

March 17, 2015

MEMORANDUM TO: Edward H. Roach, Chief
Mechanical Vendor Inspection Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

FROM: Yamir Diaz-Castillo, Reactor Operations Engineer */RA/*
Mechanical Vendor Inspection Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

SUBJECT: RESPONSE TO PUBLIC COMMENTS ON DRAFT 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"

A notice of opportunity for public comment on this Regulatory Issue Summary (RIS) was published in the *Federal Register* (80 FR47957) on August 10, 2015, for a 60-day comment period. One member of the public, and one organization provided comments, which were considered before issuance of this RIS in final form. Comments were received from Mr. Daniel Cronin (Agencywide Documents Access and Management System Accession (ADAMS) No. ML15244A394), and the Nuclear Energy Institute (ADAMS Accession No. ML15282A022). Enclosed are the staff responses to all public comments.

Enclosure:
As stated

CONTACT: Yamir Diaz-Castillo, NRO/DCIP
301-415-2228

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ADAMS Accession Nos.: Pkg: ML15323A341; Memo: ML15323A345; RIS: ML15323A346

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**NRC STAFF RESPONSE TO PUBLIC COMMENTS ON
DRAFT 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**

Comments on the subject draft regulatory issue summary (RIS) are available electronically in the U.S. Nuclear Regulatory Commission's (NRC's) Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. Comments were received from the following individuals or groups:

Letter No.	ADAMS Accession No.	Commenter Affiliation	Commenter Name
1	ML15244A394	Public	Daniel Cronin
2	ML15282A022	Nuclear Energy Institute (NEI)	Russell J. Bell

The NRC assigned each of the two submittals a letter number. Each submittal contains comments. For each comment, the NRC has provided a summary of the comment followed by the NRC's response. Each comment is referred to below by its associated letter number, and its own sequential number.

Comments

Comment No. 1-1: The commenter stated that the inclusion of non-power reactor licensees within the "Addresses" section of the draft RIS may give the impression that the NRC intends to impose power reactor Quality Assurance Program (QAP) regulations and guidance on non-power reactor licensees.

The commenter recommended removing non-power reactor licensees from the "Addresses" section since the regulations and NEI document are well beyond the scope of QAP regulation for non-power reactors.

NRC Response: The NRC agrees with the comment. The RIS will be modified to remove the inclusion of non-power reactor from the "Addresses" section of the RIS.

Comment No. 2-1: The commenter stated that there is an inconsistency between the stated intent, and the title and content of the draft RIS. The NRC stated intent is for the RIS to "notify addresses of methods found acceptable by the NRC staff for procurement of calibration and testing services performed by calibration and testing laboratories." The commenter also stated that this wording could lead to an incorrect conclusion that "use of accreditation in lieu of commercial grade surveys" is the only acceptable NRC method.

Enclosure

The commenter suggested that the first sentence in the Intent section should be revised to state, "The NRC staff is issuing this regulatory issue summary (RIS) to notify addressees of one methods found acceptable by the NRC staff for procurement of calibration and testing services performed by domestic and international laboratories." The following two sentences should also be added after the first sentence, "The NRC accepts the following four methods:

1) performance of calibration and test services under a QA Program that complies with Appendix B to 10 CFR Part 50, 2) dedication of commercial grade calibration and test services, which includes a commercial grade survey or source verification, pursuant to 10 CFR Part 21, 3) dedication of commercial grade calibration and test services, which uses accreditation in lieu of a commercial grade survey, pursuant to 10 CFR Part 21, and 4) calibration and test services performed by a National Metrology Institute. The purpose of this RIS is to clarify the NRC's acceptance of the use of accreditation in lieu of commercial grade surveys in method #3."

NRC Response: The NRC agrees with the comment, in part. The proposed language of the first sentence in the "Intent" section may give the impression that laboratory accreditation is the only acceptable NRC method to procure calibration and testing services from domestic and international laboratories. The RIS will be modified to make this clarification.

The NRC disagrees with the second part of the comment about adding the proposed two sentences. As documented in a letter dated April 30, 2015 (ADAMS Accession No. ML15111A477), to Mr. Marcus Nichols, NEI's Senior Project Manager, Quality Issues and Licensing Actions, the NRC's position on the use of National Metrology Institutes is only applicable for primary reference standards and calibration services, not testing services. In addition, the NRC considers this proposal to be beyond the scope of the RIS. This RIS is not intended to list all the methods available for licensees and suppliers for procurement of calibration and testing services from domestic and international laboratories. Furthermore, any additions could create unnecessary confusion. No change was made to the RIS in response to this comment.

Comment No. 2-2: The commenter stated that the draft RIS does not explicitly state that the scope is for only safety-related services and this could lead to an incorrect conclusion that it is applicable to the procurement of laboratory calibration and test services for non-safety related applications.

The commenter recommended that the first sentence in the "Intent" section should be revised to state "...procurement of calibration and testing services performed by domestic and international laboratories for use in safety-related applications."

NRC Response: The NRC agrees with the comment. The recommended language represents a relevant distinction that more clearly defines the applicability. The RIS will be modified to include this distinction.

