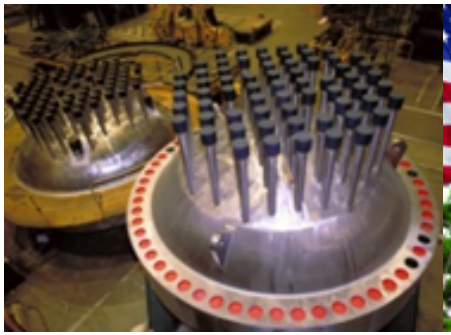




NRC UPDATE

January 30, 2018

NUPIC General Membership Meeting

Orlando, Florida

Rich McIntyre and Greg Galletti

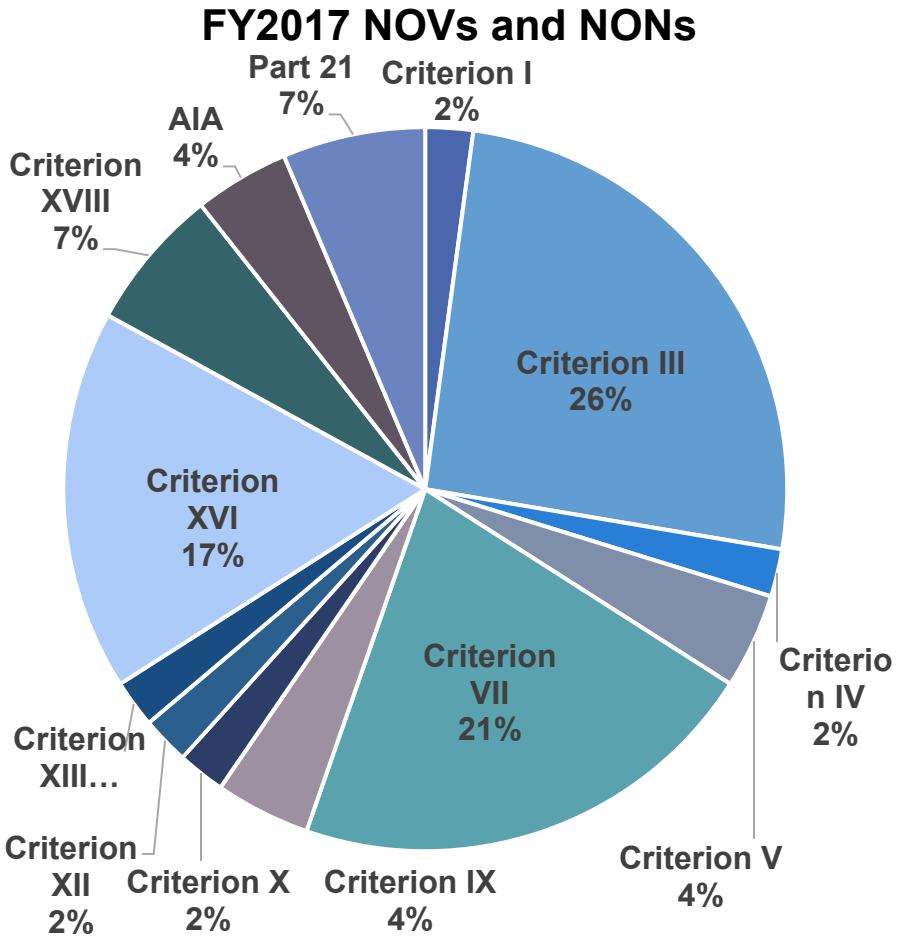
Quality Assurance Vendor Inspection Branch, Office of New Reactors

