# Standardization of Standards

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By Anna Orlova, PhD

In 1898 Yale University graduate Charles Dudley, PhD, looked for a solution to the seemingly intractable problem of building a consensus on standards for industrial materials used on the Pennsylvania Railroad. To sooth the antagonistic attitudes that marred relationships between the Pennsylvania Railroad and its suppliers, Dudley proposed the creation of an innovative system of technical committees. These committees provided representatives from the primary parties with a forum to discuss every aspect of specifications and testing procedures for a given material (steel, paint, etc.).

The goal was to reach a consensus that was acceptable to both producers and to the customers of the railroad. Although many initial meetings ended in failure due to the inflexibility of the parties involved, Dudley's system held considerable promise and later formed the basis for the International Association for Testing Materials (IATM). The association encouraged members to form national chapters. On June 16, 1898, 70 IATM members met in Philadelphia, PA to form the American Section of the International Association for Testing Materials (ASTM). Dudley's call for consensus building, which he articulated in meetings of the American Chemical Society and the International Railway Congress, fell on fertile ground in the engineering community.

ASTM dedicated itself to "the development and unification of standard methods of testing; the examination of technically important properties of materials of construction." The members grappled with two questions that were widely discussed throughout the engineering community at the turn of the 20th century. First, "How could standards for materials contribute to industrial progress?" And second, "How could producers and users of industrial materials reach a consensus on standards?"

## Standards Emerge in Healthcare

Following Dudley's innovation in creating a standards development approach, standards emerged in healthcare as well. Various public and private entities have been involved in developing standards in healthcare, including the professional medical associations that created best practice standards such as clinical and public health guidelines and protocols, as well as business standards.

Many of these professional associations were accredited by the American National Standards Institute (ANSI), formed in 1918, and became standards development organizations (SDOs). For example, the College of American Pathologists originally developed the Systematic Nomenclature for Medicine (SNOMED); the American Medical Association developed the Current Procedural Terminology (CPT) standard; the American Nursing Association developed nursing terminology standards; the Association for the Advancement of Medical Instrumentation created medical device standards; and so on. Governmental agencies also participate in standard development activities, such as the National Library of Medicine, which developed the Unified Medical Language Systems (UMLS).

With the rise of health informatics, the ASTM Committee E31 on Healthcare Informatics was established in 1970 to develop standards related to the architecture, content, storage, security, confidentiality, functionality, and communication of information used within healthcare.

Other specialized healthcare SDOs were created to standardize the use of information and communication technology in healthcare. These include Health Level Seven (HL7); Accredited Standards Committee ACS X12 (administrative data standards); Digital Imaging and Communications in Medicine (DICOM); National Council for Prescription Drug Programs (NCPDP); Clinical Data Interchange Standards Consortium (CDISC) for clinical research standards; and others.

At the International Organization for Standardization (ISO), founded in 1946, the Technical Committee 215 Health Informatics was created in 1998 for "standardization in the field of health informatics, to facilitate the coherent and consistent interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system."[1]

International agencies also develop standards. For example, the World Health Organization (WHO) develops the family of International Classification of Diseases (ICD) standards. International organizations originally focused on information and communication technology, such as the International Telecommunication Union (ITU) and the International Electrotechnical Commission (IEC), have also begun working on standards for healthcare, creating liaisons with healthcare SDOs.

Each of these entities operates various committees and workgroups of experts that produce a variety of standards-related documents, such as guidelines, standard specifications, technical reports, technical specifications, and implementation guides. Each standard is developed through a consensus-based process that consists of the following three phases:

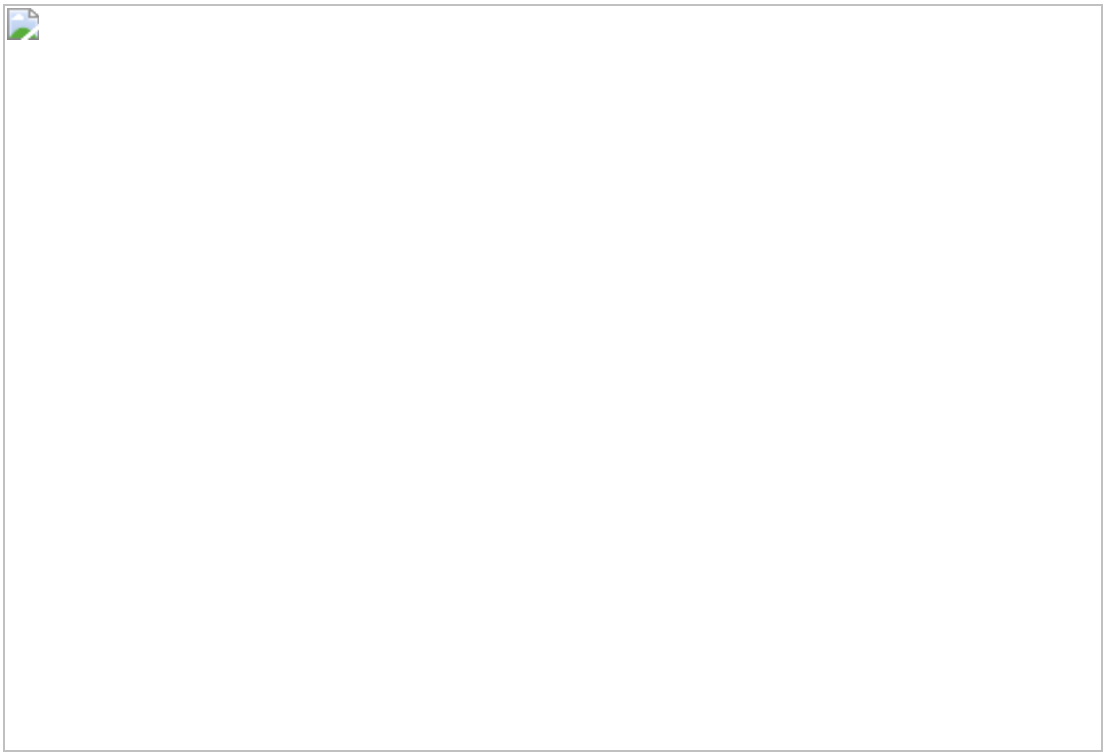
1. Propose New Standard
2. Develop Standard
3. Maintain Standard

All these standards are produced as books, that is, published documents originally distributed as books and now available for download from correspondent SDO websites in PDF format. Some documents are free, others are for sale. Figure 1 below presents examples of data standards (volcabularies and terminology standards) in healthcare. Thousands of various standards in health information technology (HIT) and health informatics have been published in the past 40 years.

The adoption of standards in HIT products has been slow and inconsistent. As the adoption of non-standards based HIT products grew, a critical tipping point was reached when the global community of standards developers and adopters began to realize that this disjointed approach for developing standards should be reconsidered.

### Figure 1: Examples of Data Standards in Healthcare

BELOW ARE EXAMPLES of standards developed specifically for the Data Standards category, one of seven standards categories that includes: Data Standards; Information Content Standards; Information Exchange Standards; Identifier Standards; Privacy and Security Standards; Functional Standards; and Other Standards such as Business Standards (clinical guidelines) and ICT Standards.



## Industry Efforts for Standardization of Standards

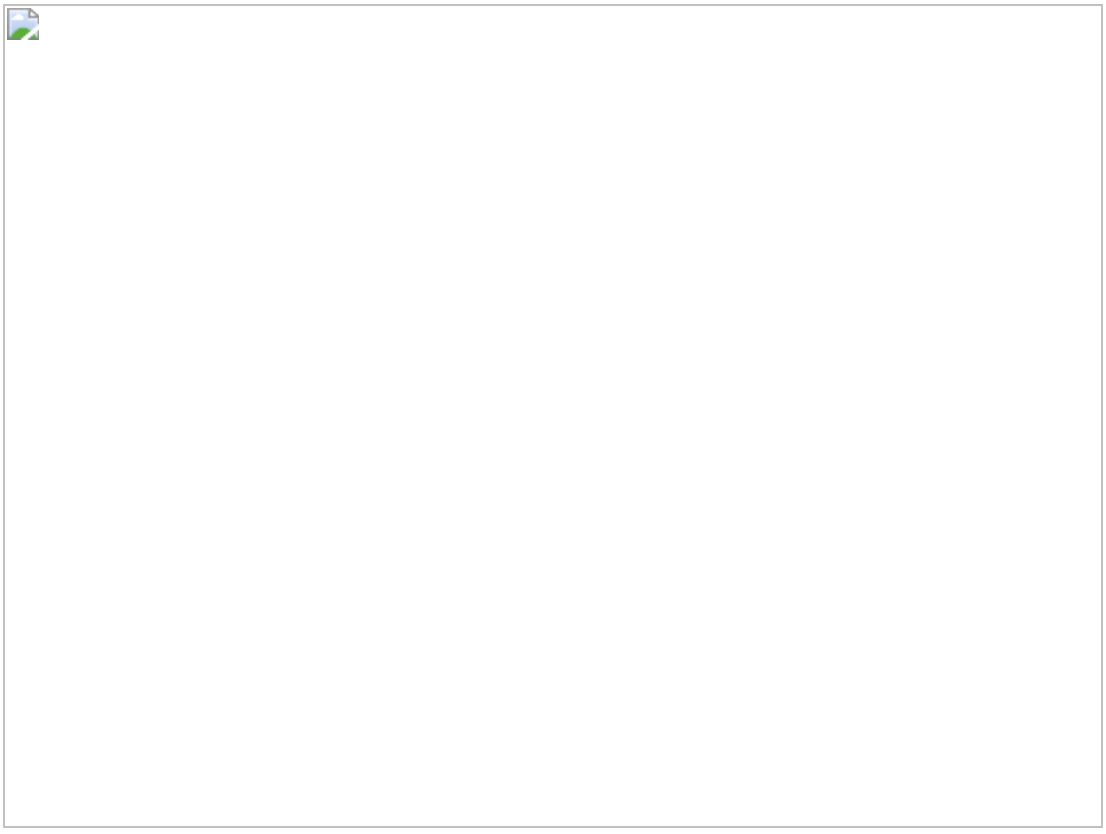
In 1999, based on the success of standardization and interoperability of digital imaging in DICOM, Integrating the Healthcare Enterprise (IHE) was created as a collaborative of HIT vendors, professional associations, and governmental entities. The approach was to assemble individual standards into a portfolio of standards, or technical frameworks, that could work together to support data exchanges for a specific clinical scenario, or use case. In this new approach, the standards portfolio undergoes the following standardization phases as follows:

1. Identify Needs and Priorities for Standards
2. Develop and Maintain Standards
3. Select and Harmonize Standards
4. Test Standards
5. Certify Standards-based HIT Products
6. Deploy Standards-based HIT Products

Adding new phases—"Select and Harmonize" and "Test Standards"—became critical to improving the quality of the individual standards developed by various SDOs. The "Select and Harmonize Standards" phase enabled comparison of individual standards to identify overlaps and gaps in existing standards and provide feedback to the SDOs to improve their standards. The "Test Standards" phase allowed the SDOs to validate the ability of individual standards to work together. The "Certify Standards-based HIT Products" phase is aimed at verifying that HIT products use standards. The "Deploy Standards-based HIT Products" phase validates whether the standards-based HIT product supports user needs for information. Feedback from the latter phase helps to validate the HIT solution and identify the needs and priorities for new standards as needed.

Additional standards documents emerged under these phases, including technical frameworks, integration profiles, content profiles, testing scenarios and reports (integration statements), and certification criteria and statements. Figure 2 below presents the "Standardization of Standards" approach depicting HIT standardization phases, examples of standardized entities, and their products.

**Figure 2: Standardization of Standards Approach: HIT Standardization Phases, Examples of Standardization Entities and their Products**



## Governmental Efforts to Facilitate Standardization

Governments across the globe undertake a range of national approaches to boost the development and adoption of HIT standards. In 2005 the United States' Office of the National Coordinator for Health IT (ONC) adopted an industry approach for the "Standardization of Standards" from the IHE by creating the American Health Information Community (AHIC), Health Information Technology Standards Panel (HITSP), and Certification Commission for HIT (CCHIT)—entities responsible for standardization efforts by phase:

- "Identify Needs and Priorities for Standards," AHIC: Development of the National Use Cases that defined needs and priorities for standards in the context of clinical or public health activities.
- "Select, Harmonize and Test Standards," HITSP: Building Interoperability Specifications that defined standards portfolio (technical framework in IHE terms) for these use cases to enable systems interoperability (i.e., ability to share data).
- The IHE Connectathon has become the industry testing event for standards. Today, Connectathons are held throughout the globe in North America, Europe, Asia, and Australia.
- "Certify Standards-based HIT Products," CCHIT: Creating an approach and infrastructure for the certification of standards-based HIT products.

By 2010, 152 national use cases were developed by AHIC, various interoperability specifications were developed by HITSP, and a certification criteria and approach were developed by CCHIT. ONC further continued standardization efforts under the Standards and Interoperability (S&I) Framework initiative formed in 2010. In the National Interoperability Roadmap, and the 2015 Interoperability Standards Advisory published for public comments in January 2015, ONC has been furthering the approach for standardization of standards through public and private partnership of the HIT industry, healthcare stakeholders, and SDOs.

## Note

[1] International Organization for Standardization (ISO). Technical Committee 215 Health Informatics. http://www.iso.org/iso/iso_technical_committee?commid=54960.

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