INTERNATIONAL STANDARD

ISO

21860

First edition
2020-11

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

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

Reference number
ISO 21860:2020(E)

© ISO 2020

COPYRIGHT PROTECTED DOCUMENT

Contents

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.
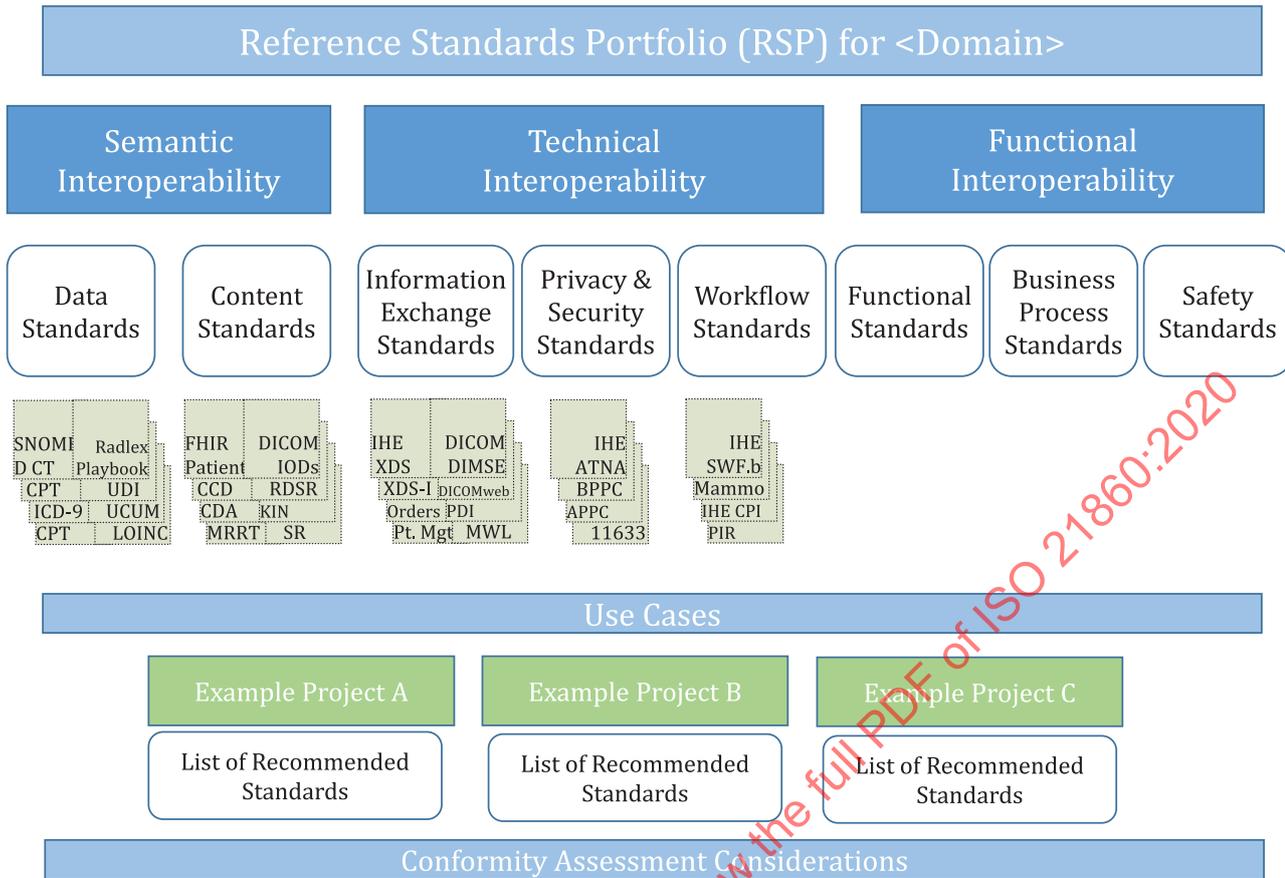
Figure 1 — RSP Organization

