ANSI Healthcare Informatics Board (HISB)

Update to the National Committee on Vital and Health Statistics (NCVHS)

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ANSI and the Voluntary Consensus Standards System in the U.S.

Overview-

- How the standards system evolved in the U.S.
- ANSI's role in the system
- Legislation and regulations that govern use of standards by government agencies
- Increasing use of standards
- Healthcare Informatics Standards Board

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American National Standards Institute

The U.S. Standards System is the Product of U.S. History and Culture

- A Bottom Up, Dispersed System
- Tradition of Private Sector Leadership-
  - American Revolution
  - Fierce Independence
  - "The government that governs least governs best."
- Different than European and others with top-down systems
- Especially since 1995, increasing use of standards by government for regulatory and procurement purposes

Growth of the Standards System

- Late 1800's, Early 1900's - Emergence of independent standards developing organizations
  - 1894- IEEE, UL
  - 1896- NFPA
  - 1898- ASTM
  - 1905- SAE
  - 1906- IEC
  - 1917- API

- 1918 – Following WWI, recognition of need for coordination, focal point for information – *ANSI established as a joint private/public partnership*

- 1947 – Following WWII, recognition of need for intl. Coordination- *ISO created* (ANSI one of founding members, still is official U.S. rep)

- 1970's -1980's - Attempts to bring standards under federal government control. Strong reaffirmation of private sector leadership.

- 1990's - Official recognition of U.S. standards system as private-public partnership, with private sector leadership (NTTAA, PL 104-113; OMB A-119)

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Basic Principles of the U.S. System-

as incorporated in the "Essential Requirements" for American National Standards:

- Openness
- Balance
- Transparency
- Due Process
- Consensus

Integrity in the standards process- with many of the same protections required by the Rules of Federal Procedure

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Structure of the U.S. Standardization System

- ANSI – Coordinates in Private Sector; Accredits SDO's
  - Private sector, membership organization
  - Supported by membership fees, sale of publications
- NIST – Coordinator of Federal/State Government; Develops some standards-
  - Legal Metrology, Lab Accreditation, Research, specialized areas assigned by Congress
- Standards developing organizations (SDOs)
  - Independent professional, trade and exclusively standards groups
  - Many, but not all, accredited by ANSI

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Voluntary Consensus Standards in Law

- **National Technology Transfer and Advancement Act (PL 104-113) - 1995**
  - Encourages federal agencies to utilize voluntary consensus standards where feasible
  - Encourages federal participation in voluntary consensus standards development activities
  - Designates NIST as "coordinator" (no budgetary or policy authority) of government standards activities
- **Examples of legislation which require the use of standards developed by voluntary consensus standards developing organizations (SDO's)**
  - **Health Insurance Portability and Accountability Act- 1995**
  - **Telecommunications Act - 1995**
  - **Consumer Product Safety Act**

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Voluntary Consensus Standards in Public Policy

- **OMB Circular A-119 (Presidential Order)**
  - Policy guidance document directing all federal agencies' standards-related activities; guidelines for implementation of NTTAA.

- Examples of agencies utilizing voluntary consensus standards
  - **Department of Defense**
  - **Food & Drug Administration**
  - **Fed.Communications Commission Rule & Order of 12/21/00 on Part 68**
  - **HHS- CMS- HIPAA Act requirements for Medicare and Medicaid**
  - **OSHA**
  - **HUD**
  - **VA**
  - **EPA**
  - **DHS**

For Detailed Information on ANSI Procedures & Accredited SDOs:
http://www.ansi.org

- Procedures for ANSI accreditation

- Procedures for approval of American national standards

- List of ANSI-accredited standards developing organizations (with links to their websites)

- Links to ANSI-HSSP, ANSI- NSP and ANSI-HISB

Voluntary Standards increasingly are the basis for, or referenced by, Federal law

- Beginning in the early 1970's OSHA and the Consumer Product Safety commission explicitly recognized the value of government adoption of private sector – originated voluntary consensus standards.

- Following the adoption of the **National Technology Transfer and Advancement Act** in 1995 (PL 104-113), requiring all federal agencies to use voluntary consensus standards where available and consistent with agency needs and missions, use of such standards by agencies has increased dramatically.

Congress has given SDO's favored status:

- PL 104-191, **HIPPA Act of 1996** Requires use of ANSI Standards in healthcare. Defines Standard Setting Organization (SSO) as an organization accredited by ANSI

- PL 107-107, Sec 1115 (S.1437) **Defense Authorization Act of 2002**. Allows payment of dues to non-profit SDO's by government employees (exception to general rule applicability)

- PL 108-237 (HR 1086) **Standards Developing Organization Advancement Act of 2004**. Provides antitrust safe harbor to SDOs that meet certain procedural requirements, identical to the requirements of the ANSI "Essential Requirements"

ANSI has led standards coordination efforts, with the support of the private sector and the federal government

- ANSI HSSP was established in February 2003, in direct response to a Congressional GAO report that highlighted the absence of an entity to coordinate development of homeland security –related standards.
- ANSI was requested in the summer of 2004 by the White House Office of Science and Technology Policy (OSTP) to create a Nanotechnology Standards Panel to address the need for terminology, nomenclature and coordination of other nanotechnology standards.
- Both organizations are inclusive, broad-based, and agile, providing needed coordination and facilitating cooperative efforts.

ANSI

Healthcare Informatics Standards Board

ANSI HISB Mission

- The mission of the ANSI Healthcare Informatics Standards Board is to provide an environment that facilitates, coordinates, harmonizes, and promotes the use of national and international healthcare informatics standards.

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ANSI HISB Purpose

A. To serve as the coordinating body for the development efforts for health informatics standards in the United States, representing the interests of standards development organizations, as well as the interests of users, consumers, hardware and software developers and suppliers, vendors, consultants, and government.

B. To monitor, publicize, and facilitate the development of common conventions for data structure, representation, communications, security, and privacy among diverse health data acquisition, processing, and handling systems.

C. To coordinate with the US TAG on issues regarding international standards development efforts in health informatics under ISO TC 215.

ANSI HISB Accomplishments

The guiding principles used by standards development organizations in healthcare informatics include:

- ➢ A common reference information model for healthcare information;

- ➢ A common reference terminology model for healthcare information;

- ➢ A common method for implementation of healthcare information exchange;

- ➢ A common trust framework (privacy and security) for healthcare information and records; and

ANSI HISB Accomplishments (cont'd)

➢ A common approach for coordination and conflict resolution between SDOs.

➢ A strategy to identify and address healthcare informatics issues requiring harmonization or interoperability

➢ United States Health Information Knowledgebase

➢ Standards Roadmap

Summary

- ANSI has a proven track record for standards coordination

- ANSI is working with its Healthcare Informatics Standards Board to raise collaboration and coordination to a new level

- ANSI is the pathway to the international standards community

- As steward of the US standards strategy, ANSI will continue to respond to public and private sector standards coordination needs as they arise.