

THE VENDOR TIMES

NRC/NRO/DCIP The Vendor Times

December 2017

The Director's Cut

In fiscal year 2017, the U.S. Nuclear Regulatory Commission's (NRC) vendor inspection program (VIP) conducted routine, reactive, design verification and qualification testing inspections of 26 vendors that provide components, parts, structural and mechanical modules, and services to nuclear power plants under construction and to operating nuclear power plants. At these inspections, the NRC evaluates vendor compliance with Title 10 of the Code of Federal Regulations (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." Over the past year, the NRC vendor inspection staff also supported: aircraft impact assessment inspections; joint international inspections under the Multinational Design Evaluation Program; Nuclear Procurement Issues Committee observations; Inspections, Test, Analysis, and Acceptance Criteria inspections of the AP1000 construction activities; quality assurance implementation inspections; investigations by the NRC's Office of Investigation; and Region II inspections at vendor facilities.

The Vendor Inspection Program continued to meet our safety and program objectives. We continued to verify the effective implementation of the vendor Quality Assurance programs, and to verify that design requirements contained in the licensing documents are correctly implemented into engineering, procurement, fabrication, and testing activities. We checked that licensees are providing effective oversight of their supply chain, and that the quality of materials, equipment and services supplied by vendors are consistent with the regulations. Compliance to these regulatory requirements is an essential part of the NRC's mission to protect public health and safety.

The vendor inspection staff will continue to communicate issues of importance with nuclear supply chain stakeholders. One method for discussing issues of importance with the stakeholders is through the Vendor Workshop, which is scheduled for June 14, 2018 in Cleveland, OH. You should know that Vendor Workshop topics are generally determined by capturing issues of interest from stakeholder feedback, vendor fabrication activities, and NRC's inspection observations.

Our inspection reports are publicly available on the NRC's Vendor Quality Assurance Inspection website at [http:// www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html](http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html) .



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2017 Vendor Inspection Trends

The Vendor Inspection Program (VIP) verifies that reactor applicants and licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the supply chain. It accomplishes this through a number of activities, including: performing vendor inspections that will verify the effective implementation of the vendor’s quality assurance program, establishing a strategy for vendor identification and selection criteria, and ensuring vendor inspectors obtain the necessary knowledge and skills to perform inspections. In addition, the VIP addresses interactions with nuclear consensus standards organizations, industry and external stakeholders, and international constituents.

From October 1, 2016 to September 30, 2017, the vendor inspection staff completed a total of 37 inspections, including 26 vendor inspections, one Office of Investigation assist, two Region II assists, two Aircraft Impact Assessment inspections, three Nuclear Procurement Issues Committee (NUPIC) Observations, two Quality Assurance Implementation Inspections, and one Multinational Design Evaluation Program inspection. These inspections assessed vendor compliance to Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” and 10 CFR Part 21, “Reporting of Defects and Non-compliance.” From these inspections, the NRC identified 47 findings, including Notices of Violations (NOVs) and Notices of Nonconformance (NONs), and analyzed the findings to identify issues that can be acted upon by vendors, NRC licensees, and the NRC (see Figure 1).

NRC’s vendor inspectors observed mixed vendor performance in the implementation of their quality assurance programs. While almost half of the inspections did not result in findings, there was a significant increase in the quantity of NONs in the area of Criterion VII, “Control of Purchased Material, Equipment, and Services” in Appendix B to 10 CFR Part 50. In these cases, the staff noted a lack of adequate review and verification in the control and oversight of suppliers. NRC will address these findings at the next NRC vendor workshop in 2018 and give a presentation on the importance of control of purchased material, equipment, and services that addresses the common areas that were deficient. In addition, the staff is developing a regulatory issue summary (RIS) to inform our stakeholders of recent issues with lack of adequate review and verification in the control and oversight of suppliers.

