U.S. NRC's Recognition of the International Laboratory Accreditation Cooperation Mutual Recognition Agreement

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Yamir Diaz-Castillo
Mechanical Vendor Inspection Branch
Division of Construction Inspection &
Operational Programs
Office of New Reactors

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

Agenda

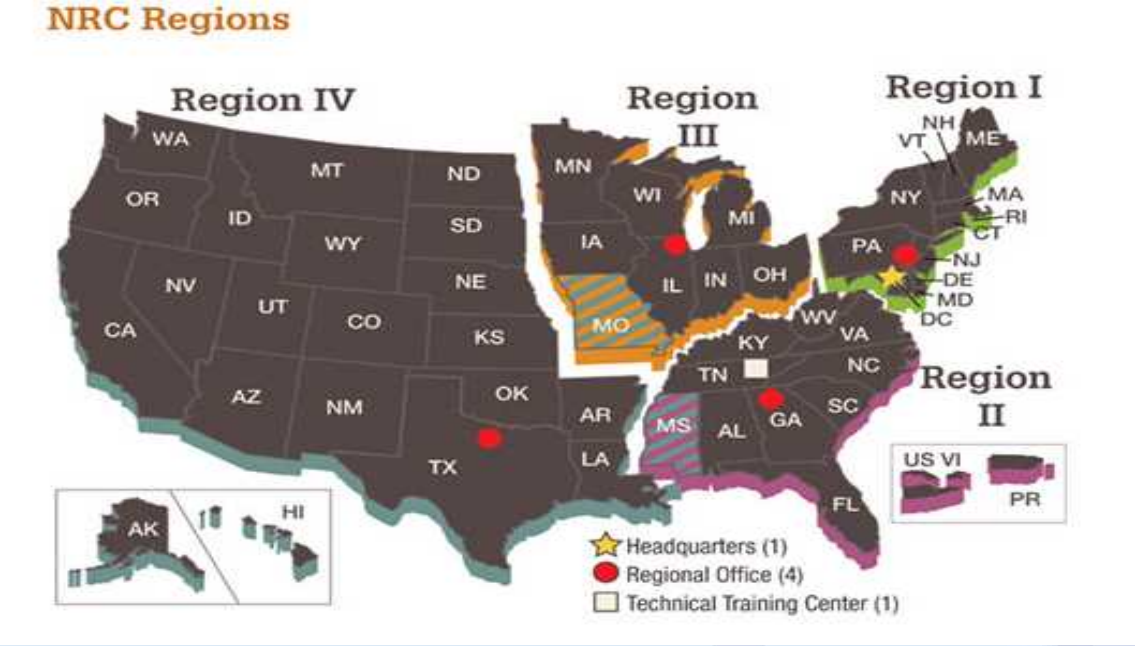
- NRC: Who We Are and What We Do
- Background
- NRC's Review & Acceptance
- NRC's Expectations
- Current Status of NRC's Recognition
- Questions

NRC: Who We Are & What We Do

- The U.S. Nuclear Regulatory Commission (NRC) was created as an independent agency by Congress in 1974 to ensure the safe use of radioactive materials for beneficial civilian purposes while protecting people and the environment.
- The NRC is headed by five Commissioners nominated by the President and confirmed by the Senate for staggered five-year terms. No more than three can be from the same political party.
- The Commission as a whole:
  - Formulates policies and regulations governing nuclear reactor and materials safety;
  - Issues orders to licensees; and
  - Adjudicates legal matters brought before it.

NRC: Who We Are & What We Do

- The NRC employs nearly 3,900 people among its suburban Maryland headquarters and four regional offices in Pennsylvania, Georgia, Illinois, and Texas.
- NRC inspectors are also assigned to 65 nuclear power plant sites and three nuclear fuel facilities.



NRC: Who We Are & What We Do

Our Mission

To license and regulate the nation's civilian use of byproduct, source and special nuclear materials to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment.

