Public Health Data Standards: Federal Laws and Regulations

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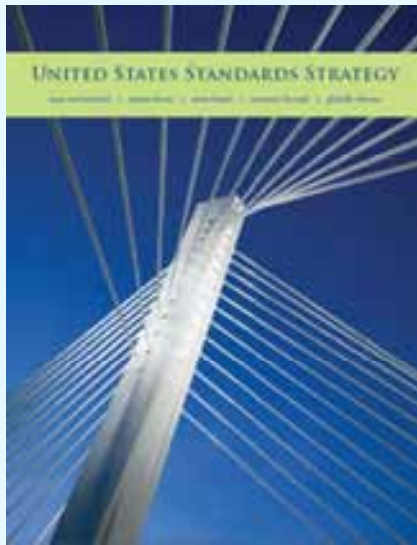
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Standards are the Building Blocks for Innovation and Competitiveness

"Today, more than ever, standards are an imperative undertaking. Standards are the building blocks for innovation and competitiveness. Our nation's ability to compete and lead in a rapidly changing global economy is closely related to our leadership in the development and effective use of standards and standardization processes. Standards provide the common language that keeps domestic and international trade flowing. It is difficult to overestimate their critical value to both the U.S. and global economy. "*

— Patrick Gallagher, Director of the National Institute of Standards and Technology, 2010

United States Standards Strategy, 2010. United States Standards Strategy Committee. At:
http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/NSSC/USSS_Third_edition/USSS%202010-sm.pdf

National Legal Framework and Policies for Standardization

1. A series of statutes, regulations, and administrative orders comprise the legal framework that defines the Federal government's use of standards, and its participation in the development of standards.

2. Statutes and administrative requirements that contain provisions addressing standardization policies, standards development, use, and related government engagement include:
   - National Technology Transfer and Advancement Act of 1995[1]
   - Office of Management and Budget Circular A-119 of 1998[2]
   - Federal Engagement in Standards Activities to Address National Priorities. Background and Proposed Policy Recommendations. Subcommittee on Standards, National Science and Technology Council of 2011[3]
   - Principles for Federal Engagement in Standards Activities to Address National Priorities. Memorandum from Executive Office of the President for Heads of Executive Departments and Agencies of 2012[4]

Sources: 1. National Technology Transfer and Advancement Act (NTTAA). URL: http://www.nist.gov/standardsgov/nttaa-act.cfm
2. Office of Management and Budget (OMB). Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities. URL: http://www.nist.gov/standardsgov/omba119.cfm
3. Executive Office of the President. National Science and Technology Council. Federal Engagement in Standards Activities to Address National Priorities. Background and Proposed Policy Recommendations Subcommittee on Standards. Washington, DC. October 10, 2011. URL: http://www.nist.gov/standardsgov/upload/Federal_Engagement_in_Standards_Activities_October12_final.pdf
4. Principles for Federal Engagement in Standards Activities to Address National Priorities. Executive Office of the President, Office of Management and Budget, United States Trade Representative, Office of Science and Technology Policy. Memorandum for for Heads of Executive Departments and Agencies, 2012. URL: http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08.pdf

National Technology Transfer and Advancement Act of 1995 (NTTAA)

1. The NTTAA's goal is to adopt voluntary consensus standards, wherever possible, in lieu of creating proprietary, non-consensus standards by federal agencies [1]

2. NTTAA directs:

    ➢ federal agencies with respect to their use of and participation in the development of voluntary consensus standards

    ➢ the National Institute of Standards and Technology (NIST) to coordinate the standards and conformity assessment activities of federal agencies, as well as state and local governments with the private sector in order to reduce unnecessary duplication and complexity of conformity assessment schemes

3. Progress towards accomplishing NTTAA aims is summarized in annual reports prepared by NIST, in collaboration with the Interagency Committee on Standards Policy (ICSP).

Source: 1. National Technology Transfer and Advancement Act (NTTAA). URL: http://www.nist.gov/standardsgov/nttaa-act.cfm

OMB Circular No A-119.

Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.

