February 9, 2015

Marcus R. Nichol, Senior Project Manager
Quality Issues and Licensing Actions
Nuclear Energy Institute
1201 F Street, NW, Suite 100
Washington, DC 20004

SUBJECT: FINAL SAFETY EVALUATION FOR TECHNICAL REPORT NEI 14-05, "GUIDELINES FOR THE USE OF ACCREDITATION IN LIEU OF COMMERCIAL GRADE SURVEYS FOR PROCUREMENT OF LABORATORY CALIBRATION AND TEST SERVICES," REVISION 1

Dear Mr. Nichol:

By letter dated April 29, 2014, the Nuclear Energy Institute (NEI) submitted Revision 0 of NEI 14-05, "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 endorsement. NEI 14-05 provides an approach for licensees and suppliers of basic components for using laboratory accreditation by Accreditation Bodies (ABs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (hereafter referred to as the ILAC accreditation process) in lieu of performing commercial-grade surveys for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

By letter dated July 22, 2014, the NRC issued requests for additional information (RAIs) to complete its review of NEI 14-05. Two conference calls were held on July 3, 2014, and August 13, 2014, to clarify the concerns in the NRC's RAIs. By a letter dated August 28, 2014, NEI submitted RAI responses and NEI 14-05, Revision 1, which incorporates the RAI responses.

The staff has reviewed the NEI submittal and supporting documentation. On the basis of its review, the NRC staff concludes that NEI 14-05, Revision 1, provides an acceptable approach for licensees and suppliers subject to the quality assurance requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," for using laboratory accreditation by ABs that are signatories to the ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

NRC's endorsement of NEI 14-05, Revision 1, expands the NRC's acceptance of the ILAC accreditation process first documented in a safety evaluation (SE) on an Arizona Public Service (APS) request (Agencywide Documents Access and Management System (ADAMS) Accession No. ML052710224). NRC's earlier acceptance was limited to laboratory calibration services accredited by specific U.S. ABs. The enclosed SE (1) confirms that NEI 14-05, Revision 1, reflects the ILAC accreditation process previously approved; (2) provides an evaluation of the unique aspects of NEI 14-05, Revision 1; (3) constitutes formal NRC endorsement of the guidelines in NEI 14-05, Revision 1, for using the ILAC accreditation process in lieu of performing a commercial-grade survey; and (4) finds that the ILAC accreditation process continues to satisfy the requirements of Appendix B to 10 CFR Part 50 and, therefore, is acceptable.

When purchasing commercial-grade calibration and testing services from domestic and international calibration and testing laboratories accredited by an ILAC MRA signatory, licensees and suppliers of basic components may use the ILAC accreditation process in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process provided each of the following conditions are met:

1) The method to use accreditation by an ILAC MRA signatory in lieu of performing a commercial-grade survey (alternative method) is documented in the licensees and supplier's quality assurance (QA) program.

2) The method the licensees and suppliers need to follow, and document in their QA program, consists of:

    1. A documented review of the supplier's accreditation is performed and includes a verification of the following:

        a. The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories."

        b. For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

        c. For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.

    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.

b. As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance *(for calibration services only).*

c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration *(for calibration services only).*

d. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.

e. Any additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

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.

Our acceptance applies only to material provided in NEI 14-05, Revision 1. The NRC does not intend to repeat reviews of the acceptable material described in NEI 14-05, Revision 1, when referenced in a license amendment request or combined license application. However, the NRC will confirm that the conditions described in NEI 14-05, Revision 1 have been met. Finally, licensing requests that deviate from NEI 14-05, Revision 1, will be subject to a plant-specific or site-specific review in accordance with applicable review standards.

In accordance with the guidance provided in NRR Office Instruction, LIC-500, which can be found on the NRC public web site, we request that NEI publish the accepted version of NEI 14-05, Revision 1 within 3 months of receipt of this letter. The accepted version should incorporate this letter and the enclosed SE. The accepted version should also contain historical review information, including NRC RAIs and your responses. The accepted versions shall include a "-A" (designating accepted) following the report identification symbol.

If future changes to the NRC's regulatory requirements affect the acceptability of NEI 14-05A, NEI will be expected to revise NEI 14-05A appropriately, or justify its continued applicability for subsequent referencing.