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

— E.g. digital worklists, status tracking and notifications, and data flow

Functional interoperability

— <u>Functional standards</u>

— Define procedures for business actors to achieve particular goals

— E.g. functional requirements (procedures, checklists, organizational rules) that an actor would follow to capture, manage, exchange, analyze, present information for a specific use case

— <u>Workflow standards</u>

— Define interactions between business actors to achieve particular tasks

— E.g. functional requirement analysis, evaluation of human users needs in the context of specific use cases

— <u>Business process standards</u>

— Define process interactions between business and technical systems to achieve particular tasks,

— E.g. practice standards, clinical pathways built from guidelines, worklists.

— <u>Safety standards</u>

— Define methods for addressing risks when using HIT products. E.g. criteria for classification and prioritization of risks and best practices for risk mitigation

Many standards do not fit neatly into just one of the above categories. Standards that address multiple categories are listed under their primary category. For example, the DICOM CT Image Storage SOP Class includes the Storage Service (transport protocol), the CT Image IOD ("document"/content), and to a lesser degree defines code sets that include specific SNOMED®[3] and LOINC®[4] codes and introduce a few DICOM codes as needed, but the primary content is the CT image, so it and the other DICOM "Core" IODs are placed in the "Content Standards" category.

5.2.2 Standard assessment

In each category, standards have been assessed and are listed in one table with three groups (See A.4):

— <u>Preferred standards</u> are considered to be stable, well-established and well-supported.

— <u>Legacy standards</u> are widely implemented and deployed but have been superseded by another Preferred standard and no longer represent the long-term direction of the industry. Support in future products might diminish over time.

— <u>Emerging standards</u> are promising and stable but have not yet been widely implemented and deployed. Note that adoption of standards sometimes moves faster than this document is updated.

The factors assessed (See A.3) are:

— <u>Standard maturity</u> – publication, stability, and maintenance status: published draft, trial use, final, retired

---

3) SNOMED® and SNOMED CT® are the registered trademarks of International Health Terminology Standards Development Organization. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO.

4) LOINC® is the registered trademark of Regenstrief Institute. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO.

— Product adoption – international availability in clinical imaging domain products (See Clause 4): none, pilot, low, moderate, high, universal

Product adoption demonstrates Vendor endorsement of this standard

— Site deployment –installation and clinical use at imaging sites: none, pilot, low, moderate, high, universal

Site deployment demonstrates User endorsement of this standard

— Tooling – supported by readily available tools: none, low, moderate, high

Tools might include browsers, viewers, editors, validators, reference implementations, sample data, libraries/toolkits, etc.

Adoption and deployment levels are broad estimates for the combined North American, European, and Japanese regions, based on the subject matter expertise of the contributors to this document. Where uptake is known to differ geographically, this is noted in footnotes.

The specific version/release/edition of the standard that was assessed is usually not listed. Generally, the recommendation applies to recent versions of the standard.

This document does not track the terms for licensing the standards listed here. Those who adopt and/or deploy a standard are encouraged to consult the website of that standard.

5.3   Semantic interoperability

5.3.1   Data standards

Data standards define how to encode data elements or individual pieces of information. This might include vocabularies, code sets, terminologies and identifiers. Such standards commonly restrict themselves to a particular scope or purpose.

Table 1 lists the portfolio of preferred, legacy, and emerging data standards for clinical imaging.

Table 1 — Preferred, legacy, and emerging data standards

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
Preferred data standards					
LOINC	*Logical Observation Identifiers Names and Codes* Identifiers, names, and codes for identifying health measurements, observations, and documents.	Final	Moderate	Moderate	Moderate
UCUM	*Unified Code for Units of Measure* A system to encode units of measure, e.g. for associated quantities.	Final	High	High	Moderate
ICD-10	*International Classification of Diseases* A system of codes for representing medical encounter diagnoses.	Final	Moderate	a	Moderate
DICOM Codes	*DICOM Controlled Terminology Definitions* Codes and definitions for DICOM concepts.	Final	High	High	Moderate
a High in US and Canada, Low elsewhere.					
b Since SNOMED has announced that it will no longer license the use of the RT Identifiers, that standard has been moved to the Legacy group and the SNOMED CT Numeric Identifiers have been listed in the Emerging group even though the adoption and deployment of the Numeric Identifiers have not yet reached the criteria normally required (See A.4).					
See A.3 for terms.					

