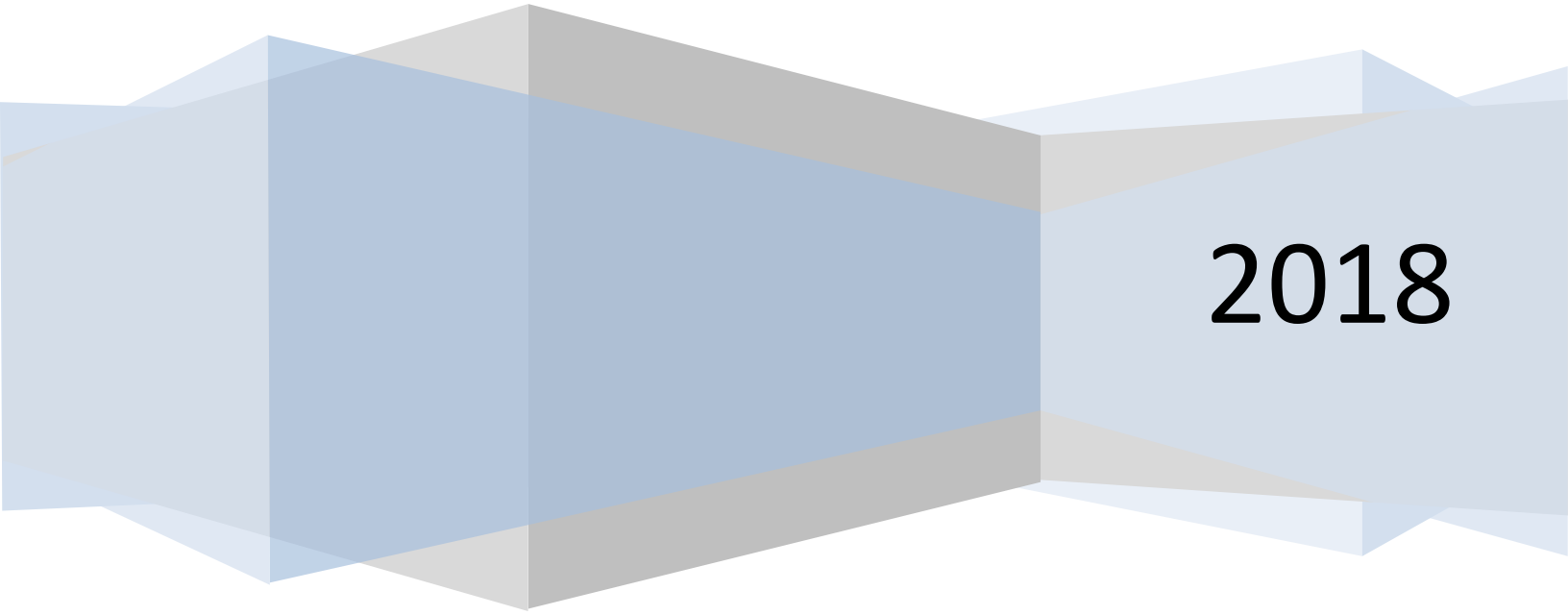
International Organization for Standardization (ISO)
Technical Committee, Health Informatics (TC 215)

ISO/TC 215 Health Informatics Standards and Project Catalog

International Standards, Technical Specifications, Technical Reports



2018

AHIMA, ISO/TC215, and Canada's Mirror Committee

The American Health Information Management Association (AHIMA) represents more than 103,000 health information professionals in the United States and around the world. AHIMA is committed to promoting and advocating for best practices and effective standards in health information and to actively contributing to the development and advancement of health information professionals worldwide. AHIMA is advancing informatics, data analytics, and information governance to achieve the goal of providing expertise to ensure trusted information for healthcare. **www.ahima.org**

The **International Organization for Standardization (ISO)** is the world's largest developer of international standards. Working as a global federation, ISO brings together public and private sectors in more than 160 countries to create consensus standards. To date, nearly 20,000 ISO standards have been published representing the work of more than 250 ISO Technical Committees and thousands of subject matter experts providing standard-based solutions and meaningful benefits for global development. **www.iso.org**

Established in 1998, **ISO Technical Committee 215, Health Informatics (ISO/TC215)** has 60 member countries and liaisons representing millions of healthcare stakeholders worldwide. The **ISO/TC215 mission** is standardization in the field of health informatics to facilitate the capture, interchange, and use of health-related data, information, and knowledge to support and enable all aspects of the health system.

The **Canadian delegation at ISO/TC215** is represented by the **ISO/TC215 Mirror Committee (MC)**, a committee accredited by the **Standards Council of Canada** (https://www.scc.ca/). The MC of TC215 develops and communicates our national positions on ISO standards. Together with the international community and a forum hosted for MC members by the Standards Council of Canada, MC members develop ISO/TC215 international standards including the interoperability standards listed herein. **Canada Health Infoway** is the national digital health agency home for publically available communications, webinars, and other information on ISO/TC215 standards (https://infocentral.infoway-inforoute.ca/en/standards/international/iso).

Since 2011 AHIMA provides Secretariat to ISO/TC215 and serves as Administrator to the US delegation at ISO/TC215 - US Technical Advisory Group (ISO/TC215 USTAG).

ONLINE RESOURCES

ISO/TC215 Website at ISO: https://www.iso.org/committee/54960.html
Canada Health Infoway: www.infoway-inforoute.ca

AHIMA-ISO/TC215 SECRETARIAT

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Foreword

On behalf of the members of Canada's ISO/TC215 Mirror Committee, it is a pleasure to provide this updated Health Informatics Standards Catalog to the health care community across Canada. Recognizing the continuing excellent work by the TC215 Secretariat, presently provided by the American Health Information Management Association (AHIMA), this catalog provides a user friendly and interoperability-focused view into the health informatics standards - published and under development - as of the fall of 2018.

