

April 16, 2019

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SUBJECT: 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

Dear Mr. Richter:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter dated October 1, 2018¹, requesting the NRC to recognize the 2017 Edition of the International Standard Organization (ISO)/International Electrotechnical Commission (IEC) standard No. 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. The request stated, in part, that in order for licensees and suppliers of basic components to continue to use the International Laboratory Accreditation Process (ILAC) accreditation process in lieu of performing a survey during the commercial-grade dedication process for calibration and testing services, the nuclear industry must first gain NRC's acceptance of ISO/IEC 17025:2017.

Your letter also stated that the Nuclear Procurement Issues Corporation (NUPIC), in conjunction with the Nuclear Energy Institute (NEI), formed a committee that evaluated the differences between the 2005 and the 2017 Editions of ISO/IEC 17025. Three attachments were provided to support your request for the NRC to provisionally recognize the 2017 Edition: (1) Attachment 1, "ISO/IEC Gap Analysis Summary," (2) Attachment 2, "ISO/IEC 17025: 2005 and 2017 Requirement Traceability/Cross Reference Matrix," and (3) Attachment 3, "Joint ILAC-ISO Communiqué on the recognition of ISO/IEC 17025 during a Three-Year Transition." Attachment 1 provided a high-level summary of the major changes between the 2005 and the 2017 Editions of ISO/IEC 17025 while Attachment 2 provided the results of a detailed review of

¹ Agencywide Documents Access and Management System (ADAMS) Accession No. ML18275A121

the changes. Attachment 3 was a joint communication issued by ISO and ILAC which stressed that during the three-year transition period, ISO/IEC 17025:2005 and ISO/IEC 17025:2017 are valid and equivalent for use.

NRC Staff's Evaluation of ISO/IEC 17025:2017

In a safety evaluation (SE) dated February 9, 2015², the NRC staff found that Revision 0 of NEI 14-05A³, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," 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 ISO/IEC 17025:2005 by Accreditation Bodies that are signatories to the ILAC Mutual Recognition Arrangement (MRA). 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 ISO/IEC 17025:2005.

The NRC staff performed an independent review of ISO/IEC 17025:2017 and a gap analysis to ensure that ISO 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 major changes include:

- Revising the scope to cover all laboratory activities, including calibration, testing, and the sampling associated with subsequent calibration and testing
- Recognizing the use of computer systems and electronic records, and the production of electronic results and reports
- Updating terminology to be in alignment with the International Vocabulary of Metrology and ISO/IEC terminology
- Providing a new structure that aligns with other recently revised and/or existing ISO/IEC standards (e.g., ISO/IEC 17025:2005 had 5 sections while ISO/IEC 17025:2017 has 8 sections)
- Adding a new section on risk-based thinking which enables reduction on the standard's prescriptive guidelines and replaces them with performance-based guidelines
- Placing emphasis on the results of a process instead of a detailed description of its tasks and steps

The NRC staff's gap analysis also confirmed that ISO/IEC 17025:2017 contains all of the relevant technical and quality requirements which provided the basis for the NRC's original recognition of the ILAC accreditation process. Specifically, ISO/IEC 17025:2017 incorporates

² ADAMS Accession No. ML14322A535

³ ADAMS Accession No. ML15075A434

all of the applicable critical characteristics for the commercial-grade dedication of calibration services identified in the NUPIC Commercial Grade Calibration Services Checklist. While NUPIC does not have a standard survey checklist for testing services, the NRC staff confirmed that the applicable critical characteristics for testing services are also incorporated in ISO/IEC 17025:2017. The NRC staff has confirmed that the applicable critical characteristics for commercial calibration and testing services continue to be properly controlled and verified in ISO/IEC 17025:2017 as part of the ILAC accreditation process.

The NRC staff would also like to note that 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 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.

Revision to NEI 14-05A

As stated in your letter, a revision to NEI 14-05A will be subsequently provided to the NRC requesting permanent recognition of ISO/IEC 17025:2017 beyond the transition period, at which point the NRC will evaluate the revision.

Since the NRC's recognition of the ILAC accreditation process, the NRC staff has identified several issues in its implementation by licensees and suppliers of basic components. The NRC staff would like to discuss these issues to ensure that they are addressed as part of the revision to NEI 14-05A.

Subcontracting of Services

The use of subcontracting services is allowed by both the 2005 and 2017 Editions of ISO 17025. At the time the NRC 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, the revision to NEI 14-05A should contain an additional condition stating that the laboratory performing the calibration and/or testing services shall not subcontract the service to any other supplier.

Conclusion

The NRC staff reviewed the NEI submittal and supporting documentation. On the basis of its review, the NRC staff concludes that ISO/IEC 17025:2017 maintains the same technical and quality requirements as ISO/IEC 17025:2005. Therefore, licensees and suppliers of basic components may procure calibration and/or testing services from domestic and international laboratories accredited to ISO/IEC 17025:2017 in lieu of performing a survey as part of the

commercial-grade dedication process in accordance with the NRC's SE of NEI 14-05A for the transition period provided by ISO.

In addition, the inclusion of the issues discussed in the next revision of NEI 14-05A will ensure that licensees and suppliers of basic components adequately implement their commercial-grade dedication process when using the ILAC accreditation process in lieu of performing a commercial-grade survey for the procurement of calibration and testing services. Furthermore, for licensees, the use of ISO/IEC 17025:2017 as part of the ILAC accreditation process in lieu of performing a commercial-grade survey represents a quality assurance alternative (QA) to the previously accepted QA program. As such, licensees may adopt the QA alternative of using ISO/IEC 17025:2017 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) during the transition period provided by ISO.

It is important to note that the NRC's acceptance of ISO/IEC 17025:2017 is only applicable during the transition period set to expire on November 30, 2020. Once the NRC receives the revision to NEI 14-05A, the NRC staff will evaluate the request to recognize ISO/IEC 17025:2017 beyond the transition period.

If you have any questions, please contact George F. Wunder at (301) 415-1494 or via email at George.Wunder@nrc.gov.

Sincerely,

/RA/ GWunder for

Jennivine Rankin, Chief
Licensing Branch 2
Division of Licensing, Siting,
and Environmental Reviews
Office of New Reactors

cc: See next page

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