Table 1 *(continued)*

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
DICOM Context Groups	*DICOM DCMR Context Groups* Sets of codes relevant to coding values for particular DICOM attributes or concepts.	Final	High	High	Moderate
Legacy data standards					
SNOMED CT (RT Identifiers)	*Systematized Nomenclature of Medicine - Clinical Terms – RT Style Codes* b Superseded by SNOMED-CT (Numerical Identifiers)	Retired	High	High	Low
ICD-9	*International Classification of Diseases* Superseded by ICD-10	Final	High	High	Moderate
Emerging data standards					
SNOMED CT (Numeric Identifiers)	*Systematized Nomenclature of Medicine - Clinical Terms* b Codes, descriptions, synonyms and relationships for findings, symptoms, diagnoses, procedures, body structures, organisms, substances, pharmaceuticals, devices and specimens.	Final	Pilot	Pilot	Moderate
RadLex Playbook	*Radiology Lexicon – Procedure Playbook* Names and codes for radiology procedures.	Final	Low	Low	Low
ICD-11	*International Classification of Diseases* Will Supersede ICD-10	Final	Low	Low	Low
UDI	*Unique Device Identifier* Globally unique identifiers for "all implantable, life-saving or life sustaining devices".	Final	Low	Low	Low

a   High in US and Canada, Low elsewhere.

b   Since SNOMED has announced that it will no longer license the use of the RT Identifiers, that standard has been moved to the Legacy group and the SNOMED CT Numeric Identifiers have been listed in the Emerging group even though the adoption and deployment of the Numeric Identifiers have not yet reached the criteria normally required (See A.4).

See A.3 for terms.

5.3.1.1   SNOMED CT®

SDO: SNOMED International [5]

SNOMED CT®[3]) codes are used to populate coded data elements in DICOM instances, in particular for anatomy and materials. For example, (81745001, SCT, "Eye") as the coded value for the Anatomic Region Sequence (0008,2218) data element of an ophthalmic image. SNOMED CT codes are also used in HL7 CDA and CCD documents. SNOMED CT also includes a model of the relationships between the codes. Although DICOM only references the nodes, applications might find uses for the graph that connects the nodes.

SNOMED CT is available in multiple languages.

SNOMED has been licensed nationally by a number of countries. The SNOMED CT terms used in the DICOM Standard (the SNOMED CT DICOM Subset) are the subject of a licensing agreement between NEMA and SNOMED International that allows the use of this defined subset in DICOM conformant applications without further license or payment of fee. Any use of SNOMED CT beyond the terms published in the DICOM Standard is subject to SNOMED CT licensing rules, which might include a fee. For definitive information about SNOMED CT licensing, see http://www.snomed.org/snomed-ct/get -snomed or contact SNOMED International at info@snomed.org.

Implementations making use of these codes shall conform to SNOMED CT.

Tooling: Tools for browsing terms, mapping codes, translating meanings, etc.:

—   https://confluence.ihtsdotools.org/tools

— https://ihtsdo.github.io/

Until 2018, SNOMED codes used in the DICOM Standard followed the older RT Identifiers which used alphanumeric code values. Since 2019, the DICOM Standard uses the newer ConceptID numeric identifiers, however significant numbers of older products and data objects might be encountered that use the older codes. Mappings to the new codes can be found in DICOM PS3.16.

