



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

September 12, 2019

MEMORANDUM TO: Christopher G. Miller, Director
Division of Inspection and Regional Support
Office of Nuclear Reactor Regulation

FROM: Kerri A. Kavanagh, Chief **/RA/**
Quality Assurance Vendor Inspection Branch
Division of Inspection and Regional Support
Office of Nuclear Reactor Regulation

SUBJECT: TRIP REPORT BY THE NUCLEAR REGULATORY COMMISSION
STAFF OF THE NUPIC EVALUATION OF
A2LA'S ISO/IEC 17025:2017 ACCREDITATION RENEWAL
ASSESSMENT OF TECHNICAL SAFETY SERVICES

On September 5 - 6, 2019, Yamir Diaz-Castillo and Jeffrey Jacobson of the Office of Nuclear Reactor Regulation, Division of Inspection and Regional Support, observed the performance of a Nuclear Procurement Issues Corporation's evaluation of the American Association for Laboratory Accreditation's accreditation renewal assessment of Technical Safety Services to the requirements of the International Standard Organization (ISO)/International Electrotechnical Commission (IEC) standard No. 17025, "General Requirements for the Competence of Testing and Calibration Laboratories," 2017 Edition. The purpose of the staff's observation was to (1) evaluate the industry's oversight of the International Laboratory Accreditation Cooperation (ILAC) accreditation process and (2) observe an accreditation assessment performed to the requirements of ISO/IEC 17025:2017, which the Nuclear Regulatory Commission's (NRC) staff has only provisionally recognized. This is consistent with the NRC staff's intent to monitor the industry's oversight of the ILAC accreditation process as described in Regulatory Issue Summary No. 16-01, "Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Calibration and Test Services," dated March 16, 2016.

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SUBJECT: TRIP REPORT BY THE NUCLEAR REGULATORY COMMISSION STAFF OF
THE NUPIC EVALUATION OF A2LA'S ISO/IEC 17025:2017 ACCREDITATION
RENEWAL ASSESSMENT OF TECHNICAL SAFETY SERVICES
Dated: September 12, 2019

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NUCLEAR PROCUREMENT ISSUES CORPORATION
OBSERVATION TRIP REPORT

Laboratory Observed: Technical Safety Services (TSS)
620 Hearst Avenue
Berkeley, CA 94710

Scope of Supply: TSS' scope of supply includes calibration of dimensional, mechanical, and thermodynamics equipment used in industries such as medical device manufacturing, biotechnology, hospitals, pharmaceutical, food and beverage industry safety, laboratory animal science, nanotechnology and aerospace, academic research, and compounding pharmacies.

Accrediting Body: American Association for Laboratory Accreditation

Lead Contact: Earl Mayhorn
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Observation Dates: September 5 - 6, 2019

Observers: Yamir Diaz-Castillo, NRR/DIRS/IQVB
Jeffrey Jacobson, NRR/DIRS/IQVB

Approved by: Kerri A. Kavanagh, Chief
Quality Assurance Vendor Inspection Branch
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Enclosure

Subject

This trip report documents observations made by members of the U.S. Nuclear Regulatory Commission (NRC), Office Nuclear Reactor Regulation (NRR), Division of Inspection and Regional Support (DIRS), during the Nuclear Procurement Issues Corporation's (NUPIC) evaluation of the American Association for Laboratory Accreditation's (A2LA) accreditation renewal assessment of Technical Safety Services (TSS) conducted on September 5 - 6, 2019, in Berkeley, CA.

Background/Purpose

The NRC currently recognizes the International Laboratory Accreditation Cooperation (ILAC) accreditation process as an acceptable alternative to a licensee 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 February 9, 2015, the NRC staff found that Revision 0 of the Nuclear Energy Institute (NEI) document 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14322A535) provided an acceptable approach for licensees and suppliers of basic components for using the ILAC accreditation process in lieu of performing surveys as part of the commercial-grade dedication process. The approach addressed procurement of calibration and testing services performed by domestic and international laboratories that are accredited to International Standard Organization (ISO)/International Electrotechnical Commission (IEC) standard No. 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." The use of the ILAC accreditation process is contingent upon meeting the conditions specified in Revision 0 of NEI 14-05A, one of which is that the laboratory must be accredited to the 2005 Edition of ISO/IEC 17025.

As described in 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 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.

With the release of the 2017 Edition of ISO/IEC 17025, ISO established a three-year transition period that began on November 30, 2017, and is set to expire on November 30, 2020; to allow accredited laboratories to transition from the 2005 to the 2017 Edition of ISO/IEC:17025. In a letter dated April 16, 2019 (ADAMS Accession No. ML19056A451), the NRC staff concluded that licensees and suppliers of basic components may procure calibration and/or testing services from domestic and international laboratories accredited to ISO/IEC 17025:2017; however, the NRC staff's acceptance of ISO/IEC 17025:2017 is only applicable during the transition period set to expire on November 30, 2020. The NRC staff reached this conclusion based on its independent review of ISO/IEC 17025 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 is anticipating that NEI will

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

The purpose of the NUPIC observation was to:

1. Verify that A2LA had revised its assessment checklist to adequately incorporate the requirements of ISO/IEC 17025:2017.
2. Verify the process for accrediting laboratories to ISO/IEC 17025:2017 is as rigorous as the accreditation to ISO/IEC 17025:2005.
3. Verify that A2LA's renewal assessment of the laboratory properly addressed each parameter covered in the laboratory's scope of accreditation.
4. Verify that A2LA's renewal assessment of the laboratory properly addressed the quality system requirements of ISO/IEC 17025:2017.
5. Verify all deficiencies are addressed in the assessor's report along with contingency measures until the deficiencies are resolved, as applicable.
6. Verify the qualifications of the assessor in accordance with A2LA's requirements.