Topics

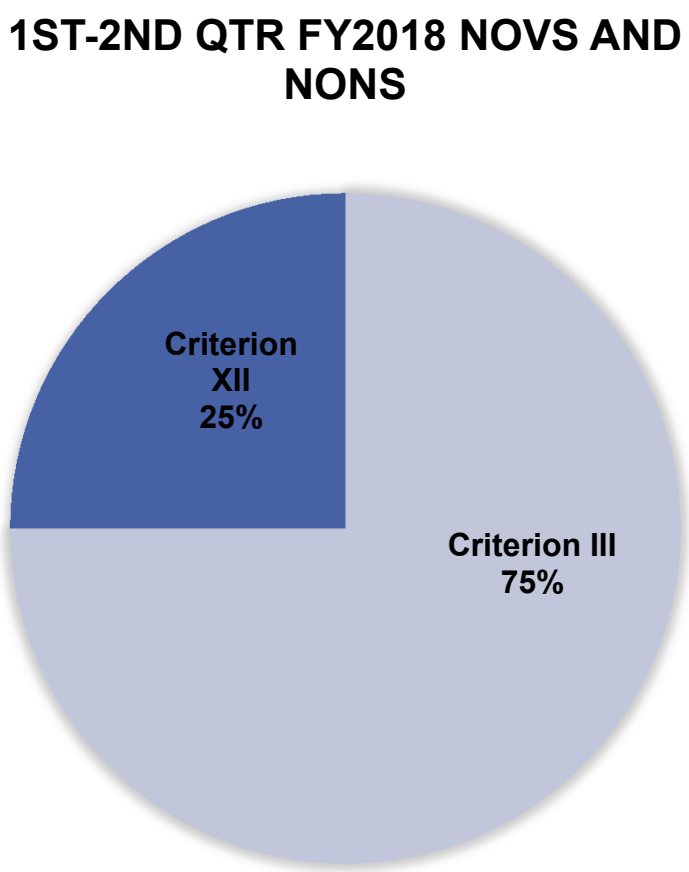
- Vendor Inspection Findings
- Quality Assurance Program Criteria – RG 1.28
- Part 21- Draft Guide 1291 (RG 1.234)
- Proposed Regulatory Issue Summary on Supplier Oversight Issues Identified During NRC Vendor Inspections
- Advanced Manufacturing (3-D Printing)
- Internal Auditor Independence

NRC Vendor Inspection Findings

Breakdown of Vendor Inspection Findings



37 inspections - 47 NOVs/NONs



7 inspections – 4 NOVs/NONs

Vendor Inspection Trends

- Significant Findings
  - Design Control:
    - Translation of Design Requirements
- Inadequate Implementation of QA Program Requirements

Design Requirements

Static O-Ring (SOR) (Lenexa, KS)

- Inspection conducted in October 2017 to assess design, fabrication, testing, and dedication of nuclear qualified pressure, differential pressure, vacuum, and temperature switches.
- Inspections Results:
  - SOR not analyzing the full temperature rise of the device due to energized parts; not accounting for the full operating range of the devices; not documenting the resolution of anomalies experienced during qualification testing

Design Requirements

SOR cont'd

- Take-away:
  - Suppliers need to assure that design requirements are met
  - Suppliers need to provide an adequate technical justification, including any communications between the customer and the supplier to any design changes or departures from the design requirements
  - Suppliers should be able to demonstrate the adequacy of the design under the most adverse conditions
  - Anomalies that occur during qualification testing should be evaluated and documented in order to determine if the anomalies could invalidate the qualification

Design Requirements

Mirion IST

- Inspection conducted in June 2017 to observe design, manufacturing, and testing activities associated with the AP1000 Ex-Core detectors nuclear instrumentation
- Inspection Results
  - Mirion IST did not establish adequate measures to assure that the purchased material conform to the design requirements specified in the procurement documents.
    - The material verification was performed using a Niton Alloy Analyzer (PMI), which can determine the family of material, but lacks the ability to distinguish between the grades of material, as required by the design specifications.
  - Take-away: Measures selected for material verification need to have the adequate sensitivity to assure that the material complies with the design requirements.

