NEI's responses to the questions contained in the July 22, 2014 letter entitled: "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 LABOARTORY CALIBRATION AND TEST SERVICES,' REVISION 0," Request for Additional Information 1-7564 are provided below. The changes indicated in our responses are included in an update to Revision 0 of NEI 14-05.

TR NEI 14.05 Guidelines-1

Question:

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.

Response

It is the intent of NEI 14-05 for the NRC to expand its recognition of the ILAC accreditation process to national and international calibration and test laboratories only in lieu of performing commercial grade surveys as a part of a commercial grade dedication. Accordingly the noted references to "in-process surveillance" and "source verification" are removed from Section 1.1, Section 4.3, and Appendix A of NEI 14-05. Recognizing that in-process surveillance and source surveillance serve a different purpose than commercial grade surveys, this NEI guidance does not support the performance or nonperformance of those types of surveillance. Instead, the decision whether to perform such surveillance should be driven by the user's QA Program.

TR NEI 14.05 Guidelines-2

Question:
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 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.

Response
The introduction of Section 4 "Purchaser's Quality Assurance Program" is intended to clarify that it is required that the purchaser document the method to use the ILAC process in lieu of a commercial grade survey in their QA Program. The first sentence has been revised as follows to make this even more clear, "Purchasers that rely on the accreditation by ILAC signatories in lieu of commercial grade surveys ~~need~~ *are required by 10 CFR Part 50, Appendix B* to document this alternative method in their QA program."

Appendix A of NEI 14-05 is included as a voluntary template, and is not mandatory. While some purchasers may be able to readily adopt the format of the template, others may need to reformat the template in order to incorporate it into their QA programs.

It is intended that users of NEI 14-05 understand the guidance as a whole, as this is necessary in order to properly dedicate commercial grade calibration and test services. An overview of the guidance is provided in Section 1.3, and this is where all of the actions and steps that a purchaser must follow are provided in one location. Thus, we do not believe that adding an additional section to provide this summary adds value or is necessary.

However, in order to provide clarity in response to the NRC's concern, the following changes have been made to NEI 14-05.

- Section 1.3 of NEI 14-05, which introduces the set of actions and steps that a purchaser must take, has been revised as follows: "The following ~~is a summary of~~ *are* the ~~conditions~~ *actions and steps* that are necessary in order for a Purchaser to accept accreditation of international calibration and test laboratory services by ILAC MRA signatories in lieu of performing a commercial grade survey as part of commercial grade dedication. *Additional detail on performing these steps is discussed in subsequent sections of this guidance.*"
- In Section 4, the paragraph has been revised as follows, "A ~~generic~~ Template *for* describing the use of the ILAC process in lieu of a commercial grade survey ~~that may be inserted into~~ *in* a Purchaser's QA Program is provided in Appendix A. *Although a Purchaser is not required to use*

the Template in Appendix A, all of the actions and steps described in Appendix A need to be included in the Purchaser's QA Program."

TR NEI 14.05 Guidelines-3

Question:
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.

Response
It is the intent of NEI 14-05 that all documents required by the purchase order (PO) requirements be reviewed by the purchaser. Commercial grade dedication of calibration and testing services currently requires that completion of the dedication can only occur after review of calibration and testing records. Therefore to ensure that all licensees and suppliers review and document the conformance to PO requirements, Section 3.3 and Appendix A have been revised to state that a review of calibration and testing records will be completed and documented. In addition, Section 3.1 of NEI 14-05 has been revised to clearly state that dedication of the contracted service is not complete until all documentation has been reviewed to ensure compliance with all purchase order requirements.

The following sentence has been added to the end of Section 3.1: "*Dedication of the contracted service is not complete until documentation has been reviewed to assure compliance with all purchase order requirements*."

The following revision has been made to Section 3.3: "*A documented review of calibration and testing records will be completed in order t*To implement the acceptance method.~~,~~ The Purchaser needs to verify*, at receipt inspection,* that the laboratory has certified that it provided the service in accordance with their accredited ISO/IEC-17025:2005 program and scope of accreditation, and have complied with any other requirements specified in the Purchaser's procurement documents."

The following has been added to the end of the list of actions in Section 1.3 and Appendix A:

"*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-17025:2005 program, and has been performed within their scope of accreditation, and*
- b. *The purchase order's requirements are met.*"

TR NEI 14.05 Guidelines-4

Question:

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.**

Response

The NRC is correct to point out that there are differences between suppliers of basic components and suppliers of commercial grade items. While there are some similarities between *audits* of suppliers of basic components and *surveys* of suppliers of commercial grade items, there are also some important differences. It is acknowledged, however, that through the use of surveys, commercial grade items can be dedicated as basic components and thus have the same QA pedigree as directly procured basic components using audits. Nonetheless, the appropriate guidance for dedication of commercial grade items, and reference for establishing the frequency for performing peer evaluations, is EPRI NP-5652, "Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications", and the reference in Section 5.3 has been revised to reflect this.

