

NEI 14-05A, Revision 0

**GUIDELINES FOR THE USE
OF ACCREDITATION IN
LIEU OF COMMERCIAL
GRADE SURVEYS FOR
PROCUREMENT OF
LABORATORY
CALIBRATION AND TEST
SERVICES**

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NOTICE

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FOREWORD

The purpose of this guidance is to describe an acceptable approach for using 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 as part of commercial grade dedication. The scope includes commercially procured calibration and test services performed by domestic and international laboratories accredited by ILAC signatories. The approach also includes continued oversight of the ILAC process by the nuclear industry to verify that the ILAC process continues to be an equivalent alternative to a commercial grade survey. In developing this approach, NEI's ILAC Task Force observed peer evaluations of international Accreditation Bodies, assessments of calibration and testing laboratories, training for peer evaluators, and ILAC accreditation meetings. Based upon these observations, it was concluded that the ILAC process is essentially equivalent to the U.S. Nuclear Regulatory Commission (NRC) accepted practices for performing commercial grade surveys.

NRC's endorsement of this guidance expands NRC's recognition of the ILAC process first documented in a Safety Evaluation Report (SER) on an Arizona Public Service (APS) request. NRC's earlier recognition was limited to laboratory calibration services accredited by specific U.S. Accreditation Bodies. With endorsement by the NRC, licensees and suppliers may use this guidance to credit accreditation by ILAC signatories, both domestic and international, in the commercial grade dedication of laboratory calibration and test services.

The Final Safety Evaluation Report on NEI 14-05, Revision 1, is incorporated as Attachment A and NEI responses to NRC RAIs as Attachment B. In accordance with NRC guidance, this accepted version is designated as NEI 14-05A, Revision 0 (with the suffix A indicating NRC acceptance).

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Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services

1 INTRODUCTION

1.1 PURPOSE

The purpose of this guidance is to provide an acceptable approach for procuring commercial grade calibration and testing services by laboratories accredited by International Laboratory Accreditation Cooperation (ILAC) signatories. Access to internationally (including both domestic and international) accredited calibration and testing services benefits licensees and their suppliers through reduced cost, expanded access to services, improved quality of services, and improved regulatory confidence.

This approach takes advantage of the internationally recognized standards and accreditation process when qualifying suppliers to perform calibration and test services for the nuclear industry. Purchasers (licensees and suppliers of basic components) 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 to provide the necessary evidence of compliance to qualify calibration or test suppliers under a Commercial Grade Dedication process. The net result will be a substantial reduction in duplication of effort for qualifying these suppliers across the industry, while ensuring that the applicable requirements for commercial grade dedication continue to be met.

1.2 REGULATORY BASIS

Items and services used in safety related applications at US commercial nuclear power plants are designated as basic components and are required to be provided in accordance with 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants". 10 CFR Part 50, Appendix B, includes requirements for calibration and testing associated with basic components.

It is not always possible or practical to procure items and services directly from suppliers that implement quality assurance programs that meet 10 CFR Part 50, Appendix B. Therefore, the NRC established requirements in 10 CFR Part 21 "Reporting of Defects and Noncompliance" that permit the use of commercial grade items and services in nuclear safety related applications through a commercial grade dedication process

applications. Although the suppliers of commercial grade items and services are not required to comply with 10 CFR Part 50, Appendix B requirements, the commercial grade dedication activities must be performed under a Quality Assurance Program that meets the requirements of 10 CFR Part 50, Appendix B.

The process for accepting items and services for use as basic components from commercial suppliers is known as Commercial Grade Dedication (CGD or Dedication). An acceptable approach for dedicating commercial grade items includes the need to verify the critical characteristics for commercial grade items and services and establishes the use of a Commercial Grade Survey as one of four acceptable methods to perform this verification. This approach is described in EPRI NP-5652, “Guideline for the Utilization of Commercial Grade Items in Nuclear Grade Safety Applications (NCIG-07),” or other equivalent EPRI guidance¹.

The Nuclear Procurement Issues Committee (NUPIC) is an association of US nuclear power plant operators and a number of international nuclear power plant operators with the mission to improve supplier quality assurance and oversight processes through cooperative efforts. NUPIC has established processes and checklists to perform Commercial Grade Surveys that meet the applicable requirements of 10 CFR Part 21 and 10 CFR Part 50, Appendix B, and associated guidance.

This guidance document describes a method for using the ILAC process in the procurement of commercial grade laboratory calibration and test services and dedication of these laboratory services in compliance with 10 CFR Part 21 and 10 CFR Part 50, Appendix B. This guidance is applicable to dedicating entities subject to the quality assurance requirements of 10 CFR Part 50, Appendix B (e.g., 10 CFR Part 50, 10 CFR Part 52, 10 CFR Part 71 and 10 CFR Part 72 licensees and affected suppliers).

¹ At the time of publication, EPRI was preparing updated guidance on Commercial Grade Dedication titles “Guideline for the Acceptance of Commercial Grade Items in Nuclear Safety-Related Applications,” Revision 1, 3002002982, which is planned to supersede EPRI-NP5652 and EPRI TR-102260. The approach in EPRI-NP5652 is partially endorsed by the NRC in GL-89-02 and it is anticipated that EPRI-3002002982 will be endorsed by NRC when completed. The user of this guidance document on the use of the ILAC process in lieu of a commercial grade survey should use the NRC endorsed guidance available at the time the dedication activities are performed.

1.3 ACCEPTANCE OF ACCREDITATION BY ILAC SIGNATORIES IN LIEU OF COMMERCIAL GRADE SURVEYS

Calibration and testing services provided by internationally accredited laboratories under the ILAC process are commercial grade services. The guidance within describes an approach to rely on the accreditation by an ILAC signatory in lieu of commercial grade surveys in the commercial grade dedication process. The approach used to develop this guidance was to compare the ILAC process with NRC accepted practices for commercial grade surveys to evaluate their equivalence and determine whether any additional actions are necessary to address differences between them. Section 2 describes the ILAC processes and Section 6 provides the US nuclear industry's evaluation of ILAC process and comparison with NRC accepted practices. Section 5 describes the approach for the US nuclear industry to provide continued oversight of the ILAC process in order to confirm that the ILAC process can continue to be used in lieu of Commercial Grade Surveys for the purpose of commercial grade dedication, as described in this guidance.