ISO standards are used throughout the health care system and particularly in the digital health community as the foundation for safe, secure, understandable, and accurate sharing of health care data between patients, clinicians, health facilities and organizations, government health ministries and our national health agencies. The standards contained within this catalogue support the foundational, structural, and semantic interoperability of shared health data communication in a secure and private digital environment.

Standards - the agreements for data clarity, accuracy, and safety - are the underpinnings of a health data exchange. The development of these standards is an ongoing process undertaken by a group of volunteer senior and leading practice health informatics experts from Canada and 30 other countries. These globally developed and accepted standards are available for all in our public health care community, in our private sector, and for those vendors and consultants that build, implement, and support the digital solutions for our health data recording, collection, storage, and exchange.

While our standards are developed through a specific set of working groups that are based on the structural components of such digital solutions, such as data frameworks and models, terminologies and semantic content, security and safety, medical devices, etc, it is easier for the digital health professionals and our overall health care community to consider the needed and available standards as part of the interoperability requirements for data sharing and communication.

This Catalog provides an organized listing of the ISO/TC215 standards, sorted by interoperability categories. The categories are the functional, semantic, and technical standards to support interoperability. A more detailed listing of each type of standard is then organized under business and functional; data, information content, and identifier; and information exchange, privacy and security, and safety categories, respectively.

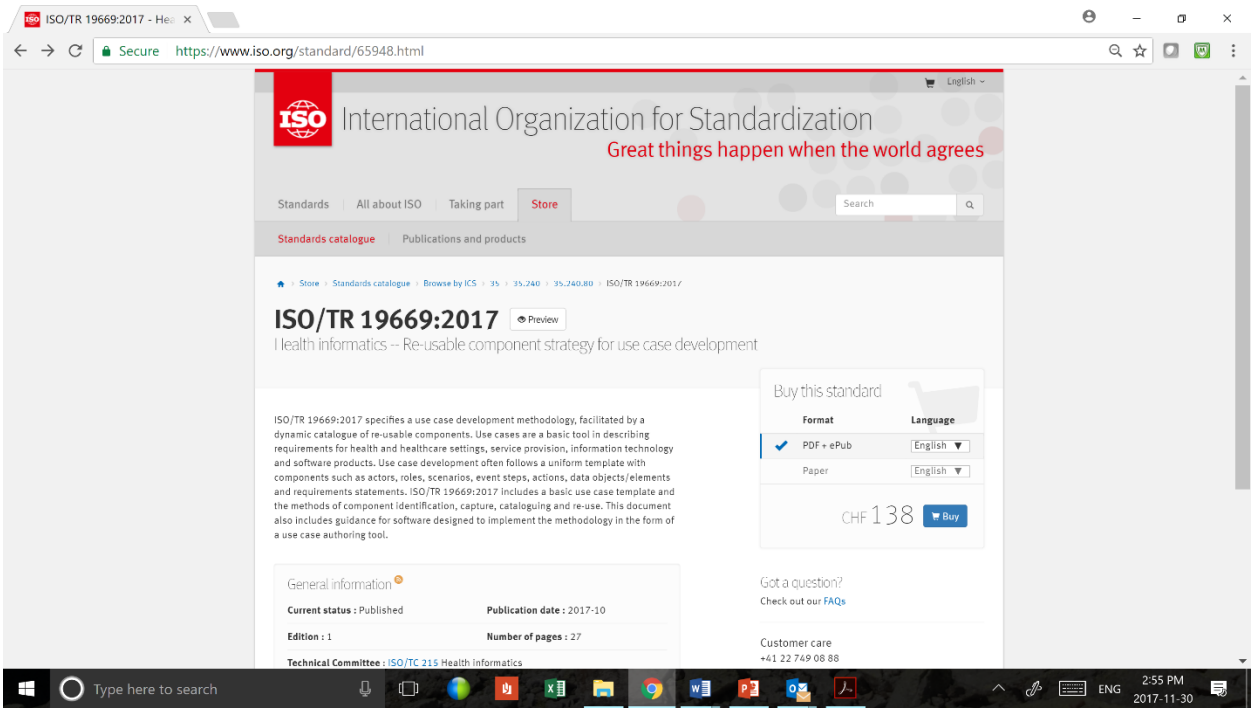
This is a catalog, a listing of standards numbers and titles. An introduction to the standard, with details on the scope, normative references, terms and definitions, and bibliography can be found under the "preview" button of any published health informatics standard on the global ISO website. To find further information about any of the standards contained herein, simply "Google" a particular standard and select the ISO online browsing platform for that standard which will provide the overview and the preview of the standard of interest.

For example, for the *ISO/TR 19669:2017 Health informatics -- Re-usable component strategy for use case development* standard, you can enter and then select in your browser the following:

Enter: “ISO/TR 19669:2017 - Health informatics -- Re-usable component”

Select: https://www.iso.org/standard/65948.html

This will take you to the page shown below. Continuing with the “preview”, you can then learn much more about this standard. The fees and means to acquire the standard are also listed.



1.

The many associations, national agencies, and provincial groups that participate in health information, health informatics, and digital health provide added benefit to their members by participating in the development of these standards and by making this catalog available and accessible. Members from the Canadian Health Information Management Association, Canada Health Infoway, Digital Health Canada, the Canadian Institute for Health Information, the Canadian Nursing Association, the Canadian Medical Association, the Canadian Nursing Informatics Association, the British Columbia Health Information Management Professionals Society, the Alberta Network for Health Information Exchange, and many other associations and agencies, are all encouraged to review and use this catalog.

