



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

FINAL SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION  
FOR THE NUCLEAR ENERGY INSTITUTE TECHNICAL REPORT 14-05A,  
"GUIDELINES FOR THE USE OF ACCREDITATION IN LIEU OF COMMERCIAL  
GRADE SURVEYS FOR PROCUREMENT OF LABORATORY  
CALIBRATION AND TEST SERVICES," REVISION 1  
EPID L-2020-TOP-0011

1.0 INTRODUCTION

By letter dated February 20, 2020 (Reference (Ref.) 1), the Nuclear Energy Institute (NEI) submitted Revision 1 to Technical Report (TR) NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," for U.S. Nuclear Regulatory Commission (NRC) staff review and endorsement. Revision 1 of NEI 14-05A provides an updated approach for licensees and suppliers of basic components for using laboratory accreditation by Accreditation Bodies (ABs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (hereby after referred to as the ILAC accreditation process) in lieu of performing commercial-grade surveys for procurement of calibration and testing services. This method of qualifying the calibration and testing supplier and accepting its calibration and testing services would be applied only to dedication of commercial-grade calibration and testing services as defined by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance."

2.0 BACKGROUND

In a letter dated August 28, 2014 (Ref. 2), NEI submitted Revision 1 to NEI 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," for NRC staff review and endorsement. In its safety evaluation (SE) dated February 9, 2015 (Ref. 3), the NRC staff determined that Revision 1 of NEI 14-05 provided an acceptable approach for licensees and suppliers subject to the quality assurance (QA) requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," for using laboratory accreditation by ABs that are signatories to the

ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

By letter dated April 1, 2016 (Ref. 4), the NRC staff approved a request to change the "Operating Quality Assurance Manual" for Callaway Plant, Unit 1, pursuant to 10 CFR 50.54(a) to incorporate the QA alternative of using the ILAC accreditation process in lieu of performing a commercial-grade survey. With this approval, other licensees could 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 signatories to the ILAC MRA provided 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).

In a letter dated October 1, 2018 (Ref. 5), NEI requested the NRC to recognize the 2017 edition of the International Standard Organization /International Electrotechnical Commission standard No. 17025 (2017 edition ISO/IEC 17025), "General Requirements for the Competence of Testing and Calibration Laboratories," for use during the three-year transition period that began on November 30, 2017, and is set to expire on November 30, 2020. This time period was established by ISO to allow accredited laboratories to transition from the 2005 to the 2017 edition of ISO/IEC 17025. Subsequently, in a letter responding to NEI's request dated April 16, 2019 (Ref. 6), the NRC concluded that the 2017 edition of ISO/IEC 17025 maintains the same technical and quality requirements as the 2005 edition of ISO/IEC 17025. Therefore, licensees and suppliers of basic components may procure calibration and/or testing services from domestic and international laboratories accredited to the 2017 edition of ISO/IEC 17025 in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process during the transition period established by ISO, with the expectation the industry would seek recognition of the 2017 edition of ISO/IEC 17025 beyond the transition period through a revision of NEI 14-05A.

By electronic mail (e-mail) dated May 1, 2020 (Ref. 7), the NRC transmitted a request for additional information (RAI) to complete its review of Revision 1 of NEI 14-05A. In a letter dated May 13, 2020 (Ref. 8), NEI submitted its response to the RAI and an update to Revision 1 of NEI 14-05A (Ref. 9), which incorporated NEI's response to the NRC staff's RAI. By e-mail dated July 6, 2020 (Ref. 10), the NRC transmitted a second round of RAIs to address issues related to the recent Coronavirus Disease 2019 (COVID-19) pandemic. In a letter dated September 11, 2020 (Ref. 11), NEI submitted its response to the RAIs and an update to Revision 1 of NEI 14-05A (Ref. 12), which incorporated NEI's responses to the NRC staff's RAIs.

Revision 1 of NEI 14-05A was updated to recognize the 2017 edition of ISO/IEC 17025 as the basis for the ILAC accreditation process and to address other minor editorial changes, clarifications, and adjustments based on operating experience identified subsequent to the NRC's initial endorsement in February 2015.