Based upon the conclusion that the ILAC process is essentially equivalent to NUPIC practices, it has been determined that the accreditation by ILAC signatories can be used, with the inclusion of a few requirements in the procurement documents, in lieu of a Commercial Grade Survey to comply with the applicable requirements of 10 CFR Part 50, Appendix B and 10 CFR Part 21, and associated guidance. Section 3 describes how Purchasers of international calibration and testing laboratory services should use the accreditation by ILAC signatories as part of their Commercial Grade Dedication activities. It is noted that this guidance should be used in conjunction with guidance on commercial grade dedication. In addition, Section 4 describes information that Purchasers should ensure is included in their Quality Assurance Programs.

The following are the 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.

- 1) The method to use accreditation by an ILAC MRA signatory in lieu of a Commercial Grade Survey (alternative method) is documented in the Purchaser's QA program.
- 2) The method the Purchaser needs 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.

1.4 ACRONYMS

A2LA – American Association for Laboratory Accreditation

AB – Accreditation Body

APLAC – Asia Pacific Laboratory Accreditation Cooperation

CAB – Conformity Assessment Body

CFR – Code of Federal Regulations

CGD – Commercial Grade Dedication

EA – European Cooperation for Accreditation

EPRI – Electric Power Research Institute
GL – Generic Letter
IAAC – Inter American Accreditation Cooperation
IAF – International Accreditation Forum
IEC – International Electrotechnical Commission
ILAC – International Laboratory Accreditation Cooperation
ISO – International Organization for Standardization
JAB – Japan Accreditation Board
JIG – Joint Inspection Group
M&TE – Measure and Test Equipment
MRA – Mutual Recognition Arrangement
NEI – Nuclear Energy Institute
NIST – National Institute of Standards and Technology
NRC – Nuclear Regulatory Commission
NUPIC – Nuclear Procurement Issues Committee
QA – Quality Assurance
QC – Quality Control

2 INTERNATIONAL LABORATORY ACCREDITATION COOPERATION (ILAC)

2.1 DESCRIPTION OF THE INTERNATIONAL LABORATORY ACCREDITATION COOPERATION

ILAC was formalized as a cooperative agreement in 1996 by a memorandum of understanding signed by 44 national bodies. In 2000, 36 laboratory accreditation bodies, (ILAC full members) signed a Mutual Recognition Arrangement (MRA or Arrangement) to promote the acceptance of accredited technical test and calibration data worldwide. The signatories had been evaluated by their peers (against the acceptance criteria of the then relevant ISO/IEC requirements) and demonstrated that they met ILAC criteria for competence. The current requirements for laboratories are in ISO/IEC 17025:2005, “General requirements for the competence of testing and calibration laboratories”.

Periodic reevaluations of ILAC signatories are conducted to maintain ILAC recognition. ILAC MRA documentation, including requirements for evaluation of accrediting bodies, is publically available on the ILAC website.

The key to the Arrangement is the developing global network of accredited laboratories and inspection bodies that are assessed and recognized as being competent by ILAC Arrangement signatory accreditation bodies (ABs). The signatories have, in turn, been evaluated by their peers (against the requirements of ISO/IEC-17011:2004) and shown to meet ILAC's criteria for competence.

ILAC has several membership levels as described below:

Full Members – Full members are also known as ILAC MRA signatories. Each accreditation body that is a signatory to the MRA must maintain conformance with ISO/IEC-17011:2004 and other ILAC guidance and requirements, and ensure that all its accredited labs comply with the relevant international standard (i.e., ISO/IEC-17025:2005 for calibration and testing laboratories). The signatories have also been peer-reviewed and shown to meet ILAC's criteria for competence. This guidance is only applicable for services provided by laboratories accredited by ILAC signatories (Full Members).

Associates – Accreditation bodies that are not signatories to the ILAC MRA, but which can provide evidence that they are operational and committed to comply with the requirements in relevant standards (e.g., ISO/IEC and ILAC) and obligations of the ILAC MRA, and are recognized in their economy as offering an accreditation service.

Affiliates – Accreditation bodies that are currently operating, being developed or intend to be developed, and declare their intention to operate their accreditation programs in compliance with the requirements in relevant standards (e.g., ISO/IEC and ILAC).

Stakeholders – Representative international, national and regional organizations having an interest in the work of ILAC, including associations of laboratories, regulatory authorities and trade organizations. NEI is a stakeholder member on behalf of the U.S. nuclear industry.

ILAC accomplishes its mission through the use of committees. The current listing of committees and their responsibilities are found on the ILAC website and are summarized as follows:

- **General Assembly** - is the primary body of ILAC and ensures that specific tasks are pursued in accordance with the objectives of ILAC. All members of ILAC are

eligible to nominate one representative (delegate) to the General Assembly. The ILAC Chair is responsible for chairing meetings of the General Assembly.

- **Executive Committee** - Responsible for the day-to-day management of ILAC and its activities. The members of this committee consist of the Chair and Vice Chair of ILAC, the Chairs of those committees having strategic responsibilities for ILAC's development, a representative of participating Regional Cooperation bodies, a representative of unaffiliated economies and other participants as determined by the General Assembly.
- **Arrangement Council** - is the decision making body for determining signatory and recognition status under the ILAC Arrangement. The members of the Arrangement Council are delegates nominated by the Full and Associate members.
- **Arrangement Committee** - Responsible for harmonized implementation and continual improvement of the ILAC Arrangement. Deals with the approach of accreditation bodies to the assessment and accreditation of laboratories, the establishment of agreements between accreditation bodies and related policy areas.
- **Accreditation Committee** - Responsible for harmonization and improvement of accreditation practice at the international level. It is involved in the investigation of technical issues related to accreditation, and the development of technical documentation related to ILAC's work.
- **Laboratory Committee** - Provides a means of interaction and exchange of ideas between ILAC and the laboratory community.
- **Marketing and Communications Committee** - Responsible for internal and external marketing and communication issues. It is involved with the promotion of ILAC's objectives, and the publication of ILAC documents, newsletters and other information.
- **Arrangement Management Committee** - Responsible for the day-to-day management activities of the ILAC Arrangement on behalf of the Arrangement Council and provides advice on its further development and operation.
- **Joint Development Support Committee** - Responsible for representing the interests of developing countries and operates in conjunction with the International Accreditation Forum (IAF). This committee provides a forum for

developing countries to present their needs and to work with ILAC and IAF on practical ways of addressing these needs.