The best of success and usefulness to everyone in our health care and digital health community:

Don Newsham
ISO/TC215 MC Chair, Head of Delegation

Elizabeth Keller
ISO/TC215 MC Chair and Head of Delegation Elect

Abbreviations

ISO Standards Documents Types

Amd – Amendment
CD – Committee Draft
Corr – Corrigendum
DS – Draft Standard
IS – International Standard
NP – New Proposal
PWI – Preliminary Work Item
TR – Technical Report
TS – Technical Specification

Standards Development Organizations

DICOM – Digital Imaging and Communication in Medicine, URL: http://dicom.nema.org/
HL7 – Health Level Seven International, URL: www.hl7.org/
IEC – International Electrotechnical Commission, URL: www.iec.ch/
IEEE – Institute of Electrical and Electronics Engineers, URL: https://www.ieee.org/
IHE – Integrating the Healthcare Enterprise, URL: https://www.ihe.net/
ISO – International Organization for Standardization, URL: https://www.iso.org/

Executive Summary

This document contains the portfolio of standards developed by the **International Organization for Standardization, Technical Committee 215 Health Informatics** (ISO/TC 215, URL: https://www.iso.org/committee/54960.html), standards development organization (SDO).

ISO/TC 215 develops standards for information and communications technology (ICT) and health information management (HIM) practices in eHealth to support healthcare delivery and public health; ensure secure interoperability between ICT products and integrity of health information and data; and assure patient safety when using ICT products in healthcare.

The **target audience** for ISO/TC 215 standards includes government agencies, healthcare organizations, clinical practitioners, health information managers and researchers, academia, developers, suppliers and integrators of ICT applications and services, and SDOs.

ISO/TC 215's portfolio includes over **200 standards** (published standards and standards [projects] under development)[1] such as International Standards (IS), Technical Specifications (TS) and Technical Reports (TR). These standards are developed by the ISO/TC215 Work Groups (WG) and Joint Work Groups (JWG) as follows:

- WG1 – Architecture, Frameworks, and Models
- WG2 – Systems and Device Interoperability
- WG3 – Semantic Content
- WG4 – Security, Safety, and Privacy
- WG6 – Pharmacy and Medicines Business
- JWG1 – Traditional Chinese Medicine
- JWG7 – Health Software, HIT Systems, and Medical Devices (abbreviated name)

ISO standards development process is a consensus-based process that may take 18, 24, 36, or 48-month depending on the project scope.[2,3]

To initiate a project for a new standard, the country member submits the proposal to the correspondent Work Group that conducts the proposal review. The accepted proposal is registered as a Preliminary Work Item (PWI) in the WG project portfolio and submitted to the full Committee for review and balloting. After successful balloting (5 countries or more agree to participate), the project is registered as a New Project (NP) in the Committee's project portfolio. Different Work Groups and other entities (Committee's liaisons) may participate in the development of the standard as a joint project. During the standard development process, the project undergoes through several stages to allow standard to mature. Upon the completion of each stage, the draft standard goes through the balloting/review by the full Committee. Figure 1 presents the standard development process by stages.

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[1] Number includes updated versions of original standards as well as standards under development.
[2] International Organization for Standardization (ISO). My ISO Job. What Delegates and Experts Need to Know. 2016. URL: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/my_iso_job.pdf
[3] International Organization for Standardization (ISO). Developing ISO Standards. 2017. URL: https://www.iso.org/stages-and-resources-for-standards-development.html

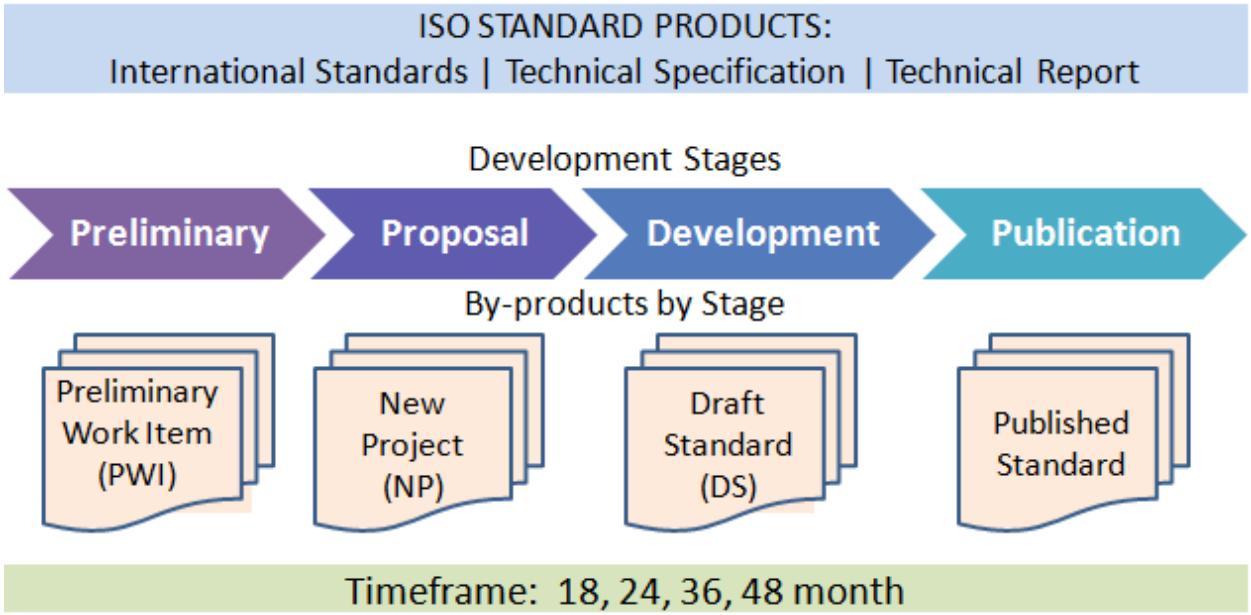

Figure 1: ISO Standards Development Process: Products, Stages, Timeframe

Sections that follow present **ISO/TC215 standards and projects** with standards under development. They are organized by the standards categories listed below.

