U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

THE VENDOR TIMES

The Director's Cut

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Fiscal year (FY) 2018 was an active year for the U.S. Nuclear Regulatory Commission's (NRC) vendor inspection program (VIP). We conducted a total of 25 inspections for both new and operating reactors, including vendor, quality assurance (QA) implementation, and aircraft impact assessment (AIA) inspection, and observed several Nuclear Procurement Issues Corporation (NUPIC) Audits. A majority of the findings were in the area of Criterion III "Design Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the Code of Federal Regulations (10 CFR) Part 50. A point of particular interest is that during FY2018 there were no findings under 10 CFR Part 21, "Reporting of Defects and Noncompliance." This is attributed to several factors, including, the vendor inspection program's continued outreach effort, involvement in oversight of the NUPIC vendor audit process, and of course sustained effort by you, the nuclear vendors.

The VIP continued to meet its safety and program objectives. One ongoing effort is to verify the effective implementation of the vendor's QA programs, and that design requirements contained in the licensing documents are correctly implemented during engineering, procurement, fabrication, and testing activities. Quality Assurance Vendor Inspection Branch (QVIB) inspectors observed that licensees are generally 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 the applicable regulatory requirements is an essential part of the NRC's mission to protect public health and safety. QA must be included from start to finish for the components provided to US Licensees.

The QVIB staff continued to communicate with the nuclear supply chain, via the NRC's 2018 Workshop on Vendor Oversight, and our involvement with industry organizations such as NUPIC, the Multinational Design Evaluation Program (MDEP), the Electric Power Research Institute (EPRI) Joint Utility Task Group (JUTG), and the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance-1 (NQA-1). Last year, we provided presentations on such topics as Challenges in the Qualification of First-of-a-Kind Components, the NRC Inspection Program, and Regulatory Updates.

On a personal note, we said goodbye to our longtime friend and colleague Richard McIntyre, who retired after serving 33 years of federal service. During his distinguished career, Rich led numerous vendor inspections, represented the NRC on the ASME Section III and NQA-1 committees for over 20 years, and performed extensive industry outreach to help promote quality in the nuclear supply chain. Rich will be missed by the NRC and the industry.

Past inspection reports, including those mentioned above, are publicly available on the NRC's Vendor Quality Assurance Inspection website at, https://www.nrc.gov/reactors/new-reactors/oversight.html.

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2018 Vendor Inspection Trends

The Vendor Inspection Program Plan (VIPP) 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 QA 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 VIPP addresses interactions with nuclear consensus standard organizations, industry and external stakeholders, and international constituents.

From October 1, 2017 to September 30, 2018, the vendor inspection staff completed a total of 25 activities, which included 20 vendor inspections, one AIA, one observations of the Korean Institute of Nuclear Safety (KINS), two NUPIC observations, and one QA implementation inspection. These inspections assessed vendor compliance to Appendix B to 10 CFR Part 50, and 10 CFR Part 21. From these inspections, the NRC identified 19 findings which were all notices of nonconformance (NONs), and analyzed these findings to identify issues that can be acted upon by vendors, NRC licensees, and the NRC (see Figures 1 & 2). No notices of violations (NOVs) were issued during FY2018.