- **Inspection Committee** - Responsible for the harmonization and improvement of accreditation practices for inspection activities at the international level. This Committee replaces the ILAC/IAF Joint Inspection Group (JIG). Members of ILAC and IAF with an interest in inspection activities participate in this Committee.
- **Financial Audit Committee** - Responsible for oversight of ILAC's financial accounting and reporting systems. Reviews and audits the finances of ILAC and provides advice on financial matters to the ILAC Executive Committee and General Assembly.
- **Joint Meetings of the ILAC Executive and the IAF Executive** - Responsible for the stewardship of joint activities between ILAC and the International Accreditation Forum (IAF).

2.2 DESCRIPTION OF THE REGIONAL ORGANIZATIONS

In addition to the global ILAC organization, the accreditation bodies also belong to Regional Cooperation Bodies. Currently the three regional cooperation bodies, whose Arrangements have been recognized by ILAC, are Asia Pacific Laboratory Accreditation Cooperation (APLAC), European Cooperation for Accreditation (EA) and Inter American Accreditation Cooperation (IAAC).

There is close cooperation between ILAC and the regional cooperation bodies, and this cooperation is formalized in the ILAC MRA Policy Statement. Regional cooperation bodies evaluate and re-evaluate their member accreditation bodies. ILAC in turn recognizes the evaluation and re-evaluation of its member accreditation bodies carried out by the regional cooperation bodies. In addition, ILAC performs peer-evaluations of the regional cooperation bodies to establish and recognize their competence in management of the Arrangement.

2.3 DESCRIPTION OF ACCREDITATION BODIES

Accreditation Bodies (ABs) are organizations that assess and accredit Conformity Assessment Bodies (CABs). ABs assess and assure the competence of the CABs to perform conformity assessment services, including testing and calibration. ABs that are signatories to the ILAC MRA undergo peer evaluation to affirm their competence.

2.4 DESCRIPTION OF CONFORMITY ASSESSMENT BODIES

Conformity assessment bodies are organizations, including laboratories, that provide conformity assessment services for calibration and testing documented under specific, individual Scopes of Accreditation. CABs assess products, services and suppliers to assure conformity to specification and/or requirements under their Scopes of Accreditation. In this guidance document, the term laboratory is used to mean CAB.

3 USE OF LABORATORY SERVICES ACCREDITED BY ILAC MRA SIGNATORIES AS PART OF COMMERCIAL GRADE DEDICATION ACTIVITIES

The ILAC process is essentially equivalent to NRC accepted practices for commercial grade surveys that comply with the applicable requirements of 10 CFR Part 50, Appendix B and 10 CFR Part 21, and associated guidance. Therefore, accreditation by ILAC signatories can be used in lieu of a Commercial Grade Survey as part of the commercial grade dedication process. This section describes how Purchasers of internationally accredited calibration and testing laboratory services should use the ILAC process as part of their Commercial Grade Dedication activities. It is noted that this guidance should be used in conjunction with EPRI guidance on commercial grade dedication (e.g., EPRI NP-5652).

3.1 OVERVIEW OF COMMERCIAL GRADE DEDICATION OF CALIBRATION AND TESTING LABORATORY SERVICES

The process of commercial grade dedication is widely utilized by Purchasers to accept commercial grade calibration and testing services from commercial laboratories based on dedication of these services in accordance with the requirements of 10 CFR Part 50, Appendix B and 10 CFR Part 21, and associated guidance.

The commercial grade dedication process described in EPRI guidance includes the following activities:

- 1) Perform a technical evaluation to identify and document the safety function of the service;
- 2) Identify and document the credible failure modes for the service;

- 3) Identify and document the critical characteristics,
- 4) Identify and document the acceptance method (s), and
- 5) Implement the acceptance method (s).

The following are the four acceptable methods of verifying the adequacy of the critical characteristics for a commercial grade item and/or service (Activities 4 and 5):

Method 1 – Special Test/Inspection

Method 2 – Commercial Grade Survey²

Method 3 – Source Verification

Method 4 – Acceptance Item/Supplier Performance Record History

Use of laboratory accreditation by ILAC signatories will be in lieu of commercial grade surveys as an acceptable alternative for Method 2. For Purchasers that use internationally accredited calibration and testing laboratories, activities #1 through #3 of the commercial grade dedication process remain mostly the same. However, activities #4 and #5 for acceptance, would credit the accreditation by an ILAC signatory in lieu of a Commercial Grade Survey (Method 2) as the means to verify the laboratory's control over the critical characteristics. Dedication of the contracted service is not complete until documentation has been reviewed to assure compliance will all purchase order requirements. The guidance in subsequent subsections describes how these activities are performed.

3.2 TECHNICAL EVALUATION

As part of the Commercial Grade Dedication process, the Purchaser will perform and document a technical evaluation for the calibration and testing services being procured. This technical evaluation includes identification of the safety function to be performed, the credible failure modes, the critical characteristics, and requirements for the purchase of calibration and/or testing services that need to be included in the purchase documents. The Purchaser may perform a single technical evaluation for calibration and/or testing services and apply it to future procurements provided the technical evaluation covers the scope of services being procured.

² It is noted that Method 2 – Commercial Grade Survey – is widely accepted as the most practical acceptance method for calibration and testing laboratories that have well documented programs for controlling the critical characteristics identified by Purchasers.

