





#### **Standards Developers**

#### Katharine Morgan Vice President, Technical Committee Operations



## **ASTM International**

- 12,000+ standards
- 35,000+ members
- 143 technical main committees
- 90+ industry sectors
- ~3,300 standards actions per year
  - 250 new standards, 2000 revisions
- ~5,000 active work items



#### **ASTM International**



#### Coherence is the goal

"In order to avoid the duplication of conflicting international standards, it is important that international standardizing bodies avoid duplication of, or overlap with, the work of other international standardizing bodies. In this respect, cooperation and coordination with other relevant international bodies is essential."

WTO/TBT Committee



# The Road to Coherence is Our Responsibility



- We need to get there
- Respect the work program and intellectual property of other organizations
  - Reference; don't reinvent
  - If existing standard is inadequate, approach SDO of jurisdiction
  - Refer industry requests to more appropriate SDO home if one exists
- Transparency and Coordination
  - Need an inclusive global database of work in progress as well as approved standards
  - Consolidation of standards developers







#### **How Do We Best Serve the Need?**

#### Claire Ramspeck Director of Technology ASHRAE



#### **Standards Coordination and Harmonization**

- SDOs respond to a need
- Effect of competition on standards development
- Obligation of the SDOs, ANSI, and stakeholders to:
  - Survey and publicize
  - Coordinate and harmonize
  - Establish a compelling need
- It's called a *standard* for a reason









## Standards Wars: Myth or Reality? (Yes)

Andrew Updegrove Gesmer Updegrove LLP

## **My Perspective:**

- Over 100 Consortia, plus a few ANSI accredited SDOs
- All manner of technologies: software, semiconductors, hardware, wireless, security, test equipment, and much more
- Often, new consortia are formed to quickly develop and promote a standard that is necessary to create a new product area that is based on the network effect
- Often, multiple technologies compete to address the same opportunity



## Standards Wars vs. Standards Competitions

#### A Standards War arises when:

- A market niche has a "winner take all" culture (e.g., consumer electronics format standards)
- A consensus process fails (IEEE 802.11 example)
- A de facto standard is challenged (or vice versa)
- The marketplace loses
- A Standards Competition arises when:
  - The technologies, the market opportunity, and the standards are all developing at once



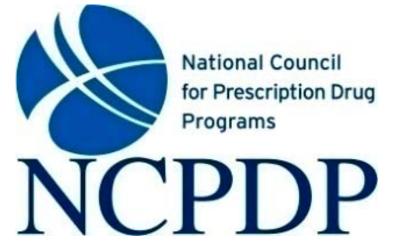
### **Standards Competition Example:**

- The first wireless standards
  - WiFi, Bluetooth, HomeRF all tried to address the same basic need
  - Over time, WiFi and Bluetooth focused on different applications (very successfully), and HomeRF died
  - WiFi and Bluetooth were each further developed to do their jobs even better
  - Other wireless standards were developed to do other jobs (e.g., Nearfield Communications)
- The result: huge new wireless-enabled markets were opened up in record time, and the way we use technology totally changed









#### **Standards Developers**

Lynne Gilbertson VP Standards Development NCPDP

## What is NCPDP?

- An ANSI-accredited standards development organization.
- Provides a forum and marketplace for a diverse membership focused on health care and pharmacy business solutions. This includes electronic prescribing solutions.
- Membership includes pharmacies, health plans, processors/payers, clearinghouses, prescribers, manufacturers, and system vendors that support many aspects of these entities.
- A member driven organization that has been named in various government legislation and rulings, such as HIPAA, Medicare Modernization Act, Healthcare Reform.
- One of several Standards Development Organizations (SDOs) involved in Healthcare Information Technology and Standardization.
- Focus on pharmacy services, and has the highest member representation from the pharmacy services sector of healthcare.

