

THE VENDOR TIMES

NRC/NRR/DRO The Vendor Times

December 2020

The Director's Cut

In fiscal year (FY) 2020, the U.S. Nuclear Regulatory Commission (NRC) vendor inspection program (VIP) conducted a total of 14 inspections for both new and operating reactors, including vendor and quality assurance (QA) implementation. Not counted in these 14 inspections were observations of one Nuclear Procurement Issues Corporation (NUPIC) audit and one Korean Institute of Nuclear Safety (KINS) inspection. At these inspections, the NRC evaluates vendor compliance with 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, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

Due to the travel restrictions and mandatory lockdowns associated with the Coronavirus Disease 2019 (COVID-19) global pandemic, the Quality Assurance and Vendor Inspection Branch (IQVB) staff was unable to perform all of the scheduled vendor inspections for FY 2020. Therefore, the vendor inspection staff has reprioritized the vendor inspection schedule for FY 2021 to include the delayed vendor inspections from FY 2020. The vendor inspection staff also performed a number of remote, virtual inspections to accommodate the travel restrictions associated with COVID-19.

The vendor inspection staff continued to maintain constant communication with the nuclear supply chain stakeholders via the NRC's 2020 biennial Workshop on Vendor Oversight. This workshop was scheduled to take place in Baltimore, MD; however, due to the travel restrictions associated with COVID-19, the workshop was held virtually. Over 500 stakeholders participated in this 3 day virtual workshop. Because of the positive feedback received on the effectiveness of this virtual workshop, the IQVB staff is planning a virtual town hall meeting in FY 2021 to provide a more frequent dialogue with the nuclear supply chain stakeholders, as well as to discuss and to provide guidance of any current issues.

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



Chris Miller,
Director,
Division of Reactor
Oversight

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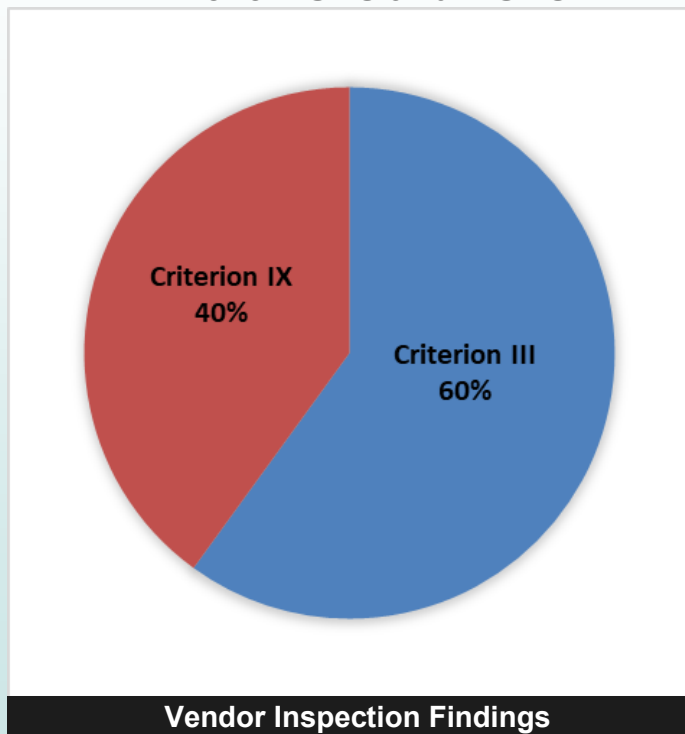
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2020 Vendor Inspection Trends