Section 6.1 identifies the critical controls/characteristics for calibration and testing services and provides a technical evaluation of the ability for the ILAC process to control the critical characteristics. The technical evaluation concludes that the critical controls/characteristics are included in the ISO/IEC-17025:2005 standard requirements and are verified to be properly controlled by a laboratory as part of the ISO/IEC-17025:2005 accreditation process. When procuring calibration and testing services, the Purchaser needs to verify that the laboratory's scope of accreditation covers the scope of services being procured. For calibration services, the published scope of accreditation for the calibration laboratory must cover the needed measurement parameters, ranges, and uncertainties. For testing services, the published scope of accreditation for the test laboratory must cover the needed testing services including test methodology and tolerances/uncertainty.

There are two situations in which commercially procured laboratory services may be used as part of the commercial grade dedication process. The first situation is when the laboratory service is procured as a stand-alone service that is being dedicated. This is typical for calibration services, but may also occur for some test services. The second situation is when the laboratory service is procured as part of a larger dedication package (e.g., where a commercial test is used as one part of the dedication of a commercial item). For example, the Charpy V-notch test when the material's fracture toughness or impact resistance is a critical characteristic for dedicating the material. The guidance described here is for the dedication of the laboratory service itself, and as such the laboratory's ISO/IEC-17025:2005 scope of accreditation includes the critical characteristics for the laboratory service. However, for the dedication of an item that relies on a dedicated laboratory service, the dedicating entity also needs to verify the scope of accreditation for the procured laboratory service addresses the critical characteristics of the item being dedicated. In this case, it is not sufficient to only verify that the laboratory's scope of accreditation is for the desired test.

For both situations discussed above, the Purchaser, as part of the technical evaluation, will verify that the laboratory is accredited to ISO/IEC-17025:2005, "General requirements for the competence of testing and calibration laboratories," by an Accreditation Body that is a signatory to the ILAC Mutual Recognition Arrangement, and the services being procured are included in the scope of the laboratory's accreditation.

3.3 ACCEPTANCE METHOD

Purchasers should document in their dedication plan the use of commercial calibration and test laboratories accredited to ISO/IEC 17025:2005 by ILAC signatories in lieu of performing a commercial grade survey. To assure the critical characteristics are met, the Purchaser should document that the acceptance method needs to include verification that the laboratory is accredited to ISO/IEC-17025:2005, "General requirements for the

competence of testing and calibration laboratories,” by an Accreditation Body that is a signatory to the ILAC Mutual Recognition Arrangement, and that the procured services are within the laboratory’s scope of accreditation.

A documented review of calibration and testing records will be completed in order 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.

4 PURCHASER’S QUALITY ASSURANCE PROGRAM

Purchasers that rely on the accreditation by ILAC signatories in lieu of commercial grade surveys are required by 10 CFR Part 50, Appendix B to document this alternative method in their QA program. The following sections discuss criteria that need to be addressed in the QA Program in order to credit the ILAC process. The Purchaser will qualify the service provider as described in Section 3 of this guidance, and will impose any additional technical or quality program requirements, as necessary, to meet regulatory requirements and Purchaser QA program commitments. A Template for describing the use of the ILAC process in lieu of a commercial grade survey 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.

4.1 ORGANIZATION

The Purchaser retains overall responsibility for assuring that purchased calibration and/or testing services meet applicable technical and regulatory requirements and that reasonable assurance of quality is provided.

4.2 PROCUREMENT DOCUMENT CONTROL

When purchasing commercial grade calibration or testing services from laboratories accredited by an ILAC signatory, the procurement documents will impose additional technical and quality requirements, as necessary, to satisfy the Purchaser’s QA Program and technical requirements. These include as a minimum:

- 1) The service must be provided in accordance with their accredited ISO/IEC-17025:2005 program and scope of accreditation.
- 2) 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)*

- 3) The equipment/standards used to perform the calibration must be identified in the certificate of calibration. *(for calibration services only)*
- 4) The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
- 5) 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.

4.3 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

In lieu of a commercial grade survey, Purchasers can take credit for accredited ISO/IEC-17025:2005 programs for commercial grade calibration and testing services suppliers by ILAC Accreditation Bodies provided Purchasers validate at receipt inspection, the service provider's documentation meets and supports their scopes of accreditation for the contracted calibration / test service, as-found calibration data is provided when calibrated items are found to be out-of-tolerance, and that purchase order technical and quality requirements are met.

For commercial grade calibration and testing service providers with programs accredited by ILAC signatories, the reliance on this accreditation process and adherence to ISO/IEC-17025:2005 requirements provides for the integrity of the technical data produced as well as the necessary evidence of compliance for the qualification of calibration or test suppliers under a Commercial Grade Dedication process. 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. The purchasers do not need to directly perform technical verification of data produced nor do they need to perform commercial grade surveys of the accredited laboratory activities.

Purchaser will review the objective evidence for conformance to the procurement documents as part of the dedication process to verify that the technical and quality requirements identified in the purchase documents are met.

4.4 CONTROL OF MEASURING AND TEST EQUIPMENT

ISO/IEC-17025:2005 does not require that the accredited supplier provide as-found calibration data when the item being calibrated is found to be out-of-tolerance. Since this data is needed to support the Purchaser in performing the required evaluations for potentially impacted services, an additional requirement will be imposed via the procurement documents for the accredited laboratory to provide as-found calibration data when the item being calibrated is found to be out-of-tolerance. This will also support the

evaluations necessary to meet the Purchaser's obligations for reporting any defects and non-compliance as required by 10 CFR Part 21.

4.5 CORRECTIVE ACTION

ISO/IEC-17025:2005 does not require the laboratory to notify the AB of any significant condition adverse to quality, and ISO/IEC-17011:2004 does not require the AB to notify the Region or ILAC of any significant conditions adverse to quality. Although ILAC procedures require laboratories to notify the AB of a condition that potentially impacts their scope of accreditation within a given period of time (typically 30 days), the notification is not required to be immediate.