The OMB Circular No A-119 for Heads of Executive Departments and Agencies[1] :

1. Guides Federal agencies on the NTTAA implementation
2. Establishes policies on Federal use and development of voluntary consensus standards and on conformity assessment activities
3. Establishes reporting requirements, and authorized the National Institute of Standards and Technology (NIST) to coordinate conformity assessment activities of the agencies
4. Issues guidance on responsibilities of Agency Heads and Agency Standard Executives in development and implementation of standards.

Guidance on National Standardization Policies

1. Federal executive departments and administrative agencies write standardization policies and regulations to implement the authority of laws. They act in a scope that is authorized by Congress.

2. The Office of the President, as authorized by Congress,
   - guides the U.S. government to coordinate agency standards activities and engagement
   - recognizing the integrity of the existing U.S. standards process, guides agencies on their roles **as active participant** in standards development and **as user** of the standards for regulation and procurement [1,2]

3. Government Leadership in Select Technology Areas.
   - "In a limited number of specific cases, such as cybersecurity, **health IT**, smart grid and public safety communications, the Federal government has taken on a leadership role in private sector standards development."[3]
   - Based on the federal regulatory guidance, federal agencies, acting in a scope of their authority, shell coordinate and lead development of data standards that used in health IT area.
   - CDC takes a leadership in health IT standardization in a scope of it's authority "to protect America from health, safety and security threats, both foreign and in the U.S.."[4]

Sources: 1. Executive Office of the President. National Science and Technology Council. Federal Engagement in Standards Activities to Address National Priorities. Background and Proposed Policy Recommendations Subcommittee on Standards. Washington, DC. October 10, 2011. URL: http://www.nist.gov/standardsgov/upload/Federal_Engagement_in_Standards_Activities_October12_final.pdf
2. Principles for Federal Engagement in Standards Activities to Address National Priorities. Executive Office of the President, Office of Management and Budget, United States Trade Representative, Office of Science and Technology Policy. Memorandum for Heads of Executive Departments and Agencies, 2012. URL: http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08.pdf
3. Principles for Federal Engagement in Standards Activities to Address National Priorities. Executive Office of the President, Office of Management and Budget, United States Trade Representative, Office of Science and Technology Policy. Memorandum for Heads of Executive Departments and Agencies, 2012. p. 6. URL: http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08.pdf
4. About CDC. Mission, Role and Pledge. URL: http://www.cdc.gov/about/organization/mission.htm

Conformity Assessment and Standardization Policies

- NTTAA and OMB Circular A-119 define the Conformity Assessment as a critical component of national standardization policies and practices

- ISO/IEC Guide 2: 1996, *Standardization and related activities — General vocabulary*, defines Conformity Assessment as "any activity concerned with determining directly or indirectly that relevant requirements are fulfilled."[1]

- Conformity assessment includes sampling and testing, inspection, supplier's declaration of conformity, certification and management system assessment and registration. It also includes accreditation of the competence of those activities by a third party and recognition (usually by a government agency) of an accreditation program's capability. [1]

- In response to the NTTAA and Circular A-119 NIST published regulations entitled *Guidance on Federal Conformity Assessment Activities (15 C.F.R. Part 287)* in August 2000[1]. It helps Federal agencies improve the management and coordination of their own conformity assessment activities in support of their regulatory, procurement and other mission objectives

- CDC has a well-established conformity assessment system for the personal protective equipment that is conducted by the National Personal Protective Technology Laboratory , NPPTL, NIOSH[2].

