Conformity Assessment Guidance and Best Practices: Canada, Mexico and USA

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Topics

- Who A2LA works with
- Examples of arrangements
- Role accreditors play
- Relationship with government
- Relationship with CABs
- What makes a good accreditation scheme?
- Trust

A Better World Through Accreditation

Working with US Regulators

- CPSC
- FCC
- NIST
- GSA
- DoD
- DoE

- CMS
- CDC
- EPA
- USDA
- Maryland
- NY City / Las Vegas

Child Product Safety Commission (CPSC)

- CPSC
  - Established program recognizing ILAC MRA signatory ABs
  - Prescribe specific test methods for products
  - Provide updates and webinars to labs and ABs
  - Monitor accreditations on AB websites
  - Maintain ILAC MRA (ISO/IEC 17011) signatory status

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Federal Communications Commission (FCC)

- Telecommunications Certification Body (TCB)
  - Program established by the FCC
  - FCC identified NIST as the Designating Authority for TCB's
  - NIST developed the NVCASE recognition program for AB's accrediting TCB's
  - A2LA applied and was recognized via the NVCASE program (ISO/IEC 17011)
  - A2LA works directly with the FCC and NIST to revise documents (FCC KDB's)
  - A2LA receives biennial NVCASE assessments
  - FCC performs market surveillance and enforcement

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Federal Communications Commission (FCC)

- FCC – Non-MRA countries
  - FCC revised rules to require all testing in support of certification be performed by an accredited and recognized laboratory
  - Only lab's in the US or in countries with a Gov't-to-Gov't MRA could obtain this recognition
  - FCC implemented a way for AB's to apply to be recognized by the FCC to accredit test labs in Non-MRA countries
  - A2LA submitted application was available for public comment before it was accepted and approved by the FCC
  - Maintain ILAC recognition (ISO/IEC 17011)

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National Institute of Standards and Technology (NIST)

- NIST/Notified Body (NB)
  - NIST is the Notifying Authority for Notified Bodies in the United States
  - NIST Developed recognition criteria for the EMC Directive and the Radio Equipment Directive
  - Occasional Teleconferences – email updates from NIST
  - Maintain ILAC (ISO/IEC 17011) and NVCASE program recognition

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ISED – Canada

- ISED – Canada – Labs in Non-MRA Countries
  - ISED followed FCC's model and revised rules to require all testing in support of certification be performed by an accredited and recognized laboratory
  - Only lab's in Canada or in countries with a Gov't-to-Gov't MRA could obtain this recognition
  - ISED implemented a way for AB's to apply to be recognized (REC-AB) to accredit test labs in Non-MRA countries
  - A2LA application was approved by ISED (no public comment period)
  - Maintain ILAC recognition (ISO/IEC 17011); reapplication every 4 years

General Services Administration (GSA)

- Federal Risk and Authorization Management Program (FedRAMP)
  - Established by General Services Administration (GSA) in 2012
  - Conducted their own "assessments" for about 1 year; decided to put out an application for an organization to take over the initial assessment/qualification process
  - A2LA applied and was granted this recognition on July 22, 2013
  - Began conducting ISO/IEC 17020 assessments of previously recognized organizations in April 2014; facilitating the assessment process ever since

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General Services Administration (GSA)

- Federal Risk and Authorization Management Program (FedRAMP)
  - 2 step approval – ISO/IEC 17020 accreditation and FedRAMP PMO grants the final recognition and approval on their website
  - Program requirements were developed at high level and have been through 2 large updates in collaboration with the FedRAMP Program Management Office (PMO) and A2LA
  - Biweekly (every 2 weeks) teleconferences with the PMO to discuss program updates and the status of accredited organizations
  - Frequent email exchanges to keep each other informed

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DoD Environmental Laboratory Accreditation Program (ELAP)

- ELAP
  - A2LA recognized as an ILAC signatory and mutually recognized Accreditation Body (AB) to provide accreditation to labs seeking to work under the Defense Environmental Restoration Program
  - Currently have 23 labs in the program
  - Assessed to the DoD/DOE Consolidated Quality Systems Manual (QSM) for Environmental Laboratories (includes ISO/IEC 17025, TNI, and DoD/DOE requirements)
  - Regular oversight on assessments
  - DoD reviews all assessment reports
  - Quarterly telecons and annual face-to-face meeting

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DoD Advanced Geophysical Classification Accreditation Program (DAGCAP)

- DAGCAP
  - Stemmed from our relationship with the DoD ELAP program
  - Extremely small market (7-10 organizations) but important relationship with a large specifier
  - Assessed to ISO/IEC 17025 and the requirements of the DoD Quality System Requirements (QSR) for Advanced Geophysical Classification
  - Currently 7 CABs in our program
  - Regular oversight on assessments
  - Quarterly telecons and annual face-to-face meeting