Since this data is needed to support the Purchaser in performing the required evaluations for potentially impacted services, an additional requirement will be imposed via the procurement documents for the accredited laboratory to provide notification of any significant conditions adverse to quality. Based upon the conclusion that the laboratory scope of accreditation encompasses the critical characteristics and because the ILAC process does not use the term "significant condition adverse to quality", an equivalent requirement would be for the laboratory to notify the purchaser of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.

5 US NUCLEAR INDUSTRY OVERSIGHT OF THE ILAC PROCESS

The objective of the continued oversight of the ILAC Process by the U.S. nuclear industry is to confirm that the ILAC process can continue to be used in lieu of commercial grade surveys as part of the Purchaser's commercial grade dedication activities. This oversight will monitor ILAC activities to verify that requirements and procedures used in the ILAC process (e.g., ISO/IEC-17011:2004 and ISO/IEC-17025:2005) continue to be consistent with the NRC accepted practices, and that the ILAC process continues to be implemented in conformance with ILAC standards and procedures. Early identification of potentially adverse changes will also afford the nuclear industry the opportunity to discuss any impact with the NRC and to modify this guidance as necessary.

5.1 ORGANIZATION

NEI has formed an industry team, consisting of licensees (including NUPIC members) and suppliers, to monitor ILAC activities as they relate to industry's use of the ILAC process as part of commercial grade dedication. NEI is a stakeholder member of ILAC as a liaison for the nuclear industry and provides to its licensee and supplier members access to ILAC information and activities in an effective and efficient manner. Membership in

ILAC permits attendance at meetings, receipt of notification of potential changes to ILAC requirements and guidelines (including related international standards), and is important for access to observing peer evaluations and laboratory assessments. The NEI team has a close association and coordinates with the NUPIC membership for monitoring of the ILAC process.

NUPIC has formed a group to support the industry's efforts to monitor the ILAC process. NUPIC plays a central role in the continued oversight activities, and a NUPIC member leads or participates in many of the oversight activities described below.

5.2 VERIFICATION THAT THE ILAC PROCESS CONTINUES TO BE CONSISTENT WITH NRC ACCEPTED PRACTICES

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-17025:2005, 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. Because ISO/IEC-17025:2005 is the main standard that assures consistency with NRC accepted practices and because it is not often revised, it is expected that changes that would make the ILAC process no longer be consistent with NRC accepted practices would be few and infrequent, if at all. A summary of the monitoring of ILAC requirements and procedures will be documented on an annual basis.

As a Stakeholder Member, NEI has the ability to participate in the process to maintain ILAC requirements and procedures. If changes are proposed, NEI will be notified by ILAC of the potential change. The NEI team, including members from NUPIC, will evaluate whether the potential changes could materially affect the manner in which the ILAC process is used by the nuclear industry. If changes would result in the ILAC process no longer being consistent with NRC accepted practices, then the nuclear industry has the ability to provide feedback in writing and at ILAC Arrangement Committee meetings that oversee ILAC policies. The nuclear industry would also make the NRC aware of any potential adverse changes and industry's actions to mitigate them.

If changes to ILAC requirements and procedures are implemented that result in the ILAC process no longer being consistent with NRC accepted practices, then the nuclear industry and NRC would have substantial advanced notification, and would have time to

implement changes to this guidance or otherwise issue communications to users of the guidance.

5.3 VERIFICATION THAT IMPLEMENTATION OF THE ILAC PROCESS CONTINUES TO BE CONSISTENT WITH NRC ACCEPTED PRACTICES

The assessments and conclusions of the rigor of the implementation of the ILAC process documented herein are based in part on the direct observations of the performance of peer evaluations of ABs. 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 U.S. nuclear industry's observation of these peer evaluations and associated laboratory assessments provide additional confidence in the ILAC processes.

As part of the continued oversight, the nuclear industry (NEI, NUPIC, and other Industry Representatives) will observe Peer Evaluations of an AB and the associated assessments of calibration and testing laboratories to verify that the ILAC process continues to be implemented consistent with ILAC requirements and procedures. U.S. nuclear industry observations of peer evaluations will be performed on a frequency of once every three (3) years. This frequency is consistent with the guidance in EPRI NP-5652 to establish the frequency for commercial grade surveys. These observations will be led by a knowledgeable NUPIC member with support from other NEI team members. The NRC may request to participate on these observations.

5.4 OPTIONAL ACTIVITIES

Several additional monitoring activities are available to the nuclear industry as ILAC stakeholder members, but are not necessary to achieve the objectives of the industry's continued oversight. These activities may provide additional benefits to the efficiency of the industry's monitoring efforts and will be considered as optional activities.

Through NEI's stakeholder membership in ILAC, the nuclear industry is permitted to attend general ILAC meetings. These meetings may provide additional information on the ILAC process and interaction with other ILAC members, but are otherwise not essential to the industry's continued oversight. Similarly, the ability to attend peer evaluator training offered by one of the Regions may provide additional insight into the ILAC process, but is not essential to the industry's continued oversight.

6 NUCLEAR INDUSTRY REVIEW OF THE ILAC PROCESS

The ILAC process was assessed by the nuclear industry to determine its rigor and whether it could satisfy requirements for commercial grade dedication of calibration and

laboratory services. This assessment was based upon an evaluation of the ILAC procedures, training, MRA meetings, and observations of peer evaluations and laboratory assessments. The ILAC process was compared to NRC requirements, NRC endorsed guidance and NUPIC practices, which conform these requirements and guidance for performing commercial grade surveys to determine if the ILAC process is equivalent.

It was concluded that the ILAC process is equivalent to NUPIC practices when the following three items are addressed by the inclusion of requirements in the procurement documents:

1. ISO/IEC-17025:2005 does not require the laboratory to include as-found calibration data in the Certificate of Calibration when calibrated items are found to be out of tolerance.
2. ISO/IEC-17025:2005 does not require the laboratory to identify in the certificate of calibration, the standards used to perform the calibration.
3. ISO/IEC-17025:2005 does not require the laboratory to notify the AB of any significant condition adverse to quality, and ISO/IEC-17011:2004 does not require the AB to notify the Region or ILAC of any significant conditions adverse to quality. Based upon the conclusion that the laboratory scope of accreditation encompasses the critical characteristics and because the ILAC process does not use the term “significant condition adverse to quality”, an equivalent requirement would be for the laboratory to notify the purchaser of any condition that adversely impacts the laboratory’s ability to maintain the scope of accreditation.