Health Informatics Standards Categories[4]

Functional Interoperability (Shared Rules)

- Business Standards (business rules, guidelines, practice checklists)
- Functional Standards (interoperability use cases, HIM practice standards)

Semantic Interoperability (Shared Content)

- Data Standards
- Information Content Standards
- Identifiers Standards

Technical Interoperability (Shared Infrastructure)

- Information Exchange Standards
- Privacy and Security Standards
- Health Information Technology (HIT) Safety Standards

[4] US Health Information Technology Standards Panel (HITSP). 2006. URL: www.hitsp.org

Functional Interoperability Standards

Business Standards	
ISO/TR 17119:2005	Health informatics profiling framework
ISO/TR 11487:2008	Clinical stakeholder participation in the work of ISO/TC 215
ISO/TR 12773-1:2009	Business requirements for health summary records -- Part 1: Requirements
ISO/TR 12773-2:2009	Business requirements for health summary records -- Part 2: Environmental scan
ISO/IS 21667:2010	Health indicators conceptual framework[5]
ISO/IS 18308:2011	Requirements for an electronic health record architecture
ISO/TS 14265:2011	Classification of purposes for processing personal health information
ISO/TR 13054:2012	Knowledge management of health information standards
ISO/TR 14639-1:2012	Capacity-based eHealth architecture roadmap -- Part 1: Overview of national eHealth initiatives
ISO/TR 14639-2:2014	Capacity-based eHealth architecture roadmap -- Part 2: Architectural components and maturity model
ISO/TS 13131:2014	Telehealth services -- Quality planning guidelines[6]
ISO/TR 19231:2014	Survey of mHealth projects in low and middle income countries (LMIC)
ISO/TR 17522:2015	Provisions for health applications on mobile/smart devices
ISO/TS 17251:2016	Business requirements for a syntax to exchange structured dose information for medicinal products
ISO/IS 17523:2016	Requirements for electronic prescriptions
ISO/IS 21298:2017	Functional and structural roles
ISO/TR 20055:2018	Person-owned document repository for PHR applications and health information exchange
Under Development	
ISO/TR 20841	Transnational Health Record
ISO/TR 22272	Methodology for enterprise business and information management needs analysis to support standards-based architectures
ISO/TS 22703	Requirements for medication safety alerts
ISO/TS 22756	Requirements for a knowledge base for clinical decision support systems to be used in medication related processes
ISO/PWI 23535	Consumer-oriented health cloud functional architecture

[5] Under revision.
[6] Under revision.

Functional Standards	
ISO/TR 22221:2006	Good principles and practices for a clinical data warehouse
ISO/TS 29585:2010	Deployment of a clinical data warehouse
ISO/IS 27789:2013	Audit trails for electronic health records[7]
ISO/IS 21091:2013	Directory services for healthcare providers, subjects of care and other entities[8]
ISO/TS 17975:2015	Principles and data requirements for consent in the collection, use or disclosure of personal health information
IEC/IS 80001-1:2010	Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities[9]
IEC/TR 80001-2-1: 2012	Application of risk management for IT-networks incorporating medical devices -- Part 2-1: Step by step risk management of medical IT-networks; Practical applications and examples
IEC/TR 80001-2-2: 2012	Application of risk management for IT-networks incorporating medical devices -- Part 2-2: Guidance for the communication of medical device security needs, risks and controls
IEC/TR 80001-2-3: 2012	Application of risk management for IT-networks incorporating medical devices -- Part 2-3: Guidance for wireless networks
IEC/TR 80001-2-4: 2012	Application of risk management for IT-networks incorporating medical devices -- Part 2-4: General implementation guidance for healthcare delivery organizations
IEC/TR 80001-2-5: 2014	Application of risk management for IT-networks incorporating medical devices -- Part 2-5: Application guidance -- Guidance for distributed alarm systems
ISO/TR 80001-2-6: 2014	Application of risk management for IT-networks incorporating medical devices -- Part 2-6: Application guidance -- Guidance for responsibility agreements
ISO/TR 80001-2-7: 2015	Application of risk management for IT-networks incorporating medical devices -- Application guidance -- Part 2-7: Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1
IEC/TR 80001-2-8: 2016	Application of risk management for IT-networks incorporating medical devices -- Part 2-8: Application guidance -- Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2
IEC/TR 80001-2-9: 2017	Application of risk management for IT-networks incorporating medical devices -- Part 2-9: Application guidance -- Guidance for use of security assurance cases to demonstrate confidence in IEC/TR 80001-2-2 security capabilities
ISO/HL7 IS 10781: 2015	HL7 electronic health records system functional model, Release 2 (EHR FM)
ISO/HL7 IS 16527: 2016	HL7 personal health record system functional model, Release 1 (PHRS FM)
ISO/TR 19669:2017	Re-usable component strategy for use case development
ISO/TS 21089:2018	Trusted end-to-end information flows

[7] Under revision.
[8] Under revision.
[9] Under revision.

Under Development	
ISO/IS 22689	Quality management requirements for patient registries
ISO/IS 80001-5-1	Application of risk management for IT-networks incorporating medical device -- Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software -- Part 5-1: Activities in the product lifecycle

Semantic Interoperability Standards

Data Standards	
ISO/IS 17115:2007	Vocabulary of compositional terminological systems[10]
ISO/IS 13606-3:2009	Electronic health record communication -- Part 3: Reference archetypes and term lists[11]
ISO/HL7 IS 27951: 2009	Common terminology services, Release 1
ISO/TR 12309:2009	Guidelines for terminology development organizations
ISO/IS 25720:2009	Genomic sequence variation markup language (GSVML)[12]
ISO/TS 22789:2010	Conceptual framework for patient findings and problems in terminologies
ISO/IS 21090:2011	Harmonized data types for information interchange
ISO/IS 13119:2012	Clinical knowledge resources -- Metadata
ISO/IS 13120:2013	Syntax to represent the content of healthcare classification systems -- Classification markup language (ClaML)[13]
ISO/TS 17439:2014	Development of terms and definitions for health informatics glossaries[14]
ISO/TR 12300:2014	Principles of mapping between terminological systems
ISO/TR 12310:2015	Principles and guidelines for the measurement of conformance in the implementation of terminological systems
ISO/IS 1828:2012	Categorial structure for terminological systems of surgical procedures
ISO/IS 18104:2014	Categorial structures for representation of nursing diagnoses and nursing actions in terminological systems
ISO/TS 18062:2016	Categorial structure for representation of herbal medicaments in terminological systems
ISO/IS 16278:2016	Categorial structure for terminological systems of human anatomy

[10] Under revision with a new title: Representation of categories, constraints and associations between categories needed to express terminology (CatStructure)
[11] Under revision in prep for publication in 2018.
[12] Under revision.
[13] Under revision.
[14] Under revision.

