NEI 14-05, 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

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 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) to 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.

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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 or in-process surveillances 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 guidance[1].

The Nuclear Procurement Issues Committee (NUPIC) is an association of all 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 and10 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 is a summary of the conditions that are necessary in order for a Purchaser to accept accreditation of international calibration and test laboratory services by ILAC signatories in lieu of performing a commercial grade survey as part of commercial grade dedication:

1) The Purchaser performs the following as part of the commercial grade dedication:
    1. Verifies 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.
        i. For calibration services, the published scope of accreditation for the calibration laboratory must cover the needed measurement parameters, ranges, and uncertainties.

ii. For testing services, the published scope of accreditation for the test laboratory must cover the needed testing services including test methodology and tolerances/uncertainty.

2. Identifies any additional technical or quality requirements for the scope of supply that need to be included in the Purchaser's procurement documents.
3. Verifies that the laboratory has certified that it has performed the calibration or test service in accordance with their ISO/IEC-17025:2005 program and scope of accreditation, and has complied with all other special requirements specified in the Purchaser's procurement documents.

2) The Purchaser's procurement documents include additional requirements for the laboratory.
   1. The laboratory must provide the service in accordance with their accredited ISO/IEC-17025:2005 program and scope of accreditation.
   2. The laboratory must include as-found calibration data in the Certificate of Calibration when calibrated items are found to be out of tolerance. *(for calibration services only)*
   3. The laboratory must identify in the certificate of calibration, the standards used to perform the calibration. *(for calibration services only)*
   4. The laboratory must notify the customer of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
   5. Any additional pertinent technical and quality requirements related to the procured scope of supply.
3) The method to use accreditation by an ILAC signatory in lieu of a Commercial Grade Survey (alternative method) is documented in the Purchaser's QA program.

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) PROCESS

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 and10 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 and10 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 Survey[2]
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. 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.

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

[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.

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.

3.2.1 Identification of Additional Requirements

Any additional technical or quality requirements for the supplier of commercial grade items or services need to be identified. As part of the generic technical evaluation performed in Section 6, three (3) differences between the ILAC process and NRC accepted practices should be addressed by including requirements in the procurement documents (Section 4.2).

The Purchaser should also review the procured scope of services to identify if there are any additional pertinent technical and quality requirements that need to be invoked on the laboratory through the procurement documents. These may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

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.

To implement the acceptance method, the Purchaser needs to verify 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 need 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 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.

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 laboratory must provide the service in accordance with their accredited ISO/IEC-17025:2005 program and scope of accreditation.
2) The laboratory must include as-found calibration data in the Certificate of Calibration when calibrated items are found to be out of tolerance. *(for calibration services only)*
3) The laboratory must identify in the certificate of calibration, the standards used to perform the calibration. *(for calibration services only)*
4) The laboratory must notify the customer of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
5) Any additional pertinent technical and quality requirements related to the procured scope of supply.

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 direct surveillance and/or 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.

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 similar to the frequency for external (supplier) audits discussed in Regulatory Guide 1.28. These observations will be led by a knowledgeable NUPIC member with support from other NEI team members.

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 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.

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 all candidates and makes recommendations to the full MRA. This is not an automatic process and there are many controls in place to ensure 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 all 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 and source verifications need not be performed provided each of the following conditions are met:

1. The purchase documents impose additional technical and administrative requirements, as necessary, to comply with the [Purchaser's] QA program and technical requirements. At a minimum, the purchase document shall require that the calibration or test certificate/report include identification of the laboratory equipment/standard(s) used.
2. The purchase documents require:

a. Reporting as-found calibration data when calibrated items are found to be out-of-tolerance. *(for calibration services only)*
b. Identifying in the certificate of calibration, the standards used to perform the calibration. *(for calibration services only)*
c. Notifying the customer of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.

3. 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.