U.S.NRC
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THE VENDOR TIMES

The Director's Cut

Chris Regan, Acting Director, Division of Reactor Oversight

In fiscal year (FY) 2021, the U.S. Nuclear Regulatory Commission (NRC) vendor inspection program (VIP) conducted routine, reactive, design verification and qualification testing inspections of 10 vendors that provide components, parts, structural and mechanical modules, and services to operating nuclear power plants. 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." In addition to inspections, the vendor inspection staff observed four Nuclear Procurement Issues Corporation (NUPIC) audits and a French Nuclear Safety Authority (ASN) inspection of a vendor in the US, conducted a vendor inspection in parallel with ASN, participated in a multinational vendor inspection under the Nuclear Energy Agency's (NEA) Multinational Design Evaluation Program (MDEP) Vendor Inspection Cooperation Working Group (VICWG), conducted three licensing audits, and participated in one NRC Region II assist.

The vendor inspection staff performed a number of remote and hybrid inspections to accommodate the travel restrictions associated with the Coronavirus 2019 (COVID-19) pandemic and each vendor's personnel availability and facility operations. Taking this approach enabled the Quality Assurance and Vendor Inspection Branch (IQVB) staff to perform all of the scheduled activities for FY 2021, which included vendor inspections that were delayed from FY 2020 due to the impact of COVID-19.

The vendor inspection staff continued to maintain constant communication with the nuclear supply chain stakeholders via the NRC's 2021 Town Hall Meeting on Vendor Oversight. The town hall meeting was held virtually with over 220 attendees participating. The next town hall meeting is scheduled for June 2023. Lastly, the IQVB staff is planning to hold its 8th Workshop on Vendor Oversight on June 23, 2022 in Detroit, MI in conjunction with the NUPIC Vendor Conference.

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

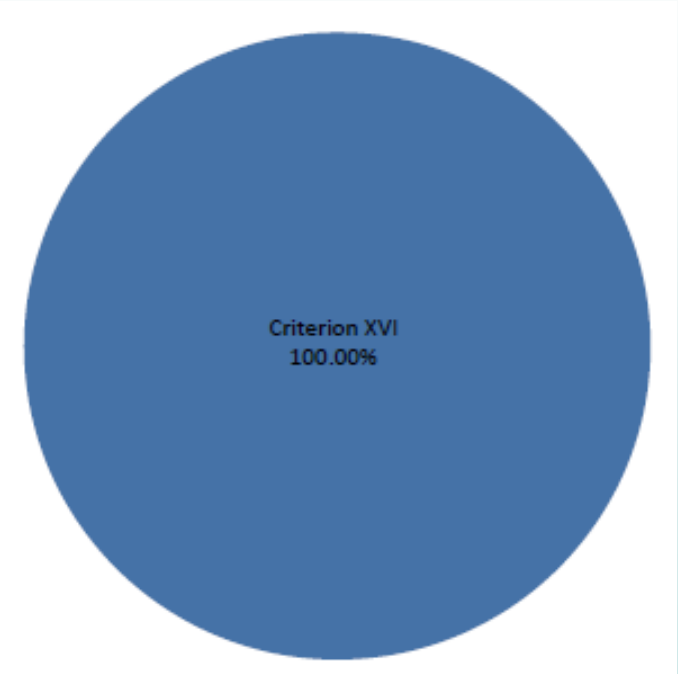
In This Issue:

2021 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 quality assurance (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.