NRC: Who We Are & What We Do

- 101 nuclear power plants supply about 20 percent of the electricity in the U.S.
- The NRC Regulates:
  - Nuclear reactors - commercial power reactors, research and test reactors, new reactor designs
  - Nuclear materials - radioactive materials for medical and academic use;
  - Nuclear waste - transportation, storage and disposal of nuclear material and waste, decommissioning of nuclear facilities
  - Nuclear security - physical security of nuclear facilities and materials from sabotage or attacks

NRC: Who We Are & What We Do

- What We Do:
  - Create Regulations
  - Issue Licenses
  - Provide Oversight
  - Enforce Regulations
  - Evaluate Operations
  - Provide Support
  - Respond to Incidents

- What We Don't Do:
  - Regulate nuclear weapons, military reactors or space vehicle reactors
  - Lobby for nuclear power
  - Own or operate nuclear power plants
  - Regulate naturally occurring radon, X-rays, and material produced in particle accelerators

NRC: Who We Are & What We Do

- www.nrc.gov
- External Blog
- Facebook Account
- YouTube Channel
- Twitter Account
- Flickr Account

Background

- In a letter dated September 5, 2004, Arizona Public Service requested NRC to provide acceptance of the NVLAP (National Voluntary Laboratory Accreditation Program) accreditation of suppliers of commercial-grade calibration services in lieu of performing a commercial-grade survey.
- In a letter dated September 28, 2005, NRC approved this request in a Safety Evaluation Report based on the review of the NVLAP and American Association of Laboratory Accreditation (A2LA) programs recognized through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).
- In a letter dated March 15, 2006, the Nuclear Procurement Issues Committee (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 suppliers may use the alternative for the qualification of commercial-grade sub-suppliers as long as the conclusions of the safety evaluation report with regards to the quality of the supplier's programs also apply to the sub-suppliers.

- On February 20, 2008, NRC met with representatives from NVLAP, A2LA, ACLASS, Laboratory Accreditation Bureau, and the International Accreditation Service to further discuss the commercial calibration and testing laboratory accreditation process through the ILAC MRA.

Background

- Currently, the NRC has recognized the accreditation provided by the following 6 U.S. accrediting bodies as an alternative to the methods used to qualify commercial-grade calibration suppliers for U.S. licensees and vendors:
  - NVLAP, A2LA, ACLASS, LAB, IAS, and Perry Johnson
- Bases for Initial NRC Approval:
  - Accreditation is to ISO 17025
  - Alternative is described in the licensee and vendor's Quality Assurance Program
  - Scope of accreditation covers the contracted services

Background

- Bases for Initial NRC Approval (cont.):
  - Purchase documents:
    - Impose additional technical and administrative requirements to satisfy necessary Quality Assurance program and technical requirements
    - Require reporting as-found calibration data when calibrated items are found to be out of tolerance
    - Require identification of the laboratory equipment and standards used

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 (NEI) 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.

- NEI is a private industry group that develops policy on key legislative and regulatory issues affecting the nuclear industry.

Background

- In a letter dated August 28, 2014, NEI submitted Revision 1 to the guidelines in response to NRC's request for additional information.

- Purpose of the guidance is to describe an acceptable approach for using the ILAC accreditation in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process.

- The guidance describes the activities performed by the U.S. nuclear industry to expand the NRC's recognition of the ILAC accreditation process to include both domestic and international calibration and testing laboratories.

NRC's Review & Acceptance

- Initial domestic recognition of U.S. Accrediting Bodies:
  - 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. Accrediting Bodies and Possible International 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 Title 10 of the Code of Federal Regulations, Part 21.
- Licensees and vendors may use the alternative method 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:
  1. Documented Review of the Supplier's Accreditation:
     - Verify that the laboratory holds accreditation by an accrediting body recognized by the ILAC MRA
     - Verify that the scope of accreditation covers the contracted services

NRC's Expectations

2. Purchase Documents Require:
   - Use of the laboratory's ISO 17025 accredited quality program
   - Reporting of as-found calibration data when calibrated items are found to be out-of-tolerance
   - Identification of the laboratory equipment and standards used
   - Notification of any condition that adversely impacts the laboratory's ability to maintain scope of accreditation
   - Any additional technical and quality requirements, as necessary
3. Acceptance of Calibration/Testing Service
   - Review calibration/testing records to verify that the purchase order requirements are met

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.
- NRC has completed its review of 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.
- Currently in the process of getting NRC Senior Management review and approval for the Safety Evaluation Report endorsing NEI's guidance.
- Regulatory Issue Summary to be issued 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