Design Requirements

Konecranes Nuclear Equipment & Services (New Berlin, WI)

- Inspection conducted in August 2017 to assess Konecranes' design and testing of the containment building polar crane upgrade for Palo Verde Nuclear Generating Station
- Inspection Results
  - Konecranes did not verify the adequacy of the design and suitability of application of materials that are essential to the safety-related function of the main hoist lower blocks and the drum sheaves:
    - Drum sheaves were manufactured from a proprietary polymer material instead of steel as required by ASME NOG-1.
    - Konecranes did not demonstrate that the main hoist lower blocks and polymer drum sheaves did not exceed the maximum allowable stress values form ASME NOG-1
  - Take-away: Suppliers need to ensure that design requirements are met, or provide an adequate technical justification, including any communications between the customer and the supplier to any design changes or departures from the design

Inadequate Implementation of QA Program Requirements

Chicago Bridge & Iron
(Laurens, SC)

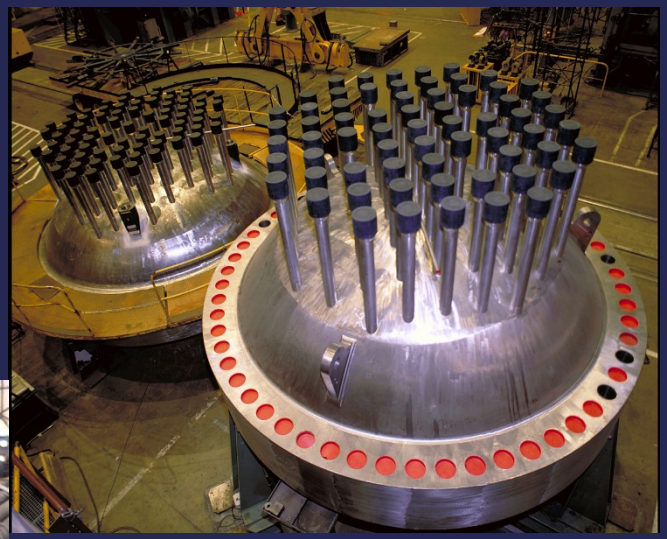
- Reactive unannounced inspection conducted in January 2017 to verify implementation of corrective actions from previous inspections
- Inspection Results
  - As required by Criterion I of Appendix B, CB&I Laurens did not assure that portions of the QA program were effectively executed, and failed to verify that activities affecting safety-related functions have been correctly performed

Inadequate Implementation of QA Program Requirements

Chicago Bridge & Iron cont'd

- Criterion I finding issued due to:
  - 3rd inspection in a period of years with multiple findings (6 NONs, 1 NOV identified during this inspection)
  - Self imposed stop work (during 2nd NRC inspection in March 2015) identified a significant number of deficiencies in the QA program - 13 of the 18 criteria had issues
  - Actions taken in response to the stop work failed to address the deficiencies identified in the implementation of the QA program
- Take-away: Suppliers need to assure that their QA programs are being adequately implemented, including the CAP, and that there is management involvement at all levels to assure that the corrective actions are effectively implemented.

QUALITY ASSURANCE PROGRAM CRITERIA



Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction) "

- Revision 5 of 1.28 was issued final in October 2017 (ML17207A293)
- RG 1.28 endorses, with certain clarifications and regulatory positions, various versions of the ASME NQA-1 standard; the standards included are the NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015.
- The staff determined that the NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015 provide the most current guidance for QA programs.

Part 21 Evaluation and Reporting

Draft Guide-1291, "Evaluating Deviations and Reporting Defects and Noncompliance"

Proposed New Regulatory Guide - RG 1.234

- Endorses Revision 1 of NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance" (ML16054A825)
- Provides clarification on Part 21 requirements for reporting and evaluating
- *Comment period closed on October 4, 2017*
- *Staff evaluated industry and stakeholder comments received and plans to issue the regulatory guide as final by the end of March 2018.*

