

Workshop on Vendor Oversight

Supplier Oversight Issues Identified During Recent NRC Vendor Inspections



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Background

NRC Vendor Inspection Findings on Supplier Oversight

Regulatory Issue Summary (RIS)

Summary



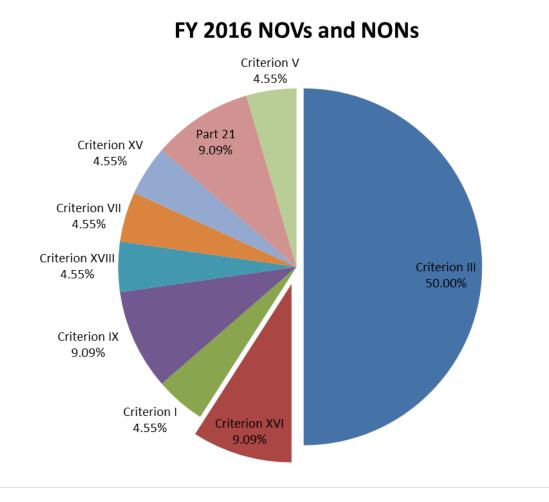




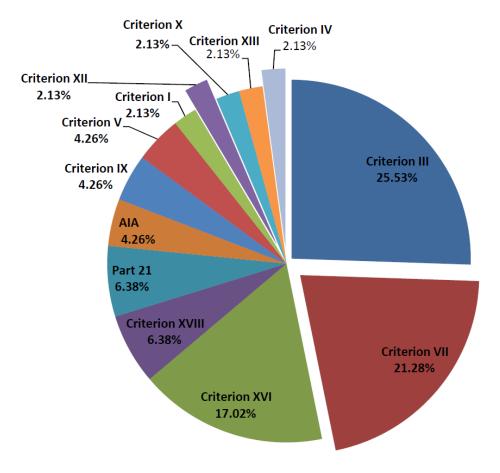
- □ NRC conducts between 25 and 35 vendor inspections per fiscal year
- Vendor inspections performed to verify effective implementation of:
 - Appendix B to 10 CFR Part 50 quality assurance requirements
 - 10 CFR Part 21 reporting requirements
- Trend identified in recent vendor inspections:
 - Failure to impose applicable regulatory requirements in the procurement documents
 - Failure to provide adequate oversight of suppliers (domestic & international)



Background



FY 2017 NOVs AND NONs



34 inspections - 21 NOVs/NONs

37 inspections - 47 NOVs/NONs



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NRC Vendor Inspection Findings on Supplier Oversight

Failure to Impose the Applicable Regulatory Requirements in the Procurement Documents





Babcock & Wilcox Canada Ltd. (Ontario, Canada)

- Inspection conducted in June 2013 to assess Babcock & Wilcox's design, fabrication and testing of the replacement once-through steam generators for the Davis Besse Nuclear Power Station
- Inspection Results
 - Babcock & Wilcox did not specify in the procurement documents for suppliers of safety-related materials and services to be procured as basic components that the provisions of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 apply.
 - Babcock & Wilcox did not impose the requirements of Appendix B to 10 CFR Part 50 in procurement documents for ASME B&PV Code and non-Code safety-related components.
 - Babcock & Wilcox would impose in the procurement documents for international suppliers that they notify Babcock & Wilcox of any deviations.



Babcock & Wilcox Canada Ltd. (continued)

Take-away:

- Vendors need to ensure that for the procurement of basic components:
 - Appendix B to 10 CFR Part 50 is imposed on the procurement documents along with any other technical requirements such as the ASME B&PV Code, as applicable.
 - IO CFR Part 21 is imposed on the procurement documents and suppliers are implementing and understand their responsibilities under 10 CFR Part 21.



