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Zdravstvena informatika - Portfelj referenčnih standardov (RSP) - Klinično slikanje (ISO 21860:2020)

Health Informatics - Reference standards portfolio (RSP) - Clinical imaging (ISO 21860:2020)

Medizinische Informatik - Portfolio von Referenzstandards (RPS) - Klinische Bildgebung (ISO 21860:2020)

Informatique de santé - Normes de référence du portefeuille (REEECI) - Imagerie clinique (ISO 21860:2020)

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Health Informatics — Reference standards portfolio (RSP) — Clinical imaging

Informatique de santé — Normes de référence du portefeuille (REEECI) — Imagerie clinique

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee, ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Modern healthcare is supported by medical devices and information systems that capture, manage, exchange, process and present clinical, operational, research and public health data. This occurs at scales from individual clinics and hospital departments, up to networks of hospitals and regional or national healthcare systems. Adopting standards and using them consistently would make it easier to install, operate and, over time, update and replace these devices and information systems.

This document presents a portfolio of standards that have been selected as being mature, fit for purpose and most appropriate to address use cases related to the clinical imaging domain. Clinical imaging is considered throughout the enterprise.

It should be noted, however, that achieving full interoperability within a given environment or set of systems is a large endeavor of which the selection of underlying standards is an important component, but just one component. Additional guidance can be found in the Process clause of the TR on IHE Global Standards Adoption [1].

This document was developed based on concepts and methodology described in the Healthcare Informatics – Reference Standards Portfolio (RSP): Development framework. RSPs are an evolution of past work, such as that done by the Board of Directors of the American Medical Informatics Association[2] and the Joint Initiative Council (JIC) work on the Patient Summary Standards Set[28].

This work reflects the experience and learning of the international community in developing interoperability standards in the clinical imaging domain, including representatives of:

— DICOM®[1)] (Digital Imaging and Communication in Medicine)

— IHE Radiology (Integrating the Healthcare Enterprise)

— ISO/TC215, Health Informatics.

1) DICOM® is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO.

Health Informatics — Reference standards portfolio (RSP) — Clinical imaging

1 Scope

This document establishes the Reference Standards Portfolio (RSP) for the clinical imaging domain (as defined in Clause 4).

An RSP lists the principle health information technology (HIT) standards that form the basis of implementing and deploying interoperable applications in the target domain.

An RSP includes a description of the domain, a normative list of standards, and an informative framework for mapping the standards to example deployment use cases.

The lists do not include standards that are specifically national in scope.

The primary target audience for this document is policy makers (governmental or organizational), regulators, project planners and HIT managers. This document will also be of interest to other stakeholders such as equipment and HIT vendors, clinical and health information management (HIM) professionals and standards developers.

The intended usage of this document is to inform decisions about selecting the standards that will form the basis of integration projects in geographic regions or healthcare organizations. For example:

— What standards to use for capturing/encoding/exchanging certain types of information

— What standards to use for interfaces between the devices and information systems that support information capture, management, exchange, processing and use

— What standards to use for specific use cases/deployment scenarios

The selected standards, and/or corresponding RSP clauses, might be useful when drafting project specifications.

Figure 1 shows the conceptual organization of this document. The top part represents individual HIT standards grouped under semantic, technical and functional interoperability categories. The bottom part shows use cases for example implementation projects with a selected list of standards.