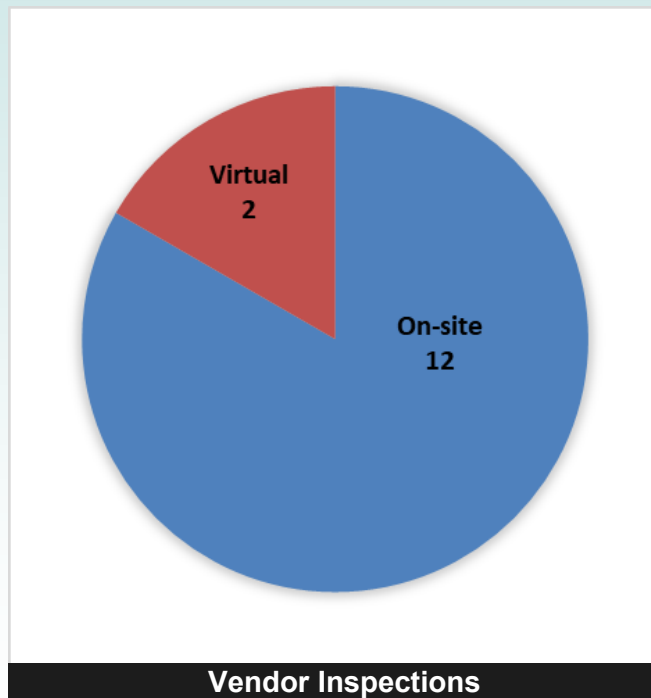
The Vendor Inspection Program Plan (VIPP) verifies that reactor applicants and licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the supply chain. It accomplishes this through a number of activities, including performing vendor inspections that will 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, 2019 to September 30, 2020, the vendor inspection staff completed a total of 16 activities, which included 14 vendor inspections, one observation of the KINS, and one NUPIC observation. These inspections assessed vendor compliance to provisions of Appendix B to 10 CFR Part 50 and 10 CFR Part 21. The NRC issued a total of five Notice of Nonconformances (NONs) against vendors during FY 2020. The decrease in the total number of NONs from FY 2019 to FY 2020 follows a similar decrease from FY 2018 to FY 2019, during a time of a

FY 2020 NOVs and NONs

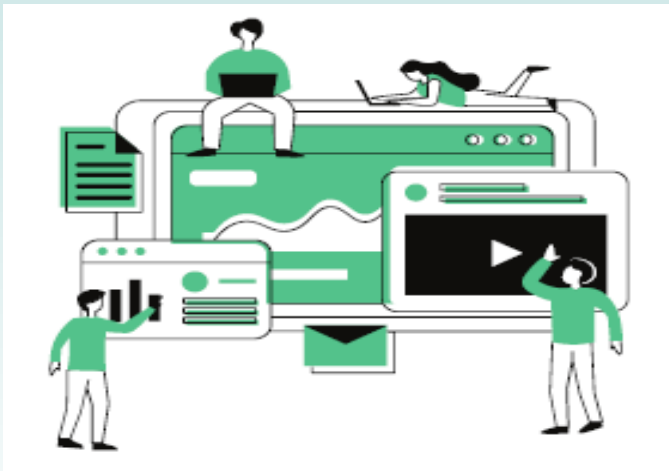


FY 2020 Inspections



reduced number of vendor inspections. The reduced number of vendor inspections performed in FY 2020 is largely due to the travel restrictions associated with COVID-19. Regarding 10 CFR Part 21, no Notice of Violations (NOVs) were issued to vendors during FY 2020, as was the case during FY 2019.

All five NONs cited against vendors fall within either Criterion III, “Design Control,” or Criterion IX, “Control of Special Processes” of Appendix B to 10 CFR Part 50. While this is not indicative of any industry trend considering that this was an one year performance and the reduced number of vendor inspections performed, more focus will be placed in these two criteria during future vendor inspections. This also indicates the continued need for a robust and wide-ranging VIP in order to distribute inspection resources for greatest efficacy throughout the industry’s supply chain of hundreds of safety-related Appendix B to 10 CFR Part 50 vendors. In addition to inspections for new and operating reactors, it is also anticipated that there will be a need to continue to perform limited inspections of vendor’s safeguards information programs and inspections of National Strategic Alliance for FLEX Emergency Response (SAFER) facilities.



