

Accreditation Acceptance by USA Regulators

Presented by

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Topics

- Regulatory policy
- Government agency use of accreditation

Characteristics of the U.S. System

- In the United States, conformity assessment activities are not centrally organized
- Activities are a mix of government (regulations) and private sector (market activities)
- Approaches vary among sectors



U.S. Regulatory Philosophy

Rely on manufacturer's declaration of conformity

- U.S. legal system imposes severe penalties on defective or hazardous products
- U.S. consumers have broad access to information about products
- Dissatisfied customers can easily switch to a competing product
- U.S. laws and regulations on truth in labeling and advertising protect consumers as well



Regulatory Policy

- Executive Order 12866 – Regulatory Planning and Review (September 1993) states that agencies should:
 - Promulgate only such regulations as are required
 - Analyze all costs and benefits of available regulatory alternatives, including not regulating
 - Select approaches that maximize net benefits wherever possible



Regulatory Policy

- Choice of conformity assessment approach determined in part by assessment of risk:
 - Agencies must conduct risk assessments of proposed new or revised regulations
 - Risk assessment comes down to regulators exercising judgment
 - Transparency and openness are important characteristics of the assessment process

Regulatory Policy

- Guidance on Federal Conformity Assessment Activities – August 2000
 - Outlines Federal agencies' responsibility for evaluating their conformity assessment activities
 - Each agency is responsible for coordinating its conformity assessment activities with those of other appropriate government agencies and with those of the private sector:
 - to make more productive use of the increasingly limited Federal resources available for the conduct of conformity assessment activities, including accreditation
 - to reduce unnecessary duplication.



Types of Government Agency Programs

- Administer government laboratories and product certification
- Accredite private sector laboratories and product certification bodies
- Recognition of domestic accreditation bodies
- Recognition of international mutual recognition arrangements such as International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF)



Federal vs. State & Local Government Programs

- Congress has given Federal agencies overriding responsibility for most health and safety regulation
- State & local governments enforce on:
 - regulation of buildings and construction
 - agricultural products
 - workplace safety enforcement
 - environmental safety enforcement
 - food service facilities
 - nursing homes



Sector-specific Accreditation Programs

- Government (all levels)
 - environmental
 - clinical labs
 - food safety
 - animal health
 - drug abuse
 - calibration
 - firearms & body armor
 - manure
 - information technology
- Private-sector
 - automotive
 - EMC
 - building materials
 - environmental
 - clinical labs
 - forensic science
 - industrial hygiene
 - solar equipment
 - safety equipment
 - packaging



Numerous State/Local Programs Requiring Accreditation

- California:
 - I7024 for crane operators
 - I7024 for personal trainers
 - Guide 65 for plumbing products
- Pennsylvania: I7024 for crane operators
- Florida: Guide 65 for building products
- New Mexico: Guide 65 for electric fireplaces
- Boston: Guide 65 for plumbing products
- New York City: I7020 for special inspection bodies



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Health and Human Services (HHS)

- Commission for Medicare and Medicaid Services (CMS) recognizes accreditation bodies in both the public (state government) sector and private sector (e.g., College of American Pathologists, Commission for Office Laboratory Accreditation, Joint Commission for Accreditation of Health Care Organizations)
 - Does not use ISO/IEC 17011 for accreditation body requirements
 - Does not use ISO/IEC 17025 or ISO 15189
 - Uses Clinical Laboratory Improvement Act (1988)
 - Will not recognize the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatories



Customs and Border Protection (CBP)

- Customs accredits laboratories for several types of import testing and inspection
- Does not follow ISO/IEC 17011
- Criteria similar to, but not quite, ISO/IEC 17025 or 17020
- No recognition of ILAC MRA signatories or private sector laboratory accreditation bodies
- Customs laboratories themselves are accredited by A2LA



Federal Highway Administration (FHWA)

- One FHWA department recognizes ILAC MRA signatories to accredit testing of highway crash mitigation equipment
- Another FHWA department does not recognize ILAC MRA signatories and relies on the American Association for State and Highway Transportation Officials (AASHTO) Accreditation Program (AAP) plus accreditation bodies recognized by the National Cooperation for Laboratory Accreditation (NACLA) which adopt the AAP assessment approach for construction materials testing laboratories



Federal Communications Commission (FCC)

- Regulates telecommunications and the radio-frequency spectrum
- Recognizes certain accreditation bodies for both Guide 65 and 17025
- Does not accept the ILAC MRA, but will review accreditation bodies on a case-by-case basis
- Moving more toward acceptance of supplier self declaration of conformity underpinned by accredited test data
- FCC labs are not accredited



Federal Aviation Administration (FAA)

- Accredited certification to AS 9100/AS9110/AS9120
- Aerospace industry, through International Aerospace Quality Group (IAQG) and Americas Aerospace Quality Group (AAQG), has succeeded in having FAA recognize accredited certification in place of direct supplier audits by OEMs though OEMs still hold legal responsibility



Department of Energy (DoE)

- For superior energy performance programs, DoE cites accredited organizations for
 - I4065 verification and
 - I7024 personnel certification

Department of Justice (DoJ)

- ANAB is close to announcing accredited certification to BA9000 which is a body armor industry-specific standard based on ISO 9001 developed by DoJ
- NVLAP accredits body armor testing laboratories whose data are used DoJ certification of body armor.