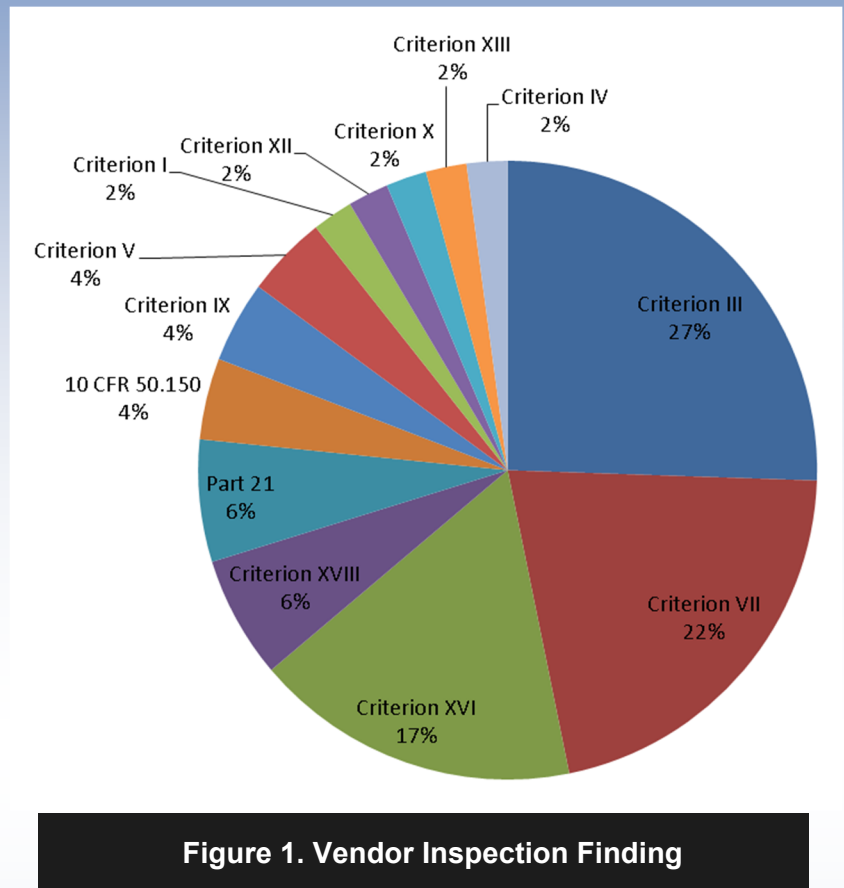


Figure 1. Vendor Inspection Finding

**2016 Vendor Workshop**

2018 Vendor Workshop

The Division of Construction Inspection and Operational Programs (DCIP), Office of New Reactors (NRO), is planning their 2018 Vendor Workshop scheduled for June 14, 2018 in Cleveland, Ohio. Since 2008, the vendor branches have facilitated biennial public workshops related to vendor oversight. These vendor workshops generate an audience of approximately 550 individuals, comprised of industry representatives, licensees, vendors, and members of the public. The past five vendor workshops have been held in conjunction with the Nuclear Procurement Issues Committee (NUPIC) Vendor Conference, in order to generate the maximum attendance, since both meetings share the same large target audience. Some of the proposed topics for the 2018 vendor workshop include international vendor inspections; reverse engineering; counterfeit, fraudulent and suspect items; Appendix B to 10 CFR Part 50 and quality standards; commercial grade dedication issues; and additive manufacturing for nuclear facilities. For more information visit <https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor->



Upcoming RIS on Supplier Oversight Issues Identified during NRC Vendor Inspections