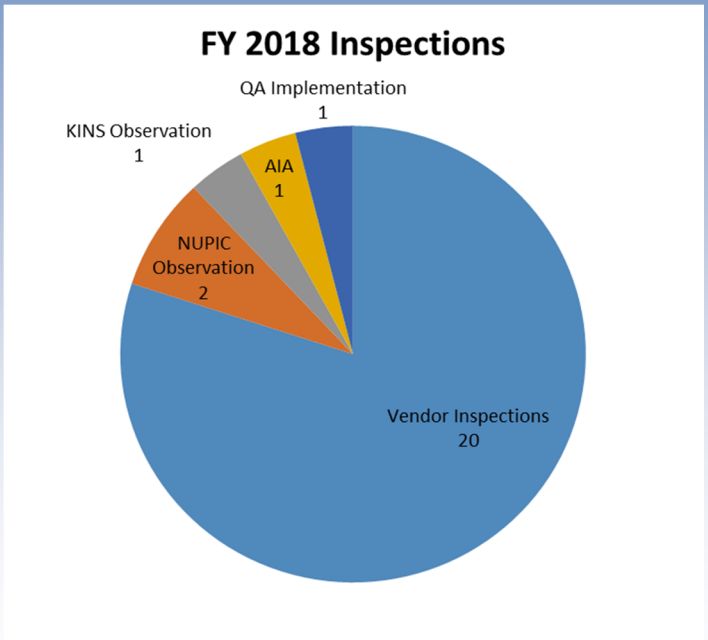

Figure 1. Vendor Inspections

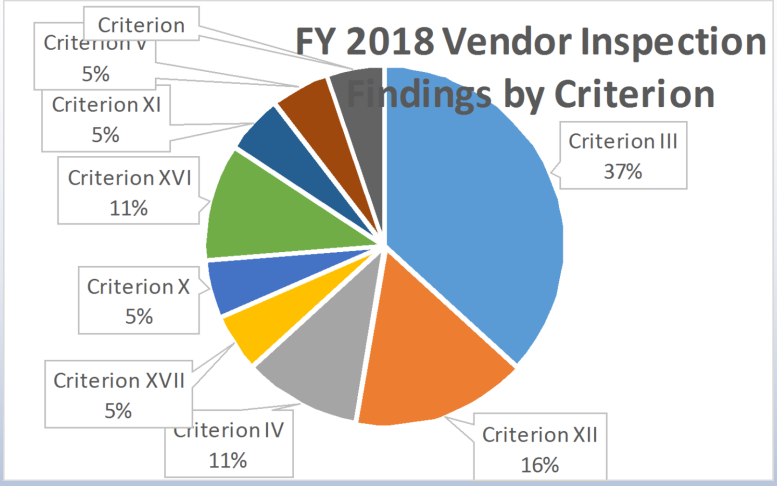

Figure 2. Vendor Inspection Findings

NRC's vendor inspectors observed an improvement in vendor performance over previous years in the implementation of their QA programs. More than half of the inspections did not result in findings,

2018 Vendor Workshop

2018 Vendor Workshop

On June 14, 2018, the Office of New Reactors (NRO), Division of Construction Inspection and Operational Programs (DCIP), hosted the NRC Workshop on Vendor Oversight in Cleveland, Ohio. The workshop had an audience of about 400 attendees, including licensees, applicants, suppliers of basic components, industry organizations, and representatives from 14 countries. The workshop provided an open forum for exchanging information regarding the supply of components and materials to both new and operating nuclear power plants. The workshop followed the NUPIC vendor meeting to enable maximum participation by suppliers to the nuclear industry. The NRC Vendor Workshop included a keynote address by NRC's Commissioner Stephen G. Burns, as well as presentations by members of the NRC staff, NUPIC, the EPRI, the National Institute of Standards and Technology (NIST), the National Intellectual Property Rights Coordination Center (NIPRCC), reactor licensees, and nuclear vendors. The 6th Workshop on Vendor Oversight included a plenary session on such issues as a safety conscious work environment (SCWE); reverse engineering; counterfeit, fraudulent, and suspect items (CFSI), and recent supplier oversight issues. The workshop also included afternoon panel discussions regarding commercial--grade dedication (CGD) topics and additive manufacturing as related to the nuclear industry.

Vendor Inspection Center of Expertise involvement in 10 CFR 50.55a, "Codes and Standards," Rulemaking Activity

The ASME develops and publishes the ASME Boiler and Pressure Vessel (B&PV) Code, which contains requirements for design, construction, and inservice inspections (ISI) of nuclear power plant components, and the ASME Operational Maintenance (OM) Code, which contains requirements for operation and in-service testing (IST) of nuclear power plant components.