Department of Agriculture (USDA)

- Regulates certain food and agricultural products to protect consumers' health, safety, and pocketbook, specifically:
 - meat, poultry, dairy products and raw agricultural products
- Accredits meat and dairy labs
 - User fees imposed
 - Does not use ISO/IEC 17025 & does not follow ISO/IEC 17011
 - Relies heavily on proficiency testing programs
- Some USDA labs are accredited by A2LA



Department of Agriculture (USDA)

- USDA is developing a process for recognition of tests results on products for the school lunch program provided by laboratories accredited by ILAC MRA signatory accreditation bodies

Environmental Protection Agency

(EPA)

- Environmental lead (Pb) program recognizes A2LA and AIHA/LAP
- ANAB offers accredited certification for responsible recycling (R2), a standard developed with involvement of EPA
- ISO 14001 certification has some degree of support by EPA which has determined 14001-certified organization do better for EPA Performance Track, so EPA focuses its audits on non-certified organizations
- EPA Water Sense program recognizes ILAC MRA and IAF MLA signatory accreditations
- EPA Energy Star program recently established requirements for data provided by laboratories accredited by ILAC MRA signatories and IAF MLA for product certification bodies



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Environmental Protection Agency

(EPA)

- National Environmental Laboratory Accreditation Program (NELAP)
- Recognizes state government agencies as the sole accreditation authorities; private sector ABs are considered *assessment* bodies, not accreditation authorities
- Recognition criteria based on ISO/IEC 17011
- Uses ISO/IEC 17025, with detailed technical applications
- No recognition of ILAC MRA signatories or private sector laboratory accreditation bodies
- Recognizes A2LA to accredit proficiency testing providers



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Department of Defense (DoD)

- Environmental Laboratory Accreditation Program: for US Defense Department environmental restoration sites
- DoD recognizes US based ILAC MRA signatory accreditation of 3rd party labs
- DoD has additional quality control/assurance requirements
- Information security directive uses I7024 personnel certification



Department of Homeland Security (DHS)

- DHS recognizes ANAB as the sole AB for the Private Sector Preparedness Voluntary Certification (PS-Prep) Program adopting ASIS SPC.1, BS 25999-2 and NFPA 1600



National Institute for Standards and Technology (NIST) USGv6 Test Program

- Recognizes ILAC MRA signatories
 - ABs must collaborate with NIST to develop specific technical requirements in order to formalize their recognition by NIST
- ISO 17025 accreditation by 1st, 2nd or 3rd party labs for conformance and interoperability testing of information technology hosts, routers and network protection devices
 - Technical requirements and proficiency testing requirements in NIST document SP 500-273 (www.nist.gov/usg6/testing)



National Institute for Standards and Technology (NIST)

- NIST administers the National Voluntary Conformity Assessment Systems Evaluation (NVCASE) Program which supports government-to-government trade agreements and a couple of federal agencies which desire a recognition scheme for accreditation bodies.
- NVCASE does not formally use the ILAC MRA and IAF MLA peer evaluation processes .
- NVCASE evaluating USDA Agricultural Marketing Service as an AB to accredit quality system verification program certifiers



Nuclear Regulatory Commission (NRC)

- Regulates components for nuclear reactors
- Recognizes certain ILAC MRA signatory accreditation bodies in the USA for calibration laboratories
- Wants to expand recognition to foreign ILAC MRA signatories, for both testing as well as calibration
- But first, wants to gain confidence in MRA peer evaluation process by observation of regional evaluations of ABs



Food and Drug Administration (FDA)

- Probably the world's largest regulatory body established to protect consumers' health, safety, and pocketbook for:
 - Food, drugs, biologics, medical devices, animal feed and drugs, cosmetics, and radiation-emitting and combination products
- FDA food labs are getting accredited as they are encouraged by draft guidance issued in early 2009, and pending Congressional legislation in 2010

Food and Drug Administration (FDA)

- FDA Office of Regulatory Affairs

- Draft Guidance Document: *Submission of Laboratory Packages by Accredited Laboratories*

- Applicable for biological products, drugs, devices and food
 - Should be an ISO/IEC 17025 accredited lab
 - Should also meet *AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food and Pharmaceuticals*
 - Should be accredited by an ILAC Signatory



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Food and Drug Administration (FDA)

- All 12 FDA Office of Regulatory Affairs laboratories are accredited by A2LA
- Accreditation would allow private sector laboratories to submit an abbreviated package substantiating the testing performed:
 - Import documentation (if applicable)
 - Summary of Analysis
 - Affirmation by Lab Director
 - www.fda.gov/regulatoryinformation/guidance

Consumer Product Safety Commission (CPSC)

- Wide ranging CPSC regulations being issued in rapid order to protect children under Consumer Product Safety Improvement Act of 2008:
 - First, Lead (Pb) in Paint in Children's Toys,
 - Then, Mechanical Properties of Children's Toys...then...

- Recognizes ILAC MRA signatories



US Government Benefits from Accepting ILAC-MRA & IAF-MLA Accreditation

- Eliminates expense of government administered programs
- Increases confidence in results used to determine compliance with regulations
- Eliminates duplication in conformity assessment by reliance on recognized accreditation bodies
- Reduces costs of trade
- Encourages conformity assessment at sources of supply
- Upholds WTO/Technical Barriers to Trade treaty commitments



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Thank you!

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