Velan Inc. (Montreal, Canada)

- Inspection conducted in May 2017 to assess Velan's design, fabrication and testing of safety-related values
- Inspection Results
 - Velan did not specify in the procurement documents for suppliers of safety-related materials and services to be procured as basic components that the provisions of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 apply.
 - Velan would impose for the work to be performed under the supplier's quality assurance manual approved by Velan.
 - Velan would impose that international suppliers follow a procedure that would notify Velan of any deviations given that these suppliers would not accept 10 CFR Part 21.



Velan Inc. (continued)

Take-away:

- Vendors need to ensure that for the procurement of basic components:
 - Appendix B to 10 CFR Part 50 is imposed on the procurement documents along with any other technical requirements, as applicable.
 - IO CFR Part 21 is imposed on the procurement documents and that suppliers are implementing and understand their responsibilities under 10 CFR Part 21.



Failure to Provide Adequate Oversight of Suppliers (Domestic & International)





Konecranes Nuclear Equipment & Services (New Berlin, WI)

- Inspection conducted in August 2017 to assess Konecranes' design, fabrication, and testing of the containment building polar crane upgrade for the Palo Verde Nuclear Generating Station
- Inspection Results
 - Konecranes did not assess the effectiveness of the control of quality by contractors.
 - Konecranes did not perform an implementation audit of a supplier of safety-related weld filler material on the basis that the supplier has a Quality System Certificate from ASME.
- Take-away: Vendors need to ensure that implementation audits are performed to demonstrate that the supplier is effectively implementing their approved quality assurance program.



Flowserve Corporation (Raleigh, NC)

- Inspection conducted in July 2017 to assess Flowserve's design, fabrication and testing of safety-related valves
- Inspection Results
 - Flowserve did not assess establish adequate measures for source evaluation and selection of contractors and subcontractors.
 - Flowserve did not adequately qualify material organizations with ISO 9001 quality programs as approved suppliers in accordance with the requirements of NCA-3820 and NCA-3842.2.
 - Flowserve's evaluation to audit and approve safety-related heat treating and testing service suppliers' quality assurance programs (ISO 9001 & ISO 17025) did not provide sufficient objective evidence to demonstrate that they had met the applicable requirements of Appendix B to 10 CFR Part 50.



Flowserve (continued)

Take-away:

- Vendors need to ensure that when qualifying supplier as a Material Organization, there is sufficient objective evidence to support the conclusion that the supplier's quality assurance program has the processes and controls in place to meet the applicable quality assurance requirements of NCA-3850.
- Implementation audits of suppliers with quality assurance programs based on ISO 9001 or ISO 17025 must clearly demonstrate how the supplier meets the applicable requirements of Appendix B to 10 CFR Part 50.



Velan Inc.

Additional Inspection Results

- Velan did not establish adequate measures for source evaluation and selection of contractors and subcontractors.
 - Velan did not adequately qualify material organizations with ISO 9001 and ISO 17025 quality assurance programs as approved suppliers in accordance with the requirements of NCA-3820 and NCA-3842.2.
- Take-away: Vendors need to ensure that when qualifying supplier as a material organization, there is sufficient objective evidence to support the conclusion that the supplier's quality assurance program has the processes and controls in place to meet the applicable quality assurance requirements of NCA-3850.



Regulatory Issue Summary (RIS)

- Remind stakeholders of the applicable regulatory requirements for:
 - Procuring basic components
 - Providing oversight of their suppliers (domestic & international)
- □ Inform stakeholders of recent NRC inspection findings
- RIS expected to be issued in the Fall of 2018



Summary

- Imposing Appendix B and 10 CFR Part 21 in procurement documents:
 - Ensures that adequate quality assurance is applied to the manufacturing process
 - Ensures that both of these regulatory requirements are passed down to the subsuppliers
 - Provides reasonable assurance that basic components will perform their intended safety function
 - Provides a method for licensees and the NRC to be notified of any problems that could potentially render a component inoperable and create a substantial safety hazard
- Implementation audits to verify compliance with Appendix B to 10 CFR Part 50 must demonstrate that suppliers have the processes and controls in place to meet the applicable requirements of Appendix B to 10 CFR Part 50



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Questions

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