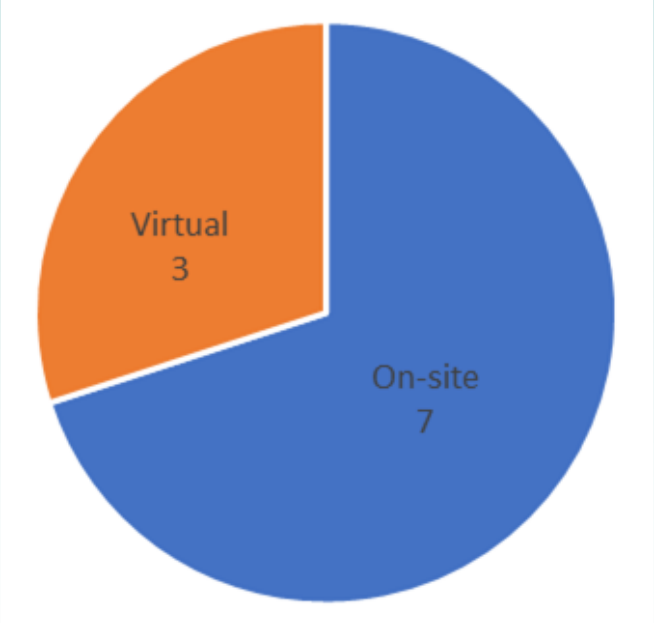
From October 1, 2020 to September 30, 2021, the vendor inspection staff completed a total of 21 activities, which included 10 vendor inspections, four observations of NUPIC audits, one observation of a French ASN inspection, one parallel vendor inspection with ASN and one multinational vendor inspection under the MDEP, three licensing audits, and one Region II assist.

FY 2021 NOVs and NONs



Vendor Inspection Findings

FY 2021 Inspections



Vendor Inspections

These inspections assessed vendor compliance to provisions of Appendix B to 10 CFR Part 50 and 10 CFR Part 21. The NRC issued one Notice of Nonconformance (NON) against a vendor during FY 2021. Regarding 10 CFR Part 21, no Notice of Violations (NOVs) were issued to vendors during FY 2021, as was the case during FY 2020.

The NON cited against the vendor fell within Criterion XVI, "Corrective Actions" of Appendix B to 10 CFR Part 50. The decrease in the total number of NONs issued from FY 2020 to FY 2021 is indicative of the implementation of the more than minor guidance in Inspection Manual Chapter (IMC) 0617. In addition to inspections for 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.

- Odunayo Ayegbusi, Reactor Operations Engineer

2021 Town Hall Meeting

2021 Town Hall Meeting

On June 24, 2021, the Office of Nuclear Reactor Regulation (NRR), Division of Reactor Oversight (DRO), successfully hosted the first Town Hall Meeting on Vendor Oversight. Due to concerns regarding COVID-19 and the importance of social distancing in response to the pandemic, the NRC held this town hall meeting virtually. The town hall meeting had an audience of about 220 attendees representing companies and organizations from 10 countries including vendors, industry groups, and government regulatory agencies. The town hall meeting provided an opportunity to our stakeholders in the nuclear supply chain to engage directly with the NRC staff to discuss regulatory and technical issues of interest to them. The town hall meeting included a keynote address by the NRR Office Deputy Director for Reactor Safety Programs and Mission Support, Mr. Mike King, as well as three presentations from members of the NRR/DRO's IQVB staff. The topics presented by the NRC staff included the importance of adhering to procurement specifications, regulatory alternatives for supplier oversight during exigent conditions, and an update on the NRC's recognition of the International Laboratory Accreditation Cooperation (ILAC) accreditation process. The rest of the town hall meeting was dedicated to an open Question & Answer session where the meeting attendees had an opportunity to ask questions to the NRC staff on a variety of topics. The next town hall meeting is tentatively scheduled for June 2023. For more information, please visit: https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/town-hall-meetings.html.

NRR/DRO/IQVB is currently planning its 8th Workshop on Vendor Oversight tentatively scheduled for June 23, 2022 in Detroit, MI. These vendor workshops generate an audience of approximately 500 individuals, comprised of industry representatives, licensees, vendors, and members of the public. The past seven vendor workshops have been held in conjunction with the NUPIC Vendor Conference in order to generate maximum participation since both meetings share the same target audience. For more information, please visit: https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight.html

- Yamir Diaz-Castillo, Reactor Operations Engineer

Remote Techniques and Supplier Oversight During Exigent Conditions

On January 2020 the U.S. Department of Health and Human Services declared a public health emergency for the United States to aid the nation's healthcare community in responding to COVID-19. Then, on March 2020, COVID-19 was characterized as a pandemic by the World Health Organization.

These unforeseen situations, along with travel restrictions domestically and internationally, resulted in licensees and their suppliers having significant challenges meeting their regulatory commitments associated with oversight of their suppliers. 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 travel restrictions, licensees became increasingly concerned that they might need to extend the grace period beyond the allowance to complete their oversight activities within an acceptable timeframe.

