

From: [Fields, Leslie](#)
To: [RICHTER, Mark](#)
Cc: [Kavanagh, Kerri](#); [Morey, Dennis](#); [Diaz-Castillo, Yamir](#); [Park, Dong](#); [Earl Mayhorn \(EMayhorn@ameren.com\)](#) ([EMayhorn@ameren.com](#)); [Coren, Mark \(Mark.Coren@duke-energy.com\)](#); [McCULLUM, Rodney](#)
Subject: RE: 2nd Round Request for Additional Information (RAI) for NEI 14-05A, Revision 1
Date: Monday, July 13, 2020 6:57:00 AM

Dear Mr. Richter:

Thanks for your response.

NRC would like to formally accept August 31, 2020 as the Nuclear Energy Institute (NEI) RAI response date for NRC's RAI request for RAI 02 and RAI 03, dated July 6, 2020. In addition, NRC accepts NEI's RAI response to RAI 01 which was formally submitted May 13, 2020.

Feel free to contact me if you have any additional questions.

Sincerely,
Leslie C. Fields
US NRC
301.452-3970
leslie.fields@nrc.gov

From: RICHTER, Mark <mar@nei.org>
Sent: Thursday, July 09, 2020 3:42 PM
To: Fields, Leslie <Leslie.Fields@nrc.gov>
Cc: Kavanagh, Kerri <Kerri.Kavanagh@nrc.gov>; Morey, Dennis <Dennis.Morey@nrc.gov>; Diaz-Castillo, Yamir <Yamir.Diaz-Castillo@nrc.gov>; Park, Dong <Dong.Park@nrc.gov>; Earl Mayhorn (EMayhorn@ameren.com) (EMayhorn@ameren.com) <EMayhorn@ameren.com>; Coren, Mark (Mark.Coren@duke-energy.com) <Mark.Coren@duke-energy.com>; McCULLUM, Rodney <rxm@nei.org>; RICHTER, Mark <mar@nei.org>
Subject: [External_Sender] 2nd Round Request for Additional Information (RAI) for NEI 14-05A, Revision 1

Dear Ms. Fields:

NEI acknowledges receipt of RAI 02, "Section 1.3, "Acceptance of Accreditation by ILAC Signatories in Lieu of Commercial Grade Surveys" and RAI 03, "Section 5.2, "Verification That the ILAC Process Continues to be Consistent with NRC Accepted Practices" relative to NEI 14-05A, "Guidelines for the use of Accreditation In Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1.

We understand the questions being posed in both RAIs and have initiated the process of developing responses. The industry's response to RAI 02, although complex, is nearly complete. The response to RAI-03 will require additional time to prepare as it will require engaging various accreditation bodies. As a result, we request an extension of the response date to August 31, 2020.

Please advise if August 31, 2020 is an acceptable response date. In addition, the response to RAI 01 was submitted on May 13, 2020 and we ask if the response to RAI 01 is acceptable. We look forward to your reply.

If you need additional information, please contact Earl Mayhorn at 314-605-9701 or by email at emayhorn@ameren.com.

Sincerely,

Mark Richter

Mark A. Richter, Ph.D. | *Senior Project Manager Decommissioning and Used Fuel*
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From: Fields, Leslie <Leslie.Fields@nrc.gov>
Sent: Monday, July 6, 2020 11:08 AM
To: RICHTER, Mark <mar@nei.org>
Cc: Kavanagh, Kerri <Kerri.Kavanagh@nrc.gov>; Morey, Dennis <Dennis.Morey@nrc.gov>; Diaz-Castillo, Yamir <Yamir.Diaz-Castillo@nrc.gov>; Park, Dong <Dong.Park@nrc.gov>
Subject: [EXTERNAL] 2nd Round Request for Additional Information (RAI) for NEI 14-05A, Revision 1

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Dear Mr. Richter of the Nuclear Energy Institute:

With respect to NEI 14-05 A, Revision 1, "Guidelines for the use of Accreditation In Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," enclosed below you will find additional Requests for Additional Information (RAI).