The NRC staff is currently developing a regulatory issue summary (RIS) to inform our stakeholders of recent NRC inspection findings involving: (1) the inadequate oversight of suppliers that provide basic components to NRC-licensed facilities; and, (2) not adequately imposing the requirements of Appendix B “Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities” quality assurance and 10 CFR Part 21, “Reporting of Defects and Noncompliance,” to their sub-suppliers in the procurement documents. During recent NRC inspections at domestic and international vendor facilities that supply basic components to NRC-licensed facilities, the NRC staff has identified several examples where vendors failed to provide adequate oversight and failed to adequately impose the requirements of Appendix B to 10 CFR Part 50 and 10 Part 21 to their sub-suppliers. The RIS will also reinforce the applicable requirements when procuring basic components from suppliers implementing quality programs based on the International Organization for Standardization (ISO) 9001:2008, “Quality Management System – Requirements,” ISO 17025:2005, “General Requirements for the Competence of Testing and Calibration Laboratories,” Subsection NCA-3800, “Metallic Organization’s Quality System Program,” and Article NCA-4000, “Quality Assurance Requirements,” of Subsection NCA, “General Requirements for Division 1 and Division 2,” of Section III, “Rules for Construction of Nuclear Facility Components,” of the American Society of Mechanical Engineers Boiler & Pressure Vessel Code.

The NRC staff expects to issue the RIS in Spring of 2018, and also plans to do a presentation on this topic at the upcoming 2018 NRC Workshop on Vendor Oversight.

Vendor Center of Expertise Industry Outreach

In addition to holding a biennial workshop on vendor oversight, staff from the U.S. Nuclear Regulatory Commission's vendor Center of Expertise (COE) participate in numerous professional organizations to further the NRC's industry outreach. The vendor COE staff's communication and outreach with these organizations enhances the NRC's commitment to openness, efficiency, and clarity.

For example, the vendor COE staff interfaces with the Nuclear Procurement Issues Committee (NUPIC) by routinely observing NUPIC audits. The NUPIC organization, made up of utilities, serves as a cooperative program for the evaluation of suppliers furnishing safety-related components and services and commercial-grade items. The vendor COE staff observes approximately two NUPIC audits per year to help ensure that the NUPIC audit process remains consistent with the regulations in Appendix B, "Quality

Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." In addition, vendor COE staff participates in NUPIC meetings by providing updates on ongoing NRC vendor inspection activities, including NRC initiatives such as regulatory guide updates associated with quality assurance standards, commercial-grade dedication, and Part 21, and shares the results of recent NRC NUPIC audit observations.

Additionally, the vendor COE staff interacts with the Electric Power Research Institute (EPRI) by attending the EPRI-Joint Utility Task Group (JUTG) procurement forum, which provides open communication amongst utilities and suppliers to discuss issues related to procurement engineering. The purpose of vendor COE staff's participation at this forum is to inform industry stakeholders on current regulatory guidance and rulemaking with potential impacts on procurement processes. Additionally, vendor COE staff identifies and addresses issues of concern that need clarification regarding regulatory compliance for implementation of procurement processes.

Furthermore, the vendor COE staff participates in vendor inspections led by foreign regulatory authorities, as a part of the Multinational Design Evaluation Program (MDEP), to provide additional insights relative to the effectiveness of licensee (both foreign and domestic) oversight of international vendors. Vendor COE staff also serve on the Vendor Inspection Cooperation Working Group (VICWG), which is an issue-specific working group established under the MDEP organization.

Vendor COE staff also interface with the Nuclear Energy Institute (NEI) to discuss mutual items of interest (i.e., commercial-grade dedication, Part 21 implementation, procurement, software dedication, and vendor oversight). These interactions ensure that both the NRC's and industry's concerns are addressed during the development of vendor and supplier guidance documents. The vendor COE staff has endorsed several NEI documents related to quality and vendor oversight.

Last but not least, the vendor COE staff participates as voting members of the American Nuclear Society (ANS), the American Society of Mechanical Engineers (ASME), and the Institute of Electrical and Electronics Engineers (IEEE). Vendor COE staff participation in these organizations allow for enhanced regulatory consistency in the development of industry standards.