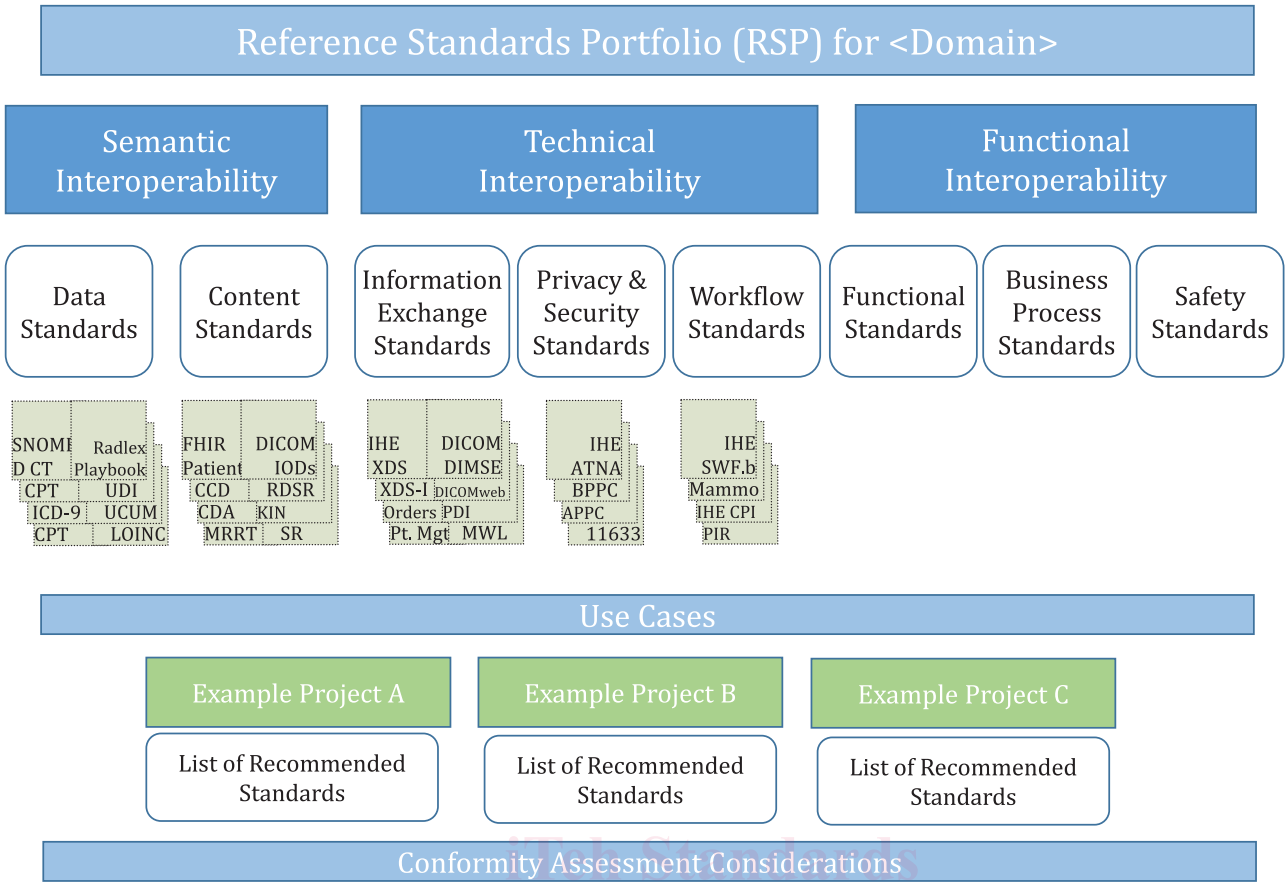

Figure 1 — RSP Organization

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

DICOM PS3, Digital Imaging and Communication in Medicine, Parts 1-22, National Electrical Manufacturers Association

HL7 V2.3.1, HL7 Messaging Standard Version 2.3.1 - An Application Protocol for Electronic Data Exchange in Healthcare Environments, HL7 International

HL7 V2.5.1, HL7 Messaging Standard Version 2.5.1 - An Application Protocol for Electronic Data Exchange in Healthcare Environments, HL7 International

HL7 CDA R2, HL7 Version 3 Standard: Clinical Document Architecture Framework, Release 2, HL7 International

IHE Cardiology Technical Framework, Volumes 1-2 and associated supplements, Integrating the Healthcare Enterprise

IHE IT Infrastructure Technical Framework, Volumes 1-4 and associated supplements, Integrating the Healthcare Enterprise

IHE Radiology Technical Framework, Volumes 1-4 and associated supplements, Integrating the Healthcare Enterprise

ICD-9, International Classification of Diseases revision 9, World Health Organization

ICD-10, International Classification of Diseases revision 10, World Health Organization

ICD-11, International Classification of Diseases revision 11, World Health Organization

LOINC, Logical Observation Identifier Names and Codes, Regenstrief Institute

RadLex, A Lexicon for Uniform Indexing and Retrieval of Radiology Information Resources, Radiological Society of North America

RSNA Radiology Reporting Templates, Radiological Society of North America

SNOMED CT, Systematized Nomenclature of Medicine - Clinical Terms, SNOMED International

UCUM, Unified Code for Units of Measure, Regenstrief Institute

UDI, Unique Device Identification System, US Food and Drug Administration

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
clinical imaging
medical imaging
production of visual representations of body parts, tissues, or organs, for use in clinical diagnosis; encompassing x-ray methods, magnetic resonance imaging, single-photon-emission and positron-emission tomography, and ultrasound

3.2
imaging modality
class of medical device that utilizes a certain physical mechanism, such as x-rays, magnetic fields, ultrasound, or visible light, to detect patient signals that reflect either anatomical structures or physiological events

Note 1 to entry: Imaging modalities include Conventional radiography, Fluoroscopy, Angiography, Mammography, Computed Tomography (CT), Ultrasound and Ultrasound/Doppler, Magnetic Resonance Imaging (MRI) and Nuclear Medicine.

3.3
interoperability
ability to capture, 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

[SOURCE: HL7, Coming to Terms: Scoping Interoperability for Health Care. White Paper, 2007 [39]]

3.4
semantic interoperability
category of interoperability based on standardizing content, where content includes vocabularies, code sets, terminologies, identifiers, information models, composite data structures, data object definitions, and templates

3.5
technical interoperability
category of interoperability based on standardizing infrastructure, including messaging and transport protocols, message sets and sequencing, encryption, certificates, access controls, digital worklists, and status tracking

3.6
functional interoperability
category of interoperability based on standardizing legal and organizational rules, including definitions of business processes, practice guidelines, clinical treatment pathways, business rules, information governance, and safety/risk classification and mitigation

Note 1 to entry: Also referred to by HITSP and HL7®[2] as Process Interoperability.