This email serves as the formal transmittal for these RAIs. Your formal response, provided via email/letter under authorized signature, will generate the public version of the RAI response. Please confirm if there is any proprietary information in the RAI response for future processing.

In order to support the NRC staff's review schedule, please provide your response no later than August 6, 2020.

Let me know if you have any questions or would like to discuss the RAIs with NRC staff to ensure you understand the NRC request.

A copy of this email and RAIs will be uploaded in ADAMS and declared publicly available under ADAMS Accession No. ML20184A288, entitled NEI-14-05A 2 ROUND RAI.

NRC'S REQUEST FOR ADDITIONAL INFORMATION

ASSOCIATED WITH NEI 14-05 A, REVISION 1, "GUIDELINES FOR THE USE OF ACCREDITATION
IN LIEU OF COMMERCIAL GRADE SURVEYS FOR PROCUREMENT OF LABORATORY CALIBRATION
AND TEST SERVICES"
PROJECT NO. 689

By letter dated February 20, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20034F042), the Nuclear Energy Institute (NEI) submitted Revision 1 of NEI 14-05 A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," to the U.S. Nuclear Regulatory Commission (NRC) for NRC staff review and approval. To complete its review, the NRC staff has the following questions it would like NEI to address.

RAI 02 - Section 1.3, "Acceptance of Accreditation by ILAC Signatories in Lieu of Commercial Grade Surveys"

Section 1.3 states, in part, that "ISO/IEC 17025:2017 was released on November 30, 2017. During the three year transition period, both ISO/IEC 17025:2005 and ISO/IEC 17025:2017 are valid. After November 30, 2020, ISO/IEC 17025:2005 will become invalid and only accreditation to ISO/IEC 17025:2017 can be achieved and recognized under the ILAC MRA process. Therefore, this document recognizes accreditation to ISO/IEC 17025:2005 through November 30, 2020."

As result of the ongoing Coronavirus Disease 2019 (COVID-19) pandemic, ILAC extended the transition period for ISO/IEC 17025:2017 from November 30, 2020 to June 1, 2021.

In light of ILAC's extension of the transition period, please clarify if Revision 1 of NEI 14-05 A also recognizes June 1, 2021 as an acceptable date for laboratories to transition to ISO/IEC 17025:2017.

RAI 03 - Section 5.2, "Verification That the ILAC Process Continues to be Consistent with NRC Accepted Practices"

Section 5.2 states, in part, that "The assessments and conclusions of the rigor of the ILAC process documented herein are based in large part on the evaluation of the ILAC requirements and procedures. The comparison of ILAC requirements and procedures, in particular standard ISO/IEC 17025:2017, to NRC requirements, NRC endorsed guidance, and NUPIC checklists, which conform to these requirements and guidance, is the primary basis for the approach documented within to use the ILAC process in lieu of a commercial grade survey. As part of the continued oversight, the nuclear industry (NEI, NUPIC members, and other industry representatives) will monitor the ILAC requirements and procedures to verify that they continue to be consistent with NRC accepted practices."

Due to the ongoing COVID-19 pandemic, the NRC staff recently learned that accrediting bodies are currently performing renewal assessments remotely. This is not a position the NRC staff has had the opportunity to evaluate and determine to be an acceptable approach for performing renewal assessments. The NRC's recognition of the ILAC accreditation process allows licensees and vendors 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 accrediting bodies, the critical characteristics for calibration and testing services would be verified as part of the on-site renewal assessment. Given that these renewal assessments are now being done

remotely:

- a. Please clarify if NEI has considered how these remote assessments still provide the same degree of confidence to determine that the laboratories are adequately implementing the requirements of ISO/IEC 17025.
- b. As part of its continued oversight, please explain how the nuclear industry (NEI, NUPIC members, and other industry representatives) will effectively monitor the implementation of the ILAC accreditation process to verify that it continues to be consistent with NRC's accepted practices.

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