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Department of Energy Consolidated Assessment Program – Accreditation Program (DOECAP)

- DOECAP
  - DoE has recognized A2LA to perform assessments of organizations previously assessed under the DOECAP program. All labs must be accredited in 2018
  - Utilize the Quality Systems Manual (QSM) that we currently use for the DoD ELAP program
  - DoE Technical Experts utilized on every assessment
  - DoE reviews all assessment reports
  - Quarterly telecons and annual face-to-face meeting

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Local Government Specifiers

- New York City Department of Buildings / Clark County Department of Building & Fire Prevention
  - Requested by local organizations that we approach specifiers for approval; in both cases only one AB was approved and organizations wanted options
  - Met with them to present our program to gain approval
  - Both programs require organizations to become ISO/IEC 17020 accredited and to provide proof of accreditation
  - Frequent communications with main point of contact in both jurisdictions

Maryland - Forensics

- Maryland - Fx
  - A2LA recognized as an AB for forensic testing
  - Maryland program started as a piece of legislation
    - Required that the department of health and mental hygiene develop a licensure program for forensic laboratories
    - Established an advisory committee to assist in development of the regulations
  - A2LA invited to sit on that committee; worked them from there vary beginning to develop the regulations
  - Once published, we provided a crosswalk, showing how A2LA planned to meet their requirements and received approval to offer services under the program
  - We continue to be an active participant on the committee

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A2LA Clinical Services

- Clinical laboratories – defined as a laboratory examining materials derived from the human body for the purposes of providing information for the diagnosis, management, prevention, and treatment of disease in, or assessment of the health of human beings
- A2LA offers the following types of clinical assessments:
  - ISO 15189:2012
  - Clinical Laboratory Improvement Amendments (CLIA)
  - Clinical Laboratory Improvement Program (CLIP)
  - Platinum (combines ISO 15189 with CLIA in one assessment)
- ISO 15189 is voluntary and includes management system and technical requirements
- CLIA Accreditation is regulatory-driven and required for testing on US citizens
- CLIP is regulatory-driven and is similar to CLIA but directed at DoD laboratories

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Centers for Medicare & Medicaid Services (CMS)

- CMS
  - Regulates all testing (except research) on humans in the US through CLIA
  - Grants "deemed status" to accreditation organizations (AO) and oversees the accreditation processes
  - Currently seven AOs maintain CMS deemed status
  - A2LA is the only AO in the world holding both CMS deemed status and ILAC

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CMS

- Obligations
  - A2LA must conduct unannounced laboratory assessments on a two-year cycle
  - A2LA must notify CMS within 30 days of the action taken, of any laboratory that has:
    - Had its accreditation or licensure suspended, withdrawn, revoked, or limited
  - A2LA must notify CMS within 10 days of any deficiency in an accredited laboratory if the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public

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CMS

- **Obligations** (continued)
  - A2LA must maintain systems to provide CMS with electronic data in compatible code
  - A2LA must notify CMS within 30 days in advance of the effective date to any proposed change in our requirements related to the CLIA Accreditation program
  - As a condition for accreditation, laboratories must authorize A2LA to release to CMS their PT data
  - A2LA must undergo CMS re-evaluations on a four year cycle

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Role Accreditors Play

- Perform assessments of CABs
  - Full biennial renewal
  - Surveillance
  - Proficiency Testing
- Assess specific scope/technical requirements
- Accredit CABs
- Liaison between CABs and Gov't
- Technical Advisory Committees

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Relationship with Government

- Work directly with Regulators:
  - Assist to develop assessment/accreditation criteria
  - Manage database with accreditation specifics
  - Training of assessors
  - Use their TEs on assessments
- Monthly/Quarterly telecons
- Evaluations (annual or biennial)
- Invitation to observe assessments
- Invitation to participate in peer review

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Relationship with CABs

- Partner in accreditation
- Dedicated Accreditation Services Staff
  - Manage accreditation process
  - Monitor corrective actions/PT/complaints/Red Alerts
- Technical Advisory Committees
  - CABs have a voice
- Assessor selection
  - Identify COIs

What Makes a Good Accreditation Scheme?

- Single AB, Multiple AB, or ILAC
- Proficiency Testing
- Accreditation Requirements
- Technical Specifics (e.g. NSA measurement)
- Assessor Competence
- Assessment Sampling
  - Locations
  - Scope content

Why Accreditors are Important to the Trust Framework

- Impartiality
- Confidentiality
- Complaint Handling Process
- Peer Reviewed
- Relationship with Government and CABs

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