Ashley Ferguson at the JUTG

NRC Receipt of Incoming Vendor Communications

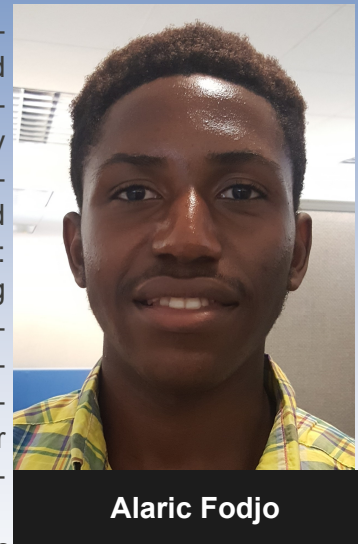
In order to ensure that vendor related communications become official NRC records, they must be entered into the NRC's Agencywide Documents Access and Management System (ADAMS). Therefore, please continue to address all vendor related communications and envelopes, and mail via the U.S. Postal Service to:

US Nuclear Regulatory Commission
Document Control Desk (DCD)
Washington, DC 20555-0001

Once the DCD has received your communication, they will properly profile and add them to ADAMS so that the lead inspector or branch chief can prepare an official response. No agency response can be prepared prior to ADAMS' receipt of your letter. Any envelopes or electronic communications will be considered a courtesy copy and not an official NRC record.

DCIP Summer RISE Student

In the summer of 2017, I participated in a locally funded initiative led by Work Source Montgomery in collaboration with Montgomery County Public Schools and the NRC's Division of Construction Inspection and Operational Programs; entitled: "Summer R.I.S.E. (Real Interesting Summer Experience). As an emerging senior, I was given the opportunity to learn that vendor inspections are conducted at vendor shops principally to examine whether the vendor has been complying with Appendix B, "Quality Assurance



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Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," as required by procurement contracts with licensees. Under these regulations, qualified NRC inspectors review areas such as design control and control of purchased materials, equipment and services. For example, there are acceptance processes they review called commercial grade dedication. Commercial grade dedication is performed to provide reasonable assurance that an item or service will successfully perform its intended safety function. Over the summer I also had the experienced to work with the American Society of Mechanical Engineers (ASME) codes, Early Site Permits reviews; AP1000 construction Inspection Test, Analysis, and Acceptance Criteria (ITAAC); and 10 CFR Part 21 Reporting Defects and Noncompliance. With college on the horizon; I participated in several meet and greets with NRC senior staff engineers, health physicists, and materials, human factors, chemical, mechanical and electrical engineers. In such a short time I was exposed to a lot but most importantly; I learned the important role DCIP contributes to the NRC's mission to license and regulate the Nation's civilian use of radioactive materials to protect public health and safety, promote the common defense and security, and protect the environment.

