U.S.NRC
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THE VENDOR TIMES

The Director's Cut

Chris Miller,
Director,
Division of Reactor Oversight

In fiscal year (FY) 2019, the U.S. Nuclear Regulatory Commission's (NRC's) vendor inspection program (VIP) completed its transition to the Division of Reactor Oversight (DRO) in the Office of Nuclear Reactor Regulation (NRR). We conducted a total of 20 inspections for both new and operating reactors, including vendor, quality assurance (QA) implementation, and aircraft impact assessment (AIA) inspections. Not counted in these 20 inspections were observations of Korea Institute of Nuclear Safety and Nuclear Procurement Issues Corporation (NUPIC) audits, and an International Laboratory Accreditation Cooperation (ILAC) NUPIC observation.

The NRC has maintained a VIP focused on ensuring the integrity of the nuclear supply chain, an objective that is critical to ensuring the safety of the nation's nuclear power fleet. Through direct inspection of suppliers of nuclear safety-related materials, components, and services, the NRC's VIP provides the regulatory oversight necessary to ensure the integrity, quality, and performance of the materials, components, and services that are relied upon to maintain nuclear safety. Since the establishment of the VIP, the mission has not changed, and we continue 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 and Vendor Inspection Branch (IQVB) inspectors observed 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 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 vendor inspection staff will continue to communicate with the nuclear supply chain stakeholders via the NRC's 2020 Workshop on Vendor Oversight. Our oversight consists of three primary activities: (1) direct inspections of vendors providing safety-related components, materials, and services, (2) observation of joint utility audits of suppliers conducted via NUPIC, and (3) NRC participation on the American Society of Mechanical Engineers (ASME) Committee on Nuclear Certification (CNC) and Committee on Authorized Inspection Agencies (CAA) which oversees the accreditation of ASME certificate holders and the authorized inspection agencies, respectively. We continue to engage industry organizations such as NUPIC, the Multinational Design Evaluation Program (MDEP) Vendor Inspection Cooperation Working Group (VICWG), the Electric Power Research Institute (EPRI) Joint Utility Task Group (JUTG), and the ASME Nuclear Quality Assurance-1 (NQA-1). The Vendor Workshop is scheduled for June 18, 2020 in Baltimore, MD. Based on stakeholder feedback, the Vendor Workshop topics are going back to the basics.

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

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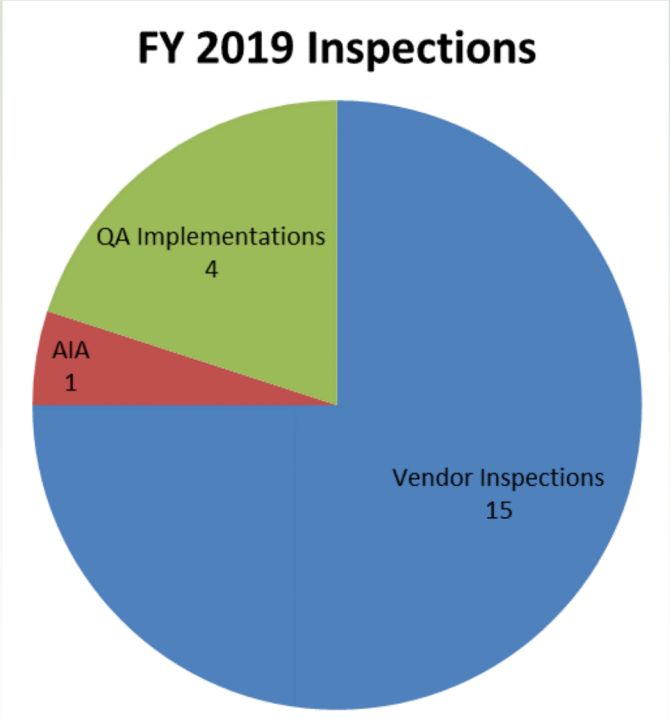
2019 Vendor Inspection Trends