5.3.1.2 LOINC

SDO: Regenstrief Institute [6]

LOINC codes are incorporated in many data elements in DICOM instances, HL7v2 messages and CDA documents to encode the measurement concepts. For example, (2160-0, LN, "Serum Creatinine") to indicate that the subsequent numeric value represents an observation of serum creatinine.

Implementations making use of these codes shall conform to LOINC.

Tooling: Tools for browsing terms, mapping codes, translating meanings, etc.:

— https://loinc.org/downloads/

5.3.1.3 UCUM

SDO: Regenstrief Institute [7]

UCUM codes are incorporated in many numerical data elements in DICOM instances to encode the unit of measure of the value. For example, mg/dl for a serum creatinine value.

UCUM codes are based on ISO 80000:2009 [8].

Implementations making use of these codes shall conform to UCUM.

Tooling: Tools for finding and validating codes:

— https://ucum.nlm.nih.gov/

5.3.1.4 DICOM Codes

SDO: DICOM [9], See PS3.16, Annex D

DICOM Codes are used to encode a variety of concepts inside DICOM instances. DICOM Codes are typically defined for concepts that do not clearly belong in one of the other Data Standards listed here.

Implementations making use of these codes shall conform to DICOM PS3.

Tooling: Code tables downloadable in XML or OWL. Also available through BioPortal in OWL, CSV, and RDF/XML.

5.3.1.5 DICOM Context Groups

SDO: DICOM [9], See PS3.16, Annex B

DICOM Context Groups provide selected sets of codes appropriate for coding values of associated DICOM attributes or DICOM SR Template concepts. The codes are typically drawn from coding schemes like SNOMED, LOINC, UCUM, DICOM, and ICD-10. Many Context Groups include equivalent codes from several coding schemes.

Implementations making use of these codes shall conform to DICOM PS3.

Tooling: Context Group code tables are downloadable in HTML, FHIR JSON, FHIR XML, and IHE SVS XML.

5.3.1.6   ICD-9, ICD-10, ICD-11

SDO: World Health Organization [10]

ICD-9, ICD-10 and ICD-11 are, respectively, the 9th, 10th, and 11th revisions of the International Statistical Classification of Diseases and Related Health Problems. ICD codes are used to encode diagnoses, symptoms, and findings in structured reports and fields such as admitting diagnosis, etc. Various countries publish national variants of the ICD codeset, distinguished by a suffix, e.g. ICD-10-GM.

Since diagnosis is a very significant detail for many types of data analysis and population health, some jurisdictions (e.g. Germany) make the use of ICD codes required for reimbursement.

Implementations making use of these codes shall conform to ICD-9, ICD-10, and/or ICD-11.

Tooling: A variety of free and commercial tools exist for searching, browsing, and mapping ICD codes.

5.3.1.7   RadLex Playbook

SDO: RSNA [11] and Regenstrief Institute [6]

Playbook codes are used in worklists to encode the ordered imaging procedure to be performed. For example, (36244-2, LN, "MR Prostate W contrast IV"). The codes might also appear in images and reports to encode the imaging procedure that was actually performed and reported on. The code might also be used to drive workflow, e.g. standard procedure at a given site might be to perform a 3D reconstruction for all cardiac CT studies.

The codes are managed by RSNA and published as part of LOINC in version 2.6 and later.

Implementations making use of these codes shall conform to Radlex.

5.3.1.8   UDI

SDO: United States Food and Drug Administration (FDA) [12]

The UDI standard is managed by the US FDA in collaboration with other international medical device regulators for use worldwide. UDI codes are administered by several Issuing Agencies, such as GS1, HIBCC, or ICCBBA.

UDI codes identify specific instances of a medical device. Each code combines a device id (DI), which is unique to the manufacturer, make and model, and a production id (PI), which is the serial #, or lot #, or manufacturing date, or expiration date. Each DI is issued by an FDA accredited Issuing Agency. The Issuing Agency chooses a format within certain constraints.