The NRC staff held several meetings with industry

representatives, including the Nuclear Energy Institute (NEI), the Electric Power Research Institute (EPRI), NRC licensees, industry suppliers, and members of the public, to evaluate various proposals and determine appropriate measures licensees could put in place to address these challenges. The industry presented approaches to address procurement from suppliers that have exceeded the 3-year audit/commercial-grade surveys (CGS) cycle due to COVID-19. Some of the interim approaches included: (1) procuring from an alternate source, (2) performing commercial-grade dedication, (3) implementing a hybrid method for performing the audit on-site and remotely, and (4) using a provisional procurement authorization in conjunction with the corrective action program (CAP). The NRC staff stated that the industry's approach to use the CAP appeared appropriate. Licensees' use of the CAP for conditions adverse to quality is within the licensee's licensing basis and/or regulatory framework. The NRC staff understood that this approach was intended to be temporary while the NRC awaits a formal submittal from a licensee for review and approval of performing remote supplier audits and CGS.

On March 31, 2021, an Observation Public Meeting, formerly known as a Category 1 public meeting (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21092A008), was held between the NRC and representatives of Southern Nuclear Operating Company (SNC, the licensee). The purpose of the meeting was for SNC to describe its plan to submit a license amendment request (LAR) to change their Quality Assurance Topical Report (QATR) in accordance with the requirements of 10 CFR 50.54(a)(4). Subsequently, on May 7, 2021, SNC submitted a LAR (ADAMS Accession No. ML21127A184), to modify their QATR to utilize the guidance in EPRI Technical Report (TR) 3002020796, "Remote Assessment Techniques: Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions," in lieu of the regulatory requirements of Criterion VII, Control of Purchased Material, Equipment, and Services of Appendix B to 10 CFR Part 50, for performing audits and CGS at the supplier's location. The proposed change will provide alternate methods of performing audits and CGS at the contractor or subcontractor source under certain conditions. The use of these remote assessment techniques (i.e. provisional and fully remote assessments) will only be applicable when a pandemic or similar state of emergency has been declared restricting access or travel to and/or from those locations affected by State and national declarations. Furthermore, these methods are to be used for those previously qualified suppliers to renew their qualifications. These methods are not to be used for the evaluation and approval of new suppliers.

The NRC reviewed and approved this submitted revision to SNC's QATR in a safety evaluation dated June 22, 2021 (ADAMS Accession No. ML21161A201).

- Jonathan Ortega-Luciano, Reactor Operations Engineer

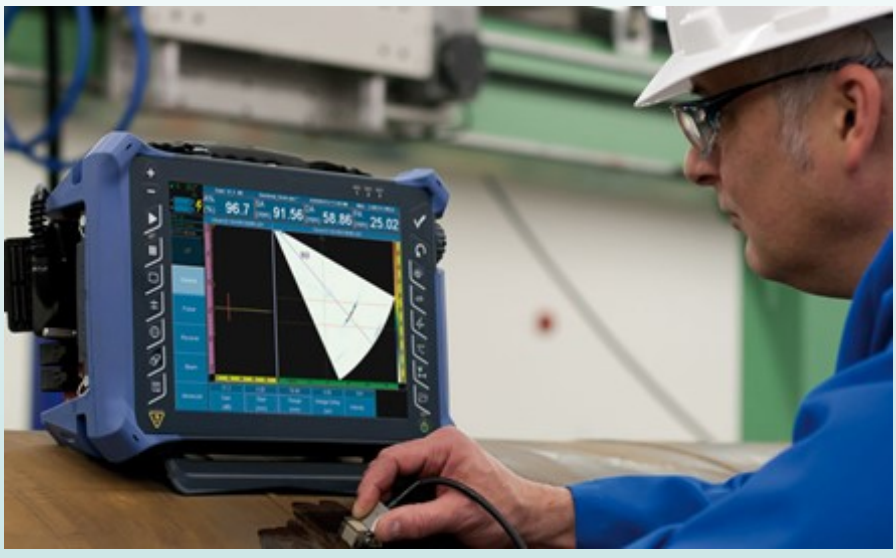
Use of NEI 17-06 as part of the Modernization of the NRC's Digital I&C Regulatory Infrastructure

In March 2016, as a part of the Integrated Action Plan to modernize digital instrument and control (DI&C) regulatory infrastructure, NEI proposed the concept of leveraging Safety Integrity Level (SIL) certificates to support the dedication of commercial digital equipment. This concept was initially presented in Draft B of NEI 17-06, "Guidance on Using International Electrotechnical Commission (IEC) 61508 SIL Certification to Support the Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Related Applications," which NEI submitted to the NRC for feedback in September 2019.