\* HIPAA - Health Insurance Portability and Accountability Act of 1996



#### Pharmacy and ePrescribing Industry Drivers

- Business needs requiring champion(s)
  - To either solve a problem for which a standard does not exist or
  - To address situations where one (or more) proprietary standards have been created and there is a desire to create an industry standard
  - Follow the money
- Regulation (may be state, often federal)
  - When industry is involved ahead of time, the regulations may be in sync with industry usage
  - When industry is not involved ahead of time *Katie bar the door. The pharmacy industry can express their needs very strongly. Much time can be wasted trying to make something "work" after the fact.*
  - Difficulty with 51 states doing things differently
  - As a rule, the pharmacy industry does not seek out regulation to force adoption of standards. Business need is the usual successful driver. *The pharmacy industry can be unusual in healthcare because of this.*



## **Coordination in Healthcare**

- Is often a challenge
  - There may be regulation(s) that already names a standard, which might limit options or may frame harmonization goals
  - Overlapping environments may have grown from different perspectives (focused standards, financially-based origins, impact from other countries where healthcare operations are different)
  - Where standards have already been adopted, to change to another standard requires business justification and return on investment (ROI).
    - Example: Harmonization of Gender effort SDOs created crosswalks verses changing the existing, established, standards.



## **Coordination in Healthcare**

- Different perspectives
  - Building transactional exchanges (bottom up) versus model-based (top down)
  - Different healthcare settings often precipitate different formats (integrated hospital settings versus retail pharmacy), mode of transmission (real-time versus batch)
  - Difficulty with expression and exchange of coded concepts of healthcare. The perspective may be very different.
    - Example: the medication a prescriber chooses for a prescription versus the medication that a pharmacy dispenses.
    - Example: the site of the body for a patient to apply a medication versus the site of the body for surgical requirements



## **Coordination in Healthcare**

- There are challenges to standards organizations
  - Built on different business and financial models
  - Protection of standards development work and intellectual property
  - Recognize the voluntary effort of healthcare companies. In some cases SDOs are pulling from the same pool. In other cases volunteers wish to work on a focused solution before committing.
  - Operating in a global world, but healthcare business and operations in the USA are different.
- Where there have been focused needs, with focused champions, coordination has occurred in projects between organizations.
  - *Example: A standard has adopted another standard inside a given transaction sharing the development work to harmonize the exchange of like information.*
- There are (and have been) focused efforts to address the vocabulary needs. *But there are many needs*.









#### Cycle of Innovation in the ICT Sector

Karen Higginbottom JTC 1 Chairman

#### **Market Driven Standards**

- "in the home" technology highlighted the debate
- ICT standardization highly competitive
- Who chooses?
- JTC 1 develops standards that integrate ICT technologies
  - Publicly Available Specifications
  - Fast Track Process
- Interoperability a strong motivator
- Innovation a key driver of great standards
- Purpose of the National Body process to judge the value



## JTC 1 Resolution 49 – November 2008

#### **Clarification on Consistency of Standards vs Competing Specifications**

- JTC 1 notes the nature of standardization is to attract innovative ideas from multiple sources, choose the best ones and codify them in specifications that facilitate widespread use.
- Further, consistent with ISO's and IEC's "one standard" principle (for example TMB's policy and principle statement on Global Relevance), there are times when one standard is all that is required to meet the needs of the marketplace, especially in a particular application area, and there are other instances where multiple standards make the most sense to respond to market requirements and to the needs of our society. In reducing the number of alternatives to a reasonable minimum, JTC 1 and other SDOs have demonstrated that it is not necessary and may not be desirable to choose only one alternative or option for standardization.
- Further, JTC 1 notes that the cycle of innovation in the ICT sector has resulted in the continuous introduction of new technologies that improve upon existing standards. Any attempt to choose only one standard would ignore and threaten to inhibit the cycle of innovation that continues to fuel this industry.
- Therefore, JTC 1 recognizes its commitment to ISO's and IEC's "one standard" principle; however, it recognizes that neither it nor its SCs are in a position to mandate either the creation or the use of a single standard, and that there are times when multiple standards make the most sense in order to respond to the needs of the marketplace and of society at large. It is not practical to define, a priori, criteria for making these decisions.

Therefore each standard must be judged by the National Bodies, based on their markets, on its own merits.

Unanimous