Comment No. 2-3: The commenter stated that the draft RIS references Revision 1 of NEI 14-05, instead of the reissued and approved Revision 0 of NEI 14-05A. This approved version includes the NRC's Safety Evaluation Report (SER), NRC's requests for additional information (RAIs) on the original NEI version submitted for NRC review, and the NEI responses to the NRC's RAIs.

The commenter recommended that the RIS should reference Revision 0 of NEI 14-05A instead of Revision 1 of NEI 14-05.

NRC Response: The NRC agrees with the comment. The NRC verified that Revision 0 of NEI 14-05A, issued at the request of the NRC, met all the applicable requirements. The RIS will be modified to reference Revision 0 of NEI 14-05A.

Comment No. 2-4: The commenter stated that the second through fifth sentences in the “Intent” section discuss the ILAC process and the NRC’s acceptance of accreditation through the ILAC process in lieu of commercial grade dedication, as documented in NEI 14-05A Revision 0 and the associated NRC safety evaluation report. These sentences provide valuable clarity to licensees and their suppliers of basic components. However, including this information in the Intent section could create confusion, and the information is better covered in other sections of the RIS.

The commenter recommended that these sentences be relocated to either the “Background Information” or “Summary of Issue” section.

NRC Response: The NRC agrees with the comment. The information contained in the “Intent” section is better covered in the “Background” section of the RIS. The RIS will be modified to clarify the significance of this information.

Comment No. 2-5: The commenter stated that the RIS does not include a discussion about the necessary actions that a licensee or supplier must take prior to being able to implement the method described in NEI 14-05. These actions are described on page 9, Section 5 of the NRC’s SER of NEI 14-05. An absence of these actions in the RIS could lead to an incorrect conclusion that a licensee or supplier does not need to do anything else beyond the major elements of the method summarized in the RIS.

The commenter recommended that the RIS should include a description of the actions licensees and suppliers must take in order to be able to implement the methodology described in NEI 14-05. Specifically:

- a. 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 QA program. As such, once the NRC approves the QA program change for a licensee in accordance with 10 CFR 50.54(a)(4), other licensees may adopt the QA 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 requirement of 10 CFR 50.54(a)(3)(ii).
- b. Suppliers are not subject to 10 CFR 50.54 and thus use of the ILAC accreditation process in lieu of performing a commercial-grade survey is not considered a reduction in commitment to the previously accepted QA program. As such, suppliers may adopt the method of using the ILAC accreditation process in lieu of performing a commercial-grade, consistent with the NRC’s approval of NEI 14-05A.

NRC Response: The NRC agrees with the comment. Although suppliers may adopt the method of using the ILAC accreditation in lieu of performing a commercial-grade survey immediately, for licensees this method represents a reduction in commitment to the previously accepted QA program. An absence of this distinction could lead to an incorrect conclusion that a licensee may start implementing the alternative method without doing anything else. The RIS will be modified to include this distinction.

Comment No. 2-6: The commenter stated that the NRC has issued an SER on a license amendment request [LAR] from the MOX Fuel Fabrication Facility (MFFF), related to changes to the QA programs in order to use accreditation in lieu of commercial grade surveys for the procurement of calibration and test services for use in safety-related applications. The commenter also stated an understanding that another licensee plans to submit soon a similar license amendment request for a nuclear power station. Related to NEI Comment #5, including this information in the RIS would provide clarity to licensees about the actions they must take prior to implementing NEI 14-05A Revision 0. References to the SERs for both of these LARs could avoid the need for the NRC to review and approve additional LARs, which would be unnecessary for licensees that can demonstrate the bases of the NRC approvals are applicable to the licensee's facility pursuant to the requirements of 10 CFR 50.54(a)(3)(ii).

The commenter recommended that the NRC should include a discussion of the SERs on the MFFF and nuclear power plant LARs for QA program changes related to the use of accreditation in lieu of commercial grade surveys. If necessary, the publication of the Final RIS should be delayed until the SER is issued for the Calloway LAR.

NRC Response: The NRC disagrees with the comment. Refer to the answer to Comment 2-5 above for resolution on including information to provide clarity to licensees. The NRC is currently reviewing Calloway's LAR that will allow other licensees to adopt the alternative method. No change was made to the RIS in response to this comment.

Comment No. 2-7: The commenter stated that although the draft RIS mentions the earlier SER for the [Arizona Public Service's] (APS) LAR that served as the NRC's initial review and approval of the use of accreditation through the ILAC process in lieu of commercial grade surveys, the draft RIS does not explicitly state whether the NRC continues to find this approach acceptable. An absence of a clear position on the continued use of the APS approach could lead to an incorrect conclusion that existing QA programs implementing this approach need to be revised, and/or that the approach may not be acceptable for future adoption by licensees or suppliers.

The commenter recommended that the NRC should explicitly state that it continues to find the APS SER acceptable.

NRC Response: The NRC agrees with the comment. The NRC continues to find the APS's SER 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 are adequately implemented. The RIS will be modified to include this clarification.