Currently, licensees follow the NRC-endorsed EPRI TR-106439, "Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications," guidance for dedicating commercial digital items. EPRI TR-106439 was accepted by the staff in a safety evaluation, dated July 17, 1997 (ADAMS Accession No. ML12205A284). For verification of dependability characteristics of the digital item being dedicated, this guidance typically requires a survey of the original equipment manufacturers (OEM) design and developmental processes. Consistency of these surveys is largely dependent on the level of cooperation received from the OEM and the specific approach employed by the licensees. In contrast, the use of the SIL certification process for the same digital item could be more standardized and consistently applied because the OEM would need to provide all necessary design and development details required by the IEC 61508 standard used for SIL certification.

If NEI 17-06 is endorsed, all commercial-grade digital items could be dedicated by a standard set of design details that is necessary for demonstration of the dependability characteristics. This standardization could allow NRC inspections to be streamlined, consistent with NEI 17-06 guidance, and provide less regulatory uncertainty in the dedication of commercial digital items while continuing to ensure safety and security.

From November 3-6, 2020, the vendor inspection staff observed an accreditation evaluation of Exida LLC, a SIL certifying body, performed by the ANSI National Accreditation Board (ANAB), the accrediting body, to facilitate the NRC staff's review of NEI's guideline. The ANAB accreditation and NRC observations were conducted remotely via video teleconferencing. Specifically, the staff focus was to observe NEI activities to validate aspects of the ANAB accreditation process and to confirm information provided in NEI 17-06 that addresses the use of the SIL certification process to support dedication activities related to dependability characteristics of an item. The specific goals of the audit included ensuring the adequacy of the SIL accreditation and certification processes with respect to compliance with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.



Following the audit observations, NEI continued to work on finalizing NEI 17-06 with periodic engagements with the NRC staff during several public meetings. In February 2021, NEI submitted NEI 17-06, Rev. 0 "Guidance on Using IEC 61508 SIL [Safety Integrity Level] Certification to Support the Acceptance of Commercial Grade

Digital Equipment for Nuclear Safety Related Applications," for NRC review and endorsement. On September 28, 2021, the NRC staff held a public meeting with NEI to discuss the staff's comments on the current version of NEI 17-06, and in November 2021, the NRC vendor inspection staff participated in a second observation of an accreditation evaluation performed by the ANAB of Exida LLC, as part of the NRC staff's review of NEI 17-06.

NEI is planning to revise NEI 17-06 to address the staff's comments and audit observations, and resubmit the report later this calendar year. The staff is continuing their review with the focus on ultimately developing a regulatory guide to endorse the finalized version of NEI 17- 06.

- Greg Galletti, Senior Reactor Operations Engineer

Waterford Unit 3 Core Protection Calculator Replacement Project Licensing Review and Vendor Inspections

By letter dated July 23, 2020, Entergy Operations, Inc. submitted a request to amend the license of Waterford Steam Electric Station, Unit 3 (ADAMS Accession No. ML20205L588) to upgrade its core protection calculator system (CPCS). The NRC staff performed this LAR review using the alternate review process (ARP) in Digital Instrumentation and Controls (DI&C) Interim Staff Guidance (ISG)-06, Revision 2, "Digital Instrumentation and Controls Licensing Process, Interim Staff Guidance" (ADAMS Accession No. ML18269A259). Under the ARP, the acceptability of the DI&C system is based on system-level and architectural design information, the framework for the DI&C system development processes, and the licensee's oversight, as documented in the vendor oversight plan, and evaluation of the vendor's DI&C system development process activities. Detailed design, implementation, and factory acceptance testing information is not evaluated during the LAR review. Therefore, verification that the design, implementation, and factory acceptance testing that were performed in accordance with the development processes described in the LAR may be confirmed using a combination of vendor inspections and audits/inspections of the licensee's vendor oversight activities as described in the LAR.