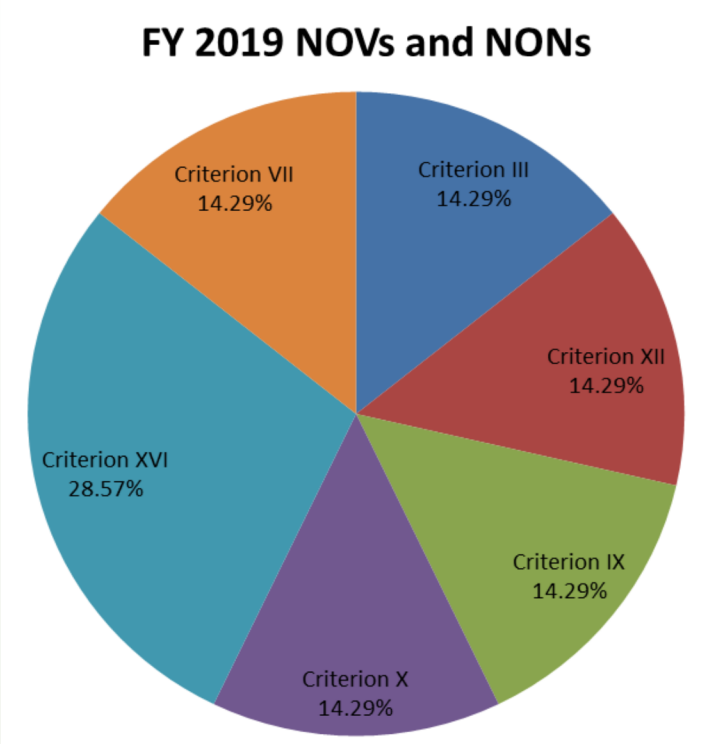
The Vendor Inspection Program Plan (VIPP) verifies that reactor applicants and licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the supply chain. It accomplishes this through a number of activities, including: performing vendor inspections that will verify the effective implementation of the vendor's QA program, establishing a strategy for vendor identification and selection, 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, 2018 to September 30, 2019, the vendor inspection staff completed a total of 23 activities, which included 20 vendor inspections, one observation of the Korean Institute of Nuclear Safety (KINS), and two NUPIC observations. These inspections assessed vendor compliance to provisions 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," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." The NRC issued a total of seven Notice of Nonconformances (NONs) against vendors during FY 2019. The decrease in the total number of NONs from FY 2018 to FY 2019 follows a similar decrease from FY 2017 to FY 2018, during a time of a decreasing number of vendor inspections from both FY 2017 to FY 2018, and then again from FY 2018 to FY 2019. Regarding 10 CFR Part 21, no Notice of Violations (NOVs) were issued to vendors during FY 2019, as was the case during FY 2018.

The balanced spread of one to two NONs each (among various different Appendix B criteria) demonstrates the continued need to distribute our inspection resources for maximum efficiency throughout the industry's supply chain. Although it is anticipated that the number of vendor inspections necessary for routine oversight, and inspection, tests, analyses and acceptance criteria (ITAAC) review associated with new reactor projects will continue to decline, there has been an increasing trend in the number of allegation related inspections. In addition to the inspections for new and operating reactors, it is also anticipated that we will need to continue to perform limited inspections of vendors' safeguards information programs and inspections of National Strategic Alliance for FLEX Emergency Response (SAFER) facilities.



Vendor Inspections



Vendor Inspection Findings

2010 Vendor Workshop in New Orleans, LA

2020 Vendor Workshop

The Division of Reactor Oversight (DRO), Office of Nuclear Reactor Regulation, is planning their 2020 Vendor Workshop scheduled for June 18, 2020 in Baltimore, Maryland. Since 2008, the vendor inspection program has facilitated biennial public workshops related to vendor oversight. These vendor workshops generate an audience of approximately 500 individuals, comprised of industry representatives, licensees, vendors, and members of the public. The past six vendor workshops have been held in conjunction with the NUPIC Vendor Conferences in order to generate maximum participation, since both meetings share the same target audience.

Some of the proposed topics for the 2020 vendor workshop include new Part 21 guidance (Regulatory Guide 1.234), international vendor inspections, compliance with Appendix B to 10 CFR Part 50 through the use of code and quality standards, commercial grade dedication, and controlling a commercial item under an Appendix B program. For more information visit https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight.html

- Jonathan Ortega-Luciano, Reactor Operations Engineer

Incorporation of Safety Conscious Work Environment in Vendor Inspections

As the Agency transforms, the Office of New Reactors has been merged into the Office of Nuclear Reactor Regulation (NRR). With this merger, the IQVB is currently reviewing and updating Inspection Manual Chapters, Inspection Procedures and staff guidance documents. One of the of the areas currently being updated is the inclusion of Safety Conscious Work Environment (SCWE) observations and assessments into the VIP. Although SCWE observations and assessments have been performed at vendor facilities in the past, no documented guidance existed for the vendor inspection staff. In efforts to align with NRR, guidance has been included in an Inspection Manual Chapter. The inclusion of SCWE in Inspection Manual Chapter 0617, “Vendor Quality Assurance Implementation Inspection Reports,” does not change the expectations of past vendor SCWE practices. Identified strengths and weaknesses are documented in vendor inspection reports subsequent to review and approval by IQVB’s Branch Chief.