Two additional differences with NUPIC practices were identified, but determined to be acceptable and thus do not need to be addressed through the inclusion of requirements in the procurement documents.

1. ISO/IEC-17025:2005 Section 4.4 requires the laboratory to establish and maintain the capability and resources to meet Purchaser’s procurement requirements. However, it was noted during an observation of a peer evaluation, that the AB assessment of the laboratory only verified that the laboratory could meet procurement document requirements related to the scope of accreditation, and did not evaluate the capability to meet requirements not related to the scope of accreditation. This is acceptable because the scope of accreditation encompasses the critical characteristics, and thus there is reasonable assurance that the requirements of 10 CFR Part 21 and 10 CFR Part 50, Appendix B will be met for the dedicated service. Furthermore, this difference cannot be addressed through a requirement in the procurement documents, because the Purchaser does not have the capability to independently verify it. However, this difference was discussed with ILAC representatives, who indicated that they would consider if training could be enhanced to clarify that assessments should include verification of the

ability to comply with all special contract requirements, and are not limited to only those specifically related to the scope of accreditation.

2. ISO/IEC-17025:2005 includes quality controls that address suspect counterfeit and fraudulent items. In particular, Section 4.5 establishes requirements for subcontracting tests and calibrations, including verification that the subcontractor is accredited and notification to the Purchaser when subcontracting these services. Section 4.6 establishes requirements for purchasing services and supplies, including inspections to verify that they meet the requirements and the evaluation of suppliers. However, ISO/IEC-17025:2005 does not include a specific requirement for laboratory controls to identify suspect counterfeit and fraudulent items. NUPIC checklists include a question that would identify controls the supplier has in place to prevent ingress of suspect counterfeit or fraudulent items. The risk of counterfeit and fraudulent items is low in an environment that procures and uses traceable standards to perform calibration. However, counterfeit or fraudulent items could enter the supply chain in certain cases, such as when the laboratory subcontracts calibration services and the subcontractor misrepresents their accreditation. The topic of counterfeit and fraudulent items was discussed with ILAC representatives, who indicated that the topic would be discussed further by ILAC membership to determine if any enhancements to the ILAC process are warranted. EPRI updated guidance on counterfeit and fraudulent items, “Plant Support Engineering: Counterfeit, Fraudulent and Substandard Items,” EPRI-1019163 Revision 1 in 2014. Use of the EPRI guidance on counterfeit and fraudulent items is voluntary; however, it does provide practical measures to further enhance protections against counterfeit and fraudulent items and includes a standard procurement clause that could be used in the procurement of calibration and testing services.

6.1 TECHNICAL EVALUATION OF ILAC REQUIREMENTS AND PROCEDURES

A technical evaluation of the ILAC requirements and procedures was performed in order to assess whether the ILAC process is an acceptable alternative to Commercial Grade Surveys for dedication. ISO/IEC-17025:2005, “General requirements for the competence of testing and calibration laboratories,” and ISO-17011:2004, “Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies,” were reviewed and compared with NUPIC checklists for supplier surveys. Based upon this evaluation, it is concluded that 1) the ILAC process meets the criteria for a commercial grade survey, and 2) the ISO/IEC-17025:2005 standard is equivalent to the critical characteristics identified in the NUPIC Commercial Grade Item Survey Checklist and Commercial Grade Calibration Services Checklist.

Acceptable Alternative Method

For a Commercial Grade Survey, EPRI guidance and NRC Commercial Grade Dedication Inspection Procedure 43004 indicate that the commercial grade surveys should be used when:

1. The purchaser desires to verify one or more of the critical characteristics based on the merits of a laboratory's commercial quality controls.
2. The laboratory has a documented and effectively implemented program and/or procedures to control the critical characteristics of the services being procured.
3. The survey should be conducted by an individual(s) that is also trained in auditing and knowledgeable in the operation of the item(s) and the associated critical characteristics to be verified.
4. The verification is accomplished by reviewing the vendor's program/procedures controlling these characteristics and observing the actual implementation of these controls in the manufacture of items identical or similar to the items being purchased.

All of the above criteria are met for laboratories accredited to ISO/IEC-17025:2005 by AB's that are signatories to the ILAC MRA. Therefore, the ILAC process is an acceptable alternative to performing commercial grade surveys.

Critical Characteristics

The technical evaluation includes identification of critical characteristics as part of the dedication process. Below are lists of the typical critical characteristics for calibration services and laboratory testing services.

Critical Characteristics for Calibration Services

The critical controls/characteristics for calibration services are identified in the NUPIC Commercial Grade Calibration Survey Checklist and consist of the following attributes. These characteristics apply to all calibration services regardless of the type of Measuring & Test Equipment (M&TE):

- Traceability of calibration and calibration standards to nationally recognized standards (e.g. NIST), equivalent international standards or other acceptable measurement standards (intrinsic)
- Calibrations performed in accordance with written procedures/instructions
- Documented training/qualification of personnel
- Environmental Conditions, i.e., temperature, humidity, vibration, etc.
- Adequacy, accuracy, stability, tolerances (uncertainty) and range of measurement standards
- Intervals of calibration for standards

- Software control, i.e., adequate review/approval, verification, validation, error notification, etc.
- Calibration status
- Out of tolerance & corrective action
- Subcontractor calibration controls
- Calibration certification documentation

Critical Characteristics for Laboratory Testing Services:

While NUPIC does not have a standard survey checklist for laboratory testing services, licensees have widely determined the following critical characteristics to apply to all testing services regardless of the type of testing being performed:

- Identification/traceability of the item during testing/and processing is maintained.
- Testing for the required characteristics/parameters is performed in accordance with written industry recognized standards or other validated and approved test methods.
- Actual testing is performed in accordance with written and approved procedures.
- Testing is performed by trained and qualified personnel.
- M&TE including chemical standards are calibrated as applicable and are traceable to national, international, or intrinsic properties/natural law.
- Traceability of the test results to the item being tested is maintained.
- Certification includes test results, identification of the item, test method used, results, and signature of responsible laboratory authority.