If you have any questions, please contact Dennis J. Galvin at (301) 415-6256 or via email 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.: 689

Enclosure:
Safety Evaluation Report

cc: See next page

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**ADAMS Accession No.: ML14322A535** ***via email** **NRO-002**

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FINAL SAFETY EVALUATION BY THE OFFICE OF NEW REACTORS RELATED TO

NUCLEAR ENERGY INSTITUTE TECHNICAL REPORT 14-05

"GUIDELINES FOR THE USE OF ACCREDITATION IN LIEU OF COMMERCIAL

GRADE SURVEYS FOR PROCUREMENT OF LABORATORY CALIBRATION

AND TEST SERVICES," REVISION 1

## 1.0 Introduction

By letter dated August 28, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14245A392), the Nuclear Energy Institute (NEI) submitted Revision 1 to NEI 14-05, "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 endorsement (NEI 14-05 hereafter refers to NEI 14-05, Revision 1). NEI 14-05 provides an approach for licensees and suppliers of basic components for using laboratory accreditation by Accreditation Bodies (ABs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (hereby after referred to as the ILAC accreditation process) in lieu of performing commercial-grade surveys for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA. This method of qualifying the calibration and testing supplier and accepting its calibration and testing services would be applied only to commercial-grade calibration and testing services as defined by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance."

## 2.0 Background

On September 28, 2005 (ADAMS Accession No. ML052710224), the NRC approved a request from Arizona Public Service Company (APS), in accordance with the regulations in 10 CFR 50.54(a)(4), which proposed a change to the quality assurance (QA) program for the Palo Verde Nuclear Generating Station. The proposed change provided for use of accreditation of commercial-grade (as defined by 10 CFR Part 21) calibration services by a nationally-recognized AB, in lieu of performing a commercial-grade survey, using procedures consistent with international standards and guidelines, specifically those found in International Standard Organization (ISO)/International Electrotechnical Commission (IEC) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories," and to establish that there is sufficient depth of examination to determine competence. In its proposed change to the QA program, APS stated that nationally-recognized ABs included the National Voluntary Laboratory Accreditation Program (NVLAP) and others recognized by NVLAP through an MRA.

In a letter dated March 15, 2006 (ADAMS Accession No. ML061140023), the Nuclear Procurement Issues Committee (NUPIC) requested the NRC to clarify whether the alternative to performing commercial-grade surveys for domestic procurement of commercial-grade calibration services as defined in 10 CFR Part 21 may be adopted by suppliers for qualifying

sub-suppliers. In its response dated June 6, 2006 (ADAMS Accession No. ML061580386), the NRC stated that 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,” suppliers may use the alternative for the qualification of commercial-grade sub-suppliers as long as the conclusions of the safety evaluation (SE) with regards to the quality of the supplier’s programs also apply to the sub-suppliers.

Subsequently, in a letter dated February 26, 2009 (ADAMS Accession No. ML090771324), Equipos Nucleares, S.A. (ENSA) requested the NRC to evaluate acceptance of international ABs belonging to ILAC as third party accreditation for commercial-grade calibration services in lieu of performing a commercial-grade survey. ENSA is a supplier of nuclear components for operating and potential new reactors in the U.S.

## 3.0 Regulatory Evaluation

Items and services used in safety-related applications at U.S. commercial nuclear power plants are designated as basic components and are required to be provided in accordance with Appendix B to 10 CFR Part 50, which includes requirements for calibration and testing associated with basic components. The predominant criteria of Appendix B to 10 CFR Part 50 that are related to the use of accreditation in lieu of performing commercial-grade surveys for procurement of laboratory calibration and test services are Criteria 1, 4, 7, and 12.

Criterion 1, "Organization," allows for the delegation of authorities and duties for carrying out portions of the QA program to others. Delegation of commercial-grade services would be controlled through procurement documents and purchasing requirements. The portion of the QA process that is delegated, specifically that of qualifying the supplier, would be clearly established and delineated in the QA program.

