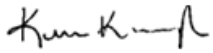




UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 13, 2021

MEMORANDUM TO: Christopher M. Regan, Acting Director
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

FROM: Kerri A. Kavanagh, Chief  Signed by Kavanagh, Kerri
Quality Assurance and Vendor Inspection Branch on 09/13/21
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

SUBJECT: TRIP REPORT BY THE NUCLEAR REGULATORY
COMMISSION STAFF OF THE REMOTE NUPIC EVALUATION
OF APAC'S ASSESSMENT OF PJLA

On May 10, 12, 13, 24, 25, and 28, 2021, Dong Park and Yamir Diaz-Castillo of the Office of Nuclear Reactor Regulation, Division of Reactor Oversight, Quality Assurance and Vendor Inspection Branch, observed the performance of a Nuclear Procurement Issues Corporation's remote evaluation of the assessment by the Asia Pacific Accreditation Cooperation (APAC) of the Perry Johnson Laboratory Accreditation, Inc. (PJLA) to the requirements of the International Standard Organization (ISO)/International Electrotechnical Commission (IEC) standard No. 17011, "Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies," 2017 edition, and ISO/IEC No. 17025, "General requirements for the competence of testing and calibration laboratories," 2017 edition.

The purpose of the NRC staff's observation was to evaluate the industry's oversight of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) accreditation process. This was the first NRC's observation of a NUPIC evaluation of the ILAC MRC accreditation process using the 2017 editions of ISO/IEC 17011 and ISO/IEC 17025.

CONTACT: Dong Park, NRR/DRO/IQVB
(301) 415-0001

Yamir Diaz-Castillo, NRR/DRO/IQVB
(301) 415-2228

SUBJECT: TRIP REPORT BY THE NUCLEAR REGULATORY COMMISSION STAFF OF
THE REMOTE NUPIC EVALUATION OF APAC'S ASSESSMENT OF PJLA
Dated: September 13, 2021

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OFFICE	NRR/DRO/IQVB	NRR/DRO/IQVB	NRR/DRO/IQVB
NAME	DPark	YDiaz-Castillo	KKavanagh
DATE	09/08/2021	09/09/2021	09/13/2021

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NUCLEAR PROCUREMENT ISSUES CORPORATION OBSERVATION TRIP REPORT

Accrediting Body Observed: Perry Johnson Laboratory Accreditation, Inc. (PJLA)

Laboratory Observed: Environmental Test Systems, Inc. (ETS)
209 Turner Avenue
Berthoud, CO 80513

Scope of Supply: PJLA is a private organization that offers third-party accreditation services for calibration and testing laboratories. ETS is a commercial laboratory that offers laboratory and field calibration of electrical, mechanical, and thermodynamic calibration.

Lead Licensee: Ameren Missouri (Union Electric Company)

Lead Contact: Earl Mayhorn
Nuclear Procurement Issues Corporation Lead Auditor
(314) 605-9701
emayhorn@ameren.com

Observation Dates: May 10, 12, 13, 24, 25, and 28, 2021

Observers: Dong Park, NRR/DRO/IQVB
Yamir Diaz-Castillo, NRR/DRO/IQVB

Approved by: Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

Enclosure

Subject

This trip report documents observations made by members of the U.S. Nuclear Regulatory Commission (NRC), Office Nuclear Reactor Regulation, Division of Reactor Oversight, Quality Assurance and Vendor Inspection Branch, during a Nuclear Procurement Issues Corporation's (NUPIC) remote evaluation of the Perry Johnson Laboratory Accreditation, Inc. (PJLA) assessment by the Asia Pacific Accreditation Cooperation (APAC) to the requirements of International Standard Organization (ISO)/International Electrotechnical Commission (IEC) standard No. 17011, "Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies," 2017 edition, and ISO/IEC No. 17025, "General requirements for the competence of testing and calibration laboratories," 2017 edition.

Background/Purpose

The NRC currently recognizes the International Laboratory Accreditation Cooperation's (ILAC) accreditation process as an acceptable alternative to a licensee's or supplier's commercial-grade survey as part of the commercial-grade dedication process for domestic and international laboratories that provide calibration and testing services for U.S nuclear power plants. In a safety evaluation dated November 23, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20322A019), the NRC staff found that Revision 1 of the Nuclear Energy Institute (NEI) Technical Report 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," (ADAMS Accession No. ML20259B731) provides an acceptable approach for licensees and suppliers of basic components for using the ILAC accreditation process in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process. This approach addresses procurement of calibration and testing services performed by domestic and international laboratories that are accredited to ISO/IEC 17025.

As described in Revision 1 of NEI 14-05A, NEI formed an industry team, consisting of licensees (including NUPIC members) and suppliers, to monitor ILAC activities as they relate to the nuclear industry's use of the ILAC accreditation process as part of the commercial-grade dedication process. NEI is a stakeholder member of ILAC as a liaison for the nuclear industry and provides to its licensee and supplier members access to ILAC's information and activities. NUPIC plays a central role in the continued oversight activities as a NUPIC member leads the observations of assessments of calibration and testing laboratories to the requirements of ISO/IEC 17025.

The purpose of the NRC staff's observation was to evaluate the industry's oversight of the ILAC accreditation process. This was the first NRC's observation of a NUPIC evaluation of the ILAC accreditation process using the 2017 editions of both ISO/IEC 17011 and ISO/IEC 17025. The NRC staff independently observed how NUPIC performed its oversight of the evaluation of ANAB by APAC as well as how ANAB performed a renewal accreditation assessment of a calibration laboratory.

Observation Activities

PJLA is a private organization that offers third-party accreditation services for calibration and testing laboratories. PJLA is a fully recognized accrediting body (AB) by APAC to provide calibration and testing accreditation services. Due to the travel and workplace restrictions associated with the pandemic caused by the Coronavirus Disease 2019 (COVID-19), PJLA's assessment was performed remotely, including the assessment of the calibration laboratory.