The NRC establishes requirements for the design, construction, operation, ISI, and IST of nuclear power plants by approving the use of editions and addenda of the ASME BPV and OM Codes (ASME Codes) in 10 CFR Part 50.55a, "Codes and Standards." The NRC mandates the use of certain parts of ASME Code editions and addenda in 10 CFR 50.55a through the rulemaking process known as "incorporation by reference" (IBR). Upon IBR of the ASME Codes into 10 CFR 50.55a, the provisions of the ASME Codes are legally binding NRC requirements as delineated in 10 CFR 50.55a.

The Vendor Inspection (VI) center of expertise (COE) staff is actively involved in the rulemaking process by participating in the committee and working group for the endorsement of the ASME B&PV Code Section III, Subsection NCA, "General Requirements," into the NRC rule. The VI COE staff coordinates with other parts of the NRC on the development and effects of implementation of the new codes as regulatory requirements.

The NRC staff is working to complete review of the 2015 and the 2017 Editions of the ASME B&PV Code Section III, Section XI, Division 1, and the 2017 Edition of the OM Code to support their IBR into 10 CFR 50.55a. The NRC is working toward publishing the proposed revised 10 CFR 50.55a rule in the Federal Register by the end of 2018. Members of the public will be able to provide written comments to NRC for 75 days after publication of the proposed rule.

GUIDANCE TO HELP CLARIFY THE REQUIREMENTS OF 10 CFR PART 21

Over the past several years the NRC had considered rulemaking to revise and clarify Part 21 of Title 10 of the Code of Federal Regulations (10 CFR Part 21), "Reporting of Defects and Noncompliance." On September 2011, the staff issued SECY 2011-0132 to inform the Commission of the staff's plan to clarify the requirements for the evaluation and the reporting of defects and to provide the proper regulatory framework needed for the CGD process. In April of 2016, this Part 21 rulemaking was cancelled due to Project AIM (NRC's self study to identify potential increases in it's efficiency..) This was based on recommendations for rebalancing of the NRC's work as recommended by a management study. However, the Commission recognized the need to provide clarification to industry on this critical regulation. Therefore, the staff was directed to continue working with stakeholders in a public process. The intended results were to clarify the requirements for the evaluation and reporting of defects and, provide the proper regulatory framework for CGD. The results were published in two Regulatory Guides (RGs):

- RG 1.234, "Evaluating Deviations and Reporting Defects and Noncompliance"
- RG 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants"

RG 1.234 (published in April 2018) endorses Nuclear Energy Institute (NEI) 14-09 "Guidelines for Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance" Revision 1, which was published February 2016. NEI developed the guidance to: promote consistent guidance to implement NRC requirements; to incorporate guidance previously published in NUREG-0302, "Remarks Presented (Questions/ Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) For Reporting of Defects and Noncompliance;" to add clarity in the specific areas where history has shown issues to occur; and to include experience gained from the nearly 40 years of complying with 10 CFR Part 21. This new guide provides licensees and applicants with a method of evaluating and reporting defects under 10 CFR Part 21 that is acceptable to NRC staff, but is not the only method of compliance. The purpose this RG is to reduce the compliance challenges faced by licensees and vendors, which the NRC staff has identified through its inspections, over the years.

RG 1.164 (published in June 2017) conditionally endorses EPRI 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," Revision 1 to EPRI NP-5652 and TR-102260 dated September 2014. EPRI 3002002982 describes a methodology that can be used to dedicate commercial-grade items for use in safety-related applications. The scope of applications for which commercial-grade item dedication is used has evolved significantly since the EPRI published its reports: "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07) (NP-5652)" and "Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial-Grade Items (TR-102260)," in 1988 and 1994, respectively. The guidance in this final report reflects lessons learned and addresses challenges that have been identified through expanded use of the original guidance. EPRI 3002002982 supersedes the original versions of EPRI reports NP-5652 and TR-102260 in their entirety.

EPRI NP-5652 was the first guidance document to provide a detailed acceptance methodology specific to CGD for items used in nuclear power plants. Industry's use of the CGD process has significantly increased over time as the number of suppliers with nuclear quality assurance programs has decreased. However, the previous industry dedication guidance was developed in the late 1980's and the NRC has only previously endorsed EPRI dedication guidance in Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently marketed Products," and Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs." Therefore, to address the need for current guidance the NRC endorsed the latest EPRI methods published in EPRI 3002002982 for CGD. The NRC had participated in the development of these methods.

