

Status of Accreditation Within the United States Market

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by

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Topics

- ◆ US Government Philosophy of Regulation
- ◆ Types of US Accreditation Programs
- ◆ US Agency Use of 3rd Party 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
 - ◆ In the final analysis, risk assessment comes down to regulators exercising judgment
 - ◆ Transparency and openness are important characteristics of the assessment process

Regulatory Policy

◆ NIST Guidance on Federal Conformity Assessment Activities – August 2000

- ◆ Outlines Federal agencies' responsibility for evaluating the efficacy and efficiency of 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
- ◆ Out of date; A2LA has suggested revisions to specify use of the ILAC/IAF MRA/MLA

Types of Government Agency Programs

- ◆ One on one approval
- ◆ Accreditation/qualification of private sector programs
- ◆ Recognition of accredited private sector programs

Federal vs. State and Local Government Programs

- ◆ Congress has given Federal agencies overriding responsibility for most health and safety regulation
- ◆ State and local governments are involved in:
 - ◆ regulation of buildings and construction
 - ◆ agricultural products
 - ◆ workplace safety enforcement
 - ◆ environmental safety enforcement

Last 30 Years

- ◆ There are seven ILAC signatory Accreditation Bodies providing broad based accreditation to ISO/IEC 17025:
 - ◆ NVLAP, A2LA, IAS, ACLASS, LAB, PJLA, AIHA
- ◆ Still many sector-specific programs that do **not** use ISO/IEC standards

Government Involvement

- ◆ 1989 Government Accountability Office Report:
 - ◆ Of 20 different federal programs reviewed, there were 10 different terms for accreditation used with at least 18 different meanings
 - ◆ Different terms have different legal implications or reflect differences between various agencies' legal authority to conduct specific programs
- ◆ Significant progress is being made now, but there is still duplication and complexity

Consumer Product Safety Commission

- ◆ Wide Ranging Regulations being issued in Rapid Order to protect Children:
 - ◆ First, Lead (Pb) in Paint in Children's Toys,
 - ◆ Then, Mechanical Properties of Children's Toys...
 - ◆ Then, Children's Jewelry.... Then
- ◆ Recognizes ILAC MRA signatories

Federal Highway Administration

- ◆ One FHWA department recognizes ILAC MRA signatories to accredit testing of highway crash mitigation equipment
- ◆ But another FHWA department refuses to recognize ILAC signatories and relies on the 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 laboratories

Food and Drug Administration

- ◆ 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

Food and Drug Administration

- ◆ FDA Office of Regulatory Affairs
 - ◆ 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

Food and Drug Administration

- ◆ Accreditation would allow the laboratory to submit and abbreviated package substantiating the testing performed:
 - ◆ Import documentation (if applicable)
 - ◆ Summary of Analysis
 - ◆ Affirmation by Lab Director
 - ◆ www.fda.gov/regulatoryinformation/guidance
- ◆ Legislation pending that MIGHT require accreditation of all food testing labs by ILAC signatories

Department of Agriculture

- ◆ 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
- ◆ USDA labs are getting accredited; usually precursor to requiring accreditation of others

Health and Human Services

- ◆ Commission for Medicare Services (CMS) program recognizes accreditation bodies in both the public (state government) sector and private sector (e.g., CAP, COLA, Joint Commission)
 - ◆ Does not use ISO/IEC 17011;
 - ◆ Does not use ISO/IEC 17025 or ISO 15189; uses CLIA (1988) as accreditation standard
 - ◆ Will not recognize ILAC MRA signatories but CMS is starting to look closer at management system requirements

Environmental Protection Agency

- ◆ National Environmental Laboratory Accreditation Program (NELAP) for potable and non potable water and solid/hazardous waste testing
- ◆ Recognizes state government agencies as the sole accreditation authorities; private sector ABs are *assessment* bodies
 - ◆ But state agencies' accreditation programs are taking severe criticism; EPA may recognize 3rd party accreditation
- ◆ Recognition criteria based on ISO/IEC Guide 58 with intention to move to ISO/IEC 17011
- ◆ Uses ISO/IEC 17025, with onerous technical applications
- ◆ Recognizes A2LA to accredit supportive proficiency testing providers

Environmental Protection Agency

- ◆ Water Sense: product certification program – recognizes IAF signatories for product certification and ILAC signatories for testing of the products
- ◆ Energy Star Program: recognizes ILAC signatories

Department of Defense

- ◆ Environmental Laboratory Accreditation Program: for US environmental restoration sites
- ◆ DOD recognizes US based ILAC signatory accreditation of 3rd party labs
- ◆ US based ILAC signatories are assessing State certified laboratories with surprising (and disturbing to the EPA) results.

Federal Communications Commission

- ◆ Regulates telecommunications and the radio-frequency spectrum
- ◆ Recognizes certain accreditation bodies
- ◆ Resists the acceptance of 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
- ◆ Its own labs are not accredited

NIST USGv6 Test Program

- ◆ Recognizes ILAC 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 IT hosts, routers and network protection devices
 - ◆ Technical requirements and PT requirements in NIST document SP 500-273 (www.nist.gov/usg6/testing)

Nuclear Regulatory Commission

- ◆ Sporadic nuclear site-specific recognition of accreditation of commercial grade calibration labs by ILAC signatories.
- ◆ Re-assessing this requirement to make it applicable to all NRC sites or to withdrawn the requirement.
 - ◆ Could also expand the requirement to include testing as well.

Forensics Testing

- ◆ Accreditation is not required
- ◆ ASCLD-LAB has been sole source for forensic accreditation; now FSQ-I and A2LA
- ◆ National Academy of Sciences (A Path Forward”): recommending mandatory accreditation of all forensics labs (ISO 17025) and crime scene units (ISO 17020)
- ◆ White House National Science & Technology Council on Forensic Science
 - ◆ Reacting to serious concerns (fraud; bad test results; wrongful convictions) from forensics labs;
 - ◆ Legislation proposed to require mandatory accreditation of all federal crime labs

Special Inspections

- ◆ State, County and Municipal Regulations
 - ◆ May specify ISO 17020
 - ◆ Additional requirements for the Inspection Agencies and their inspectors
 - ◆ A2LA recognized in NY City; pursuing recognition in Las Vegas and California

US Government Role in An Ideal World

- ◆ Recognize WTO/TBT obligations
- ◆ Increase influence on state and local government bodies
- ◆ Implement policy that requires a reduction in duplication and complexity at federal level by relying on recognized accreditation bodies
- ◆ Support efforts by ILAC to provide recognition and reduce duplication
- ◆ Support working with ILAC to establish technical applications for global use



Any Questions?