- Aaron Armstrong, Reactor Operations Engineer

Quality Assurance and Vendor Inspection Public Web Pages

As an Agency that prides itself on openness, the NRC has a long history of, and is committed to transparency, participation, and collaboration in our regulatory activities. As such, in our effort to build on this, the IQVB maintains a public Web site with information associated with how the NRC implements the regulations for new reactor licensing and vendor QA inspections. This Web site 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 Web site can be found on the following address: https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance.html.

- Antoinette Sakadales, Vendor Inspection Program Analyst

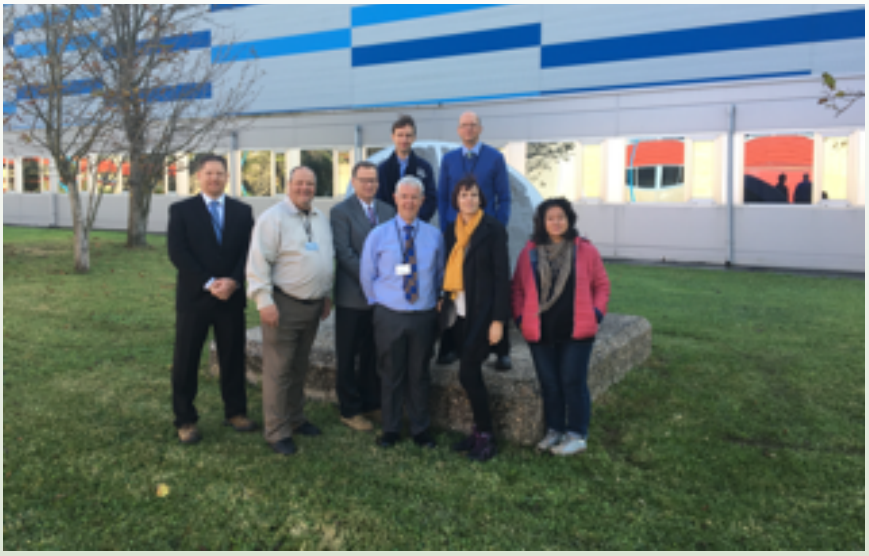
NRC Participation in MDEP/VICWG Inspection

From October 21-25, 2019, NRC Vendor Inspectors led a team of inspectors representing France, the United Kingdom, and the United States in performing the third MDEP inspection at Equipos Nucleares, S.A. S.M.E. (ENSA) in Cantabria, Spain.

The purpose of the multinational inspections is to foster international cooperation amongst nuclear regulatory agencies to leverage the resources and talents of our regulatory peers in other countries. To this end, we actively participate in bilateral and multilateral interactions with our international counterparts to help enhance our vendor oversight capabilities, and to foster more effective and efficient monitoring of the nuclear industry supply chain.

The MDEP inspections are comprised of two different inspection types: multinational and joint inspections. These inspection types are described in the MDEP protocol VICWG-01, “Witnessed, Joint, and Multinational Vendor Inspection Protocol,” Revision 2, dated March 20, 2014.

A multinational inspection (in the MDEP protocol, paragraph 4.3) is an inspection carried out by two or more regulators based on the MDEP Common QA requirements described in the MDEP VICWG Technical Report, TR-VICWG-03, “QA/QM Criteria for Multinational Vendor Inspection,” Revision 1, dated January 20, 2014. This type of inspection was conducted during the first MDEP inspection at Valinox, in Montbard, France in 2014.



The second type of MDEP inspection is a joint inspection activity (in the MDEP protocol, paragraph 4.2)

in which one regulator conducts an inspection according to its own regulatory framework with the participation of one or more other regulators' inspectors. For the ENSA inspection, this was the protocol followed. The US lead the inspection and France and United Kingdom participated as inspectors. The inspection was performed in accordance with NRC inspection procedures and provided an opportunity for our regulatory counterparts to gain inspection experience using the NRC's inspection methodologies.