### 3.0 TECHNICAL EVALUATION

#### 3.1. Limitations of Use

Section 3.4, "Limitations of Use," in Revision 1 of NEI 14-05A clarifies that the guidance for the use of the ILAC accreditation process was developed as part of the commercial-grade dedication process for laboratory calibration and testing services by licensees and suppliers of basic components. The NRC staff recognizes that the use of the 2017 edition ISO/IEC 17025 for procurement of calibration and testing services is not limited to licensees and suppliers of basic components. However, the NRC's approval for using the ILAC accreditation process in lieu of performing commercial-grade surveys, and the acceptance of inspection and tests results to determine conformance with the applicable requirements, can only be implemented by a supplier who has a QA program that meets the applicable requirements of Appendix B to 10 CFR Part 50. When commercial-grade surveys are utilized as an acceptance method, the commercial-grade survey report must document the commercial supplier's control over the identified critical characteristics and the associated quality controls that affect the critical characteristics such as calibration of measuring and test equipment. Subsequent use of the ILAC accreditation process by commercial sub-suppliers is inadequate and should be adequately controlled irrespective of the fact that the commercial sub-suppliers are implementing the same QA program based on ISO 17025. The commercial-grade survey report must document the acceptability of the commercial sub-supplier's control over calibration and not merely state the commercial sub-supplier uses accredited calibration or testing service providers based on the accreditation to the 2017 edition of ISO/IEC 17025. Commercial-grade survey reports should address the selection and approval of supplier and the overall procurement controls as applicable for such suppliers.

Section 3.4 also describes the use of the ILAC accreditation process for nondestructive examination (NDE) or nondestructive testing (NDT) since these services can potentially be dedicated. For the purposes of this SE, the terms NDE and NDT are considered equivalent and can be used interchangeably. The Electric Power Research Institute (EPRI) TR No. 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," dated September 2014 (Ref. 13), states that the procurement of NDE services performed on safety-related equipment may be dedicated. Although EPRI 3002002982 is endorsed by Regulatory Guide (RG) 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants," Revision 0, dated June 2017 (Ref. 14), the NRC's recognition of the ILAC accreditation process did not intend to include the commercial-grade dedication of NDE services based on a laboratory's accreditation to the 2017 edition of ISO/IEC 17025. There are specific personnel qualification and certification requirements for personnel performing safety-related NDE activities for the nuclear industry that are not addressed by the ILAC accreditation process. Therefore, the ILAC accreditation process cannot be used as part of the commercial-grade dedication process of NDE services in lieu of performing a commercial-grade survey. This is applicable to both American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code and non-ASME B&PV Code safety-related applications. It should be noted that use of the ILAC accreditation process for NDE services required by the ASME B&PV Code is also prohibited by the ASME B&PV Code.

### 3.2 Performing and Documenting a Technical Evaluation for the Calibration and/or Testing Services

As part of the commercial-grade dedication process, licensees and suppliers of basic components should perform and document a technical evaluation to ensure that the correct technical requirements are specified in the procurement documents. The NRC's recognition of the ILAC accreditation process allows licensees and suppliers of basic components to use this accreditation in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process for calibration and testing services. As such, the NRC staff expects licensees and suppliers of basic components to follow the commercial-grade dedication process, which includes performing and documenting a technical evaluation for the calibration and/or testing services being procured.

Attachment 1 and Attachment 2 to Revision 1 of NEI 14-05A include acceptable examples of a technical evaluation for calibration services and testing services, respectively. These technical evaluations address measuring and calibration services from commercial calibration service providers and laboratory testing services from commercial testing service providers including ISO/IEC 17025:2005 and ISO/IEC 17025:2017 accredited laboratories and non-accredited service providers.

### 3.3 New Conditions: Subcontracting of Services and Remote Accreditation Assessments

#### 3.3.1 Subcontracting of Services

The use of subcontracting services is allowed by the 2017 edition of ISO/IEC 17025. At the time the NRC staff recognized the ILAC accreditation process, none of the conditions imposed prohibited the use of subcontractors to perform any calibration and/or testing work. However, in order to ensure that the calibration and/or testing work is performed by an ILAC accredited laboratory and reduce the chance of misuse of the ILAC accreditation process and not receive an accredited service, the procurement documents must prohibit the accredited calibration or testing laboratory from subcontracting the service being procured. The procurement document for accredited services must be submitted directly to the entity performing the calibration or testing. It should be noted when using the ILAC accreditation process under the ASME B&PV Code, subcontracting of services is also prohibited.

