U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Workshop on Vendor Oversight

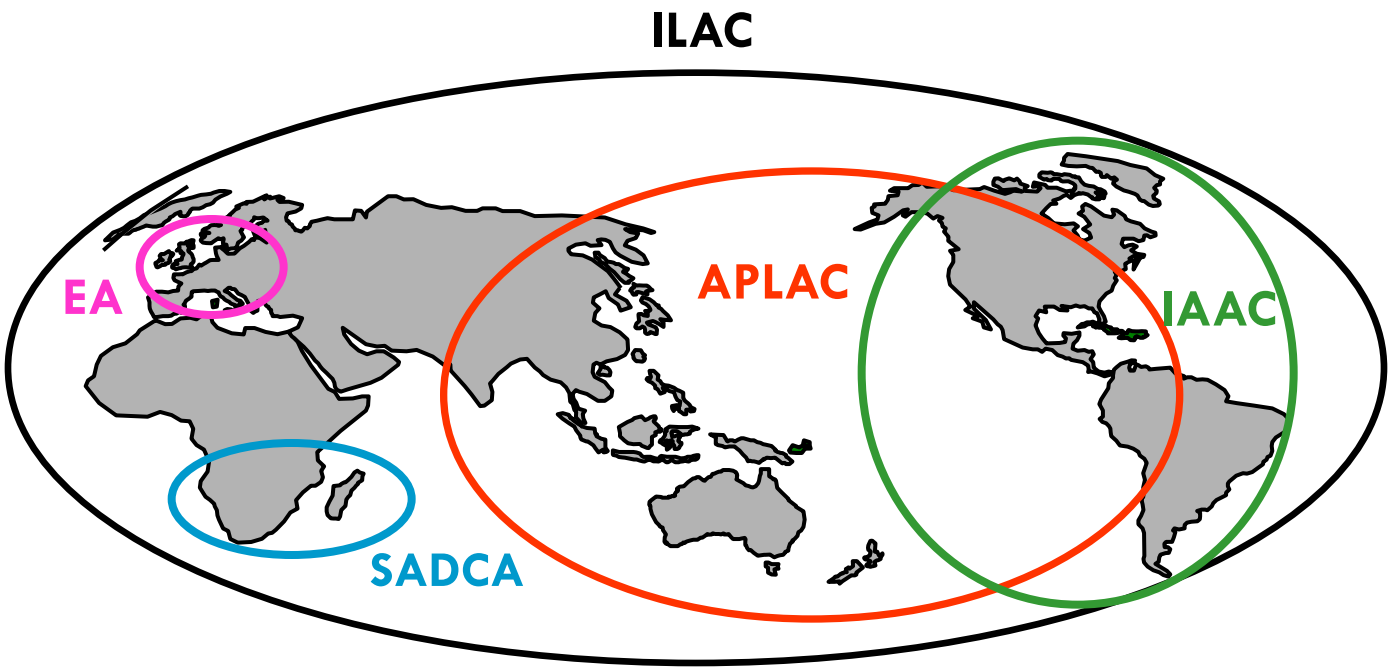
NRC's Expectations when using the International Laboratory Accreditation Cooperation (ILAC) Process

Yamir Diaz-Castillo
Mechanical Vendor Inspection Branch, Office of New Reactors

Agenda

- Background
- NRC's Review & Acceptance
- NRC's Expectations
- Current Status of NRC's Recognition
- Questions

Background



EA	European Cooperation for Accreditation
APLAC	Asia Pacific Laboratory Accreditation Cooperation
IAAC	Inter-American Accreditation Cooperation
SADCA	Southern African Development Community Accreditation

Background

- In a letter dated September 5, 2004, Arizona Public Service (APS) requested NRC to provide acceptance of the NVLAP (National Voluntary Laboratory Accreditation Program) accreditation of suppliers of commercial-grade calibration services in lieu of commercial-grade survey.
- In a letter dated September 28, 2005, NRC approved APS's request in a Safety Evaluation Report based on the review of the NVLAP and American Association of Laboratory Accreditation (A2LA) programs recognized through the Mutual Recognition Arrangement (MRA) of International Laboratory Accreditation (ILAC).
- In a letter dated March 15, 2006, NUPIC requested NRC to clarify whether this alternative may be adopted by suppliers for qualifying sub-suppliers.