ISO/TS 19256:2016	Requirements for medicinal product dictionary systems for health care
ISO/IEEE IS 11073-10101:2004/Amd 1:2017	Point-of-care medical device communication -- Part 10101: Nomenclature And Amendment 2017
ISO/IEEE IS 11073-10102:2014	Point-of-care medical device communication -- Part 10102: Nomenclature -- Annotated ECG
ISO/IEEE IS 11073-10103:2014	Point-of-care medical device communication -- Part 10103: Nomenclature -- Implantable device, cardiac
ISO/TS 20428:2017	Data elements and their metadata for describing structured clinical genomic sequence information in electronic health records
ISO/TR 20831:2017	Medication management concepts and definitions
ISO/IS 17117-1:2018	Terminological resources -- Part 1: Characteristics
Under Development	
ISO/IS 17117-2	Terminological resources -- Part 2: Implementation capability (TIC)
ISO/IS 17117-3	Terminological resources -- Part 3: Maturity Model (TMM)
ISO/IS 12381	Explicit time-related expressions for healthcare-specific problems
ISO/IS 21393	Omics Markup Language (OML)
ISO/TS 21564	Terminology resource map quality measures (MapQual)
ISO/TR 21835	Health-related data which a person generates daily
ISO/PWI 17583	Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange (Binding)
ISO/PWI 22229	Graphical symbols
ISO/PWI 22218	Ophthalmic examination device data
ISO/PWI 22227	Endoscopy and related data
ISO/PWI 23357	Clinical genomics data sharing specification for next generation sequencing
ISO/PWI 23358	Registration of cardiology device and related data for research
ISO/PWI 23541-1	Categorial structure for representation of 3D human body position system -- Part 1: Bones
ISO/PWI 23536	Elderly homecare system
ISO/PWI 21394	Whole genome sequence markup language (WGML)

Information Content Standards

ISO/IEEE IS 11073-10201:2004	Point-of-care medical device communication -- Part 10201: Domain information model
ISO/TR 20514:2005	Electronic health record -- Definition, scope and context

ISO/HL7 IS 27932: 2009	Data Exchange Standards -- HL7 clinical document architecture, Release 2
ISO/HL7 IS 21731: 2014	HL7 version 3 -- Reference information model, Release 4
ISO/TR 14292:2012	Personal health records -- Definition, scope and context
ISO/IS 20301:2014	Health cards -- General characteristics
ISO/IS 21549-1:2013	Patient healthcard data -- Part 1: General structure
ISO/IS 21549-2:2014	Patient healthcard data -- Part 2: Common objects
ISO/IS 21549-3:2014	Patient healthcard data -- Part 3: Limited clinical data
ISO/IS 21549-4:2014	Patient healthcard data -- Part 4: Extended clinical data
ISO/IS 21549-5:2015	Patient healthcard data -- Part 5: Identification data
ISO/IS 21549-6:2008	Patient healthcard data -- Part 6: Administrative data
ISO/IS 21549-7:2016	Patient healthcard data -- Part 7: Medication data
ISO/IS 21549-8:2010	Patient healthcard data -- Part 8: Links
ISO/TS 27790:2009	Document registry framework
ISO/IS 11239:2012	Identification of medicinal products (IDMP) -- Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
ISO/TR 13128:2012	Clinical document registry federation
ISO/IS 11240:2012	IDMP -- Data elements and structures for the unique identification and exchange of units of measurement
ISO/TS 13972:2015	Detailed clinical models, characteristics and processes
ISO/IS 14199:2015	Information models -- Biomedical research integrated domain group (BRIDG) model[15]
ISO/IS 13940:2015	System of concepts to support continuity of care
ISO/IS 22077-1:2015	Medical waveform format -- Part 1: Encoding rules
ISO/TS 22077-2:2015	Medical waveform format -- Part 2: Electrocardiography
ISO/TS 22077-3:2015	Medical waveform format -- Part 3: Long term electrocardiography
ISO/TS 13582:2015	Sharing of OID registry information
ISO/TS 20440:2016	IDMP -- Implementation guide for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

[15] Under revision.

ISO/IS 11615:2017	IDMP -- Data elements and structures for the unique identification and exchange of regulated medicinal product information
ISO/IS 11616:2017	IDMP -- Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information
ISO/TS 20443:2017	IDMP_-- Implementation guidelines for ISO 11615 Data elements and structures for the unique identification and exchange of regulated medicinal product information
ISO/TS 20451:2017	IDMP -- Implementation guidelines for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information
ISO/IS 11238:2018	IDMP -- Data elements and structures for the unique identification and exchange of regulated information on substances
ISO/TS 19844:2018	IDMP -- Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances
ISO/TS 18864:2017	Quality metrics for detailed clinical models
ISO/TS 19293:2018	Requirements for a record of the dispense of a medicinal product
Under Development	
ISO/TS 21526	Metadata repository requirements (MetaRep)
ISO/TS 22077-4	Medical waveform format -- Part 4: Stress test electrocardiography
ISO/PWI 22077-5	Medical waveform format -- Part 5: Neurophysiological Signals
ISO/TS 22287	Workforce roles and capabilities for terminology and terminology services (TermS)
ISO/PWI 22693	Structured clinical gene fusion report in electronic health records
ISO/PWI 23422	Implementation guide for ISO/TS 19256 -- Requirements for medicinal product dictionary systems for health care
ISO/TS 23261	Requirements for accessing digital medicinal products information by using the existing data carrier

Identifier Standards	
ISO/IS 18232:2006	Messages and communication -- Format of length limited globally unique string identifiers
ISO/TS 27527:2010	Provider identification
ISO/TS 22220:2011	Identification of subjects of health care
ISO/IS 20302:2014	Health cards -- Numbering system and registration procedure for issuer identifiers
ISO/TS 18530:2014	Automatic identification and data capture marking and labelling -- Subject of care and individual provider identification
ISO/TS 16791:2014	Requirements for international machine-readable coding of medicinal product package identifiers[16]

[16] Under revision.