Software

During inspection activities in FY's 2016-2017, the NRC staff identified a need for inspection guidance associated with safety-related software used for Digital Instrument and Control (DI&C) and Design and Analysis applications to ensure development under a Quality Assurance Program (QAP) that complies with the requirements of Appendix B to 10 CFR Part 50.

The NRC evaluated the necessity for guidance and issued inspection procedure (IP) 35710, "Quality Assurance Inspection of Software used In Nuclear Applications." The IP provides guidance for NRC inspectors to verify basic software lifecycle activities for translating conceptual design information into system requirements, allocating those requirements into hardware and software, designing and implementing both hardware and software, and testing of the components and/or system to ensure system requirements have been implemented correctly.

During FY's 2017- 2018, the vendor inspection staff successfully implemented IP 35710 in conjunction with other vendor-related inspection procedures (IP43002, "Routine Inspections of Nuclear Vendors" and IP 43004, "Inspection of Commercial-Grade Dedication Programs") on several vendor inspections that involved the use of software for safety-related applications. These included vendors providing safety-related design and analysis services, vendors developing software applications for use in safety-related DI&C systems, and vendors that performed CGD of software use in safety-related systems and components. As a result of these inspections, the staff confirmed that IP 35710 guidance provides a broad and useful foundation for the development of vendor inspection plans, covering a variety of software-related development approaches currently in use by the industry. The inspector's focus on critical areas such as configuration management, requirements traceability, and verification and validation activities, as described in the IP guidance, was paramount to ensuring effective and efficient inspections were conducted.

With current NRC actions underway to modernize the NRC's DI&C regulatory infrastructure, the effective implementation of inspection activities for the evaluation of vendors' software quality assurance controls and licensee oversight of vendor activities will remain vital.

Regulatory Issue Summary 2018-05

During recent NRC inspections at domestic and international vendor facilities that supply basic components to NRC-licensed facilities, the NRC staff identified several examples of vendor failures to adequately impose the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21. Specifically, the vendors failed to provide adequate oversight of their suppliers, and impose the regulations in the procurement documents sent to their suppliers. In these examples, vendors supplying basic components did not implement sufficient controls to ensure that applicable regulatory requirements were being adequately imposed in their procurement documents for basic components, and they did not demonstrate their suppliers had processes and controls in place to meet the applicable requirements of Appendix B to 10 CFR Part 50. Imposing the applicable regulatory requirements in the procurement documents for basic components and providing adequate oversight of suppliers is not only required, but it is also key in providing reasonable assurance that basic components will perform their intended safety function. Consequently, the NRC issued Regulatory Issue Summary (RIS) No 2018-05, "Supplier Oversight Issues Identified during Recent NRC Vendor Inspections," dated October 5, 2018, to remind our stakeholders of the applicable regulatory requirements for procuring basic components for NRC-licensed facilities and for providing oversight of their suppliers. This includes suppliers implementing quality assurance programs based on the following standards:

- International Organization for Standardization (ISO) 9001, "Quality Management System—Requirements," ISO/International Electrotechnical Commission (IEC) 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories"

- Subsection NCA-3800, "Metallic Material Organization's Quality System Program," in Subsection NCA, "General Requirements for Division 1 and Division 2," in Section III, "Rules for Construction of Nuclear Facility Components," of the American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel (B&PV) Code

- Article NCA-4000, "Quality Assurance Requirements," in Subsection NCA in Section III of the ASME B&PV Code • Subsection NCA-4200, "Metallic Quality System Program Requirements," in Subsection NCA in Section III of the ASME B&PV Code

- Subsection NCA-4200, "Metallic Quality System Program Requirements," in Subsection NCA in Section III of the ASME B&PV Code

In addition, the RIS also provides examples of common violations and nonconformances the NRC has identified during recent vendor inspections.

If you would like to suggest a topic, or have questions, comments, or want to be added to our electronic distribution list, please contact Toni Sakadales, Program Analyst, Quality Assurance Vendor Inspection Branch-2, by telephone at 301-415-6441 or by email at Antoinette.Sakadales@nrc.gov.