Review of the ISO/IEC-17025:2005 standard and observations of the accreditation process by NEI/NUPIC has determined that each of the above critical characteristics are included in the ISO/IEC-17025:2005 standard and are verified to be properly controlled by a laboratory as a part of the ISO/IEC-17025:2005 accreditation process.

Supplier's Quality Program

In order for laboratories to be accredited to ISO/IEC-17025:2005, they must have an adequately documented quality program. The laboratory also needs to comply with any additional quality requirements specified in the procurement documents. The quality program of an accredited supplier is adequate for the Purchaser's commercial grade dedication activities, which must be invoked in a procurement document.

6.2 OBSERVATION OF TRAINING

An observation of the ILAC/APLAC Evaluator Training Course was performed in order to gain a comprehensive understanding of the capabilities and experience of assessment personnel, and to evaluate the rigor of the training. Based upon these observations, it was

concluded that ILAC/Regional training for peer evaluators is essentially equivalent to NUPIC auditor training.

The training course consists of ten (10) modules presented over a three (3) day period and it was conducted by senior representatives of Accreditation Bodies. The class that was observed consisted of 17 individuals from 12 different countries. Students are recommended by AB leadership and must pass a screening process (at the regional level), which may include demonstrating written and oral capability in the English language.

The training session included the establishment of scenarios for each of the teams with questions and deliverables assigned for each activity. Specific activities assessed through this process included Team Selection, Agenda Development, and Activity Scheduling. Each team was provided a unique scenario that was challenging and realistic. Each training instructor, as well as several students, shared their experience in performing these evaluations. It became apparent to the students that the resources allocated to the assessment are a key decision and deployment strategies are not identical. Each group performed well and used several different acceptable strategies. For example, one group used a “vertical slice” approach, having each individual look at each element in their area; while other groups used an approach which parceled out individual sections.

A detailed walk through of the Standard Checklist was performed. Each question was discussed and expectations as to what was required were provided for each question. The training instructors shared personal experience in each area addressed. Active participation was noted with very good questions being asked at appropriate times.

It was reinforced that recognition decisions are made by competent persons based on the results of the Peer Evaluations; therefore, it was emphasized that enough accurate information must be provided to allow for appropriate decisions.

Training includes a section that mirrors many of the requirements of 10 CFR Part 50, Appendix B. The presentation to the training class was very effective and represented the material in the handouts.

Training emphasized the importance of maintaining independence. Each team was provided with a unique scenario with different challenges and issues. Teams worked for one hour to evaluate the organizational structures and legal entities. The teams were provided immediate feedback on their presentations. Similar to previous courses, the learning was achieved through the student engagement with appropriate references with training instructors providing key insights which contributed to the learning experience. Organizational learning was accomplished through review of the individual scenarios with the entire class. The effectiveness of this training, as evidenced by interviews with students and facilitators, was determined to be very good.

Additional training sessions focused on the writing of findings and other issues. The class was tasked with documenting appropriate findings from a set of information provided. The instructors placed a significant amount of focus on improving the strength and consistency in the student's ability to write findings and document issues. This included developing appropriate problem statements based upon objective evidence. It was judged that the capabilities of the students exiting the class to write findings were on par with the capabilities of auditors at the completion of NUPIC training.

This training is favorably compared to NUPIC Lead Auditor training in as much as most Lead Auditor classes have an element of role playing with various scenarios played out and discussions are held critiquing the team. In addition, the observed training contained elements of NUPIC's annual auditor training which is held each February where the auditors are brought up to date on changing regulations and changes to the checklist.

6.3 OBSERVATION OF A MUTUAL RECOGNITION ARRANGEMENT MEETING

An observation of an APLAC MRA meeting was performed in order to evaluate the rigor of the recognition decision making process. The purpose of the MRA council is to review and ensure standards for accreditation are established and met. The MRA meeting was observed to be a rigorous process and was well controlled and implemented. Based upon these observations, it was concluded that the ILAC/Regional decision making process is essentially equivalent to NUPIC practices.

The APLAC MRA meeting lasted three (3) days, during which decisions on initial accreditations and renewals were made. It was observed that the group was very effective and demonstrated excellent technical skills and management capabilities. The technical capabilities were evident; however, as with most technical groups, the challenge is in regard to auditing and "understanding" the standard and not "rationalizing" the standard. The MRA has achieved a good balance and works effectively through these challenges.

It was noted that many challenges that the MRA is addressing have been addressed by NUPIC; examples include team formation and the use of technical specialists during evaluation (audit) and surveillances, team feedback, scorecards, and sharing of Operating Experience. Differences between regions poses a challenge, while at the same time creating a dynamic that encourages continuous improvement.

During the meeting, a decision on the initial assessment of a national accreditation body was made. The MRA council considered the report from the peer evaluation team for the initial assessment, which it reviewed prior to the meeting and was also presented by the Team Leader at the meeting. The team recommended approval of the accreditation body on the basis of their review of the responses to the issues identified in the peer evaluation.

The evaluation included several locations, key meetings and other activities, and was conducted after the accreditation body addressed all of the findings from the earlier performed Pre-Peer Evaluation. The questioning and process of the MRA council deliberation was rigorous. Finally, the accreditation body was requested to leave, and the MRA council voted to make their decision. The accreditation body was approved and accepted as an APLAC/ILAC MRA signatory.