Source: 1. Guidance on Federal Conformity Assessment Activities (15 C.F.R. Part 287). NIST, 2000. URL:
        http://www.standardsportal.org/usa_en/conformity_assessment/conformity_assessment.aspx
        2. CDC/NIOSH, National Personal Protective Technology Laboratory . URL: http://www.cdc.gov/niosh/npptl/

Publishing the CDC Report on NTTAA/ OMB Circular A-119 Implementation

- CDC annual reports on implementation of NTTAA and OMB Circular A-119 are included into the HHS reports to NIST/OMB
- They are published by NIST at www.standards.gov through the agencies' reporting tool[1]
- They include information on implementation of data standards

Reference:
1. https://standards.gov/NTTAA/agency/index.cfm?fuseaction=agencyReports.main

Examples of 2013 CDC Standardization Efforts

1. Supporting the ONC efforts on facilitation of the Health IT Standardization (http://wiki.siframework.org/)
   - Participation in the ONC Standards and Interoperability (S&I) Public Health Reporting Initiative (PHRI)
   - Supporting the ONC S&I Structured Data Capture through the PH Tiger Team
   - Supporting the ONC S&I Health eDecisions

2. Adding standards into CDC regulations
   - National Institute of Occupational Safety and Health, NIOSH, conformity assessment activities[1]
   - NIOSH efforts on collection and use of nonfatal workplace violence information from the National Crime Victimization Survey[2]
   - National Center for Health Statistics, NCHS- proposed data collection changes for the National Health Interview Survey[3]

3. Collaborating with Standards Development Organizations (SDOs)
   - Center for Chronic Disease Prevention and Health Promotion, NCCDPHP, HL7 Version 2.5.1 Implementation Guide (IG) : Height and Weight Report, Release 1 - US Realm, 2013[4]
   - NCDPHP. IHE: Quality, Research and Public Health (QRPH), Technical Framework Supplement. Healthy Weight (HW). Trial Implementation. 2013[5]
   - National Center for Health Statistics
     - HL7 Version 2.5.1 IG: Birth & Fetal Death Reporting, R1 (US Realm – DSTU) [6]
     - HL7 Version 2.5.1 IG: Vital Records Death Reporting, R1 (US Realm – DSTU) [6]
     - IHE QRPH Birth and Fetal Death Reporting (BFDR). Trial Implementation. 2013[7]
     - HL7 CDA IG for National Medical Care Surveys in development 2013

Sources:
1. The Scope of a National Framework for Conformity Assessment of Non-respiratory Personal Protective Technologies. Draft. URL: http://www.cdc.gov/niosh/docket/review/docket237A/pdfs/237-A_DRAFTScopeNationalFramework9-12-13.pdf
2. Request for information about collection and use of nonfatal workplace violence information from the National Crime Victimization Survey, 2013. URL: http://www.cdc.gov/niosh/docket/review/docket269/default.html
3. Proposed Data Collections Submitted for Public Comment and Recommendations. National Health Interview Survey (NHIS), (OMB No. 0920-0214, Expiration 3/31/2016)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). URL: https://www.federalregister.gov/articles/2013/09/25/2013-23302/proposed-data-collections-submitted-for-public-comment-and-recommendations
4. HL7 Version 2.5.1 Implementation Guide: Height and Weight Report, Release 1 - US Realm, 2013. URL: www. HL7.org
5. IHE: Quality, Research and Public Health, Technical Framework Supplement. Healthy Weight (HW). 2013 . URL: http://ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_HW.pdf
6. HL7 Vital Records Standards Initiative. URL: http://wiki.hl7.org/index.php?title=PHER_Vital_Records-Related_Activities
7. IHE QRPH Birth and Fetal Death Reporting (BFDR). September 13, 2013. URL: http://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_BFDR.pdf
8. HL7 Project Summary for HL7 CDA IG for National Medical Care Surveys. URL: ttp://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1002

CDC: Development and Maintenance of Data Interchange Standards

- Facilitating CDC-wide development and implementation of standards, CDC Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) collects implemented by CDC programs data interchange standards, classifications and other standardized shared content through the Standard and Interoperability Program [1]
- This reference source is publicly available through the Public Health Information Network website[1]
- CSELS makes updates of this web site on a semi-annual basis

Source: 1. CDC. Public Health Information Network, PHIN. Data Interchange Standards. URL:
http://www.cdc.gov/phin/resources/standards/data_interchange.html

Thank you!

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

Visit: www.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info

Center for Surveillance, Epidemiology, and Laboratory Services (proposed)

Division of Health Informatics and Surveillance (proposed)