated by reference in 10 CFR 50.55a, “Codes and Standards.”
- Current rulemaking will incorporate the 2019 Edition of the ASME B&PV Code and the 2008 through 2015 Editions of NQA-1.
- New rule expected to be issue in the Summer of 2022

# Information Notice 86-21

- IN 86-21, “Recognition of American Society Of Mechanical Engineers Accreditation Program For N Stamp Holders,” and its 2 supplements:
  - Documents the NRC’s recognition of ASME’s Accreditation Program as evidence the holder of the certificate has a documented QA program that meets Appendix B to 10 CFR Part 50
- However, there are 2 stipulations!!

# Information Notice 86-21

- Stipulation #1
  - Recognition of ASME's accreditation program only applies to the programmatic aspects of the QA programs. Licensees, applicants, and suppliers are still responsible for ensuring that their sub-suppliers are effectively implementing the approved QA program.

# Information Notice 86-21

- Stipulation #2
  - Recognition of 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.

# Information Notice 86-21

- IN 86-21 also clarified that implementation audits are not necessary for procuring items that are:
  - Relatively simple and standard in design, manufacturing and testing
  - Adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery

# Quality Assurance Manuals

- Criterion II, “Quality Assurance Program,” of Appendix B to 10 CFR Part 50, requires, amongst other things:
  - the establishment of a Quality Assurance Program.
  - Program shall be documented by written policies, procedures, or instructions.

# Quality Assurance Manuals

- NCA-3211.6, “Filing of the Quality Assurance Manual,” requires the Certificate Holder to file copies of the Quality Assurance Manual with the Authorized Inspection Agency.
- NCA-4134.2, “Quality Assurance Program,” requires the use of NQA-1, Requirement 2, and the system used to meet these requirements to be described in the Quality Assurance Manual.

# Quality Assurance Manuals

- NCA-4253.1, “Quality System Manual,” requires the Quality System Program be described and summarized in a Quality Manual that shall be the basis for demonstration of compliance with the rules of this section.

# Quality Assurance Manuals

- Are suppliers required by regulation to implement two Quality Assurance Manuals to meet regulatory and Code requirements?
  - No, there is no regulatory requirement to establish two different Quality Assurance Manuals.
- What happens if there's a conflict between Appendix B and ASME Code requirements?

# Quality Assurance Manuals

- Example: Use of the ILAC Accreditation Process
  - ASME not up to date with all the latest conditions for use
  - 2021 Edition of ASME still includes the 2005 edition of ISO 17025
- A supplier's Quality Assurance Manual **SHALL** include the necessary requirements to meet Appendix B to 10 CFR Part 50

# Procurement Requirements

- When buying a basic component (i.e., safety-related) from an ASME accredited supplier, Appendix B to 10 CFR Part 50 and 10 CFR Part 21 **SHALL** be imposed in the procurement documents.
- Important because:
  - Ensures adequate Quality Assurance is applied throughout the manufacturing process
  - Ensures Appendix B to 10 CFR Part 50 and 10 CFR Part 21 is passed down to the sub-suppliers

# Qualification of Sub-Suppliers

- NCA-3842.2 allows for ASME accredited suppliers to qualify Material Organizations (MOs)
- Qualified MOs QA program shall meet the requirements of NCA-4200
- Majority of qualified MOs QA programs are based on ISO 9001, others on ISO 17025, and most are located outside the US

# Qualification of Sub-Suppliers

- When inspecting how a MO was qualified, ensure that:
  - There is sufficient objective evidence to support the conclusion that the sub-supplier met the controls and applicable requirements of NCA-4200; and
  - The verification of the MO's 10 CFR Part 21 program is adequate.

# Commercial-Grade Dedication vs. Utilization of Unqualified Source Material

- Utilization of Unqualified Source Material (also known as material upgrade)
  - Acceptance process for material not produced by an ASME accredited supplier
- ASME rules for material upgrade can be used for the commercial-grade dedication process when the material will be used for non-Code safety-related applications. For Code related applications, the material upgrade process is enough.

# Knowledge Check

- **True or False:** When buying a basic component from a supplier holding an N-Type certificate, Appendix B and 10 CFR Part 21 do not need to be imposed in the purchase order (PO).
  - False, Appendix B & Part 21 ALWAYS need to be imposed in POs when buying a basic component.
- **True or False:** All ASME Code material is considered safety-related.
  - True, ASME Code material is pressure retaining, therefore, it is always safety-related.

# Knowledge Check

- Can ASME Code material procured from an un-audited ASME accredited supplier be classified as a basic component?
  - If the vendor did not perform an implementation audit and performs material testing upon receipt, there's a small window of time where the material is not considered a basic component until testing is completed. Alternatively, if the vendor had performed the implementation audit, then the material would already be considered a basic component.

# Knowledge Check

- **True or False:** ASME's material upgrade process and commercial-grade dedication are the same.
  - False, both processes implement different requirements.
- If I'm buying a relatively simple and standard item and I'm not planning to audit the supplier, am I required to do anything else besides issuing the PO?
  - Yes, use of this exception should be documented and evaluated.

# Knowledge Check

- Can ASME's material upgrade process be applied for performing commercial-grade dedication?
  - Yes, provided this method of selection, identification, and verification of critical characteristics is documented in the suppliers' commercial-grade dedication process.

# Questions



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