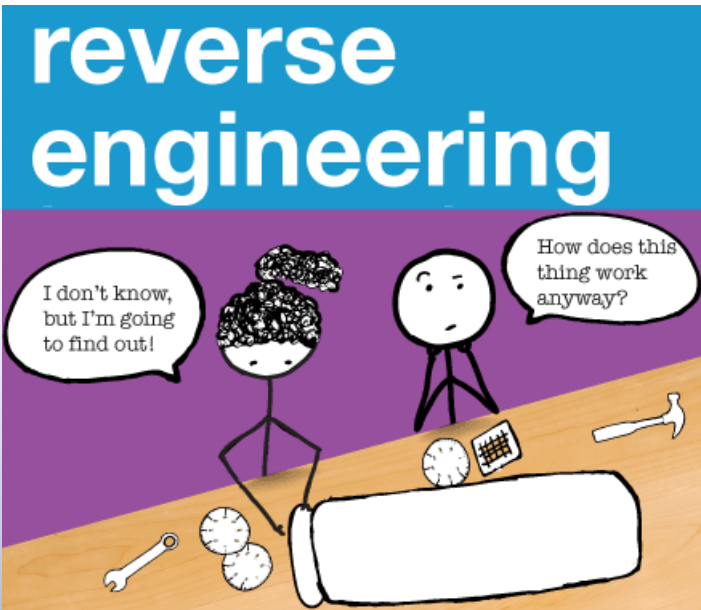


MDEP AP1000 Working Group

Status of Industry Initiatives to Improve Reverse Engineering Guidance

On July 15, 2016, the NRC issued Information Notice (IN) 2016-09, "Recent Issues Identified When Using Reverse Engineering Techniques In The Procurement Of Safety-Related Components." In this IN, the NRC discussed instances where reverse engineering techniques were used to manufacture replacement components, where the components were supplied without first verifying the supplied components met all safety-related design requirements, and in some instances, where these components failed in service. Among the concerns raised in the information notice were examples where licensees and/or vendors had:

- not developed a full understanding of design requirements
- inappropriately assumed that a reverse-engineered component was identical to the original equipment manufacturer (OEM) component, even though it was not subject to the same design and manufacturing specifications and processes as the original component
- assessed only the physical attributes of the component without properly evaluating functional design requirements
- not passed on all relevant design requirements to the supplier
- not verified that all safety-related design requirements had been met, either by testing or analysis or a combination of the two
- not clearly established which organization is responsible for which portion of the reverse engineering process.



In response to the concerns identified in IN 2016-09, EPRI formed a task group to evaluate and rewrite its existing guidance on reverse engineering which is contained in EPRI, TR107372, "Guidelines for Reverse Engineering at Nuclear Power Plants," dated July 1998. Over the last year or so the task force has been meeting and has developed an extensive revision to the existing guidance, focusing specifically on the concerns raised in IN 2016-09. Staff from the NRC's Quality and Vendor Inspection Branch have participated on the task force and have worked with the EPRI members to help ensure that the revised guidance fully addresses the concerns identified. Currently a draft of the revised guidance has been completed and has been circulated to select EPRI members for review

with the intent of issuing the revised guidance sometime early in 2018.

Would you like to be added to the newsletter distribution? Or suggest topics? We welcome useful and informative feedback on the content of this newsletter. Please contact Nicholas Savwoir, Reactor Operations Engineer, Quality Assurance Vendor Inspection Branch-1, by telephone at 301-415-0256 or by email at Nicholas.Savwoir@nrc.gov.



Richard McIntyre was awarded with the 2017 NQA Outstanding Service Medal



Richard McIntyre was awarded with the Dedicated Service Award for ASME

NQA Outstanding Service Medal and Dedicated Service Award for ASME

Mr. Richard McIntyre is a Senior Reactor Operations Engineer in the Quality Assurance & Vendor Inspection Branch #2 in the Office of New Reactors and is responsible for quality assurance and vendor inspection activities related to mechanical systems and components for the current operating fleet and new reactor construction.

In 2017, Mr. McIntyre was awarded the 2017 Nuclear Quality Assurance (NQA) Outstanding Service Medal and the Dedicated Service Award from the American Society of Mechanical Engineers (ASME).

Mr. McIntyre was awarded the 2017 NQA Outstanding Service Medal for his extraordinary service and technical contributions to the ASME NQA Standards Committee. As an NRC Representative to NQA, since 2000, his contribution in the Committee was crucial in recent revisions to NQA-1. Mr. McIntyre worked with NQA-1 leadership to determine the issues the NRC had with NQA-1, and coordinated resolution of those issues with NRC staff, which led to a revision to the NRC endorsement of NQA-1 through Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)," as well as the Committee's approval and issuance of NQA-1-2008 and 1a-2009.

Mr. McIntyre also received the Dedicated Service Award for his dedicated service of over 20 years to ASME Conformity Assessment activities. Conformity assessment refers to the system of auditing certificate holders, authorized nuclear inspection agencies and their inspectors, and ensuring compliance of these activities to the ASME Code. He is the only NRC employee to have received this award for conformity assessment.