



NRC Update on Supplier Oversight

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Presentation Overview

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- Summary of RIS 2018-05
- Common Nonconformances and Violations Identified
 - ASME B&PV Code Section III, Subsections NCA 3800 and 4000
 - ISO 9001
 - ISO/IEC 17025:2005
 - 10 CFR Part 21
- NRC Perspectives



Summary of RIS 2018-05

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- RIS was Issued on October 5, 2018 (ADAMS Accession No. ML18151A739)
- Remind stakeholders of the applicable regulatory requirements for:
 - ▣ Procuring basic components
 - ▣ Providing oversight of suppliers (domestic and international)
- Inform our stakeholders of recent NRC inspection findings involving:
 - ▣ Inadequate oversight of suppliers (domestic & international)
 - ▣ Suppliers not adequately imposing the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 to their sub-suppliers in the procurement documents



ASME B&PV Code Section III, Subsections NCA 3800 and 4000

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- Several instances identified in which vendors did not impose the applicable regulatory requirements.
- When procuring basic components from organizations holding a quality system certificate (QSC) with a QA program that meets the requirements of NCA-3800, procurement documents must specify that Appendix B and Part 21 apply.
 - Certificate holders (CHs) and QSC material organizations (MOs) must also reference these regulations in the procurement documents for basic components to their sub-suppliers.

ASME B&PV Code Section III, Subsections NCA 3800 and 4000

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- Example: Nonconformance against Criterion IV of Appendix B for a vendor's failure to include applicable regulatory requirements on procurement documents that ensure adequate quality is included or referenced.
 - The vendor did not impose Appendix B in its safety-related POs for materials and services procured as basic components.
 - Instead, PO stated that the work must be performed in accordance with the suppliers' QA manual approved by the vendor.



ISO 9001

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- NRC staff identified an issue with vendors procuring basic components from commercial suppliers with QA programs based on the requirements of ISO 9001
 - The staff has not approved ISO 9001 for use as an acceptable method for meeting the requirements of Appendix B
 - The staff has not considered accreditation under ISO 9001 as an acceptable basis for qualifying a supplier of basic components
- SECY-03-0117, “Approaches for Adopting More Widely Accepted International Quality Standards,” dated July 9, 2003 (ADAMS Accession No. ML031490421) compares the requirements of ISO 9001 to Appendix B
 - Supplemental quality requirements would be needed when implementing ISO 9001 within the existing regulatory framework



ISO/IEC 17025:2005

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- The NRC staff has not approved ISO/IEC 17025:2005 by itself for use as an acceptable method for meeting the requirements of Appendix B.
- Solely having ISO/IEC 17025:2005 accreditation is not considered an acceptable basis for qualifying laboratory calibration or testing services.
 - RIS 2016-01, “Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” dated March 16, 2016 (ADAMS Accession No. ML16323A346)
- When purchasing commercial-grade calibration and testing services from domestic and international laboratories accredited by ILAC, licensees and suppliers of basic components may use the ILAC accreditation process in lieu of performing a commercial-grade survey as a part of the commercial-grade dedication process



10 CFR Part 21

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- Part 21 is directly applicable to suppliers of basic components or commercial grade items which have successfully completed the dedication process, but several situations were identified where vendors did not impose the requirements in procurement documents.
- Example: a vendor imposed in POs that suppliers shall meet a procedure developed by the vendor rather than imposing the requirements of Part 21.
- Part 21 ensures that licensees are expeditiously alerted to a defect that could create a substantial safety hazard.



NRC Perspectives

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- The RIS highlights a current trend in issues identified during NRC vendor inspections.
- Inspection finding examples listed in the RIS were identified in 2017 inspections. However, inspection results from 2018 inspections have identified the same trends and issues.
- NUPIC, as a learning organization, reviews and evaluates NRC vendor inspection reports to identify issues that may have been missed during NUPIC audits.



For More Information...

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- The Quality Assurance for New Reactors Website offers a variety of information including:
 - Vendor Inspection Program (VIP) Plan
 - <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/vendor-insp-prog-plan.html>
 - Vendor Quality Assurance (QA) Inspection Reports for New Reactors
 - <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html>
 - Quality Assurance (QA) Inspections for New Reactor Licensing
 - <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/qual-assure-license.html>