2020 Vendor Workshop

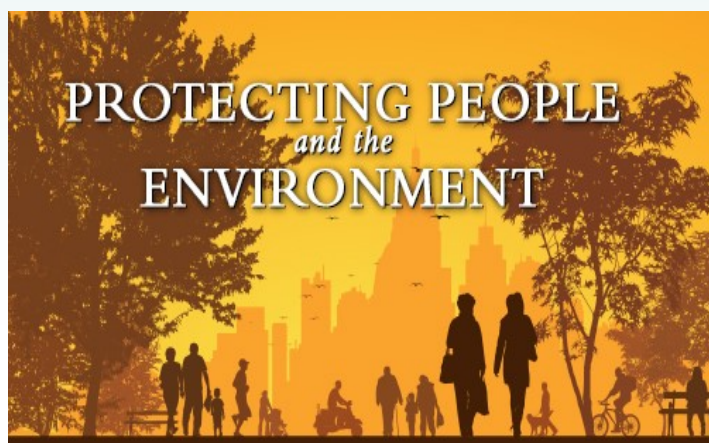
2020 Vendor Workshop

On June 2020, the Office of Nuclear Reactor Regulation (NRR), Division of Reactor Oversight (DRO), successfully hosted the first virtual NRC Workshop on Vendor Oversight. Due to concerns regarding COVID-19 and the importance of social distancing, the NRC held its Seventh Workshop on Vendor Oversight over the course of three days, June 23 to June 25, 2020. The workshop had an audience of about 500 attendees, representing companies and organizations from 15 countries including suppliers of basic components, industry groups, government regulatory agencies, and both foreign and domestic utilities. 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 included a keynote address by the NRR Office Director, Mr. Ho Nieh, as well as presentations from members of the NRC staff, Department of Homeland Security, Electric Power Research Institute (EPRI), Sargent & Lundy, Paragon Energy Solutions, Luminant, NuSource, Curtiss Wright Electro-Mechanical Division (EMD), and the United Kingdom. Presentations included topics such as 1) oversight of the supply chain under exigent conditions; 2) industry guidance for commercial-grade dedication; 3) 10 CFR Part 21 requirements and new guidance; 4) Safety Culture

and the Safety Conscious Work Environment; 5) critical manufacturing sector; and 6) qualifying a supplier using American Society of Mechanical Engineers (ASME) Section III.

For more information, visit <https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight.html>

- Jonathan Ortega-Luciano, Reactor Operations Engineer



Quality Assurance and Inspection Public Website

As an Agency that prides itself on openness, the NRC has a long history of, and commitment to transparency, participation, and collaboration in our regulatory activities. As such, in our effort to build on this, the IQVB maintains a public website with information associated with how the NRC implements the regulation for new reactor licensing and vendor QA inspections. This website contains information such as QA regulations, new reactor licensing and vendor inspection reports, inspection procedures, industry interactions, regulatory positions, past NRC meeting presentations, and information on past and future Workshops on Vendor Oversight, etc. The website can be found on the following address:

<https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance.html>

- Antoinette Sakadales, Vendor Inspection Program Analyst

COVID-19 Pandemic and Supplier Oversight

The current COVID-19 pandemic emergency limiting domestic and international travel, has resulted in licensees and their suppliers having significant challenges meeting their regulatory commitment associated with external audit or survey frequencies. In accordance with NRC regulatory guidance and nuclear industry quality standards, a typical supplier audit or survey is conducted on a triennial basis with a 90 day grace period afforded for unforeseen administrative issues. However, as a result of COVID-19 issues in the first quarter of 2020, licensees and suppliers became increasingly concerned that they might need to extend the grace period beyond the existing regulatory allowance in order to complete their oversight activities within an acceptable timeframe.

The NRC staff and industry representatives initially discussed the current challenges to performing required audits and surveys of the nuclear supply in a conference call on March 25, 2020. Issues discussed included, but were not limited to, the duration of an additional grace period, limitations on the use of that grace period, licensee measures that would need to be implemented to use the additional grace period, and methods to approve and disseminate any new regulatory positions for industry adoption.

Following the March 25th meeting, the NRC and industry stakeholders including the Nuclear Energy Institute (NEI), EPRI, NRC licensees, industry suppliers, and members of the public convened several additional meetings to evaluate various proposals and to determine appropriate measures licensees and the supply chain could put in place.

The results included proposed changes to licensee and supplier QA program descriptions to adopt an overall extension of 25% for the triennial audit or survey frequency (i.e., 9 months) during exigent conditions or extenuating circumstances. Examples of these conditions include, but not limited to: 1) declaration of a national emergency; 2) severe localized or national weather conditions; or 3) localized outbreak of a severe health concern to the public and licensee. To use this grace period, a licensee or supplier would also need to develop a documented evaluation for each supplier or sub-supplier they are going to extend in this manner. The evaluation would focus on verifying that the supplier is still implementing a QA program that meets Appendix B to 10 CFR Part 50 or have maintained adequate documented programmatic controls in place for the activity affecting quality; receipt inspection and industry operating experience are reviewed on an ongoing basis as the information becomes available; review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions; and a review of the results of previous source verifications, audits, survey and receiving inspection activities, and operating experience. Importantly, this alternative method of allowing the 25% extension is applicable to both domestic and international suppliers.