Criterion 4, "Procurement Document Control," requires that measures be established to assure that applicable regulatory requirements, design bases, and other requirements necessary to assure quality are stipulated or referenced in procurement documents. Licensees and suppliers of basic components would continue to impose the pertinent requirements of Appendix B to 10 CFR Part 50 on approved and accredited suppliers of commercial-grade calibration and test services. However, the methods and criteria for evaluating and selecting suppliers would be based on American National Standards Institute (ANSI)/ISO/IEC 17025, as implemented by recognized internationally accrediting bodies.

Criterion 7, "Control of Purchased Material, Equipment, and Services," requires that measures be established to assure that purchased material, equipment, and services conform to the procurement documents. In the case of commercial-grade calibration and test services, the licensees and suppliers of basic components would be responsible for reviewing objective evidence for conformance to the procurement documents.

Criterion 12, "Control of Measuring and Test Equipment," requires that measures be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. The licensees and suppliers of basic components

would specify through procurement documents that as-found calibration data be provided when the item being calibrated is found out-of-tolerance.

10 CFR Part 21 allows for the use of commercial-grade items and services in nuclear safety-related applications through the commercial-grade dedication process. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, a commercial-grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. 10 CFR Part 21 also defines critical characteristics, which are those important design, material, and performance characteristics that, once verified, will provide reasonable assurance that the item will perform its intended safety function. An acceptable method for dedicating commercial-grade items includes the need to verify the critical characteristics for commercial-grade items and services and establishes the use of commercial-grade surveys as one of four acceptable methods to perform this verification. This approach is described in the Electric Power Research Institute (EPRI) NP-5652, “Guideline for the Utilization of Commercial Grade Items in Nuclear Grade Safety Applications,” dated June 1988. The four acceptance methods are described in NP-5652 and are conditionally endorsed by NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," March 21, 1989.

## 4.0 Technical Evaluation

### 4.1 Laboratory Accreditation

The ILAC first started as a conference in 1977 with the aim of developing international cooperation for facilitating trade by promotion of the acceptance of accredited test and calibration results. In 1996, ILAC became a formal cooperation with a charter to establish a network of MRAs among ABs. Then, on November 2, 2000, 36 ABs from 28 countries worldwide signed the ILAC MRA in Washington, DC to promote the acceptance of technical test and calibration data. The ILAC MRA came into effect on January 31, 2001. The key to the ILAC MRA is the developing of a global network of accredited calibration and testing laboratories that are assessed and recognized as being competent by signatory ABs. Currently, 79 ABs throughout the world are signatories to the ILAC MRA.

Acceptance of an AB into the ILAC MRA is dependent upon being successfully evaluated by peers from other ABs. Each AB that is a signatory to the ILAC MRA commits to:

- Maintain conformity with the current version of ISO/IEC 17011:2004, “Conformity Assessment - General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.”
- Ensure that all laboratories that are accredited comply with appropriate requirements of ISO/IEC 17025.

The ILAC MRA has been structured to build on existing and developing regional MRAs established around the world. Regional Cooperation Bodies (RCBs) who are operating a regional MRA, coordinate peer evaluations and thereby maintain confidence in the accreditation bodies that are signatories to the regional MRA. In turn, each RCB that has been recognized by

ILAC must also abide by ILAC's procedures and requirements and undergo routine peer evaluations by members of another RCB or ILAC.

Currently, the European Cooperation for Accreditation (EA), the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and the Inter-American Accreditation Cooperation (IAAC) are the only ILAC RCBs. This means that the MRAs and evaluation procedures of EA, APLAC and IAAC have been peer evaluated by ILAC and deemed to be satisfactory. Recognized RCBs are peer re-evaluated on an on-going basis over a 4 year period.

The calibration and testing laboratories are accredited by the ABs by verifying technical competence and assessing their quality management systems to ISO/IEC 17025. The process begins with the calibration laboratory's submittal of an application, applicable fees, and a quality management system manual. An accreditation contact is selected to partner with the laboratory throughout the accreditation process, beginning with a review of the quality manual and the requested scope of accreditation. Once the quality manual has been reviewed and approved, an assessment team is selected based on the requested scope of accreditation. The team conducts an on-site assessment of the laboratory and develops an assessment report. Once a laboratory has satisfied the accreditation requirements of the AB and demonstrated competence, an accreditation certificate is issued. The calibration and testing laboratories typically undergo full renewal assessments at least every two years. The objective of the assessment is to establish whether or not a laboratory complies with the requirements for accreditation and can competently perform the types of tests or calibrations the laboratory is accredited for. Although accreditation is granted for two years, after the initial year of accreditation each laboratory typically undergoes an annual surveillance assessment each year prior to the full renewal assessment. The objective of the surveillance assessments is to confirm that the laboratory's management system and technical capabilities remain in compliance with the accreditation requirements.

