

## What is a Standard?:

"A standard is a document, established by consensus that provides rules, guidelines or characteristics for activities or their results" - ISO

## Purpose of Standards:

"Standardization in the field of Information for Health, and Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between independent systems. Also, to ensure compatibility of data for comparative statistical purposes (e.g. Classifications), and to reduce duplication of effort and redundancies." -ISO

This essentially means,

- To enable different software to work together and exchange data
- To help gather and compare statistics about different healthcare services
- To make all this possible without wasting too much human effort by re-inventing the wheel

## Main Organizations:

- ISO (International Organization for Standardization)
- CEN (European Committee for Standardization)
- HL7 (Health Level 7)

Another main organization working in the health informatics standards arena is the DICOM Committee that is part of the NEMA Medical organization.

There are also many other standardization efforts by different groups like ASTM, NCPDP, IEEE, EDIFACT, ADA, ANA, ICD, CPRI-HOST, LOINC, NCCLS etc that focus on some limited part of healthcare.

## ISO (International Organization for Standardization):

Medical Informatics Standards are dealt with by TC 215 (Technical Committee 215) of ISO and its activities are divided in to five streams which are managed by working groups. These are:

- WG1 Data structure
- WG2 Data interchange
- WG3 Semantic content
- WG4 Security
- WG5 Health cards
- WG6 Pharmacy and medicines business
- WG7 Devices
- WG8 Business requirements for an EHR

There is an additional task force for DICOM which liaises with DICOM Committee.

## CEN (European Committee for Standardization)

TC 251 (Technical Committee 251) handles everything concerned with medical informatics. TC 251 is again divided in to working groups.

- CEN WG1 Information models
- CEN WG2 Terminology and knowledge representation
- CEN WG3 Security, safety and quality
- CEN WG4 Technology for interoperability

### **HL7 (Health Level 7):**

HL7 has developed a model for interaction between software applications in the healthcare domain. This model works at the seventh level of the network model ISO OSI.

The work of HL7 is again divided in to many committees and special interest groups.

### **Developing a Standard:**

People involved in developing standards are those who:

- Sell products that conform to a standard
- Buy those products
- Collect taxes when someone buys something from another
- Are in competition with any of the above
- Are academic experts largely innocent of the above dynamics

### **Here is how CEN works for developing a standard:**

1. If a standard is needed in some area CEN has three methods for getting one,
  - Ask ISO to do it
  - Adopt a standard made elsewhere
  - Convene a CEN TC to draft a new standard
2. TC 251 prepares a document and circulates it
3. The work is assigned to some consortium
4. Interim reports (IRM) about progress of the work
5. First working draft (FWD) is circulated for comments
6. Final version (FFV) after all the serious comments have been resolved
7. FFV goes for vote at the full TC 251 meeting
8. If the FFV is accepted it becomes a European Pre-standard (ENV)
9. ENV adopted and tested at one or more sites
10. Accepted as full standard

### **Standards: The other side:**

- Standards create markets
- Standards protect against customer lock-in
- Standards create customer lock-in that the customer will accept
- Standards are a marketing tool
- Standards act as trade barriers

The main reason standards are so wonderful is that there are so many to choose from - Anonymous.

Useful Links:

ISO : <http://www.iso.org>

CEN : <http://www.cenorm.be>

HL7 : <http://www.hl7.org>

DICOM : <http://medical.nema.org>