Under Development	
ISO/PWI 14872	IDMP -- Core principles for maintenance of identifiers and terms

In addition, the following are traditional medicine standards focused on quality and safety of natural materials and devices used in traditional medicine and informatics.

Traditional Medicine Standards	
ISO/TS 17948:2014	Traditional Chinese medicine literature metadata
ISO/TS 17938:2014	Semantic network framework of traditional Chinese medicine language system
ISO/TS 18790-1:2015	Profiling framework and classification for Traditional medicine informatics standards development -- Part 1: Traditional Chinese medicine
ISO/TS 16277-1:2015	Categorial structures of clinical findings in traditional medicine -- Part 1: Traditional Chinese, Japanese and Korean medicine
ISO/TS 16843-2:2015	Categorial structures for representation of acupuncture -- Part 2:[17] Needling
ISO/TS 16843-1:2016	Categorial structures for representation of acupuncture -- Part 1: Acupuncture points
ISO/TS 16843-3:2017	Categorial structures for representation of acupuncture -- Part 3: Moxibustion
ISO/TS 16843-4:2017	Categorial structures for representation of acupuncture -- Part 4: Meridian and collateral channels
Under Development	
ISO/TS 16843-5	Categorial structures for representation of acupuncture -- Part 5: Cupping
ISO/TS 21831	Categorial structures for representation of processing Chinese materia medica
ISO/TS 22558	Classification of traditional Chinese medicine datasets
ISO/TS 22773	Categorial structures for representation of decocting process in traditional Chinese medicine
ISO/TS 22835	Categorial structures for representation of combination of Chinese medicine
ISO/TS 23303	Categorial structures for representation of pharmaceutical technology of Chinese materia medica

[17] Part 2 is published before Part 1.

Technical Interoperability Standards

Information Exchange Standards	
ISO/TR 18307:2001	Interoperability and compatibility in messaging and communication standards -- Key characteristics
ISO/IS 18812:2003	Clinical analyser interfaces to laboratory information systems -- Use profiles
ISO/TR 16056-1:2004	Interoperability of telehealth systems and networks -- Part 1: Introduction and definitions
ISO/TR 16056-2:2004	Interoperability of telehealth systems and networks -- Part 2: Real-time systems
ISO/TS 16058:2004	Interoperability of telelearning systems
ISO/IS 17432:2004	Messages and communication -- Web access to DICOM persistent objects
ISO/TR 21730:2007	Use of mobile wireless communication and computing technology in healthcare facilities -- Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices
ISO/IS 13606-1:2008	Electronic health record communication -- Part 1: Reference model[18]
ISO/IS 13606-2:2008	Electronic health record communication -- Part 2: Archetype interchange[19] specification
ISO/IS 13606-5:2010	Electronic health record communication -- Part 5: Interface specification[20]
ISO/HL7 IS 27931: 2009	Data Exchange Standards -- Health Level Seven Version 2.5 -- An application protocol for electronic data exchange in healthcare environments
ISO/IS 12967-1:2009	Service architecture -- Part 1: Enterprise viewpoint[21]
ISO/IS 12967-2:2009	Service architecture -- Part 2: Information viewpoint[22]
ISO/IS 12967-3:2009	Service architecture -- Part 3: Computational viewpoint[23]
ISO/IS 10159:2011	Messages and communication -- Web access reference manifest
ISO/TR 28380-1:2014	IHE global standards adoption -- Part 1: Process
ISO/TR 28380-2:2014	IHE global standards adoption -- Part 2: Integration and content profiles
ISO/TR 28380-3:2014	IHE global standards adoption -- Part 3: Deployment
ISO/IS 12052:2017	Digital imaging and communication in medicine (DICOM) including workflow and data management
ISO/IEEE IS 11073-00103:2015	Personal health device communication -- Part 00103: Overview

[18] Under revision in prep for publication 2018.
[19] Under revision in prep for publication 2018.
[20] Under revision in prep for publication 2018.
[21] Under revision.
[22] Under revision.
[23] Under revision.

ISO/IEEE IS 11073-10404:2010	Personal health device communication -- Part 10404: Device specialization -- Pulse oximeter
ISO/IEEE IS 11073-10406:2012	Personal health device communication -- Part 10406: Device specialization -- Basic electrocardiograph (ECG) (1- to 3-lead ECG)
ISO/IEEE IS 11073-10407:2010	Personal health device communication -- Part 10407: Device specialization -- Blood pressure monitor
ISO/IEEE IS 11073-10408:2010	Personal health device communication -- Part 10408: Device specialization – Thermometer
ISO/IEEE IS 11073-10415:2010	Personal health device communication -- Part 10415: Device specialization -- Weighing scale
ISO/IEEE IS 11073-10417:2017	Personal health device communication -- Part 10417: Device specialization -- Glucose meter
ISO/IEEE IS 11073-10418:2014/Cor 1:2016	Personal health device communication -- Part 10418: Device specialization -- International Normalized Ratio (INR) monitor. And Technical Corrigendum (Cor) 1
ISO/IEEE IS 11073-10419:2016	Personal health device communication -- Part 10419: Device specialization -- Insulin pump[24]
ISO/IEEE IS 11073-10420:2012	Personal health device communication -- Part 10420: Device specialization -- Body composition analyzer
ISO/IEEE IS 11073-10421:2012	Personal health device communication -- Part 10421: Device specialization -- Peak expiratory flow monitor (peak flow)
ISO/IEEE IS 11073-10424:2016 Cor:2018	Personal health device communication -- Part 10424: Device specialization -- Sleep apnoea breathing therapy equipment (SABTE) And Technical Corrigendum 1
ISO/IEEE IS 11073-10425:2016	Personal health device communication -- Part 10425: Device specialization -- Continuous glucose monitor (CGM)[25]
ISO/IEEE IS 11073-10441:2015	Personal health device communication -- Part 10441: Device specialization -- Cardiovascular fitness and activity monitor
ISO/IEEE IS 11073-10442:2015	Personal health device communication -- Part 10442: Device specialization -- Strength fitness equipment
ISO/IEEE IS 11073-10471:2010	Personal health device communication -- Part 10471: Device specialization - Independent living activity hub
ISO/IEEE IS 11073-10472:2012	Personal health device communication -- Part 10472: Device specialization -- Medication monitor
ISO/IEEE IS 11073-20601:2016/Cor 1:2016	Personal health device communication -- Part 20601: Application profile -- Optimized exchange protocol. And Technical Corrigendum 1
ISO/IEEE IS 11073-20101:2004	Point-of-care medical device communication -- Part 20101: Application profiles -- Base standard
ISO/IEEE IS 11073-30200:2004/Amd 1:2015	Point-of-care medical device communication -- Part 30200: Transport profile -- Cable connected and Amendment 1
ISO/IEEE IS 11073-30300:2004	Point-of-care medical device communication -- Part 30300: Transport profile -- Infrared wireless