### 4.2 NRC's Initial and Continued Recognition of the ILAC Accreditation Process

The NRC's initial recognition of the ILAC accreditation process is documented in the APS's SE dated September 28, 2005 (ADAMS Accession No. ML052710224). The recognition of the ILAC accreditation process was based on the NRC staff's evaluation of the accreditation programs for both the National Voluntary Laboratory Accreditation Program (NVLAP) and the American Association for Laboratory Accreditation (A2LA) with the following conditions:

- NRC review and approval limited to NVLAP and A2LA
- Alternative method documented in the QA program
- Accreditation is to /ISO/IEC 17025
- Scope of accreditation covers the contracted services
- Purchase documents should: (1) Impose additional technical and administrative requirements; (2) require reporting as-found calibration data and (3) require identification of the laboratory equipment/standards used

Subsequent to the issuance of the APS SE, the NRC extended its recognition of the accreditation programs of the other four domestic ABs: ACLASS, International Accreditation Service (IAS), Laboratory Accreditation Bureau (LAB), and Perry Johnson Laboratory Accreditation (PJLA). The NRC's recognition of the ILAC accreditation process was expanded to include the use of domestically accredited calibration laboratories by suppliers and sub-suppliers as documented in the NRC letter to the NUPIC Chairman dated June 6, 2006, (ADAMS Accession No. ML061580350). It is important to note that the NRC's initial recognition of the ILAC accreditation process was limited to domestic calibration service suppliers.

Between 2010 and 2013, the NRC performed 6 observations of accreditation assessments of commercial calibration and testing laboratories performed by A2LA, LAB, ACLASS, IAS, and PJLA. The observation of the accreditation process performed by A2LA, LAB, and PJLA also included observing ILAC's evaluation of A2LA, LAB, and PJLA as well. In addition, the NRC staff, along with members of NUPIC, observed the Japan's Accreditation Board (JAB) evaluation by ILAC as well as JAB's accreditation of calibration and testing laboratories. The JAB is one of the three ABs in Japan. The NRC decided to perform these observations to maintain our confidence in the ILAC accreditation process and also as part of our initial evaluation to expand our recognition of the ILAC accreditation process.

### 4.3 Evaluation of NEI 14-05

NEI 14-05 was developed by the NEI ILAC Task force with the assistance of the NEI QA Task Force and NUPIC. In evaluating the adequacy of NEI 14-05, because the NRC has already recognized the ILAC accreditation process for domestic calibration service suppliers, the NRC staff's evaluation of NEI 14-05 focused on (1) the conditions that licensees and suppliers of basic components must meet to rely on the accreditation by an ILAC signatory in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process; (2) documentation requirements when using the ILAC accreditation process; and (3) the continued oversight of the ILAC accreditation process by the U.S. nuclear industry.

#### 4.3.1 Acceptance of Accreditation of Domestic and International Calibration and Test Laboratory Services by ILAC MRA Signatories

Section 1.3 of NEI 14-05, "Acceptance of Accreditation by ILAC Signatories in Lieu of Commercial Grade Surveys," contains the conditions that licensees and suppliers of basic components must follow to accept the accreditation of calibration and test laboratory services by ILAC MRA signatories in lieu of performing a commercial-grade survey as part of the licensee and supplier's commercial-grade dedication process. These are:

1) The method to use accreditation by an ILAC MRA signatory in lieu of performing a commercial-grade survey (alternative method) is documented in the licensees and supplier's QA program.

2) The method the licensees and suppliers need to follow, and document in their QA program, consists of:

1. A documented review of the supplier's accreditation is performed and includes a verification of the following:

    a. The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories."

    b. For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

    c. For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.

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.

    b. As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance *(for calibration services only).*

    c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration *(for calibration services only).*

    d. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.

    e. Any additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

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.

