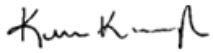




UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 14, 2023

MEMORANDUM TO: Russell Felts, 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 11/14/23
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

SUBJECT: TRIP REPORT BY THE NUCLEAR REGULATORY
COMMISSION STAFF OF THE NUPIC EVALUATION OF THE
ASSESSMENT BY THE IAAC OF THE CGCRE

On September 24 - 29, 2023, Yamir Diaz-Castillo, Reactor Operations Engineer, and Dong Park, Reactor Operations Engineer, 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 (NUPIC) evaluation of the Inter-American Accreditation Cooperation's (IAAC) assessment of the General Coordination of Accreditation (CGCRE) 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. Specifically, the Nuclear Regulatory Commission (NRC) staff observed the evaluation of CGCRE as well as the renewal accreditation assessments of a calibration laboratory and of a testing laboratory. As part of this observation, the NRC staff also witnessed field calibrations and field testing performed by the calibration and testing laboratories.

The purpose of the NRC staff's observation was to evaluate the nuclear industry's oversight of the International Laboratory Accreditation Cooperation (ILAC) accreditation process to ensure it continues to meet the applicable requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* Part 50, "Domestic Licensing of Production and Utilization Facilities." The ILAC accreditation process is used by licensees and suppliers of basic components in lieu of performing a commercial-grade survey of domestic and international laboratories as part of the commercial-grade dedication of calibration and testing services. Licensees and suppliers of basic components procure calibration and testing services for use in safety-related applications from domestic and international laboratories accredited to ISO/IEC 17025.

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SUBJECT: TRIP REPORT BY THE NUCLEAR REGULATORY COMMISSION STAFF OF THE NUPIC EVALUATION OF THE ASSESSMENT BY THE IAAC OF THE CGCRE DATE: November 14, 2023

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DATE	11/6/2023	11/9/2023	11/14/2023

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Nuclear Procurement Issues Corporation (NUPIC) Observation Trip Report

Accrediting Body Observed: Coordination General of Accreditation (CGCRE)
Rua Nossa Senhora das Graças, 50 - Building 06
Xerém - Duque de Caxias - RJ - CEP 25250-020

Laboratories Observed: A chemical testing laboratory and a mass calibration
laboratory located in the Rio de Janeiro, Brazil
metropolitan area.

Scope of Supply: CGCRE is a government organization that offers third-
party accreditation services for calibration and testing
laboratories. The mass calibration laboratory and the
chemical testing laboratory are commercial laboratories.

Lead Licensee: Ameren Missouri (Union Electric Company)

Lead Contact: Mr. Earl Mayhorn
NUPIC Team Leader
(314) 605-9701
emayhorn@ameren.com

Observation Dates: September 24 - 29, 2023

Observers: Yamir Diaz-Castillo NRR/DRO/IQVB
Dong Park 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 the 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) evaluation of the Inter-American Accreditation Cooperation's (IAAC) assessment of the General Coordination of Accreditation (CGCRE) 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 standard No. 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 (CGD) process for domestic and international laboratories that provide calibration and testing services for U.S nuclear power plants. This recognition is documented in a safety evaluation dated November 23, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20322A019), in which the NRC staff found that Revision 1 of the Nuclear Energy Institute (NEI) Technical Report No. 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 CGD process. This approach addresses the 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 CGD process. NEI is a stakeholder member of ILAC as a liaison for the nuclear industry and provides access to ILAC's information and activities to its licensee and supplier members. 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 nuclear industry's oversight of the ILAC accreditation process to ensure it continues to meet the applicable requirements of 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."

IAAC is one of the six Regional Cooperation Bodies (RCBs) currently part of ILAC Mutual Recognition Arrangement (MRA). For the purposes of the ILAC MRA, ILAC delegates its authority to its RCBs for the evaluation, surveillance, re-evaluation of the accrediting bodies (ABs). CGCRE is a government organization that offers third-party accreditation services for calibration and testing laboratories. CGCRE is a fully recognized AB accredited by IAAC to provide calibration and testing services, among others.

This was the third 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 and the first in South America. NUPIC performs these on-site evaluations every 3 years to ensure that the ILAC accreditation process continues to be adequately implemented and can still be used in lieu of performing commercial-grade surveys for the procurement of calibration and testing services to be used for safety-related applications. The location chosen by NUPIC to perform the evaluation is based on a variety of factors including, but not limited to: (1) the scope and date of the assessments; (2) the willingness of the AB and laboratories to host observers; and (3) whether additional travel within the host country will be required. For this evaluation, NUPIC chose IAAC's assessment of CGCRE as the scope included both calibration and testing, CGCRE and the laboratories were willing to accept both the NRC and NUPIC as observers, and there was no additional travel required. In addition, NUPIC had not performed an evaluation of an AB in South America.