The evaluation of an AB involved a team of peers (generally senior staff of experienced ABs) to establish its qualification to be a member of ILAC. APAC's evaluation of PJLA involved a team of peers from Australia, Canada, Sri Lanka, India, Gulf Cooperation Council for Arab States, and the United States. APAC performs re-evaluations of its ABs every four years. The evaluation consisted of a review of PJLA's compliance with the requirements of ISO/IEC 17011, as well as a renewal accreditation assessment of a calibration laboratory performed by PJLA to verify compliance with the requirements of ISO/IEC 17025. The objective of an evaluation of the AB is to establish confidence in the endorsed reports and certificates (i.e. reports and certificates containing the ABs accreditation symbol) issued by its accredited laboratories. The evaluation focuses on how the AB ensures the technical competence of its accredited laboratories. The re-evaluation concentrated on examining changes at the AB and in its documentation, on compliance with the current issues of the relevant ISO/IEC standards (especially since a new edition of the standard has been issued since the previous evaluation) and any other new supplementary requirements adopted by APAC, and on obtaining evidence that accredited laboratories continue to operate in compliance with the relevant ISO/IEC standards.

PJLA conducts a full renewal assessment of all accredited laboratories at least every two years. According to PJLA's "Accreditation Procedure: SOP-1," Revision 1.14, dated March of 2021, regarding virtual remote assessments, PJLA evaluates each Conformity Assessment Bodies' (CAB) internal system (i.e., electronic documentation, Wi-Fi connection, use of portable devices) to ensure they are capable to have a remote assessment. The objective of the assessment is to determine the laboratory's compliance with PJLA requirements for accreditation and observe competent performance of tests or calibrations covered in the laboratory's scope of accreditation. Although accreditation is granted for two years, after the initial year of accreditation each laboratory must undergo an annual surveillance assessment each year prior to the full renewal assessment. The objective of the surveillance assessments is to confirm that the laboratory's management system and technical capabilities remain in compliance with the accreditation requirements.

Assessments are performed by assessors who are selected based on their testing or calibration expertise. Prior to the assessment, PJLA performed a review of the required documentation. The document review is typically performed by the lead assessor. After the lead assessor reviews the management system documentation and determines that the documentation meets the requirements of the accreditation standard, the laboratory will be able to demonstrate technical competence identified on the proposed scope of accreditation and certification. Assessors are given an assessor's guide and a checklist from the AB based on ISO/IEC 17025 to follow when performing the assessment. During the assessment, any findings are identified as deficiencies which are nonconformities to the accreditation requirements as described in ISO/IEC 17025. At the conclusion of the assessment, the assessor prepares a report of findings in which any deficiencies are identified and must be corrected by the assessed laboratory before accreditation is granted. If there are any deficiencies identified, the laboratory is requested to submit corrective action on their corrective action forms in accordance with their corrective action procedure within 60-days from the last day of the assessment.

The renewal assessment started with the PJLA assessor performing a thorough review of ETS' scope of accreditation. The assessor witnessed the demonstration of measurement capabilities for instruments calibrated within the scope to accreditation. During the renewal assessment, the NRC staff observed PJLA's review of Environmental Test Systems' Management System Requirements in accordance with the requirements of the 2017 edition of ISO/IEC 17025. The PJLA assessor reviewed records associated with internal audits, corrective action, complaints,

purchasing, equipment calibration, proficiency testing, and the training records of those performing the calibrations. The NRC staff noted that the PJLA assessor was continuously asking for objective evidence throughout the assessment to verify full compliance by the laboratory to the requirements of the 2017 edition of ISO/IEC 17025 listed in the checklist.

PJLA defines classifies findings with two levels of nonconformities and observations. “A single lapse in discipline or control” is classified as minor, whereas, “a total absence of a required system element, or a series of minor nonconformities which, taken together, indicate a total breakdown of a required system element” is classified as a major nonconformance.

The PJLA assessor concluded the renewal assessment with the review of the draft assessment report which included 1 minor nonconformity with laboratory personnel, management, and observers. The exit meeting consisted of discussions on verifying and understanding the background of the nonconformities and on the current status of those corrective actions.

Discussion

The NRC staff verified that both the NUPIC evaluation, PJLA’s assessment by APAC, and PJLA’s renewal accreditation assessment of ETS adequately considered PJLA and ETS’s scope of accreditation and remotely observed in-process work practices to verify activities were in accordance with applicable procedures. While being onsite is always the preferred method for performing an assessment, advances in technology that provide sufficient resolution allowed for adequate viewing of live demonstrations using remote virtual assessment techniques. Although technology tools are available, these resources need to be better managed to have an efficient remote virtual experience. During the remote virtual assessment, the evolutions naturally take longer because only one activity can be performed on the screen.

The NRC staff found that the NUPIC lead evaluator, APAC’s per reviewers, and PJLA’s assessor were thorough in their assessments, were very knowledgeable, and possessed the technical experience necessary to perform the evaluations.

Conclusion

For the NUPIC evaluation of PJLA and PJLA’s renewal assessment of ETS, the NRC staff determined that both were adequately performed by observing specific activities to a sufficient level to be able to conclude whether the renewal assessment was performed consistent with the requirements of 2017 editions of ISO/IEC 17011 and ISO/IEC 17025, and PJLA’s and ETS’ procedures, as applicable. The NRC staff concluded that the renewal assessment covered sufficient program and technical areas highlighted in the PJLA assessment plans to provide assurance that the laboratory is adequately implementing the management, program, and technical requirements of the 2017 edition of ISO/IEC 17025 and PJLA’s policies and procedures, as applicable.