

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

March 16, 2016

**NRC REGULATORY ISSUE SUMMARY 2016-01
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 under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

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 one method found acceptable by the NRC staff for procurement of calibration and testing services performed by domestic and international laboratories for use in safety-related applications. 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. The NRC finds that Revision 0 of Topical Report (TR) of the Nuclear Energy Institute (NEI) 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,"¹ presents an acceptable accreditation methodology provided by ILAC for the addressees to use in lieu of performing a commercial-grade survey when procuring calibration

¹ Agencywide Documents Access and Management System (ADAMS) Accession No. ML15075A434

and testing services from domestic and international laboratories. This RIS requires no action or written response on the part of an addressee.

BACKGROUND INFORMATION

The NRC's initial review and approval of the ILAC accreditation process is documented in the Arizona Public Service's (APS) safety evaluation (SE) dated September 28, 2005², which approved a proposed change to the Quality Assurance Program (QAP) for the Palo Verde Nuclear Generating Station. The NRC approved APS's request in accordance with 10 CFR 50.54, "Conditions of licenses," paragraph (a)(4). 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."³

In a letter dated March 15, 2006⁴, 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, 2006⁵, 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 regard to the quality of the supplier's programs also apply to the sub-suppliers.

Subsequently, in a letter dated September 16, 2011⁶, 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 formed an ILAC Task Force with members of the NEI Quality Assurance Task Force and 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. The NRC staff observed the ILAC Task Force process to understand if guidance developed by NEI would satisfy the requirements of 10 CFR Part 50, Appendix B.

Consequently, in a letter dated April 29, 2014⁷, NEI submitted Revision 0 of TR NEI 14-05. By letter dated July 22, 2014⁸, the NRC issued requests for additional information (RAI) to complete its review of TR NEI 14-05. By letter dated August 28, 2014⁹, NEI submitted RAI responses and

² ADAMS Accession No. ML052710224

³ Copies may be purchased from ISO; www.iso.org.

⁴ ADAMS Accession No. ML061140023

⁵ ADAMS Accession No. ML061580386

⁶ ADAMS Accession No. ML112620079

⁷ ADAMS Accession No. ML14155A353

⁸ ADAMS Accession No. ML14197A171

⁹ ADAMS Accession No. ML14245A389

Revision 1 of TR NEI 14-05, which incorporated the RAI responses. By letter dated February 9, 2015¹⁰, the NRC staff transmitted the SE approving the guidelines developed by NEI in Revision 1 of TR NEI 14-05¹¹. Following the issuance of the SE, by letter dated March 4, 2015¹², NEI submitted an approval (“-A”) version of Revision 0 of TR NEI 14-05A as requested by the NRC staff. The NRC requested an approval version of this TR for publication, as detailed in the February 9, 2015 transmittal letter of the NRC SE for Revision 1 of TR NEI 14-05. Revision 0 of TR NEI 14-05A was subsequently approved for use.

SUMMARY OF ISSUE

Revision 0 of NEI 14-05A provides industry-developed guidelines for licensees and suppliers of basic components for using laboratory accreditation by ABs that are signatories to the ILAC MRA. In the February 9, 2015, NRC SE, the NRC stated:

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:

- 1) 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 quality assurance (QA) program.
- 2) The method the licensees and suppliers need to follow, and document in their QA program, 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:

¹⁰ ADAMS Accession No. ML14322A535

¹¹ ADAMS Accession No. ML14245A391

¹² ADAMS Accession No. ML15075A433

- 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 QAP 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.

The NRC staff considers the guidance contained in Revision 0 of TR NEI 14-05A 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. In addition, the NRC still considers the APS SE, dated September 28, 2005, an acceptable way for licensees and suppliers to implement the ILAC accreditation process in lieu of performing a commercial-grade survey as long as the conditions listed in the APS SE are adequately implemented.

For licensees, use of the ILAC accreditation process in lieu of performing a commercial-grade survey represents a reduction in commitment to the previously accepted QAP, which requires NRC approval under 10 CFR 50.54(a)(4). As such, once the NRC approves a QAP change for a licensee in accordance with 10 CFR 50.54(a)(4), other licensees may adopt the quality assurance alternative of using the ILAC accreditation process in lieu of performing a commercial-grade survey provided that the bases of the NRC approval are applicable to the licensee's facility pursuant to the requirements of 10 CFR 50.54(a)(3)(ii).

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. Section 5, “U.S. Nuclear Industry Oversight of the ILAC Process,” to Revision 0 of NEI TR 14-05A, describes that 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 0 of NEI 14-05A. 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 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 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

The NRC published a notice of opportunity for public comment on this draft RIS in the *Federal Register* (80 FR 47957) on August 10, 2015. The agency received comments from two commenters. The staff considered all comments, which resulted in minor clarifications to the RIS. The evaluation of these comments, and the resulting changes to the RIS are discussed in a publicly available memorandum¹³.

CONGRESSIONAL REVIEW ACT

This is not a rule as defined in the Congressional Review Act (5 U.S.C. §§ 801-808).

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.

¹³ ADAMS Accession No. ML15323A345

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

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