



**International Organization
for Standardization
TC 215 Health Informatics**

**Professor Yun Sik Kwak
ISO/TC 215 Chair**

Topics

- Introduction to ISO TC 215, Health Informatics

Definitions

Structure

Membership

Working Groups

International Liaisons

- Support for health informatics
- Future – Next Steps

**ISO/TC 215 Health Informatics
Executive Council
(HOD's-Conveners-Vice Conveners)**

Infrastructure Working Groups

**WG 6
Pharmacy
&
Medication**

**WG 1: Data
Structure**
(Definitions,
Frameworks and
Models, Templates,
Data Sets)

**WG 2: Data
Interchange**
(Harmonization and
Adaptation of Clinical
and Administrative
Messages)

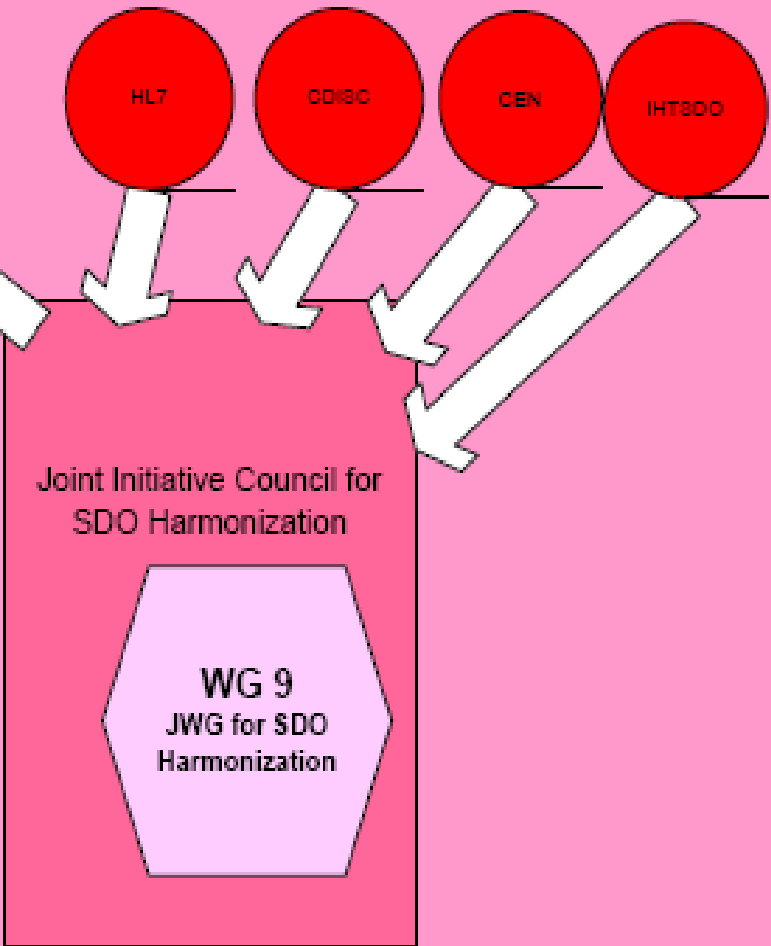
**JWG Harmonized
for Devices**

**WG 7
Devices**

**WG 3: Semantic
Content**
(Terminology,
Knowledge
Representation)

**WG 4: Privacy,
Security &
Patient Safety**
(Confidentiality, Integrity
and Availability,
Accountability, Security
Management, Information
Systems Safety)

**WG 8
Bus/Req
for EHR**



**e-Business for
Healthcare
Transactions
TF**

**Health Cards
TF**

**Multi-
Disciplinary
TF**

ISO/TC 215 Health Informatics

Chair : Yun Sik Kwak, MD, PhD (Korea/USA)

Secretariat : ANSI (USA) Delegated to HIMSS

Secretary : Audrey Dickerson, MS, RN (HIMSS, USA)

Scope :

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 TC 215 Membership

'P' (Participating) Member Bodies = 26

Africa : None

N America : Canada USA (Secretariat)

S America : Brazil

Asia : China Japan Korea Malaysia

Europe : Austria Belgium Denmark Czech Republic
Finland France Germany Ireland Italy
Netherlands Norway Russian Federation
Serbia Spain Sweden Turkey
United Kingdom

Oceania : Australia New Zealand

ISO TC 215 Membership

'O' (Observing) Member Bodies = 21

Africa : Kenya South Africa Zimbabwe

South America : Argentina Ecuador

Asia : Hong Kong India Iran Mongolia
Singapore Thailand

Europe : Bulgaria Croatia Cyprus

Hungary Israel Poland
Portugal Slovakia
Switzerland Ukraine

Definitions used in the TC

- Technical committee (TC) : International group unified with specific knowledge of the core elements related to a specific topic.