The nuclear industry's reasonable assurance that the ILAC process can be used in lieu of commercial grade surveys in order to demonstrate compliance with NRC regulations is based upon the existence of three important factors: 1) the ILAC requirements established in ISO/IEC-170025:2005, 2) the interpretation and standardization of complying with those requirements as established in ILAC procedures, and 3) the use of peer evaluations in the ILAC process for ensuring compliance to these requirements and procedures. Our conclusions are based upon reviewing the ILAC requirements and procedures, observing peer evaluations of accreditation bodies, observing the process for reviewing peer evaluation results and determining whether the accreditation body complies with ILAC requirements and procedures, and observing the training of peer evaluators. We acknowledge that

the large number of accreditation bodies that are ILAC MRA signatories, and the large number of laboratories that they accredit, will result in variability of actual practices. However, through our assessment of the ILAC process we have concluded that the accreditation bodies, and the laboratories they accredit, meet or exceed the minimum ILAC requirements, and the minimum ILAC requirements are adequate to be used in lieu of commercial grade surveys.

As stated, a key factor in our confidence in the ILAC process is based upon the peer evaluations to ensure that accreditation bodies, and the laboratories they accredit, continue to meet the ILAC requirements and procedures. In this manner, the industry observations continue to focus on the peer evaluations on which the original confidence is based. Because peer evaluations confirm compliance of the accreditation bodies in their activities to assess laboratories and confirm that the laboratories are meeting ILAC requirements and procedures, the industry approach is focused on confirming the adequacy of the ILAC process itself, rather than on confirming the adequacy of individual accreditation bodies or individual laboratories. Intermediate observations on assessments of individual laboratories would be focused on very discrete parts of the ILAC process, and would not measurably increase the level of confidence that the ILAC process can continue to be used in lieu of commercial grade surveys. For this reason it is more appropriate for the industry oversight activities to focus on those elements that the initial conclusion is based upon, i.e., ILAC requirements and procedures, and peer evaluations.

a) The three year frequency is consistent with current industry practices for the performance of Commercial Grade Surveys as part of dedication of commercial calibration and test service providers. EPRI NP-5652 indicates that the three year frequency cited for audits in RG 1.28 should be used as a benchmark for determining the frequency for commercial grade surveys, and that annual evaluations should be incorporated into the dedicating entities' program. It was concluded that a three year frequency for observing the peer evaluations of the ILAC process would be adequate to provide reasonable assurance that the implementation of the ILAC process continues to comply with ILAC requirements and procedures. It should be pointed out that although the industry observation of peer evaluations is on a three year frequency, there are numerous oversight activities being performed within the ILAC process. This includes regular peer evaluations of the accreditation bodies, and regular assessments of laboratories by the accreditation bodies. The competence of peer evaluators and assessors was observed to be a key strength of the ILAC process, as the peer evaluators lead or direct other accreditation bodies, and are experienced through performance of multiple peer observations per year. Consideration was also given to the three year period based upon additional oversight activities described in Section 5.2. As a stakeholder member of ILAC, NEI is allowed participation in the process to maintain ILAC requirements and procedures, and will monitor this process on an on going basis. The on going monitoring of ILAC requirements and procedures will be documented on an annual basis and will serve as the annual evaluation. To reflect this, the following sentence has been added to Section 5.2, "*A summary of the monitoring of ILAC requirements and procedures will be documented on an annual basis*." Although there are no plans to formally submit the annual documentation to the NRC, it would be available upon request.

b) It is recognized that there would be benefit in alternating between international and domestic observations, and it is our intention to do so. However, selection is based on the peer evaluations occurring when the industry schedules the observation, and thus it may not always be possible to alternate between domestic and international observations.

c) The documentation of industry's observations of peer evaluations will be available to the NRC upon request, but there are no plans to formally submit them.

d) We would welcome the NRC staff to participate in any of our planned observation activities. It is recognized that approval for all observers must be obtained from the peer evaluation team, the peer being evaluated, and any laboratories being assessed. If we are notified of the NRC's interest in attending an observation, then we will assist the NRC in requesting those approvals. The following sentence is added to Section 5.3, "*The NRC may request to participate on these observations*."

TR NEI 14.05 Guidelines-5

Question:
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.

Response
It is not the intent of NEI 14-05 to substitute any of the optional activities in place of performing observation of peer evaluations. These optional activities could be used to supplement the observation of peer evaluations if so desired by the industry. For example, they could be used to provide input to the annual oversight of the process, if they provide clarity on proposed changes to ILAC requirements or procedures that could materially affect the manner in which the ILAC process is used by the nuclear industry.