#### 3.3.2 Remote Accreditation Assessments

The NRC's recognition of the ILAC accreditation process allows licensees and suppliers of basic components to take credit for the ILAC accreditation process in lieu of performing an on-site commercial-grade survey as part of the commercial-grade dedication process of calibration and testing services. In its initial recognition of the ILAC accreditation process, the NRC staff determined that as part of the on-site renewal assessments performed by the ABs, the critical characteristics for calibration and testing services would be verified as part of the on-site renewal assessment. Due to the travel restrictions caused by the COVID-19 pandemic, ABs are performing remote accreditation assessments. While use of remote accreditation assessments were determined by the nuclear industry to be acceptable during extenuating circumstances, it is necessary to impose a limitation on the use of remote assessment for laboratories performing calibrations and testing for licensees and suppliers of basic

components. Accredited calibration or testing services performed on behalf of licensees and suppliers of basic components cannot be accepted from laboratories who have not undergone an on-site accreditation assessment within the past 48 months of the date of services. Such laboratories cannot be used by licensees and suppliers of basic components if their accreditation is based on consecutive remote accreditation assessments. Due to the travel restrictions caused by the COVID-19 pandemic, the NRC approved an overall 25 percent extension (9 months) prior to the end of the 90-day grace period for triennial audits or surveys during periods where performance of such activities is not feasible as a result of extenuating circumstances. With the added assurance that remote renewal accreditations are 24 months, the NRC staff concludes that there is reasonable assurance that the on-site accreditation assessments within 48 months meet the requirement with respect to performing commercial-grade surveys as part of the commercial-grade dedication process.

#### 3.4 Implementation of the ILAC Accreditation Process in Lieu of a Commercial-Grade Survey

The following are the actions and steps that are necessary for a licensee and/or a supplier of basic components to accept accreditation of domestic and international calibration and test laboratory services by ILAC MRA signatories in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process:

- 1) The method to use accreditation by an ILAC MRA signatory in lieu of a commercial-grade survey (alternative method) is documented in the licensee and/or supplier of basic components' QA program.
- 2) The method the licensee and/or supplier of basic components needs to follow, and document in their QA program, consists of:
  1. A documented review of the laboratory'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-17025:2017, "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.
    - d. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

2. The purchase documents require that:
  - a. The service must be provided in accordance with their accredited ISO/IEC-17025:2017 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. Subcontracting of these accredited services is prohibited.
  - e. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
  - f. Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the AB within the past 48 months.
  - g. 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-17025:2017 program, and has been performed within their scope of accreditation, and
  - b. The purchase order's requirements are met.

#### 4.0 APPLICABILITY

Due to the travel restrictions resulting from the COVID-19 pandemic, ILAC extended the transition period originally scheduled to end on November 30, 2020, to June 1, 2021. During the transition period between the issuance of this SE endorsing Revision 1 of NEI 14-05A through June 1, 2021, the NRC staff determined that the 2005 and 2017 editions of ISO/IEC 17025, as well as Revision 0 and Revision 1 of NEI 14-05A, are acceptable for use. Starting on June 2, 2021, after the transition period has ended, Revision 0 of NEI 14-05A will become superseded by Revision 1 of NEI 14-05A and licensees and suppliers of basic components using the ILAC accreditation process in lieu of performing a commercial-grade survey for calibration and testing services will have to start implementing Revision 1 of NEI 14-05A. However, if a licensee or a supplier of basic components incorporates Revision 1

of NEI 14-05A into its QA program before the transition period ends on June 1, 2021, the new conditions as described in Revision 1 of NEI 14-05A will go into effect.

For licensees, the use of the 2017 edition of ISO/IEC 17025 as part of the ILAC accreditation process in lieu of performing a commercial-grade survey represents a QA alternative to the previously accepted QA program. As such, licensees may adopt the QA alternative of using the 2017 edition of ISO/IEC 17025 provided that the bases of the NRC's approval are applicable to the licensee's facility pursuant to the requirements of 10 CFR 50.54(a)(3)(ii).

After June 1, 2021, the 2005 edition of ISO/IEC 17025 will become invalid and only accreditation to the 2017 edition of ISO/IEC 17025 can be achieved and recognized under the ILAC MRA process. Therefore, this SE recognizes accreditation to the 2005 edition of ISO/IEC 17025 through June 1, 2021.

## 5.0 CONCLUSION

On the basis of its review, the NRC staff concludes that Revision 1 of NEI 14-05A continues to provide an acceptable approach for licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50 for using laboratory accreditation by ABs that are signatories to the ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

## 6.0 REFERENCES

1. Letter from Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, to Ms. Kerri A. Kavanagh, Chief, Quality Assurance and Vendor Inspection Branch, "Submittal of NEI 14-05A, Revision 1, 'Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,'" dated February 20, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20054C066).
2. Letter from Mr. Marcus R. Nichol, Senior Project Manager, Quality Issues and Licensing Actions, NEI, to Mr. Joseph Colaccino, Chief, New Reactor Rulemaking and Guidance Branch, Division of Advanced Reactors and Rulemaking, Office of New Reactors, "Submittal of NEI 14-05, Revision 1, Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated August 28, 2014 (ADAMS Accession No. ML14245A391).
3. Letter from Mr. Joseph Colaccino, Chief, New Reactor Rulemaking and Guidance Branch, Division of Advanced Reactors and Rulemaking, Office of New Reactors, to Mr. Marcus R. Nichol, Senior Project Manager Quality Issues and Licensing Actions, Nuclear Energy Institute, "Final Safety Evaluation for Technical Report 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," dated February 9, 2015 (ADAMS Accession No. ML14322A535).