With the exception of conditions 2.1.c, 2.2.d, 2.3.a, and 2.3.b, the conditions above are consistent with the conditions imposed in the APS SE as well as those described in Section 17.5, "Quality Assurance Program Description-Design Certification, Early Site Permit and New License Applicants," of NUREG 0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants."

Because one of the objectives of NEI 14-05 is to expand the NRC's recognition of the ILAC accreditation process to include testing services, condition 2.1.c ensures that when licensees and suppliers of basic components procure commercial testing services as part of the commercial-grade dedication process, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.

During the assessment of the ILAC accreditation process, the NEI ILAC Task Force identified that ISO/IEC-17025:2005 does not require the laboratories to notify the ABs of any significant condition adverse to quality, and ISO/IEC-17011:2004 does not require the ABs to notify the RCBs or ILAC of any significant conditions adverse to quality. As a result of this, condition 2.2.d ensures that licensees and suppliers of basic components are notified of any conditions that could adversely impact the laboratory's ability to maintain its scope of accreditation, and therefore could impact the services provided.

As part of the commercial-grade dedication process, licensees and suppliers of basic components should assure that the calibration or testing service meet the requirements imposed on the procurement documents. Conditions 2.3.a and 2.3.b ensure that licensees and suppliers of basic components verify, at receipt inspection, that there is objective evidence that the laboratory has certified that it provided the service in accordance with its accredited ISO/IEC 17025:2005 program and scope of accreditation, and have complied with any other requirements specified in the procurement documents. The dedication of the calibration and testing service is not complete until a documented review of the calibration and testing records has been performed to assure that all of the purchase order requirements have been met.

### 4.3.2 Documentation Associated with the Use of the ILAC Accreditation Process

As with all activities performed under a QA program that meets the requirements of Appendix B to 10 CFR Part 50, the activities associated with the use of the ILAC accreditation process in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process shall be documented by the licensees and suppliers of basic components who choose to use this alternative.

Section 6.1 of NEI 14-05, "Technical Evaluation of ILAC Requirements and Procedures," identifies all of the critical characteristics for calibration and testing services based on EPRI NP-5652. The technical evaluation concluded that all of the critical characteristics for calibration and testing services are already included in ISO/IEC-17025:2005 and are verified to be properly controlled by a laboratory as part of the ILAC accreditation process. The NRC staff verified this as part of its initial recognition of the ILAC accreditation process. As such, it is not expected that licensees and suppliers need to perform a technical evaluation to identify additional technical requirements. Therefore, a documented review of the calibration or testing laboratory's accreditation is equivalent to the technical evaluation. Licensees and suppliers of

basic components may choose to perform a single documented review calibration or testing laboratory's accreditation and apply it to future procurements provided the scope of accreditation has not changed.

When using the alternative, licensees and suppliers are responsible for reviewing objective evidence to verify that the calibration and testing service was performed in accordance with the purchase order requirements. As stated in Section 4.3.1 above, the dedication of the calibration and testing service is not complete until a documented review of the calibration and testing records has been performed to assure that all of the purchase order requirements have been met.

### 4.3.3 Oversight of the ILAC Accreditation Process

Section 5 of NEI 14-05, "US Nuclear Industry Oversight of the ILAC Process," describes the approach for the U.S. nuclear industry to provide continued oversight of the ILAC accreditation process in order to confirm that the process can continue to be used in lieu of commercial-grade surveys as part of the commercial-grade dedication process.

The NEI has formed an industry team, consisting of licensees (including NUPIC members) and suppliers, to monitor the ILAC activities associated with the industry's use of the ILAC accreditation process as part of the commercial-grade dedication process. NEI is currently a stakeholder member of ILAC, which allows NEI to have access to ILAC information and activities. In addition, being a stakeholder allows NEI attendance at meetings, notification of potential changes to ILAC requirements and procedures, and access to observation the peer evaluations of ABs and laboratory assessments.