TR NEI 14.05 Guidelines-6

Question:
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.

Response
It is the intent of NEI 14-05 that services be provided in accordance with the laboratory's accredited ISO/IEC-17025:2005 program as stated in Section 4.2. The lists in Section 1.3 and Appendix A have been revised to require the purchase order to invoke the laboratory's accredited ISO/IEC-17025-2005 program, as follows:

"2. The purchase documents require *that*:

a. *The service must be provided in accordance with their accredited ISO/IEC-17025:2005 program and scope of accreditation*."

TR NEI 14.05 Guidelines-7

Question:
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.

Response
It is not the intent of NEI 14-05 to require licensees and suppliers to include the procurement clause from EPRI 1019163, Revision 1. The EPRI guidance and procurement clause are mentioned to bring awareness to the topic of counterfeit and fraudulent items (CFI). The NRC has decided not to endorse the EPRI guidance, and its use is voluntary. It is acceptable if a purchaser does not use the procurement clause. Further, the NRC is planning to issue a Regulatory Issue Summary (RIS) on CFI in 2014. Any clarifications in the RIS would apply equally to procurement of calibration and testing services accredited by an ILAC MRA signatory the same way that it would apply to other commercial grade procurements. The discussion in Section 6 has been revised to highlight the voluntary nature of the EPRI guidance on CFI, and to update the reference to the recently published final version as follows: "EPRI ~~issued~~ *updated* guidance on counterfeit and fraudulent items, "Plant Support Engineering: Counterfeit, Fraudulent and Substandard Items," EPRI-1019163 *Revision 1 in 2014*~~, and is in the process of updating this guidance~~. *Use of the EPRI guidance on counterfeit and fraudulent items is voluntary; however, it does* ~~The guidance~~ provide~~s~~ practical measures to further enhance protections against counterfeit and fraudulent items and includes a standard procurement clause that ~~can~~ could be used in the procurement of calibration and testing services."

TR NEI 14.05 Guidelines-8

Question:
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.

Response
NEI 14-05 does not intend that a technical evaluation is needed to identify any additional technical or quality requirements, only that any additional requirements be identified. While Section 6 of NEI 14-05 does identify three requirements that must be included in the procurement documents, and Section 6.1 contains a generic technical evaluation, the additional requirements were not identified through the generic technical evaluation. Nor is it expected that the purchaser needs to perform a technical evaluation for the purpose of identifying additional technical requirements. The statement leading to confusion has been removed (note that the contents of Section 3.2.1 are combined into Section 4.2 in response to Question TR NEI 14.05 Guidelines-9).

All of the critical characteristics for calibration and testing services are identified in Section 6.1. There are no situations anticipated for which additional critical characteristics would be necessary. The critical characteristics for calibration and testing services are included in the ISO/IEC 17025:2005, the accreditation process and thus the NEI Guidance Document. These critical characteristics apply to all types of calibration and testing services respectively. The only procurement requirement necessary to control the critical characteristics is for the laboratory to perform the service in accordance with their ISO/IEC-1702:2005 program and scope of accreditation. It may be necessary, however, for the procurement document for such services to impose specific acceptance criteria that a laboratory must meet as a part of the dedicated service being provided.

For instance, in regard to calibration services, the purchaser may include specify acceptance criteria for the following critical characteristics: "Environmental Conditions, i.e., temperature, humidity, vibration, etc." The accreditation process verifies the laboratory controls this critical characteristic but the procurement document may specify the calibration has to be performed in an environment of 68 degrees F and Relative humidity of less than 60%. In regard to testing services, the purchaser may specify acceptance criteria for the following critical characteristic: "Testing for the required characteristics/parameters is performed in accordance with written industry recognized standards or other validated and approved test methods". The accreditation process verifies that the laboratory controls this critical characteristic, but the procurement document may specify the testing must be performed using ASTM E23 – 12, "Standard Test Methods for Notched Bar Impact Testing of Metallic Materials. Even in these cases where special or different acceptance criteria are identified for a critical characteristic, ISO/IEC 17025:2005 verifies that the laboratory will perform the service in compliance with this special requirement.

TR NEI 14.05 Guidelines-9

Question:
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.

Response

Appendix A has been revised to ensure consistency with the guidance in the body of the document. As identified by the NRC, step three (the review of the supplier's accreditation and scope) has been moved to the first step. Section 3.2.1 has been deleted and the guidance combined into Section 4.2. As a result, the corresponding steps described in the lists in Section 1.3 and Appendix A have been combined. As described in the responses to questions TR NEI 14.05 Guidelines-3 and 6, additional changes to Appendix A have been made to ensure consistency with the guidance in the body of the document.