[24] Under revision.
[25] Under revision.

ISO/IEEE IS 11073-30400:2012	Point-of-care medical device communication -- Part 30400: Interface profile -- Cabled ethernet
ISO/IEEE IS 11073-90101:2008	Point-of-care medical device communication -- Part 90101: Analytical instruments -- Point-of-care test
ISO/IS 11073-91064:2009	Standard communication protocol -- Part 91064: Computer-assisted electrocardiography
ISO/IEEE 11073-10422:2017	Personal health device communication -- Part 10422: Device specialization -- Urine analyser
ISO/IEEE IS 11073-10427:2018	Personal health device communication -- Part 10427: Device specialization -- Power status monitor of personal health devices
ISO/IEEE IS 11073-20702:2018	Point-of-care medical device communication -- Part 20702: Medical devices communication profile for web services
Under Development	
ISO/PWI 22228	Healthcare applications of blockchain technologies
ISO/IEEE IS 11073-10207	Personal health device communication -- Part 10207: Domain information and service model for service-oriented point-of-care medical device communication management

Privacy and Security Standards	
ISO/TR 11633-1:2009	Information security for remote maintenance of medical devices and medical information systems -- Part 1: Requirements and risk analysis[26]
ISO/TR 11633-2:2009	Information security management for remote maintenance of medical devices and medical information systems -- Part 2: Implementation of an information security management system (ISMS)[27]
ISO/TR 11636:2009	Dynamic on-demand virtual private network for health information infrastructure
ISO/TS 13606-4:2009	Electronic health record communication -- Part 4: Security[28]
ISO/TS 21547:2010	Security requirements for archiving of electronic health records -- Principles
ISO/TR 21548:2010	Security requirements for archiving of electronic health records -- Guidelines
ISO/TS 14441:2013	Security and privacy requirements of EHR systems for use in conformity assessment
ISO/IS 22857:2013	Guidelines on data protection to facilitate trans-border flows of personal health data
ISO/IS 17090-1:2013	Public key infrastructure -- Part 1: Overview of digital certificate services
ISO/IS 17090-2:2015	Public key infrastructure -- Part 2: Certificate profile
ISO/IS 17090-3:2008	Public key infrastructure -- Part 3: Policy management of certification authority
ISO/IS 17090-4:2014	Public key infrastructure -- Part 4: Digital Signatures for healthcare documents

[26] Under revision.
[27] Under revision.
[28] Under revision in prep for publication 2018.

ISO/IS 17090-5:2017	Public key infrastructure -- Part 5: Authentication using Healthcare PKI credentials
ISO/IS 22600-1:2014	Privilege management and access control -- Part 1: Overview and policy management
ISO/IS 22600-2:2014	Privilege management and access control -- Part 2: Formal models
ISO/IS 22600-3:2014	Privilege management and access control -- Part 3: Implementations
ISO/IS 27799:2016	Information security management in health using ISO/IEC 27002
ISO/IS 25237:2017	Pseudonymization
ISO/TR 18638:2017	Guidance on health information privacy education in healthcare organizations
Under Development	
ISO/TR 21332	Cloud computing considerations for health information systems security and privacy
ISO/PWI 22696	Guidance for an identification and authentication framework of networked personal health devices
ISO/PWI 22697	Application of privacy management to personal health information

HIT Safety Standards	
ISO/TS 25238:2007	Classification of safety risks from health software
ISO/TR 27809:2007	Measures for ensuring patient safety of health software
ISO/HL7 IS 27953-1:2011	Individual case safety reports (ICSRs) in pharmacovigilance -- Part 1: Framework for adverse event reporting
ISO/HL7 IS 27953-2:2011	Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR
ISO/TR 17791:2013	Guidance on standards for enabling safety in health software
IEC/IS 82304-1:2016	Health software -- Part 1: General requirements for product safety
ISO/TS 20405:2018	Framework of event data and reporting definitions for the safety of health software
Under Development	
IEC/IS 62304	Software life cycle processes
ISO/IS 81001-1	Health software and health IT systems safety, effectiveness and security -- Part 1: Foundational principles, concepts, and terms
ISO/PWI 22690	Reliability assessment criteria for high-throughput gene-expression data
ISO/PWI 22691	Reliability assessment criteria for token-based document sharing
ISO/PWI 22692	Reliability assessment criteria for quality control metrics for DNA sequencing

Interoperability Standards

ISO/TC 215 develops interoperability standards – a Reference Standards Portfolios (RSP) for specific healthcare domains – an assembly of individual standards listed above that work together to enable semantic, technical and functional interoperability between information systems.