For the Waterford Unit 3 CPCS digital replacement project, Westinghouse Electric Company (WEC) is the vendor responsible for the development of the system requirements, software and hardware requirements, detailed software and hardware design and implementation, all factory acceptance testing, and delivery of the completed CPCS to the Waterford Unit 3 site. In accordance with the framework of the ARP in DI&C ISG-06, the NRC staff reviewed Entergy's Vendor Oversight Plan (VOP) summary for the CPCS digital replacement project and performed audits of the VOP, including vendor oversight activities completed by Entergy of WEC's processes and design outputs for the CPCS. In addition, the NRC performed vendor inspections at WEC on March 25 through March 29, 2021 for the Waterford Unit 3 CPCS requirements phase activities and on July 26 through August 4, 2021 for the design, implementation, and factory acceptance testing phases activities. As documented in the inspection reports (ADAMS Accession No. ML21123A080 and ML21251A610) for these two inspections, the NRC inspection team did not identify any findings of significance. These two vendor inspections complemented the NRC's licensing review activities for the Waterford Unit 3 CPCS LAR. The NRC issued the license amendment for the Waterford Unit 3 CPCS digital replacement project on August 24, 2021 (ADAMS Accession No. ML21131A243), which is the first successful use of the ARP in DI&C-ISG-06. The NRC also conducted an inspection of Entergy on their oversight of WEC for the factory acceptance

testing activities and will be conducting additional site inspections of installation and site testing activities once the CPCS equipment is delivered to the Waterford Unit 3 site.

- Deanna Zhang, Senior Reactor Operations Engineer

FY 2021 MDEP VICWG Activities

Overview

In the last year, IQVB participated in three MDEP VICWG inspections and/or observations. The purpose of these inspection/observation activities is to foster international cooperation regarding regulatory oversight of the supply chain of new and operating reactors through increased cooperation and communication. Through the MDEP VICWG, international regulatory bodies share inspection experiences, observations, and inspection methodologies to ultimately leverage international regulatory inspection activities in support of effective and efficient regulatory oversight. A summary of the areas inspected, and the overall results of the inspections are covered below.

4th Multinational Vendor Inspection at Framatome in Saint Marcel, France

On May 2, 2021 through May 6, 2021 (Session 1) and June 28, 2021 through July 02, 2021 (Session 2), the MDEP VICWG conducted a hybrid inspection of Framatome in Saint Marcel, France. The inspection was led onsite by ASN, and included inspectors from United Kingdom, Finland, South Africa that participated in a hybrid capacity while the NRC staff participated in a remote capacity. The purpose of this MDEP inspection was to obtain more information on the issues identified with Framatome's post weld heat treatment and welding processes. The NRC staff documented the inspection in a trip report (ADAMS Accession No. ML21222A051) and are currently developing lessons learned from the inspection.

At Flowserve Facility:
Greg Galletti (L) with ASN Officials

Flowserve Inspection Observation

In addition to the MDEP inspection, on September 21 and 22, NRC staff participated as an observer of a vendor inspection conducted by the ASN at Flowserve Corporation, Raleigh, North Carolina. This observation was conducted under the protocols of the MDEP VICWG. The ASN inspectors verified the quality program implemented for EDF products to ensure conformance to the requirements of the French pressure equipment code. Focus areas included traceability requirements, supplier oversight and audits, special processes including welding, heat treatment, and non-destructive testing, nonconformance program, and material control. The ASN inspectors also evaluated Flowserve's safety culture,

counterfeit, fraudulent, and suspect items program implementation.

At Fairbanks Morse Facility: Aaron Armstrong - Reactor Operations Engineer, Kerri Kavanagh - IQVB Branch Chief, and Odunayo Ayegbusi - Reactor Operations Engineer with three ASN Officials

Fairbanks Morse Inspection

On September 20 through 24, NRC continued participation with the MDEP VICWG by conducting a parallel vendor inspection with ASN at Fairbanks Morse in Beloit, Wisconsin. The parallel inspections were conducted under the protocols of the NEA's MDEP VICWG. The NRC inspectors focused on commercial-grade dedication, supplier oversight and audits, nonconformances and corrective actions. The ASN inspectors verified the quality program implemented for EDF products to ensure conformance to the French requirements. During the parallel inspections, ASN and NRC inspectors conducted joint debriefs and exit meetings, comparing approaches between the ASN and NRC vendor inspection programs.