This TC is: Health Informatics

- Working group: Division within the TC working in one topic area (TC 215 has 8)

Example: Security

- Project leader: Assigned for coordination during development for each new work item

ISO Deliverables

- IS – International Standard
 - Used for RFP references
 - Governmental regulations
 - Used in Manufacturing specifications
- TS – Technical Specification
 - Used when agreement for IS is not possible
- TR – Technical Report
 - Information on a single topic
 - Guide for implementation of a standard

ISO/TC 215 Officer Structure

- Chairman: Responsible for the overall strategic management of the TC, including working groups; works closely with secretary to ensure management of the work program.
- Secretariat: Responsible for project management, timely progress, establishing and maintaining TC's liaisons, general advice for the TC program and adherence to ISO directives.

TC Operations Meetings

- Executive Council:
 - TC Governance group
 - Members are: Heads-of-delegation, WG Convenors and Vice-convenors
- Operations and Harmonization (for internal documents)
 - TC internal document harmonization
 - Members are: WG convenor, Vice Convenor and Secretary.

ISO/TC 215 Harmonization Work with other SDOs

- Joint Initiative Council
 - Governance
 - Members: 3 or 4 leaders with each participating SDO
 - Meetings: Face-to-Face meeting held during any of the SDO meetings
 - Conference Calls: each month
 - Current Chair: Ed Hammond, HL7

ISO/TC 215 WG Leadership

- Working Group (WG) Convener:
 - Responsible for the progress of the work items within their respective working group
- Vice-Convener of Working Group
 - Assists the Convener
 - If the convener is absent, runs the meeting
 - Chairs task groups within the workgroup
- Working Group secretary
 - Manages WG documents except ballots

ISO TC 215 WG 1

Data Structure

- **Convenor** : Grant Gillis (Canada)
- **Scope** : To develop standards that establish the structure of health information in order to facilitate the sharing of information and data among enterprises, organizations, and information systems. These standards establish the definitional, context, organization (framework and models), relationship, and template requirements for health information and associated data sets.

ISO TC 215 WG 1 Data Content Topics

- **EHR architecture**

- Requirements standards

- **EHR content**

- Definition, scope and content

- **Provider/Patient ID**

- Identification of providers and patients

- **Data Mining**

- Clinical Data Warehouse – data source

ISO TC 215 WG 2

Data Interchange

- Convenor : Mike Glickman (USA)

- Scope :

The means to accomplish messaging and communication in health informatics such that electronic exchange of information between individual systems (clinical and administrative) and organizations (clinical and administrative) is facilitated.

ISO TC 215 WG 2 Data Interchange Topics

- **Clinical Genomics**
 - **Coordinated work with HL7 SIG Clinical Genomics**
- **Health Informatics Methodology**
 - **Data Types (Harmonized standard development)**
- **Adoption of IHE, HL7 and DICOM standards into ISO standards**
 - **IHE framework profiles**
 - **HL7 ANSI approved standards**

ISO TC 215 WG 3

Semantic Content

- **Convenor** : Heather Grain (Australia)
- **Scope** : To develop standards for the semantic representation of content in the health care domain; development and use of ontology's and terminological systems; and representation and management of knowledge.

ISO TC 215 WG 3 Semantic Content

- **Terminology standards for EHR**
 - HL7 Terminology standard for EHR
- **Glossary for ISO/TC 215**
- **Harmonizing terminologies for use in multinational countries**
 - Principles and guidelines documents on harmonized terminologies for use in HIT standards
 - Beginning work on Oriental Medicine terminologies
 - Mapping of terminologies to classifications

ISO TC 215 WG 4 Security

- **Convenor** : Ross Fraser (Canada)
- **Scope** : Defining guidelines for security management in healthcare and defining standards for technical and management measures to 1) protect and enhance the confidentiality, availability, and integrity of health information 2) prevent health information systems from adversely affecting patient safety; and 3) ensure the accountability of users of health information systems.

ISO TC 215 WG 4 Security

- **Security for EHR's**
 - Specific standards for EHR security
 - Pseudonymisation
 - Secure archiving of EHR's
- **Security for Health Informatics**
 - Risk Management for Health Software
 - Classification of Safety risks for health software
 - Measures for assuring patient safety
 - Privilege Management and Access Control
 - Public Key Infrastructure