4. Letter from Mr. L. John Klos, Project Manager, Plant Licensing Branch IV-1 Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation to Mr. Fadi Diya, Senior Vice President and Chief Nuclear Officer, Union Electric Company, "Callaway Plant, Unit 1 – Operating Quality Assurance Manual Revision 31, Change Notice 15-002," dated April 1, 2016 (ADAMS Accession No. ML16089A167).
5. Letter from Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, to Ms. Kerri A. Kavanagh, Chief, Quality Assurance Vendor Inspection Branches 1 & 2, "Endorsement of ISO/IEC 17025: 2017, 'General Requirements for the Competence of Testing and Calibration Laboratories,'" dated October 1, 2018 (ADAMS Accession No. ML18275A121).
6. Letter from Ms. Jennivine Rankin, Chief, Licensing Branch 2, Division of Licensing, Siting, and Environmental Reviews, Office of New Reactors to Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, Nuclear Energy Institute, "Provisional Recognition of the International Standard Organization/International Electrotechnical Commission Standard No. 17025, 'General Requirements for the Competence of Testing and Calibration Laboratories,'" 2017 Edition," dated April 16, 2019 (ADAMS Accession No. ML19056A451).
7. E-mail transmittal from Leslie Fields, Senior Project Manager, Licensing Processes Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation to Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, "Request for Additional Information for NEI 14-05A Revision 1," dated May 1, 2020 (ADAMS Accession No. ML20121A319).
8. Letter from Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, to Leslie Fields, Senior Project Manager, Licensing Processes Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation, "Submittal of Response to Request for Additional Information (RAI) for NEI 14-05A, Revision 1, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated May 13, 2020 (ADAMS Accession No. ML20135H214).
9. Revision 1 of NEI 14-05A, "Revision 1 of NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated May 2020 (ADAMS Accession No. ML20135H229).
10. E-mail transmittal dated from Leslie Fields, Senior Project Manager, Licensing Processes Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation to Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, "Request for Additional Information (RAI) for NEI 14-05A, Revision 1," dated July 6, 2020 (ADAMS Accession No. ML20184A288).
11. Letter from Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, to Leslie Fields, Senior Project Manager, Licensing Processes Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation, "Submittal of Response to Request for Additional Information (RAI) for NEI 14-05A, Revision 1,



“Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” dated September 11, 2020 (ADAMS Accession No. ML20259C391).

12. Revision 1 of NEI 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” dated September 2020 (ADAMS Accession No. ML20259B731).
13. EPRI TR 3002002982, “Plant Engineering: Guideline of Commercial-Grade Items in Nuclear Safety-Related Applications,” Revision 1, September 2014 (ADAMS Accession No. ML181999A161).
14. RG 1.164, “Dedication of Commercial-Grade Items for Use in Nuclear Power Plants,” Revision 0, dated June 2017 (ADAMS Accession No. ML17041A206).

Attachment: Comment Resolution Table

Principal Contributors: Yamir Diaz-Castillo, NRR/DRO  
Dong Park, NRR/DRO

Date: November 23, 2020

**TECHNICAL REPORT NEI 14-05A, REVISION 1  
COMMENT RESOLUTION TABLE**

Comment Number	Text Location in the DSE		Comment Type (Clarification, Editorial, Accuracy, Proprietary)	NEI Suggested Revision	NRC Response
	Page	Line			
1	2	40-44	Accuracy	Please replace the current wording in Lines 40-44 with the following: "Revision 1 of NEI 14-05A was updated to recognize ISO/IEC 17025:2017 as the basis for the ILAC process and to address other minor editorial changes, clarifications, and adjustments based on operating experience identified subsequent to the NRC's initial endorsement in February 2015."	NRC staff finds the comment acceptable and the revisions have been incorporated with a few minor edits as shown below: "Revision 1 of NEI 14-05A was updated to recognize the 2017 edition of ISO/IEC 17025 as the basis for the ILAC accreditation process and to address other minor editorial changes, clarifications, and adjustments based on operating experience identified subsequent to the NRC's initial endorsement in February 2015."