

July 22, 2014

Mr. Marcus R. Nichol, Senior Project Manager
Quality Issues and Licensing Actions
Nuclear Energy Institute
1201 F Street, NW, Suite 100
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SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING THE REVIEW OF
NUCLEAR ENERGY INSTITUTE 14-05, "GUIDELINES FOR THE USE OF
ACCREDITATION IN LIEU OF COMMERCIAL GRADE SURVEYS FOR
PROCUREMENT OF LABORATORY CALIBRATION AND TEST SERVICES,"
REVISION 0

Dear Mr. Nichol:

By letter dated April 29, 2014, the Nuclear Energy Institute (NEI) submitted Revision 0 to NEI 14-05 to the U.S. Nuclear Regulatory Commission (NRC) for NRC staff review and approval. NEI 14-05 provides an approach to utilize accreditation by signatories to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement as part of a purchaser's commercial grade dedication of laboratory services.

The NRC staff has reviewed the NEI submittal and identified that additional information is needed to continue portions of the review. The staff's request for additional information is contained in the enclosure to this letter.

If you have any questions or comments regarding this matter, please contact Mr. Dennis Galvin by telephone at (301) 415-6256 or by e-mail at Dennis.Galvin@nrc.gov.

Sincerely,

/RA/

Joseph Colaccino, Chief
New Reactor Rulemaking and Guidance Branch
Division of Advanced Reactors and Rulemaking
Office of New Reactors

Project No. 0689

Enclosure:
Request for Additional Information 1-7564

cc: See next page

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Letter to Marcus R. Nichol from Joseph Colaccino dated July 22, 2014

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(Revised 07/25/2013)

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Request for Additional Information 1-7564

Issue Date: 7/14/2014

Application Title: NEI Topical Reports

Operating Company: NEI

Docket No. PROJ 0689

Review Section: TR NEI 14.05 Guidelines

QUESTIONS:

TR NEI 14.05 Guidelines-1

Section 1.1, "Purpose," states, in part, that "Purchasers that procure commercial grade calibration or testing laboratory services are able to rely on laboratory accreditation by Accreditation Bodies (ABs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (referred to as the ILAC process) in lieu of commercial grade surveys or ***in-process surveillances*** to provide the necessary evidence of compliance to qualify calibration or test suppliers under a Commercial Grade Dedication process."

In addition, page A-1 of Appendix A, "Quality Assurance Program Template," states, in part, that, "When purchasing commercial grade calibration or testing services from a laboratory holding accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), commercial grade surveys and ***source verifications*** need not be performed provided each of the following conditions are met..."

The NRC staff's current recognition of the ILAC accreditation process allows for licensees and suppliers of basic components to use this alternative in lieu of performing a ***commercial-grade survey*** as part of the dedication process. Although similar in nature, a commercial-grade survey and source verification or in-process surveillance are different activities with different scopes. Commercial-grade surveys are conducted at a sufficient frequency to ensure that the process controls applicable to the critical characteristics of the procured item or service continue to be effectively implemented. In contrast, source verification involves witnessing quality-related activities to confirm by direct observation that the selected critical characteristics of the item or service being procured are satisfactorily controlled by the vendor. Clarify if it is the intent of NEI 14-05 for the NRC to recognize the ILAC accreditation process in lieu of performing a commercial-grade survey ***and source verification*** and the basis for it.

TR NEI 14.05 Guidelines-2

Section 4, "Purchaser's Quality Assurance Program," states, in part, that "A generic Template describing the use of the ILAC process in lieu of a commercial grade survey that ***may*** be inserted into a Purchaser's QA Program, is provided in Appendix A." Current NRC requirements for the use of the ILAC accreditation process ***require*** licensees and suppliers of basic components to document the alternative method in their QA Program description. Since Appendix A contains the conditions that must be met to use the alternative method, clarify if it is the intent of NEI 14-05 to require that Appendix A be included in the licensee's and supplier's

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QA Program description. If not, although NEI-14-05 contains the appropriate requirements that licensees and suppliers must follow when using the alternative, because there is no section within NEI 14-05 that clearly specifies the actions and steps that must be followed, it is possible for licensees and suppliers to not adequately dedicate the calibration or testing service. As such, include a section in NEI 14-05 that clearly defines what are the actions and steps that licensees and suppliers must follow when using the ILAC accreditation in lieu of performing a commercial-grade survey.