During this inspection, the MDEP inspectors evaluated implementation of selected portions of ENSA's quality assurance program applicable to on-going and completed safety-related fabrication and testing activities to assess compliance with the provisions of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.

The NRC is currently drafting a vendor inspection report documenting the MDEP inspection activities which will be available on the NRC public Web site and in the NRC's Agencywide Documents Access and Management System (ADAMS).

The inspection was considered a valuable cooperative exercise by all of the member-nations involved and based on the success of the ENSA inspection; the VICWG will likely continue performing multinational inspections.

- Greg Galletti, Senior Reactor Operations Engineer

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Issues Identified with the Environmental Qualification (EQ) Thermal Aging Analyses for Electric Equipment Important to Safety

Background

The NRC's IQVB routinely performs inspections at vendor facilities that supply EQ components or at laboratories performing EQ testing. In addition, over the last two years, as part of its baseline inspection program, the NRC has conducted focused inspections on the EQ of electric equipment important to safety. While the focus of these inspections was primarily on the licensee's program for establishing and maintaining the EQ of electric equipment, the qualification basis for most electric equipment ties back to vendor provided data and information. This information includes the vendor and laboratory conducted testing programs, the test results, and supporting information. While much of the EQ testing of components was conducted many years ago, the test reports and the associated test data are still being utilized by licensees to support new analyses. The need for these new analyses are a consequence of licensees' extending the life of EQ components to account for plant life extensions or revising previously determined accident profiles as a result of design changes (e.g., power uprates), or the discovery of new environmental hazards.

Since the cost of repeating EQ testing is high, to the extent possible, licensees try to justify the qualification of existing equipment by performing new analyses, using a combination of updated site-specific data, as well as original data taken from the original qualification testing program. One common approach that we have seen is for licensees to revise thermal aging calculations using more realistic site-specific temperature profile data taken from actual measurements at a component's installed location. Since the original qualification program generally utilized a conservative temperature profile that was designed to cover most plants, using site-specific data typically affords some margin that can be utilized to extend the qualified life of the installed equipment. Another important input into the thermal aging calculations, along with this site-specific temperature data is the activation energy of the affected materials. Many of the inspection findings identified during recent NRC inspections involved inadequate justification for the activation energies used.

Thermal Aging Analyses and the Arrhenius Equation

The Arrhenius thermal aging equation that is used for EQ applications has only a few variables: (1) the temperature at which the component is aged (which may be different than the oven temperature); (2) the length of time the component is aged; (3) the temperature the component will actually experience during installation (can be an average); and (4) the activation energies of the non-metallic materials that contribute to the overall safety function of the component. Inputting these parameters into the Arrhenius equation will provide data to support a qualified life for a given component. The choice of the aging period and aging temperature are commercial decisions, designed to provide a reasonable qualified life for a given set of conditions.

Activation Energy and Temperature Selection

EQ components are typically comprised of many different materials. When performing thermal aging calculations, all non-metallic materials that contribute to the various failure mechanisms should be considered and the most limiting combination of activation energies and temperatures for the materials in question should be selected. When determining the appropriate temperatures to input into the Arrhenius equation, consideration should be given for self-heating effects and thermal heat transfer, and any differences between the installed and laboratory aging environments (such as the use of forced air ovens). Choosing an appropriate activation energy for a given material is critical to establishing a qualified life, as small changes in the activation energy can result in large changes in the qualified life of a component. The list below includes several examples of findings in this area that were identified during recent NRC inspections.

- A verified reference was not provided for the activation energy used.
- Not all materials in a given component were assessed to determine the most limiting activation energy.
- The activation energy chosen for a given material was for a material property that was unrelated to the safety function of the material or subcomponent.
- Insufficient basis was given for using an activation energy derived from testing of non-identical materials or just a material family type.
- The testing method used to determine the activation energy was inappropriate for the application in question.
- Not accounting for the heat transfer effects when using forced air ovens (when evaluating internal temperatures of normally energized components with significant self-heating effects).
- Using non-conservative methods for determining internal heat rise due to self-heating effects

The above represent some, but not all, of the many findings that the NRC has identified in this area during recent inspections. In all cases, these issues were entered into the licensee's or the vendor's corrective action programs, and for some findings, resulted in reduction in the qualified life of the affected components.

