The U.S. Conformity Assessment System and the Role of NIST

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Key Characteristics of U.S. System (1)

- **In the United States, conformity assessment activities are not centrally organized**

- **There is no coordinating organization nor direct government oversight of the U.S. conformity assessment system**

- **Activities are a mix of government and private sector activities**

- **Approaches vary among sectors**

Key Characteristics of U.S. System (2)

- Conformity assessment may be carried out by first, second or third party

- Several laws affect the operation of the market place in the U.S. and thus affect conformity assessment activities. These laws include the Fair Packaging and Labeling Act that prevent unfair and deceptive packaging and labeling; laws regarding mandatory disclosure of information; other consumer protection laws.

- Conformity assessment activities depend on the product standard, i.e., appropriate product characteristics need to be tested, test methods need to be adequate, etc.

Conformity assessment activities in the U.S.

- **Public or private? Voluntary or mandatory?**
- **Conformity assessment may be performed by either <u>public or private</u> sector organizations**
- **Whether it is performed by a public or private entity, conformity assessment can be performed**
  - **on a voluntary or mandatory <u>basis</u>, and**
  - **to show conformity to voluntary or mandatory <u>requirements</u>**

Conformity assessment in the federal government

Conformity assessment activities of government agencies may be

- **Direct certification (FDA, USDA); some are mandatory others are not**
- **Recognition of third party private sector certification (OSHA)**
- **Recognition of manufacturer's supplier's declaration of conformity (FCC)**

Examples of mandatory federal programs
(affect health and safety)

- **FDA approval of drugs, medical devices, biologicals, and other products**

- **FAA certification of airplanes and major airplane components**

- **MSHA certification of electrical equipment used in mines**

- **NRC certification of designs for nuclear power plants**

- **EPA for drinking water and vehicle emissions**

- **USDA for food safety and grain inspection**

Examples of voluntary federal programs

- **USDA voluntary meat grading and certification programs using uniform grading standards**

- **EPA voluntary "ENERGY STAR" logo program for office equipment meeting energy efficiency criteria**

- **NOAA inspection / grading program for processed fish and shellfish at seafood processor's request**

State and local government programs

- **There are many state, local and municipal programs**

  - **building/construction**
  - **environmental**
  - **electrical/electronic**
  - **food and agriculture (citrus industry)**
  - **consumer products**
  - **mobile homes**

Product certification in the U.S.

- **It is primarily a private sector activity, based on client and market demands**

- **Sometimes, private sector programs are recognized as sufficient to meet regulatory requirements**

- **Approximately 200 non-government organizations operate product certification programs and they may operate domestically and internationally**

Some U.S. private sector certification programs

- **Professional/technical Societies (e.g., American Dental Association , ADA)**
- **Trade Associations (e.g., Association of Home Appliance Manufacturers, AHAM)**
- **Independent Testing/Inspection Organizations (e.g., UL, ITS)**
- **Consumers organizations, industrial buyers, users of products or services (i.e. Good Housekeeping Magazine)**

Why are voluntary certification programs run by the private sector?

- **Enhance industry reputation**
- **Enhance product characteristics to better compete**
- **Provide manufacturers with some assurance on safety, environmental impact and/or compliance with requirements**
- **Voluntarily establish minimum level of safety, quality or environmental performance**
- **Avoid the need for government involvement**

Markings

- **There is no U.S. national mark or national safety mark**

- **Some federal regulatory agencies have marking or labeling requirements; some do not**

- **Products may bear private sector certification marks**

Accreditation of laboratories

- **A large variety and number of programs**

- **Many programs are focused on a single sector or industry**

- **Two multisector programs: NVLAP and A2LA, both internationally recognized**

National Voluntary Laboratory Accreditation Program (NVLAP)

- **NIST program established in the U.S. CFR (Part 285, Title 15) in 1976**

- **Process for third-party accreditation of testing and calibration laboratories**

- **Accreditation programs established in response to:**
  - **Congressional mandates**
  - **Administrative actions by Federal Government**
  - **Requests by private-sector organizations**

NVLAP (continued)

- **NVLAP program based on ISO/IEC standards**
- **Available to any qualifying laboratory**
- **Fully fee supported**
- **Fields of accreditation:**

Calibration	**Chemical Calibration**
EMC and Telecom	**Environmental**
Fasteners and metals	**IT Security Tesing**
Product Testing	**Dosimetry**

- **NVLAP is a signatory to ILAC and APLAC MRAs**

Accreditation of certification bodies

— **Accreditation of certification bodies is more streamlined**

— **ANAB runs a program to accredit management system certification bodies**

— **ANSI runs a program to accredit personnel certification bodies**

— **ANSI runs a program to accredit product certification bodies**

NIST Role in Conformity Assessment

- **Metrology and Measurement Assurance**

- **Federal Conformity Assessment Guidance, per NTTAA**

- **NIST operates a laboratory accreditation program, NVLAP**

National Technology Transfer and Advancement Act (NTTAA)

- **In addition to NTTAA standards provisions, the law directs NIST to coordinate federal standards and conformity assessment activities with those of the private sector**

- **NTTAA also directed NIST to develop conformity assessment guidance; published 8/2000 http://ts.nist.gov/Standards/Global/caguidance.cfm**
  - **Agencies are to ensure effective coordination of conformity assessment activities and to eliminate unnecessary duplication and complexity**