UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NEW REACTORS
WASHINGTON, DC 20555-0001

XXXX XX, 2015

NRC REGULATORY ISSUE SUMMARY 2015-XX
NUCLEAR ENERGY INSTITUTE GUIDANCE FOR THE USE OF ACCREDITATION IN LIEU OF COMMERCIAL GRADE SURVEYS FOR PROCUREMENT OF LABORATORY CALIBRATION AND TEST SERVICES

ADDRESSEES

All holders of an operating license or construction permit for a nuclear power reactor or a non-power reactor under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

All holders of and applicants for a power reactor early site permit, combined license, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." All applicants for a standard design certification, including such applicants after initial issuance of a design certification rule.

All contractors, vendors, and suppliers, including applicants after the issuance of a final design certification rule that supply basic components and safety-related parts and services for nuclear power plants to U.S. Nuclear Regulatory Commission (NRC) licensees under 10 CFR Part 50 or 10 CFR Part 52.

INTENT

The NRC staff is issuing this regulatory issue summary (RIS) to notify addressees of methods found acceptable by the NRC staff for procurement of calibration and testing services performed by domestic and international laboratories. Both domestic and international laboratories are required to be accredited by accreditation bodies (ABs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (hereafter referred to as the ILAC accreditation process) in order for licensees and suppliers of basic components to use these services in lieu of performing commercial-grade surveys. By letter dated February 9, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14322A535), the NRC staff transmitted its safety evaluation (SE) approving the guidelines developed by the Nuclear Energy Institute (NEI) and contained in NEI 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1 (ADAMS Accession No. ML14245A391). The NRC finds this document presents an acceptable methodology for the addressees to use the accreditation provided by ILAC in lieu of performing a commercial-grade survey when procuring calibration and testing services from domestic and international laboratories. This RIS requires no action or written response on the part of an addressee.

ML15090A236

BACKGROUND INFORMATION

The NRC's initial review and approval of the ILAC accreditation process is documented in the Arizona Public Service's (APS) SE dated September 28, 2005 (ADAMS Accession No. ML052710224). The NRC-approved APS's request in accordance with the regulations in 10 CFR 50.54(a)(4), which proposed a change to the Quality Assurance program (QAP) for the Palo Verde Nuclear Generating Station. The proposed change provided for use of accreditation of commercial-grade (as defined by 10 CFR Part 21, "Reporting of Defects and Noncompliance") calibration services by a nationally recognized AB, in lieu of performing a commercial-grade survey, using procedures consistent with international standards and guidelines, specifically those found in International Standard Organization (ISO)/International Electrotechnical Commission (IEC) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."

In a letter dated March 15, 2006 (ADAMS Accession No. ML061140023), the Nuclear Procurement Issues Committee (NUPIC) requested the NRC to clarify whether the alternative to performing commercial-grade surveys for domestic procurement of commercial-grade calibration services as defined in 10 CFR Part 21 may be adopted by suppliers for qualifying sub-suppliers. In its response dated June 6, 2006 (ADAMS Accession No. ML061580386), the NRC stated that Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 suppliers may use the alternative for the qualification of commercial-grade sub-suppliers as long as the conclusions of the SE with regards to the quality of the supplier's programs also apply to the sub-suppliers.

Subsequently, in a letter dated September 16, 2011 (ADAMS Accession No. ML112620079), NEI requested the NRC to support an industry proposal to expand the NRC's recognition of third-party accreditation of domestic calibration laboratories for purposes of commercial-grade dedication. The proposal sought to expand the acceptability of third-party accreditation to include both domestic and international calibration and testing laboratories accredited under ILAC.

NEI next formed an ILAC Task Force with members of the NEI Quality Assurance Task Force and the NUPIC. The ILAC Task Force was charged with developing guidance that would provide an acceptable approach for using laboratory accreditation by ABs that are signatories to the ILAC MRA. NEI became a stakeholder member of ILAC on behalf of the U.S. nuclear industry. The NRC staff observed the ILAC Task Force process to help understand if guidance developed would satisfy the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50.