The purpose of the NRC staff's observation was to (1) evaluate the industry's oversight of the ILAC accreditation process and (2) observe an accreditation assessment performed to the requirements of ISO/IEC 17025:2017, which the NRC staff has only provisionally recognized. Observing both the NUPIC evaluation and A2LA's assessment provided additional information that the NRC staff will use in its determination of whether to permanently recognize the 2017 Edition of ISO/IEC:17025. NEI has stated that it plans to submit a revision to NEI 14-05A requesting permanent recognition of ISO/IEC 17025 beyond the transition period, at which point the NRC staff will evaluate this revision and evaluate whether to permanently recognize ISO/IEC 17025:2017. The NRC staff expects this revision sometime in the fall 2019. This is consistent with the NRC staff's intent to monitor the industry's oversight of the ILAC accreditation process as described in Regulatory Issue Summary No. 16-01, "Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Calibration and Test Services," dated March 16, 2016.

Observation Activities

The NRC staff independently observed how NUPIC performed its oversight of the renewal accreditation assessment as well as how A2LA performed the renewal accreditation assessment to the requirements of ISO/IEC 17025:2017. NUPIC implemented "NEI 17025 Accreditation Assessment Observation Checklist" to perform its evaluation, while A2LA implemented checklist No. C025, "ISO/IEC 17025:2017 Laboratory Accreditation Program."

A2LA conducts a full renewal assessment of all accredited laboratories at least every two years. The objective of the assessment is to establish whether or not a laboratory complies with A2LA requirements for accreditation and can competently perform the types of tests or calibrations for which the laboratory is accredited. Although accreditation is granted for two years, after the initial year of accreditation each laboratory must undergo a one-day surveillance assessment. The objective of the surveillance assessment 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. Assessors are given an assessor's guide and a checklist based on the latest edition of ISO/IEC 17025 to follow when performing an assessment. During the assessment, any findings that 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 respond, in writing, within 30 days after the date of the exit briefing detailing either its corrective action or why it does not believe that a deficiency exists. All deficiencies must be resolved within 60 days of the exit briefing. The corrective action response must include the laboratory's root cause analysis and a copy of any objective evidence to indicate that the corrective actions have been completed.

The checklists used by A2LA's assessor are partially completed before the start of the renewal assessment by reviewing TSS' quality systems manual (QSM) and standard operating procedures (SOPs). TSS' QSM and SOPs must meet the requirements listed in the checklist, as applicable.

The renewal assessment started with the A2LA assessor performing a vertical audit by tracing various operations from contract to final output back to the completed contract. The A2LA assessor witnessed dimensional, mechanical, and thermodynamic calibrations of equipment currently in TSS' scope of accreditation. During the renewal assessment, the NRC staff observed how the A2LA assessor reviewed records associated with internal audits, management review, corrective action, complaints, purchasing, equipment calibration, proficiency testing, and the training records of those performing the calibrations. The NRC staff noted that the A2LA assessor was continuously asking for objective evidence throughout the assessment to verify full compliance by the laboratory to the requirements of ISO/IEC 17025:2017 listed in the checklist, as applicable.

The NRC staff also observed the A2LA assessor's review of TSS' processes for calculating measurement uncertainty associated with the parameters covered by the ILAC accreditation. The NRC staff observed the A2LA assessor's review of a specific calculation and verified that the assessor appropriately considered the various measurement uncertainty terms. The A2LA assessor also verified the implementation of the corrective actions from the previous assessment.

The NRC staff also refrained from directing or leading NUPIC, as to not interfere with the conduct of NUPIC's evaluation.

Discussion

The NRC staff verified that both the NUPIC evaluation and the A2LA renewal assessment adequately considered TSS' scope of accreditation and observed in-process work practices to verify activities were in accordance with applicable procedures. The NRC staff also observed the A2LA's assessor deficiency determinations during discussions with TSS personnel. The renewal assessment resulted in several deficiencies against the requirements in ISO/IEC 17025:2017 and against specific A2LA requirements. The NRC staff found that both the NUPIC lead evaluator and A2LA's assessor were thorough in their assessments.

Overall, the NRC staff verified that NUPIC's evaluation of A2LA and A2LA's renewal assessment of TSS were performed in accordance with the requirements of ISO/IEC

17025:2017. In addition, the NRC staff found that the NUPIC lead evaluator and A2LA assessor were very knowledgeable and possessed the technical experience necessary to perform the evaluations.

The NRC staff did not observe any deficiencies during the performance of the renewal assessment by the A2LA assessor.

Conclusion

For the NUPIC evaluation of A2LA and A2LA's renewal assessment of TSS, 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 ISO/IEC 17025:2017, and TSS and A2LA procedures, as applicable. The NRC staff concluded that the renewal assessment covered sufficient program and technical areas highlighted in the A2LA assessment plans to provide assurance that the laboratory is adequately implementing the management, program, and technical requirements of ISO/IEC 17025:2017 and A2LA's policies and procedures, as applicable.