



NRC's Recognition of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreements (MRA)

**3rd NRC Workshop on Vendor Oversight for New Reactor Construction
June 28, 2012 – Baltimore, MD**

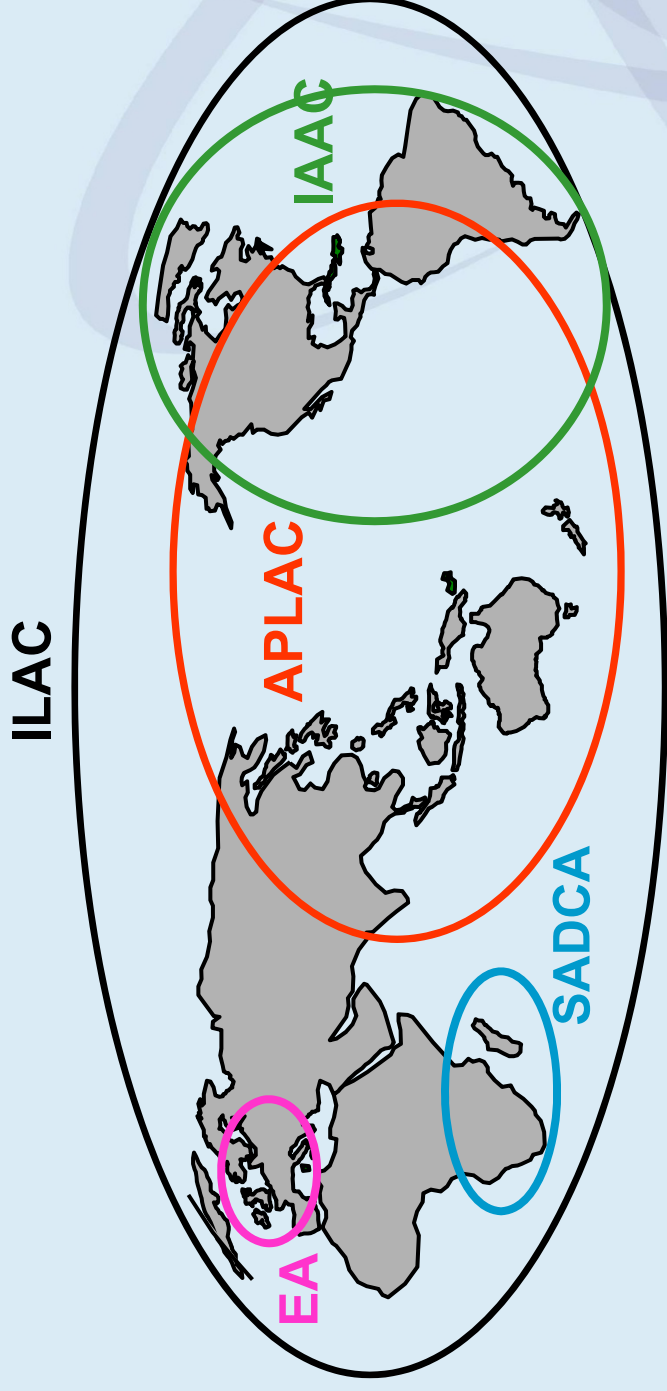
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Agenda

- Background
- NRC's Acceptance Process
- NRC's Expectations
- Inspection Findings
- Status of NRC's Recognition
- Questions