The NRC staff's independent evaluation of the NUPIC oversight of the ILAC accreditation process is documented in Regulatory Issue Summary (RIS) 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 (ADAMS Accession No. ML15323A341).

Observation Activities

The evaluation of an AB involves a team of peers (generally senior staff of other ABs within IAAC) to establish its qualification to be a member of ILAC. IAAC's evaluation of CGCRE involved a team of peers from Uruguay, Cuba, Canada, Spain, Mexico, Ecuador, Colombia, Costa Rica, Argentina, and the United States. IAAC performs re-evaluations of its ABs every four years. The evaluation consisted of a review of CGCRE's compliance with the requirements of ISO/IEC 17011, as well as a renewal accreditation assessment of a calibration laboratory and of a testing laboratory performed by CGCRE 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: (1) examining changes at the AB and in its documentation; and (2) compliance with the relevant ISO/IEC standards and any other new supplementary requirements adopted by IAAC.

CGCRE conducts a full renewal assessment of accredited laboratories at least every two years. CGCRE's assessment process is documented in DOQ-CGCRE-001, "Guidance for the Accreditation Process of Laboratories, Reference Material Producers and Proficiency Testing Providers," Revision 20, dated May 2023. The objective of the assessment is to determine the laboratory's compliance with CGCRE 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 calibration or testing expertise. Prior to the assessment, CGCRE performed a review of the required documentation 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 CGCRE based on ISO/IEC 17025 to follow when performing the assessment. During the assessment, 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 deficiencies are identified and corrected by the assessed laboratory before accreditation is granted. If there are any deficiencies identified, the laboratory is requested provide closure to corrective actions within 60 days after the date 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 NRC staff observed the renewal accreditation assessment of a calibration laboratory and of a testing laboratory. The assessments started with the CGCRE assessors performing a thorough review of the laboratory's scope of accreditation. For the testing laboratory, the CGCRE assessor witnessed the demonstration of testing capabilities for biological, chemical, mechanical, and thermal testing within the scope of the laboratory's accreditation. For the calibration laboratory, the CGCRE assessors witnessed the demonstration of measurement capabilities for scales calibrated within the scope to accreditation. During the renewal assessment, the NRC staff observed how the assessors reviewed records associated with internal audits, management review, corrective action, complaints, purchasing, equipment calibration, proficiency testing, and the training records of those performing the tests. The NRC staff noted that the CGCRE assessors were collecting evidence through interviews and records throughout the assessment to verify full compliance by the laboratory to the requirements of ISO/IEC 17025:2017 listed in the checklist. The CGCRE assessors concluded the renewal assessment of the testing laboratory with the review of the draft assessment report which identified 32 nonconformities. Similarly, for the calibration laboratory, the CGCRE assessors concluded the renewal assessment with the review of the draft assessment report which identified 11 nonconformities. Both the testing and calibration laboratories initiated corrective actions to address the nonconformities identified. None of the conformities were considered significant or impacted the laboratories' ability to maintain their scope of accreditation.

Discussion

The NRC staff independently evaluated how NUPIC performed its oversight of the assessment of CGCRE by IAAC as well as how CGCRE performed a renewal accreditation assessment of both a mass calibration laboratory and a chemical testing laboratory.

The NRC staff's independent evaluation allowed us to confirm that the ILAC accreditation process, as implemented by IAAC and CGCRE: (1) continues to be an equivalent alternative to a commercial-grade survey; (2) continues to be implemented consistent with ILAC requirements and procedures; (3) hasn't experienced any changes that could materially affect the manner in which it is used by the nuclear industry; and (4) continues to meet the requirements of Appendix B to 10 CFR Part 50, as applicable.

Consequently, the NRC staff continues to have confidence in the ILAC accreditation process and does not have any concerns with its implementation by licensees and suppliers of basic components for the procurement of calibration and testing services for use in safety-related applications as part of the CGD process.

In conjunction with providing adequate continued oversight of the ILAC accreditation process as

documented in RIS No. 16-01, the NRC staff fostered collaboration with multilateral organizations to positively influence global and domestic nuclear safety and security. The NRC staff had the opportunity to successfully communicate the purpose of the NRC's observation to CGCRE as well as to NUPIC representatives from the Brazilian nuclear industry.

Conclusion

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