- Jeffrey Jacobson, Senior Reactor Operations Engineer

Farewell - On a personal note, we say goodbye to our longtime friend and colleague Jeffrey Jacobson, who retires after almost 40 years of federal service, 34 years with the NRC. During his distinguished career, Jeff has spent most of his time either leading or managing a wide range of NRC inspections and inspection programs, including inspections at operating nuclear power plants, manufacturers, and service providers.

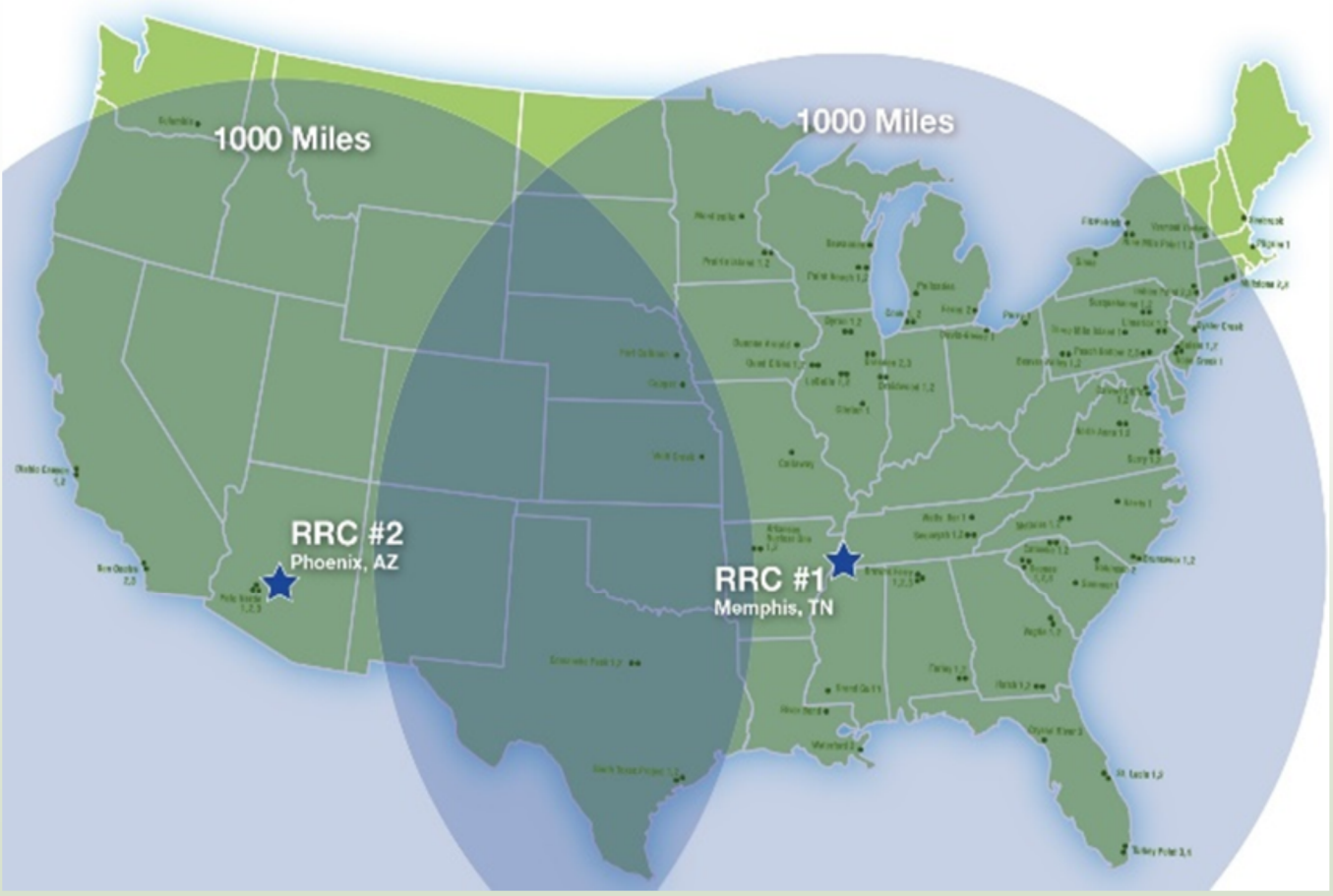
During his career at the NRC, Jeff has also worked extensively in the international arena, most notably during the period between 2006 and 2010, where he worked under NRC Chairman Nils Diaz on the development and launching of the Multinational Design Evaluation Program, currently administered by the OECD's Nuclear Energy Agency.