The Use of Commercial–Grade Replacement Parts in Environmental Qualification (EQ) Applications

Recently, there have been some questions raised over whether it is acceptable for licensee's (or third party dedicators) to use the CGD process to procure replacement parts for applications that require harsh environmental qualification under 10CFR50.49, without performing requalification testing and/or analysis. In its simplest form, the issues associated with the use of commercial-grade replacement parts in EQ applications are really issues of similarity. The similarity issues involve providing sufficient reasonable assurance that the replacement parts will perform in a similar way under accident conditions as those parts that were previously tested as part of the original qualification program. In some respects, this issue exists with all EQ items, both components and replacement parts, including those supplied by original equipment manufacturers under their Appendix B to 10 CFR Part 50 programs. The issue stems from the fact that in most cases, the subcomponents, parts, and materials that go into the manufacture of a nuclear EQ component are purchased by original equipment manufacturers (OEMs) from commercial suppliers.

OEM's that supply qualified EQ components maintain Appendix B QAP which include processes to maintain the validity of the qualification testing on the subsequently produced components and replacement parts that they provide. Specifically, controlling purchased commercial subcomponents and materials as well as evaluating any changes to manufacturing methods and processes for their potential impact on qualification. This is often a challenge, as in many cases, OEMs are relying on qualification testing performed 20, 30, or 40 years ago to certify components still being manufactured today. Throughout the life of the product being supplied, the subvendors supplying the commercial parts and materials are often changed, thus requiring the OEM to ensure that any substitution of parts and materials does not affect the validity of the original qualification process.

Typical in today's market, is that OEMs supplying EQ components rely on a combination of material testing, physical testing, surveillances, and operating experience to ensure that there haven't been any changes to the components being purchased today that would challenge or invalidate the original qualification. In some cases, vendors are forced into utilizing new sub-suppliers and due to differences in material or design, cannot make the similarity argument. In such cases, the OEMs have sometimes performed either full or partial requalification. In many cases, the OEMs are able to perform an evaluation that provides reasonable assurance that the replacement sub-components and/or materials are similar enough.

Of heightened concern, is the fact that some licensee's and third-party dedicators are now purchasing commercial replacement parts and dedicating these parts for use in a safety-related, EQ applications, without performing any specific qualification testing or analysis. This practice, while conceptually not really different from that described above, adds additional uncertainty. Some factors to consider when evaluating the acceptability of a CGD of an EQ replacement part would include:

- Where is the commercial part being procured from? Would the part be from the original EQ OEM (purchased as commercial as opposed to safety-related), directly from the same manufacturer of the part as that used by the EQ OEM, or would it be purchased from a distributor or different manufacturer.

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- Is the part being procured to the same commercial technical requirements as those used by the EQ OEM? If so, to what extent do those commercial technical specifications relate to the performance of the part in an EQ application?
- What critical characteristics are being defined and verified as part of the dedication process? How do these critical characteristics relate to ensuring the replacement part will perform in a similar manner in a harsh environment under accident conditions?
- What is the function of this part to the overall EQ component in which it is being installed?
- How much design margin exists with this replacement part with respect to its performance in a harsh environment? For example, how likely is it that small reductions in performance of this part might lead to failure of the parent component to perform its safety function? This information would likely be difficult to acquire from other than the original OEM.
- How complex is the part being dedicated in terms of materials and manufacturing?
- To what degree does operating experience exists regarding the performance of the materials used in the manufacturing of the replacement component?
- To what degree would we expect changes in the manufacturing process of the replacement component to impact its performance in a harsh environment?

While technically justifiable in some cases, there are a lot of factors that need to be considered when attempting to use the CGD process to purchase EQ replacement parts. The acceptability of the CGD of any one replacement part would need to be considered on a case by case basis, taking into account the concerns raised above and assessing to what degree the activities performed through the dedication process provide reasonable assurance that the replacement part is capable of performing its intended safety function acceptably in a harsh environment.

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