There are two elements required for an adequate oversight of the ILAC accreditation process: (1) review of ILAC's requirements and procedures, and (2) observation of peer evaluations of ABs and laboratory assessments. Section 5.2 of NEI 14-05, "Verification that the ILAC Process Continues to be Consistent with NRC Accepted Practices," states that NEI team (including NUPIC members and other industry representatives) will monitor the ILAC requirements and procedures and as a stakeholder member, NEI will be notified by ILAC of any potential changes to ILAC's requirements and procedures. The NEI team, in turn, will evaluate whether the potential changes could materially affect the manner in which the ILAC accreditation process is used by the nuclear industry. In addition, the NEI team will document the results of the monitoring activities on an annual basis.

Section 5.3, "Verification that Implementation of the ILAC Process Continues to be Consistent with NRC Accepted Practices," states that NEI will observe peer evaluations of an AB and the associated laboratory assessments of calibration and testing laboratories to verify that the ILAC accreditation process continues to be implemented consistent with ILAC's requirements and procedures. These peer evaluations are performed to verify the ABs adherence to ISO/IEC-17011:2004, and their ability to accredit laboratories to ISO/IEC-17025:2005. The NEI team plans to observe peer evaluations and the associated laboratory assessments on a frequency of once every 3 years. The observations will be will be led by a knowledgeable NUPIC member with support from other NEI team members. The NRC might also choose to participate in these observations as part of its oversight of third-party organizations implementing QA requirements. Given that commercial grade-surveys should be conducted at

sufficient frequency to ensure that the process controls applicable to the critical characteristics of the services procured continue to be effectively implemented and should not exceed the audit frequency established for 10 CFR Part 50, Appendix B, suppliers (triennial basis), the NRC staff finds the observation frequency acceptable. Furthermore, as described in Section 4.1, the ILAC accreditation process includes regular peer evaluations of the ABs, and regular assessments of the laboratories by the ABs. All these activities provide reasonable assurance that the implementation of the ILAC accreditation process will continue to comply with ILAC requirements and procedures.

## 5.0 Applicability

As described in Section 4.3.1 above, licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50 may use the ILAC accreditation process in lieu of performing commercial-grade surveys for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

However, 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 requirements of 10 CFR 50.54(a)(3)(ii).

## 6.0 Conclusion

On the basis of its review, the NRC staff concludes that NEI 14-05, Revision 1, provides an acceptable approach for licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50 for using laboratory accreditation by ABs that are signatories to the ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

NRC's endorsement of NEI 14-05, Revision 1, expands the NRC's acceptance of the ILAC accreditation process first documented in the APS SE (ADAMS Accession No. ML052710224). The staff bases this endorsement on finding that (1) NEI 14-05 reflects the ILAC accreditation process previously approved; (2) the unique aspects of NEI 14-05 satisfy the requirements of Appendix B to 10 CFR Part 50, and thus the ILAC accreditation process continues to satisfy the requirements of Appendix B to 10 CFR Part 50 and, therefore, is acceptable. Therefore, NRC endorses the guidelines in NEI 14-05 for using the ILAC accreditation process in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process.

Our acceptance applies only to material provided in NEI 14-05, Revision 1. The NRC does not intend to repeat reviews of the acceptable material described in NEI 14-05, Revision 1, when referenced in a license amendment request or combined license application. However, the NRC will confirm that the conditions described in NEI 14-05, Revision 1 have been met. Finally, licensing requests that deviate from NEI 14-05, Revision 1, will be subject to a plant-specific or site-specific review in accordance with applicable review standards.

## 7.0 References


1. Safety Evaluation Report by the U.S. Nuclear Regulatory Commission, “Palo Verde Nuclear Generating Station, Units 1, 2, and 3 - Approval of Change to Quality Assurance Program (Commercial-Grade calibration Services,” dated September 28, 2005 (ADAMS Accession No. ML052710224)

2. Letter from Michael E. Mayfield, Director, Division of Engineering, Office of Nuclear Reactor Regulation, to Ms. Sherry Grier, NUPIC Chairman, “Palo Verde Nuclear Generating Station, Units 1, 2, and 3 Approval of Change to Quality Assurance Program (Commercial-Grade Calibration Services),” dated June 6, 2006 (ADAMS Accession No. ML061580386)

3. Electric Power Research Institute Report NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications," June 1988 (ADAMS Accession No. ML14239A523)

4. NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," March 21, 1989.

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