TR NEI 14.05 Guidelines-3

Section 4.3, "Control of Purchased Material, Equipment, and Services," states, in part, that "Purchasers using the accredited laboratories will be responsible for reviewing objective evidence for conformance to the procurement documents, such as review of documentation to validate the service providers' accreditation and review of the actual certificates provided by the laboratory." As part of NRC staff's current recognition of the ILAC accreditation process, the NRC staff expects that licensees and suppliers will review the calibration records as part of receipt inspection to verify that all of the technical and quality requirements, which include the critical characteristics, imposed in the purchase order (PO) have been met. However, Appendix A does not include a condition that licensees and suppliers must review the calibration and testing records to verify conformance to the PO requirements. Provide a justification for the exclusion of this requirement from the list of conditions.

TR NEI 14.05 Guidelines-4

Section 5.3, "Verification that Implementation of the ILAC Process Continues to be Consistent with NRC Accepted practices," states, in part, that the "U.S. nuclear industry observations of peer evaluations will be performed on a frequency of once every three (3) years. This frequency is similar to the frequency for external (supplier) audits discussed in Regulatory Guide (RG) 1.28." As opposed to suppliers of basic components that hold a quality program that meets the 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" and a program that meets the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance," the required level of oversight for licensees and suppliers of basic components is different than from a commercial supplier. For example, per RG 1.28, these suppliers are evaluated at least once annually by their customers. Furthermore, ISO/IEC-17025:2005 is a standard that's used globally and could be subject to different levels of interpretation. One way of supplementing the peer evaluation observation every 3 years would be, at some point during the 3 year cycle, to observe the accreditation of a laboratory by an accrediting body.

- a. Provide a justification for performing an observation of a peer evaluation every 3 years.
- b. Clarify if the intent is to alternate the observations of the peer evaluation between domestic and international accrediting bodies.
- c. If a report is generated after the observation of the peer evaluation, is it the intent to share that report with the NRC staff?
- d. As part of our oversight activities, the NRC staff may be interested in participating in the observation of the peer evaluations. Add a statement to NEI 14-05 to reflect this request.

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TR NEI 14.05 Guidelines-5

Section 5.4, "Optional Activities," describes additional monitoring activities available to the nuclear industry as ILAC stakeholder members. Clarify under what circumstances you would use these optional activities and if the intent is to, if necessary at some point, substitute the peer evaluation observation with one of these optional activities.

TR NEI 14.05 Guidelines-6

One of the conditions, which verify the critical characteristics, currently identified by the NRC for dedication of commercial calibration services is that the PO shall require the use of the laboratory's ISO/IEC-17025:2005 for the calibration services. This requirement is also stated in Section 4.2 of NEI 14-05. However, although Appendix A requires that the purchaser must perform a review of the supplier's accreditation, it does not clearly require that the PO shall include the requirement that the laboratory must provide the service in accordance with their accredited ISO/IEC-17025:2005 program and scope of accreditation. Clarify if it is the intent of NEI 14-05 for licensees and suppliers of basic components to impose this requirement in the PO.

TR NEI 14.05 Guidelines-7

In the discussion of the two additional differences with NUPIC practices in Section 6, the second difference states, in part, that "EPRI issued guidance on counterfeit and fraudulent items, "Plant Support Engineering: Counterfeit, Fraudulent and Substandard Items," EPRI-1019163, and is in the process of updating this guidance. The guidance provides practical measures to further enhance protections against counterfeit and fraudulent items and includes a standard procurement clause that can be used in the procurement of calibration and testing services." Clarify if it is the intent of NEI 14-05 for licensees and suppliers to include the procurement clause from EPRI 1019163 when procuring calibration and testing services. If the answer is no, provide a justification for not requiring licensees and vendors to include this clause in the procurement documents.

TR NEI 14.05 Guidelines-8

As part of the commercial-grade dedication process, a technical evaluation is required. Section 6.1, "Technical Evaluation of ILAC Requirements and Procedures," describes a generic technical evaluation which identifies the critical characteristics for calibration and testing services. In addition, Section 3.2.1, "Identification of Additional Requirements," states, in part, that "Any additional technical or quality requirements for the supplier of commercial grade items or services need to be identified." Clarify if it is the intent of NEI 14-05 that licensees and suppliers shall perform an additional technical evaluation, in addition to the one described in NEI 14-05, to identify any additional technical and quality requirements such as tolerances, accuracies, ranges, industry standards, etc.

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TR NEI 14.05 Guidelines-9

In order to avoid any confusion, rearrange the conditions listed in Appendix A.

For example, within Appendix A the condition (listed third) related to the documented review of the supplier's accreditation and scope should be a part of the technical evaluation and therefore, should be the first step in the process.

In addition, the requirement that the purchase documents require that the calibration or test certificate/report include identification of the laboratory equipment and standards used should be a stand-alone requirement listed as part of the second condition in Appendix A.