Consequently, in a letter dated April 29, 2014 (ADAMS Accession No. ML14155A353), NEI submitted Revision 0 of NEI 14-05. By letter dated July 22, 2014, (ADAMS Accession No. ML14197A171), the NRC issued requests for additional information (RAIs) to complete its review of NEI 14-05. By a letter dated August 28, 2014, (ADAMS Accession No. ML14245A389), NEI submitted RAI responses and NEI 14-05, Revision 1, which incorporated the RAI responses.

SUMMARY OF ISSUE

Revision 1 to NEI 14-05 provides industry-developed guidelines for licensees and suppliers of basic components for using laboratory accreditation by ABs that are signatories to the ILAC MRA.

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 each of the following conditions are met:

- The method to use accreditation by an ILAC MRA signatory in lieu of performing a commercial-grade survey (alternative method) is documented in the licensees and supplier's QAP.

- The method the licensees and suppliers need to follow and document in their QAP, consists of:

    1. A documented review of the supplier's accreditation is performed and includes a verification of the following:

        a. The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories."

        b. For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

        c. For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.

    2. The purchase documents require that:

        a. The service must be provided in accordance with their accredited ISO/IEC 17025:2005 program and scope of accreditation.

        b. As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance *(for calibration services only).*

        c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration *(for calibration services only).*

        d. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.

e. Any additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

3. It is validated, at receipt inspection, that the laboratory's documentation certifies that:

   a. The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2005 program, and has been performed within their scope of accreditation, and

   b. The purchase order's requirements are met.

As with all activities performed under a QA program that meets the requirements of Appendix B to 10 CFR Part 50, the activities associated with the use of the ILAC accreditation process in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process shall be documented by the licensees and suppliers of basic components that choose to use this alternative.

By letter dated February 9, 2015 (ADAMS Accession No. ML14322A535), the NRC staff endorsed NEI 14-05. The NRC staff considers the guidance contained in Revision 1 to NEI 14-05 to be an acceptable method for licensees and suppliers of basic components to use 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 ILAC signatories as part of the commercial-grade dedication process.

There are two elements required for adequate continued oversight of the ILAC accreditation process: (1) review of ILAC's requirements and procedures, and (2) observation of peer evaluations of ABs and laboratory assessments. An NEI team, consisting of licensees (including NUPIC members) will monitor the ILAC requirements and procedures, and as a stakeholder member, NEI will be notified by ILAC of any potential changes to ILAC's requirements and procedures. The NEI team, in turn, will evaluate whether the potential changes could materially affect the manner in which the ILAC accreditation process is used by the nuclear industry. In addition, the NEI team will document the results of the continuous monitoring activities on an annual basis. The NRC staff will monitor the industry oversight of the ILAC accreditation process.

BACKFITTING AND ISSUE FINALITY DISCUSSION

The NRC is proposing to adopt this RIS to inform stakeholders that the NRC has approved for use industry implementation guidance in Revision 1 to NEI 14-05. The NEI document describes an alternate approach for using laboratory accreditation by ABs that are signatories to the ILAC MRA in lieu of performing commercial grade surveys as part of commercial grade dedication for nuclear power reactors.

This draft RIS does not set forth any new or changed NRC requirement, or new or changed guidance or position on compliance with any existing NRC regulatory requirement. This RIS requires no action or written response. The NRC is not imposing or requiring any new positions on licensees and suppliers of basic components. This RIS does not require licensees and

suppliers of basic components for nuclear power reactors to change or modify procedures or processes. Any action on the part of the addressees to use the guidance endorsed by this RIS is strictly voluntary. For these reasons, this RIS, if finalized, and, therefore, is not a backfit under 10 CFR 50.109, "Backfitting," and is not otherwise inconsistent with any issue finality provision in 10 CFR Part 52. Therefore, the NRC did not prepare a backfit analysis for this RIS or further address the issue finality criteria in Part 52.

FEDERAL REGISTER NOTIFICATION

[Discussion to be provided in final RIS]

CONGRESSIONAL REVIEW ACT

This RIS is not a rule as designated by the Congressional Review Act (5 U.S.C. §§ 801-808) and, therefore, is not subject to the Act.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget under approval numbers 3150-0035, 3150-0011 and 3150-0151.

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless the requesting document displays a currently valid OMB control number.

CONTACTS

Please direct any questions about this matter to the technical contact listed below.

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