- Greg Galletti (Senior) & Aaron Armstrong, Reactor Operations Engineer

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," to the U.S. Nuclear Regulatory Commission (NRC) for NRC staff review and approval. On September 11, 2020 (ADAMS Accession No. ML20259B731), NEI submitted an update to Revision 1 of NEI 14-05A. Revision 1 of NEI 14-05A provides an updated approach for licensees and suppliers of basic components to use laboratory accreditation by Accreditation Bodies (ABs) that are signatories to the 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 performed by domestic and international laboratories accredited by signatories to the ILAC MRA. NEI 14-05A was updated to recognize the 2017 edition of the International Organization for Standardization (ISO)/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories," as the basis for the ILAC accreditation process and to address other minor adjustments based on operating experience identified subsequent to the NRC's initial approval in a safety evaluation dated February 9, 2015 (ADAMS Accession No. ML14322A535). In addition, Revision 1 to NEI 14-05A includes two new conditions related to subcontracting of services and remote accreditation assessments due to the travel restrictions caused by COVID-19.

- 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).

- The NRC's endorsement of 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 caused by the COVID-19, 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).

When purchasing commercial-grade calibration and testing services from domestic and international calibration and testing laboratories accredited by an ILAC MRA signatory, licensees and suppliers of basic components may use the ILAC accreditation process in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process provided the conditions from NEI 14-05A, Revision 1, safety evaluation are met.

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

- Clarifications on limits of use have been added to indicate the ILAC process is not intended to be utilized for the commercial-grade dedication of nondestructive examination services.

- When Method 2, “Commercial Grade Surveys,” is utilized as an acceptance method, the commercial-grade 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 the 2017 edition of ISO/IEC 17025.

- 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.

For licensees, the use of the 2017 edition of ISO/IEC 17025 as part of the ILAC accreditation process in lieu of performing a commercial-grade survey represents a QA alternative to the previously accepted QA program. As such, licensees may adopt the QA alternative of using the 2017 edition of ISO/IEC 17025 provided that the bases of the NRC’s approval are applicable to the licensee’s facility pursuant to the requirements of 10 CFR 50.54(a)(3)(ii).

After June 1, 2021, the 2005 edition of ISO/IEC 17025 became invalid and only accreditation to the 2017 edition of ISO/IEC 17025 can be achieved and recognized under the ILAC MRA process.

- Dong Park, Reactor Operations Engineer

Onsite, Remote, and Hybrid Vendor Inspections

Since March 2020 when COVID-19 was declared as a national pandemic, IQVB has conducted a total of 38 vendor inspection activities, including NUPIC observations and audits. Of the 38 activities, 21 were conducted onsite at the vendors' facilities, 17 were conducted remotely and 4 conducted with a hybrid of onsite and remote inspection team members. The IQVB staff considered many factors on a case-by-case basis for each inspection to decide whether the inspection should be conducted onsite at the vendor's facility, remotely or a hybrid of both. These factors included but were not limited to:

- The severity of the COVID-19 situation at the vendor's location at the time of the inspection. This included taking into consideration availability of vendor personnel and facility operations in respect of the vendors' workplace requirements.
- The risk benefit and appropriateness of conducting an onsite inspection versus a remote inspection. For remote inspection, the inspection scope should be limited to those areas that can be effectively inspected remotely (e.g., supplier oversight, corrective actions, internal audits, 10 CFR Part 21, etc.) During the inspection, the inspection team leader monitors the inspection scope and ensures the inspection accomplishes the agency's mission.
- The safety significance and complexity of the equipment and services provided by the vendor.
- The performance history of the vendor such as the frequency of deficiencies identified during previous inspections.

The VIPP (ADAMS Accession No. ML21243A311) provides performance metrics for the VIP and establishes the required number of vendor inspections for each fiscal year.

- Yiu Law, Reactor Operations Engineer

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We welcome useful and informative feedback on the content of this newsletter. Please contact Odunayo Ayegbusi, Reactor Operations Engineer, IQVB, by telephone at 301-415-8107 or by email at Odunayo.Ayegbusi@nrc.gov.