ISO TC 215 WG 6

Pharmacy and Medication

- **Convenor** : Ian Shepherd (UK)
- **Scope** : To establish standards in the domain of pharmacy and medication e.g. research, development, regulation, supply, use and monitoring to improve the efficiency and interoperability of information systems affecting patient safety. This working group shall provide appropriate domain expertise to ensure that the business requirements for international standards in this area are identified and met by one of the following routes:
 - Co-operation with other organisations that develop standards to encourage development to meet the identified requirements. In some cases this can lead to the adoption of such external standards by ISO in which case this working group is managing the resolution of possible comments and change requests;
 - Co-operation with the other working groups of ISO/TC 215 "Health Informatics" as appropriate; to encourage, the development of new standards for this domain that may need to be coordinated with other health domains and cross-sector standards;

ISO TC 215 WG 6

Pharmacy and Medication

- **Drug Trial standards for use internationally**
 - Japan working with their counterpart to FDA
 - UK working with European Medicines Agency
 - US working with Food and Drug Administration
- **Business requirements for pharmacies**
- **WG 3 and 6 to harmonize on US based terminology for pharmacy – Called MedDRA-managed by Northrop-Grumman**

ISO TC 215 WG 7

Devices

Convener: Todd Cooper (USA)

Scope: Standardization in the application of information and communication technology (ICT) to medical devices for plug-and-play interoperability at the point of care, as well as facilitating the efficient exchange of device data in all health care environments.

ISO/TC 215 WG 7 Devices

- **Messaging standards used for communication between all types of medical devices**
- **Bringing IEEE medical device standards into ISO/TC 215**
- **Harmonizing work between International Electrical Commission (IEC) medical devices and ISO/TC 215**
- **New task group for personal medical device standards**

ISO/TC 215 WG 8 Business Requirements for an EHR

- Convener: Marion Lyver (Canada)
- Scope: Standardization in identification of business requirements for all of the health informatics aspects applied to health records for persons.
- **Business requirements for an EHR**
- **EHR Maps**
- **HL7 Functional EHR model**

WG9 Harmonization

Convener: Don Newsham (Canada)

Joint Working Group is a planning, process determination and coordinating group that makes recommendations to the Joint Initiative Council on resolving gaps, overlaps or issues of counterproductive standardization

- Identifying and analyzing, defining and documenting specific gaps, overlaps, issues and tasks to be addressed;
 - Using use cases and including all parts of the standards life cycle
- Developing, testing and using effective decision processes for international standardization needs; and
 - Developing common processes for harmonization in accordance with participating SDO processes
- Developing an integrated work program amongst the participating SDOs for approval by the Joint Initiative Council, including
 - Collection and summarization of participating SDO work plans;
 - Educating on and building awareness of, relevant standards activity;
 - Reviewing the work plans of participating SDO for purposes of coordination; and determining overlaps, gaps and counterproductive standardization
 - Monitoring and providing feedback on the outcomes of the Joint Initiative.
- Encourage stakeholder engagement and communicate output of the work program.

ISO TC 215

Task force on Health Cards

- Chair: Open
- Scope : To develop standards in field of healthcare usage of machine readable cards compliant with physical characteristics, including dimensions defined in ISO/IEC 7810, Identification cards – Physical characteristics. The WG shall place special emphasis on standards on technology independent data structure leading to inter-operability and compatibility including communication of data.

ISO TC 215 Liaison's

- CDISC – Clinical Data Interchange Standards Consortium
- Continua
- DICOM – Medical Imaging and Technology
- GSI
- ICH – International Classification of Drugs for Harmonization
- ICN-International council for Nurses
- IHE – Integrating the Healthcare Enterprise
- IHTSDO
- IMIA-International Medical Informatics Association
- WHO- World Health Organization
- ISO various Internal ISO Technical Committees and JTC1

How to Participate

- Provide comments on an ISO deliverable by becoming a member of the your Countries (National Member Body-NMB) Delegation
- Participate as an expert
- Provide feedback to appropriate organizations about ISO standards
- Participate in related organizations

Issues

- Global relevance of standards in healthcare
- Participating countries need to work with developing countries
- Standards reaching the marketplace in a timely manner
- Compliance testing
- Quality of service

ISO/CS Support

- Audrey Dickerson, RN, MS, ISO/TC 215 Secretary
 - TC 215 Committee management & general TC support
 - TC work program
 - Balloting NWIP and CD
 - Harmonization
- Atsuko Saruhashi, ISO Technical Programme Manager
Central Secretariat Contact
Coordinates ISO/CS resources for TC's use related to:
 - Procedural questions
 - General work program
 - Balloting of DIS and FDIS drafts
 - Editing/publication

WEBSITES

- ISO General Site

www.iso.org

ISO/TC 215 SharePoint site for TC 215 Members:

<https://portal.himss.org/sites/ISOTC215/default.aspx>

For information on the TC 215 member site contact Mike Kroll at mkroll@himss.org or Audrey Dickerson, TC 215 Secretary at adickerson@himss.org

- Standards specific information

www.iso.org/iso/standards_development.htm