3.7
reference information model
RIM
single information model that covers the domain of activity being addressed by a standards developing organization using this methodology

[SOURCE: ISO/TS 27790:2009, 3.62]

3.8
reference standard
standard selected as being mature, fit for purpose, and most appropriate to address use cases related to a given domain

4 Clinical imaging domain

The clinical imaging domain spans the systems, data and activities involved in planning, acquiring, processing, managing, distributing, displaying and interpreting imaging data in a clinical context.

The clinical context for imaging can include screening for disease or risk factors, documentation of observations or procedures, diagnosis, treatment (directly image-guided or simply informed or planned from imaging), monitoring of disease progression or response to treatment, palliative care, and research into the causes and treatments of disease.

The operational context for imaging can include administration, operations, and research.

Clinical imaging, also referred to as medical imaging, or diagnostic imaging, is a domain that includes various clinical specialties:

— Radiology (including interventional radiology)

— Cardiology

— Oncology

— Obstetrics/Gynecology

— Orthopedics

— Surgery

— Dermatology

— Dentistry

— Ophthalmology

2) HL7® is the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO.

— Anatomic Pathology

— Emergency Medicine

Clinical imaging encompasses x-ray methods (CT, CR/DR, angiography/fluoroscopy, mammography, etc.), magnetic resonance imaging (MRI), single-photon-emission (SPECT) and positron-emission tomography (PET), ultrasound, visible light (endoscopy, digital microscopy, medical photography, etc.) and optical coherence tomography. The scanners used to acquire these images are referred to as Acquisition Modality Devices or simply "modalities".

Imaging data refers primarily to the images produced by imaging procedures, but also includes associated data such as measurements, and other processing results. Images include single frame images (such as a conventional chest x-ray or a dermatological photograph), volumetric image sets (such as a CT series), "cine" video images (such as from an angiography or ultrasound procedure), multi-dimensional image sets (such as functional MRI volume data over time and different stimuli or a multi-focal multi-filter pathology slide scan). Images might be monochrome, true color or pseudocolor. Measurements include such things as cardiac flow metrics, fetal growth values, tissue perfusion indices, tumor sizes, Computer Aided Detection/Diagnosis findings, and the output of clinical analysis applications. Processing results include spatial registrations of datasets, segmentations, extracted surfaces, implant models, etc. Data might also include associated audio or ECG waveforms and scanned documents such as procedure requisitions.

Clinical imaging information content include test orders, images and test results reports, which have to be generated/shared across various technical actors for use by business actors.

Humans involved in clinical imaging include:

— patients and/or their legal representatives

— referring physicians

— imaging specialty technologists

— imaging specialty physicians

Devices and systems involved in clinical imaging include:

— acquisition modality devices (CT, MR, Ultrasound, Angiography, Mammography, Xray, retinal cameras, slide scanners, etc.)

— data analysis systems (clinical application SW, dose analysis, protocol management, departmental analytics)

— data management systems (PACS - Picture Archive and Communication Systems, VNA - Vendor Neutral Archives, Enterprise Imaging Systems)

— reporting systems (Reading Workstations, Image Display Systems, Report Management Systems)

— departmental systems (RIS – Radiology Information Systems, Cardiology Information Systems, Practice Management Systems, etc.)

— enterprise or practice-level electronic health record infrastructure (EHR – Electronic Health Record Systems, CPOE – Computerized Physician Order Entry Systems for imaging procedures).

The following activities generate data elements that appear in clinical imaging information content but are not inherently clinical imaging data and will be considered in other domains, not in the clinical imaging domain:

— Patient registration and account administration

— Order entry for non-imaging procedures

— Lab test result reporting

The following specialties also use clinical imaging but will also be considered in a separate domain from the clinical imaging domain:

— Radiation Therapy

— Biological Research

5 Portfolio of reference standards

5.1 Usage

Interoperability projects shall use standards listed as preferred or legacy in Table 1 to Table 5 when the scope of that standard applies to the integration project except when alternate standards are locally mandated. Such exceptions shall be described by the project documentation.

Interoperability projects should give due consideration to standards listed as emerging in the tables in this portfolio.

5.2 Portfolio structure

5.2.1 Standard categories

Within this portfolio of reference standards, individual standards are first divided into semantic interoperability, technical interoperability, and functional interoperability [4], and then organized into categories as follows:

Semantic interoperability

— Data standards

  — Define encoding for individual data elements

  — E.g. vocabularies, code sets, terminologies and identifiers

— Content standards

  — Define how content is encoded, e.g. assembled from multiple data elements

  — E.g. reference information models (RIMs), data object definitions, document structures, templates

Technical interoperability

— Information exchange standards

  — Define how content is transferred from one system to another

  — E.g. messaging and transport protocols

— Privacy and security standards

  — Define how content is protected when transferred from one system to another

  — E.g. encryption, certificates, access controls, consent directives, de-identification and pseudonymization

— Technical workflow standards

  — Define sets of transactions between systems and associated data requirements to achieve particular technical tasks