Jeff, we wish you the best.

Oversight of the Strategic Alliance for FLEX Emergency Response (SAFER) Program

Following the 2011 Fukushima Daiichi Nuclear Power Plant accident, the NRC issued Order EA-12-049 which imposed additional requirements on licensees to increase the capability of nuclear power plants to mitigate beyond-design-basis external events. The nuclear industry responded to the order by Nuclear Energy Institute (NEI) 12-06 (ADAMS Accession No. ML12242A378). NEI 12-06 outlined a process for individual licensees to define and implement site-specific diverse and flexible mitigation strategies that reduce the risks associated with beyond-design-basis conditions. NEI also supplemented the response with a white paper (ADAMS Accession No. ML14259A223) which detailed the programmatic aspects and implementation plans for the SAFER program. On September 26, 2014, the NRC issued an assessment (ADAMS Accession No. ML14265A107) which evaluated and determined the above commitments were acceptable to meet Order EA-12-049. The Program Manager Organization (PMO)/ Pooled Inventory Management (PIM), as agent for Pooled Equipment Inventory Company (PEICo), is under contractual agreements to support the SAFER program and responsible for the storage, maintenance, and testing of SAFER FLEX equipment used by NRC licensees in the event of a beyond design basis accident. Given the provision to inspect contractual agreements to reasonably assure the capabilities to deploy the FLEX strategy to meet NRC Order EA-12-049; the IQVB conducted inspections at the two National SAFER Response Centers (NSRC) in Phoenix (ADAMS Accession No. ML17012A186) and Memphis (ADAMS Accession No. ML17117A576). No findings of significance were identified. The NRC continues to work with its licensees and NUPIC to ensure proper oversight of the SAFER facilities.

- Nicholas Savwoir, Reactor Operations Engineer



Provisional Recognition of ISO/IEC 17025:2017

In a letter dated October 1, 2018 (ADAMS Accession No. ML18275A121), NEI requested the NRC to recognize the 2017 Edition of the International Standard Organization (ISO)/International Electrotechnical Commission (IEC) standard No. 17025, "General Requirements for the Competence of Testing and Calibration Laboratories," for use during a three-year transition period that began on November 30, 2017, and is set to expire on November 30, 2020. This time period was established by ISO to allow accredited laboratories to transition from the 2005 to the 2017 Edition of ISO/IEC 17025. Subsequently, in a letter responding to NEI's request dated April 16, 2019 (ADAMS Accession No. ML19056A451), the NRC concluded that ISO/IEC 17025:2017 maintains the same technical and quality requirements as ISO/IEC 17025:2005. The NRC staff reached this conclusion based on its independent review of ISO/IEC 17025:2017 and the performance of a gap analysis by both the NRC staff and NEI which demonstrated that ISO/IEC 17025:2017 did not decrease or remove any of the technical and quality requirements that provided the basis for the NRC's initial recognition of the ILAC accreditation process.

The NRC staff's gap analysis also confirmed that ISO/IEC 17025:2017 contains all of the relevant technical and quality requirements which provided the basis for the NRC's original recognition of the ILAC accreditation process. Specifically, ISO/IEC 17025:2017 incorporates all of the applicable critical characteristics for the commercial-grade dedication of calibration services identified in the NUPIC Commercial Grade Calibration Services Checklist. While NUPIC does not have a standard survey checklist for testing services, the NRC staff confirmed that the applicable critical characteristics for testing services are also incorporated in ISO/IEC 17025:2017. The NRC staff has confirmed that the applicable critical characteristics for commercial calibration and testing services continue to be properly controlled and verified in ISO/IEC 17025:2017 as part of the ILAC accreditation process.

The NRC staff is anticipating that NEI will submit, for NRC staff review, a revision to NEI 14-05A such that the staff may fully endorse the use of ISO/IEC 17025:2017, if applicable.

- Yamir Diaz-Castillo, 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 Dong Park, Reactor Operations Engineer, Quality Assurance and Vendor Inspection Branch, by telephone at 301-415-0001 or by email at Dong.Park@nrc.gov.