Background

- In a letter dated June 6, 2006, the NRC stated that Appendix B suppliers may use the alternative for the qualification of commercial-grade sub-suppliers as long as the conclusions of the safety evaluation with regards to the quality of the supplier's programs also apply to the sub-suppliers.
- Calibration services suppliers are accredited to ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."
- Accrediting bodies are accredited by ILAC to ISO/IEC 17011, "Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies."

Background

- On February 20, 2008, NRC met with NVLAP, ACLASS, LAB, IAS and A2LA to further discuss the commercial calibration and testing laboratory accreditation process through the ILAC MRA.
- Currently, the NRC has recognized the accreditation provided by the following 6 U.S. ABs (by letters) as an alternative to the methods used to qualify commercial-grade calibration suppliers for U.S. utilities:
  - NVLAP, A2LA, ACLASS, LAB, IAS, and Perry Johnson
- All of the above ABs are signatories (full members) to the ILAC MRA

Background

- In a letter dated February 26, 2009, Equipos Nucleares, S.A. (ENSA) requested the NRC to evaluate acceptance of international accrediting bodies belonging to ILAC as third party accreditation for commercial grade calibration services.

- In a letter dated April 29, 2014, the Nuclear Energy Institute submitted for NRC's review and endorsement its guidance to expand the acceptability of third party accreditation to include both domestic and international calibration and testing laboratories accredited under ILAC.

NRC's Review & Acceptance

- Initial domestic recognition of U.S. ABs:
  - Several meetings with interested parties (NVLAP, A2LA, ACLASS)
  - Comparison of NUPIC checklist with ANSI/ISO/IEC 17025
  - Observation of an accreditation assessment performed by NVLAP
- Continued recognition of U.S. ABs and Possible Expansion:
  - Observation of A2LA, LAB and Perry Johnson's evaluation by ILAC
  - Observation of ACLASS and IAS's accreditation of a commercial calibration laboratory
  - Observation of the Japan Accreditation Board's (JAB) evaluation by ILAC and observation of JAB's accreditation of commercial calibration and testing laboratories

NRC's Expectations

- Method for qualifying calibration laboratory and accepting its calibration services is applied only to commercial grade calibration services as defined by Part 21
- Licensees and vendors may use the alternative method described in the APS SER in lieu of performing a commercial grade survey as part of the dedication process if the alternative method is documented in the quality assurance program and the following is performed:
  - Technical Evaluation
    - Verify that calibration laboratory holds accreditation by one of the 6 domestic accrediting bodies
    - Verify that the scope of accreditation covers the contracted services

NRC's Expectations

- Technical Evaluation (cont.)
  - Identify any additional technical requirements for the specific purchase measuring and test equipment being calibrated that need to be included in the purchase order such as tolerances, accuracies, ranges over which the item is to be calibrated, specific industry standards to be used, etc.
- Critical Characteristics identified in the purchase order:
  - Use of the laboratory's ISO 17025 accredited quality program
  - Reporting as-found calibration data when calibrated items are found to be out-of-tolerance
  - Identification of the laboratory equipment and standards used
- Acceptance of Critical Characteristics
  - Review calibration records to verify that all of the critical characteristics are met

NRC's Expectations

- The alternative method is limited to domestic calibration service suppliers

- Licensees and suppliers of nuclear components for operating and potential new nuclear reactors in the U.S. that do not perform these actions for procurement of commercial calibration services are not in compliance with NRC regulatory requirements.

Current Status of NRC's Recognition

- NRC continues to recognize the ILAC accreditation process for domestic commercial calibration laboratories as part of a commercial grade dedication process.
- Currently evaluating NEI's proposed guidance for expanding NRC's acceptability of third party accreditation to include both domestic and international calibration and testing laboratories accredited under ILAC.
- Endorsement of NEI's guidance through a Safety Evaluation Report
- Regulatory Issue Summary to communicate and clarify NRC's technical position on the use of the ILAC accreditation process as part of the commercial grade dedication process

Questions