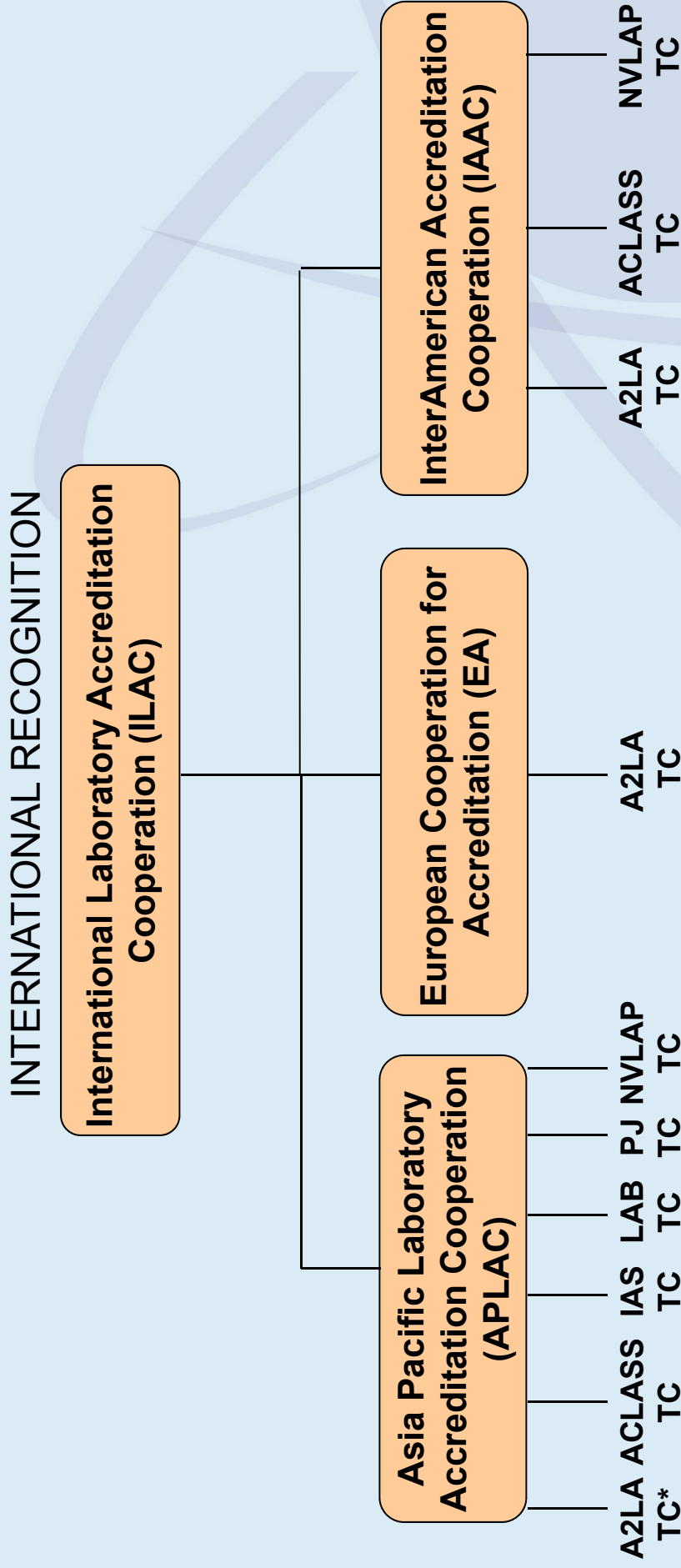
Background



EA APLAC IAAC SADCA

European Cooperation for Accreditation
Asia Pacific Laboratory Accreditation Cooperation
Inter-American Accreditation Cooperation
Southern African Development Community Accreditation

Background



* T - Testing
C - Calibration

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:
 - 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.
- ENSA is a supplier of nuclear components for operating and potential new reactors in the U.S.
- In addition to domestic commercial calibration suppliers, the NRC would like to expand its recognition of the ILAC MRA process to include international commercial calibration suppliers as well as domestic and international testing suppliers.

NRC's Acceptance Process

- 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:
 - Observation of A2LA and LAB's evaluation by ILAC
 - Observation of ACLASS and IAS's accreditation of a commercial calibration laboratory

NRC's Expectations

- Method for qualifying calibration supplier 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 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
 - Identify any additional technical requirements for the specific M&TE being calibrated that need to be included in the PO such as:
 - ✓ Tolerances
 - ✓ Accuracies
 - ✓ Ranges over which the item is to be calibrated
 - ✓ Specific industry standards to be used, etc

NRC's Expectations

- Critical Characteristics
 - Accreditation provided by one of the 6 ILAC domestic accrediting bodies
 - Scope of the accreditation covers the contracted services
 - Critical Characteristics identified in Purchase Order (PO)
 - ✓ PO requires use of the lab's ISO 17025 accredited quality program
 - ✓ PO imposes additional technical requirements identified in the technical evaluation
 - ✓ PO requires reporting as-found calibration data when calibrated items are found to be out-of-tolerance
 - ✓ PO requires identification of the laboratory equipment and standards used
 - Acceptance of Critical Characteristics
 - ✓ Review the calibration record as part of receipt inspection 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 calibration services are not in compliance with NRC regulatory requirements.

Inspection Findings

- Continuum Dynamics, Inc - June 2011
 - NON against Criterion VII for improperly allowing vendors to be placed on the ASL based on third party accreditation. Specifically, CDI was qualifying safety-related calibration suppliers based on the accreditation provided by NVLAP and A2LA without performing an audit.
- Shaw Modular Solutions - November 2011
 - NONs against Criterion II, IV, and XII for not including the description of the alternative to use the accreditation provided by one of domestic ABs in the QAM, for including the alternative in safety-related purchase orders without requiring the dedication of the calibration service, and for using a commercial laboratory to calibrate safety-related measuring and test equipment without dedicating the calibration service, respectively.

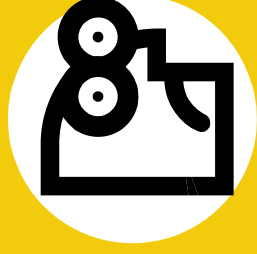
Inspection Findings (cont.)

- Clark Dynamics, LLC - March 2012
 - NON against Criterion III for failing to review the suitability of the application of commercially calibrated measuring and test equipment (M&TE) for use in safety-related (SR) applications as part of a commercial-grade dedication process. Specifically, Clark issued five purchase orders (POs) for commercial calibration services for M&TE and subsequently used the commercially procured M&TE in SR applications without dedicating the calibration service.
- Fauske & Associates, LLC - April 2012
 - Potential NON against Criterion III for failing to review the suitability of the application of commercially calibrated M&TE for use in SR applications as part of a commercial-grade dedication process. Specifically, Fauske failed to perform a technical evaluation, failed to identify the critical characteristics, and failed to review the calibration records as part of receipt inspection.

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.
- Moving forward, the nuclear industry's decision on how to provide oversight of the ILAC process will impact NRC's recognition of the ILAC accreditation process for calibration and testing laboratories as well as the recognition of international calibration and testing laboratories.

Questions



It's QUESTION TIME!!