In order to make this approach available to all licensees and most suppliers, an NRC-licensee (Ameren) submitted a request to change their Quality Assurance Program Description (QAPD) in

accordance with 10 CFR 50.54(a)(4). The NRC reviewed and approved this submitted revision in a safety evaluation (ADAMS Accession No. ML20216A681), which allowed other licensees and suppliers to adopt similar changes to their programs without prior NRC approval.

Several vendors, with prior NRC reviewed QAPD, such as the Westinghouse Electric Company, submitted similar requests in accordance with 10 CFR 50.4(b)(7)(ii). For those vendors, individual safety evaluations were developed to allow them to adopt changes to their QAPD to use the 25% audit or survey grace period as well.

The NRC considered the maturity of the industry and its supply chain oversight in determining this allowance of a 25% extension for audits and surveys to be completed by licensees and suppliers from the date of the expiration of the triennial audit or survey frequency. This revision has been broadly adopted by the industry and provides a strong example of the NRC and industry stakeholders working together to find novel solutions to challenges brought about by the COVID-19 pandemic.

- Greg Galletti, Senior Reactor Operations Engineer



At Vogtle construction site: Laura Dudes - Region II Regional Administrator, Marissa Bailey - Division Director for Division of Construction Oversight, Brian Kemker - Vogtle Senior Resident Inspector, Jason Eargle - Vogtle Senior Resident Inspector, and Raju Patel - Reactor Operations Engineer

Compliance with 10 CFR Part 21 When Procuring ASME Section III Components

10 CFR Part 21, Subpart 21.31, "Procurement Documents," states that "Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply."

The regulations in Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50 require licensees and applicants to establish measures to ensure that applicable regulatory requirements, design bases, and other requirements necessary to ensure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services.

The NRC staff has identified several instances in which both domestic and international suppliers of basic components to US licensees and applicants have failed to impose the requirements of 10 CFR Part 21 in the procurement documents to their sub-suppliers as described below:

1. When procuring ASME Boiler and Pressure Vessel (B&PV) Code pressure-retaining components (ASME B&PV Code pressure retaining components are basic components) from N-Type Certificate Holders (CH) or Quality System Certificate (QSC) Holders, and
2. When procuring ASME B&PV Code pressure-retaining components from sub-suppliers which have been qualified as Material Organizations (MOs) by a CH or a QSC Holder in accordance with the requirements of NCA-4250, "Quality System Program Requirements," and Subparagraph NCA-3842.2, "Evaluation of the Qualified Material Organization's Program by Certified Material Organizations of Certificate Holders," of Subsection NCA, "General Requirements for Division 1 and Division 2," of Section III "Rules for Construction of Nuclear Facility Components," of the ASME B&PV Code. (Typically, qualified MOs do not have a program that meets the requirements of 10 CFR Part 21. However, when buying a basic component, purchasers are required to impose 10 CFR Part 21 on the procurement documents.)

Suppliers of basic components to NRC-licensed facilities are required to adhere to these requirements when imposed by their customers in the procurement documents. It is important to remember that ASME Section III components are basic components. As such, when buying a basic component from either an N-type CH, a QSC Holder, or a qualified MO, 10 CFR Part 21 shall be imposed on the procurement documents, whether that supplier is located in the US or internationally.

Imposing the requirements of 10 CFR Part 21 in procurement documents: 1) ensures that 10 CFR Part 21 is passed down to the sub-suppliers; and 2) 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.

- Yamir Diaz-Castillo, Reactor Operations Engineer



The NRC continued to perform some onsite inspections in FY2020 practicing social distancing guideline.

Remote Source Verification

On May 18, 2020, Columbia Generating Station requested approval of a proposed change to its Operational Quality Assurance Program Description (ADAMS Accession No. ML20139A225). This submittal requested implementing guidance found in the EPRI's Technical Report 3002019436 for performing remote source verification. In addition, the NRC staff reviewed EPRI's Technical Report 3002019436 (ADAMS Accession No. ML20150A115). The NRC staff reviewed the alternative screening criteria developed in Technical Report 3002019436 and determined that it provides licensees and vendors with acceptable guidance for using remote communication and video capabilities to perform remote source verification in extreme circumstances where it is not possible to perform on-site source verification due to conditions that threaten the health and safety of individuals performing the verification.