Under Development	
ISO/IS 21860	Reference standards portfolio -- Clinical imaging (RSP-CI)

Appendix: Glossary of Terms

General Terms

Standard is a definition, set of rules or guidelines, format, or document that establishes uniform engineering or technical specifications, criteria, methods, processes, or practices that have been approved by a recognized standard development organization (SDO), or have been accepted by the industry as de facto standards, or de jure standards, i.e., formal legal requirements. De facto standards have become standards because a large number of companies have agreed to use them. They have not been formally approved as standards, but they are standards nonetheless.

Standards are technical documents: specifications, integration profiles, content profiles, implementation guides, technical reports and other.

Standardization is the process of agreeing on standards, which represent the common language that allows the exchange of data between disparate data systems. The goals of standardization are to achieve comparability, compatibility, and interoperability between independent systems, to ensure compatibility of data for comparative statistical purposes, and to reduce duplication of effort and redundancies.

Standards Development Organizations (SDOs) are organization that develop and maintain standards. In the US, SDOs are accredited by the American National Standards Institute (ANSI).

Interoperability means the ability to <capture, manage*>, communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings, and exchange data such that clinical or operational purpose and meaning of the data are preserved and unaltered. [29]

Interoperability is based on the following three interoperability components:

1. **Semantic** interoperability—shared content
2. **Technical** interoperability—shared information exchange infrastructure
3. **Functional** interoperability (legal and organizational)—shared rules of information exchanges, i.e., business rules and information governance (“*the rules of the road”*).

Interoperability Standards are special products of standards harmonization activities — a meta-standard (standard about standards), an assembly of standards, an interoperability specification, a reference standards portfolio, etc. — that define how individual standards have to work together to enable interoperability between information systems for a specific healthcare domain (care coordination, radiology, laboratory, pharmacy, data reporting, population health, etc.). Interoperability standards are harmonized and intergrated individual standards constrained to meet healthcare and business needs for sharing information among organizations and systems.[30]

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[29] HL7. Coming to Terms: Scoping Interoperability for Healthcare. White Paper. 2007.
URL: https://www.hln.com/assets/pdf/Coming-to-Terms-February-2007.pdf
*Added by AHIMA to the HL7 definition

[30] The term, **interoperability standards**, was introduced in 2005 by the Health Information Technology Standards Panel (HITSP, http://www.hitsp.org). During 2005-2010 HITSP developed various interoperability specifications for the US National Use Cases created by the American Health Information Community (AHIC).

Standards Categories

Functional Interoperability

Business Standards specify organization's business activities that are elicited via the business process analysis (BPA) used by software engineers to help organizations define their strategic goals and a process to achieve these goals via the means of information technology through internal changes to organizational capabilities including changes to policies and practices.

Functional Standards specify, in an organized format of the functional requirement analysis document (FRAD), the purpose, the participants (actors: business actors – people; and technical actors –information systems), functions (actions), workflow and data flow, non-functional (security, usability, etc.) and technical requirements needed in an information systems and/or software application as defined by a qualified group of users (subject matter experts /stakeholders).

HIT Safety Standards specify foundational principles, concepts, and guidance for health software and health IT system safety across the full IT lifecycle, from requirements gathering to disposal, taking into account the people, technology (hardware/software), organizational policies and practices, and external environment (e.g., legal). These standards collectively address all IT lifecycle stages, the context of HIT use, and focus areas necessary to ensure the safety, effectiveness, and both data and system integrity, security and privacy of health software and health IT systems.

Semantic Interoperability

Data Standards are documented agreements on representations, formats, and definitions of common data. Data standards provide a method to codify in valid, meaningful, comprehensive, and actionable ways, information captured in the course of doing business. **Vocabularies, terminologies, classifications** are data standards.

Information Content Standards specify the content of information exchanges. First level information content standards define the structure and organization of the electronic information content. Second level information content standards define a "package" in which information and data objects are represented, such as in a string, in message-based standards, templates and structured documents in a document-based standards, unstructured text or image.

Technical Interoperability

Identifiers Standards provide a universal method to identify entities [including an individual (consumer), a healthcare provider, a healthcare organization, a payer, or others (clearinghouses, vendors, products, etc.)] and objects [data, information (records, test orders/test results, medication prescription/dispensation), knowledge (rules, clinical pathways, etc.)]

Information Exchanges Standards specify the means of the electronic communication and are referred to as the standard ways of sending and receiving information.

Privacy and Security Standards ensure information security, privacy and confidentiality. *Security* refers to physical, technological, or administrative safeguards or tools used to protect identifiable health information from unauthorized access, use, disclosure, disruption, modification or destruction. Security is the set of actions an organization takes to protect that information. *Security* is an individual's right to control the acquisition, uses, or disclosures of his or her identifiable health data. *Confidentiality* refers to the obligations of those who receive information to respect the privacy interests of those to whom the information relate. It is an organization's responsibility to protect identifiable health information obtained in providing, or as a result of, a service.[31]

[31] Institute of Medicine (IOM). Disposition of the Air Force Health Study. 2006

ISO/TC 215 Standards Types

International Standards (IS) - provides rules, guidelines or characteristics for activities or for their results, aimed at achieving the optimum degree of order in a given context. Apart from product standards, other examples include test methods, codes of practice, guideline standards and management systems standards. [32]

Technical Specifications (TS) – a normative document that addresses work still under technical development, or where it is believed that there will be a future, but not immediate, possibility of agreement on an International Standard. A Technical Specification is published for immediate use, but it also provides a means to obtain feedback. The aim is that it will eventually be transformed and republished as an International Standard. [33]

Technical Reports (TR) – an informative document that may include data obtained from a survey, an informative report, or information of the perceived state-of-the-art. [34]

[32] International Organization for Standardization. ISO Deliverables. International Standards. 2007. URL: https://www.iso.org/deliverables-all.html
[33] Ibid
[34] Ibid. Revised by AHIMA Standards. 2017