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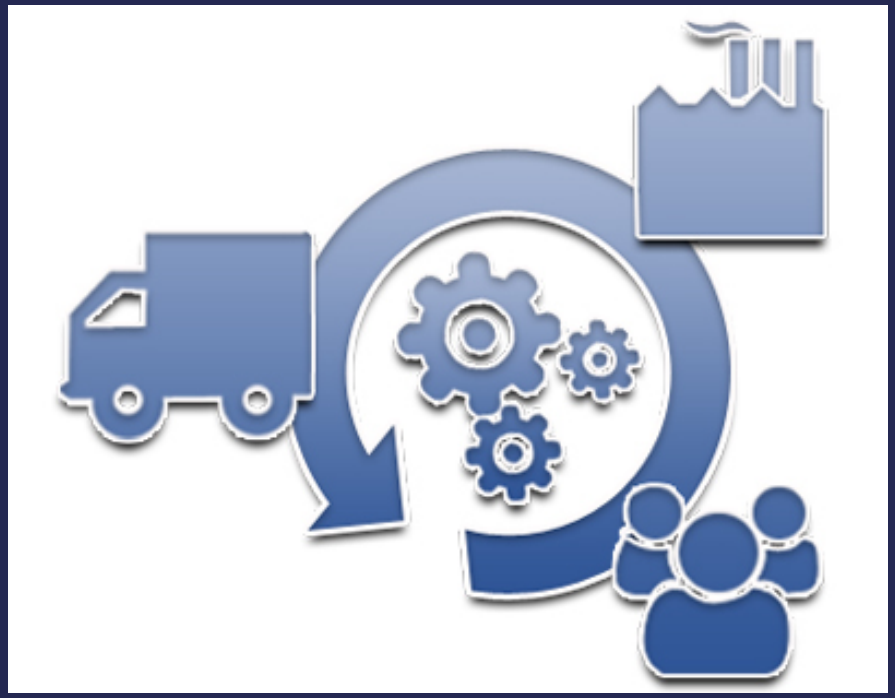
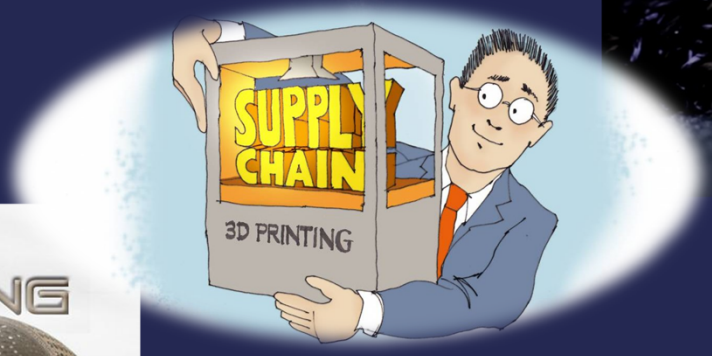
Regulatory Issue Summary Supplier Oversight



RIS on Supplier Oversight: Issues Identified during NRC Vendor Inspections

- 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 21to their sub-suppliers in the procurement documents
- NRC staff expects to issue this RIS in Spring of 2018, and also plans to do a presentation on this topic at the 6th NRC Workshop on Vendor Oversight, June 14, 2018 in Cleveland, OH

ADVANCED MANUFACTURING



Additive Manufacturing (3-D Printing)

- The staff is currently developing an Agency Action Plan:
  - Staff from the Office of Research, Office of Nuclear Reactor Regulation, and Office of New Reactors, are participating in the development of this plan
- Several interactions have taken place with other Federal Agencies and industry stake holders
- On November 28-29, 2017, NRC hosted a public meeting on Additive Manufacturing for Reactor Materials, with presentations from EPRI, FAA, GEH, ASME, WEC, NASA, NuScale, NAVSEA, NIST, ASTM, and others
- 6th NRC Workshop on Vendor Oversight to be held on June14, 2018, in Cleveland OH, will include a breakout session on Additive Manufacturing (3-D Printing)

Internal Auditor Independence

- 2017 NUPIC audit finding identified that the same lead auditor performed the internal audit portion of the audit for the last 3 years
- Issue determined to have NO impact on the engineering services provided by company
- Part 50 Appendix B, Criterion18, “Audits” requires:
  - audits be performed by appropriately trained personnel *not having direct responsibilities* in the areas being audited
  - Audit results shall be documented and *reviewed by management having responsibility in the area*

For More Information…

- 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