- Aaron Armstrong, Reactor Operations Engineer

Provisional Recognition of ISO/IEC 17025:2017

By letter dated February 20, 2020 (ADAMS Accession No. ML20054C066), NEI submitted Revision 1 to Technical Report (TR) NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," for NRC review and endorsement. Revision 1 of NEI 14-05A provides an updated approach for licensees and suppliers of basic components for using laboratory accreditation by Accreditation Bodies (ABs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (hereby after referred to as the ILAC accreditation process) in lieu of performing commercial-grade surveys for procurement of calibration and testing services.

The changes to Revision 1 of NEI 14-05A include:

- Clarifications on limits of use have been added to indicate that the ILAC process is not intended to be utilized for the commercial-grade dedication of Nondestructive Examination (NDE) services.
- Subcontracting of accredited services is prohibited. The laboratory that is contracted to perform the required accredited calibration or testing must perform the service and cannot subcontract the services to another accredited laboratory (new condition).
- When Method 2, "Commercial Grade Surveys" are utilized as an acceptance method, the survey report must document the acceptability of the commercial supplier's control over calibration and not merely state the commercial supplier uses accredited calibration or testing service providers based on accreditation to ISO/IEC 17025:2017.
- Clarification that a commercial-grade dedication technical evaluation is required as a part of the ILAC accreditation process to document the critical characteristics and acceptance method for calibration and testing services.
- The NRC's endorsement on the use of accreditation to the 2017 edition of ISO/IEC 17025 by ABs that are signatories to the ILAC MRA in lieu of performing a commercial-grade survey for the acceptance of calibration and testing services was largely based on ABs performing on-site accreditation assessments at laboratories. Due to travel restrictions associated with the COVID-19 pandemic, ABs are performing remote accreditation assessments. A limitation has been placed on the use of remote accreditation assessments to maintain accreditation. Accredited testing or calibration services performed on behalf of licensees and suppliers of basic components cannot be accepted from laboratories who have not undergone an on-site accreditation assessment within the past 48 months of the date of services (new condition).



In a letter dated September 11, 2020 (ADAMS Accession No. ML20259C391), NEI submitted an update to Revision 1 of NEI 14-05A, which incorporated NEI's responses to the NRC staff's request for additional information. Revision 1 of NEI 14-05A was updated to recognize the 2017 edition of ISO/IEC 17025 as the basis for the ILAC accreditation process and to address other minor editorial changes, clarifications, and adjustments based on operating experience identified subsequent to the NRC's initial endorsement in February, 2015.

As result of the ongoing COVID-19 pandemic, ILAC extended the transition period to the 2017 edition of ISO/IEC 17025 from November 30, 2020 to June 1, 2021. In light of ILAC's extension of the transition period, Revision 1 of NEI 14-05A also recognizes June 1, 2021, as an acceptable date for laboratories to transition to the 2017 edition of ISO/IEC 17025.

While the NRC finalizes its review and approval of the safety evaluation report endorsing Revision 1 of NEI 14-05A, the NRC extended its provisional recognition of the 2017 edition of ISO/IEC 17025 from November 30, 2020 to June 1, 2021 in a letter dated November 20, 2020 (ADAMS Accession No. ML20325A192).



- Dong Park, Reactor Operations Engineer

Potential Virtual Town Hall with External Stakeholders

Based on the positive feedback received for the virtual 2020 Workshop on Vendor Oversight, the IQVB staff is exploring the option of hosting a virtual town hall the year in 2021 to continue dialogue with the nuclear industry. The purpose of a virtual town hall is for IQVB staff to engage with external stakeholders to discuss any current issues of importance to the nuclear industry, and to provide guidance and clarification as necessary. The goal of the virtual town hall meeting is to keep the external stakeholders informed on activities related to vendor inspection, QA, etc. The town hall will be hosted on virtual platform. Like the workshop, the virtual town hall will be a Category 3 public meeting, and will not exceed more than 4 hours, depending on the topics chosen for discussion. The information on the virtual town hall will be announced on the NRC public meeting website and communicated to the external stakeholders through various organizations (EPRI, NEI, Nuclear Industry Assessment Corporation (NIAC) and NUPIC, etc.). The virtual town hall is free to attend; however, attendees will be required to register prior to the virtual town hall.

- Raju Patel, Reactor Operations Engineer

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 Yiu Law, Reactor Operations Engineer, Quality Assurance and Vendor Inspection Branch, by telephone at 301-415-0523 or by email at Yiu.Law@nrc.gov.