The MRA council also reviewed an accreditation body for a four (4) year re-evaluation that was requesting to expand their approved scope of services. In this case, the peer evaluation concluded that the accreditation body met all ILAC requirements, but also identified two non-conformities and three deficiencies. The accreditation body addressed all non-conformities and deficiencies to the satisfaction of the peer evaluation team, and the team recommended approval. The questioning and process of the MRA council deliberation followed the rigor previously described. It was noted that the IAAC process is different from APLAC as they send reports out prior to the meeting and questions are sent to the team lead as a lead up to the meeting. In addition, all issues are reviewed and discussed during the decision-making meeting. This does not appear to be a significant difference.

Several other peer evaluations were reviewed by the MRA council with the same level of rigor as previously described.

The MRA council also reviewed the list of candidates for Lead Peer Evaluator and approved four new Team Leaders. The Evaluator Performance Working Group reviews candidates and makes recommendations to the full MRA. This is not an automatic process and there are many controls in place to assure the high quality of evaluators.

6.4 OBSERVATION OF PEER EVALUATIONS AND LABORATORY ASSESSMENTS

Observations of peer evaluation of ABs and assessments of laboratories were performed in order to verify that the ILAC process is implemented according to relevant requirements and procedures and to verify the implementation is an acceptable alternative to a Commercial Grade Survey for dedication. Based upon these observations, it is concluded that the implementation of the ILAC process is essentially equivalent to NUPIC practices for supplier surveys.

Observation of Peer Evaluation of the Japan Accreditation Body

A NUPIC/NEI team, led by a NUPIC member, observed the Asia Pacific Laboratory Accreditation Cooperation (APLAC) peer evaluation of the Japan Accreditation Board (JAB) the week of November 11, 2013. The team observed the APLAC entrance

meeting, the evaluation of JAB, the evaluation of JAB assessment of calibration and testing laboratories, and the exit meeting.

Observation of Peer Evaluation of the American Association for Laboratory Accreditation

A NUPIC/NEI team, led by a NUPIC member, observed the joint APLAC/IAAC peer evaluation of the American Association for Laboratory Accreditation (A2LA) the week of March 3, 2014. The team observed the APLAC/IAAC entrance meeting, the evaluation of A2LA, the evaluation of A2LA assessment of a testing laboratory, and the exit meeting.

Conclusions

The activities observed were found to be essentially equivalent to NUPIC practices for acceptance Method 2 – Commercial Grade Survey – for dedication of commercial grade calibration and laboratory services. The following are details from the observation that support this conclusion:

- The observation team verified that the overall operations of the Peer Evaluation under the ILAC process is robust, comprehensive, and in compliance with ISO/IEC-17011:2004.
- The Peer Evaluators under the ILAC process were found to be true peers in that they currently lead or direct other Accreditation Bodies.
- The Peer Evaluation process was found to be performance-based and included real time observations of testing and calibration services. All evaluations observed were of high standard.
- Lead assessor and technical assessors/experts were found to be very knowledgeable and possessed extensive experience in the areas assessed and they were very familiar with the assessment process. The competence of the assessors and evaluators is a key strength of the ILAC process.
- The overall operation of ABs is in accordance with the requirements of ISO/IEC-17011:2004.
- Scope of accreditation specified by ABs and the laboratories was verified to accurately reflect the capabilities of the laboratory.
- AB staff members are skilled and technically qualified for the functions they perform. They have well established accreditation processes which are applied consistently to the accreditation of their testing and calibration laboratories.
- Laboratories accredited by ABs have been assessed against and found to comply with the requirements of ISO/IEC 17025:2005.

- The accreditation assessments were found to be technically equivalent to or better than a NUPIC style commercial grade survey. Both the management system and technical operation of the laboratories were effectively assessed.
- The Accreditation Assessment process was found to be performance-based and included real time observations of testing and calibration services. All assessments observed were of a high standard.

APPENDIX A – QUALITY ASSURANCE PROGRAM TEMPLATE

[X.1.a] Dedication of Commercial Grade Items

Commercial Grade items (items not originally designed or manufactured as a basic component) are subject to a Commercial Grade Dedication process as defined and authorized by Engineering in accordance with procedures that meet the requirements of the U.S. NRC, before such items are approved for safety-related applications.

Commercial Grade Dedication also applies to a commercial grade service that is associated with basic component hardware, design certification, design approval, or information in support of an early site permit application under 10 CFR Part 52, whether these services are performed by the component supplier or others (e.g., safety-related design, analysis, inspection, testing, or fabrication that is associated with a basic component).

Procedures are established to describe the responsibilities for Engineering to perform a technical evaluation, select applicable critical characteristics, and determine an appropriate dedication method for acceptance. Procedures are also established to enhance the detection of counterfeit and fraudulent items and to minimize the likelihood of the introduction of such items in safety-related applications.

[Purchaser] may utilize commercial grade items or services in its supply of basic components in a manner consistent with the guidance in [Generic Letter (GL) 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products.” GL 89-02 documents the NRC’s conditional endorsement of EPRI NP-5652, “Guideline for the Utilization of Commercial grade Items in Nuclear Safety Related Applications” (NCIG-07).”]

[Purchaser] utilizes a commercial grade dedication process consistent with Generic Letter 89-02 and 10CFR21, for the supply of basic components. When a commercial grade item is modified, inspected, and/or tested to demonstrate compliance to requirements more restrictive than the manufacturer’s original specifications such item is uniquely identified as different from the commercial grade (off-the-shelf) item and traceable to documents that record the difference.

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 need not be performed provided each of the following conditions are met:

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. 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.

Attachment A
NRC FINAL SAFETY EVALUATION REPORT

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.

M. Nichol

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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

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Safety Evaluation Report

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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

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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

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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 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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(Revised 10/02/2014)

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Attachment B
NRC RAIS AND NEI RESPONSES

July 22, 2014

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

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

Mr. Marcus R. Nichol, Senior Project Manager
Quality Issues and Licensing Actions
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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

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Sincerely,

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Project No. 0689

Enclosure:
Request for Additional Information 1-7564

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ADAMS Accession Number: ML14197A171 via e-mail* NRO-002

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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

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(Revised 07/25/2013)

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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

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.

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.

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.

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 LABORATORY 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 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 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."

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.