The primary purpose of UDI codes is to facilitate traceability and regulatory management of medical devices, e.g. for postmarket surveillance and recalls. UDI codes of devices used (e.g. scanners, pacemakers, stents) or consumed (e.g. catheters, drugs) during medical procedures can be recorded in the data produced during those procedures, such as images, medication records or procedure logs.

Device labelers ubmit information about each device to FDA's Global Unique Device Identification Database (GUDID). The public can search and download information from the GUDID at *AccessGUDID*:

— https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/
UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm444831.htm

Implementations making use of these codes shall conform to UDI.

5.3.2   Content standards

Content standards define how to encode information content, such as documents, often by assembling multiple data elements. They describe what data is mandatory in a given content structure, what is

optional and sometimes what is not to be included. These standards include object definitions, reference information models (RIMs), document structures, and templates.

Table 2 lists the portfolio of preferred, legacy, and emerging content standards for clinical imaging.

Table 2 — Preferred, legacy, and emerging content standards

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
Preferred content standards					
DICOM "Core" Image IODs	*DICOM Image Information Object Definitions ("Core")* Data structure for encoding image pixels and key metadata, including patient id and demographics, imaging technique, procedure details, order and workflow information.	Final	Universal	Universal	High
DICOM Ophthalmic Photography 8-bit IOD	*DICOM Ophthalmic Photography 8-bit Information Object Definition* Data structure for encoding image pixels and key metadata, including patient id and demographics, imaging technique, procedure details, order and workflow information.	Final	Universal	High	Moderate
DICOM Ophthalmic Tomography Image IOD	*DICOM Ophthalmic Tomography Image Information Object Definition* Data structure for encoding image pixels and key metadata, including patient id and demographics, imaging technique, procedure details, order and workflow information.	Final	Universal	High	Moderate
DICOM Visible Light IODs	*DICOM Image Information Object Definitions ("Visible Light")* Data structure for encoding image pixels and key metadata, including patient id and demographics, imaging technique, procedure details, order and workflow information.	Final	Moderate	Low	Moderate
DICOM Encapsulated PDFs	*DICOM Encapsulated PDF IOD* Data structure for encoding a PDF document in an encapsulating DICOM instance along with key metadata, including patient id and demographics, order and workflow information.	Final	High	High	Moderate
DICOM GSPS	*DICOM Grayscale Presentation State* Data structure for encoding how a specific image should be presented (windowing, zoom, graphical and text annotations, etc).	Final	High	High	High
DICOM SR	*DICOM Structured Reporting* Syntax for constructing general structured, machine-readable documents containing data related to medical imaging. SR templates define specific contents for specific types of documents.	Final	Moderate	Moderate	Moderate
DICOM CT RDSR	*DICOM CT Radiation Dose SR* Data structure (SR Template) for encoding details of x-ray irradiation events and the associated medical imaging procedure.	Final	High	Moderate	Moderate
DICOM X-Ray RDSR	*DICOM X-Ray Radiation Dose SR* Data structure (SR Template) for encoding details of x-ray irradiation events and the associated medical imaging procedure.	Final	Moderate	Low	Low
a Reflects ECG management systems in an imaging context. ECG acquisition devices are more likely to use proprietary formats or alternate standards.					
See A.3 for terms.					

Table 2 *(continued)*

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
DICOM Basic Diagnostic SR	*DICOM Basic Diagnostic Imaging Report* Data structure (SR Template) for encoding a diagnostic report and the associated medical imaging procedure.	Final	Moderate	Low	Moderate
DICOM Echo SR	*DICOM Echocardiography Procedure Report* Data structure (SR Template) for encoding observations, such as measurements, and details of the associated echocardiography procedure.	Final	High	High	Moderate
DICOM Vascular SR	*DICOM Vascular Ultrasound Report* Data structure (SR Template) for encoding observations, such as measurements, and details of the associated vascular ultrasound procedure.	Final	High	High	Moderate
DICOM OB/Gyn SR	*DICOM OB-GYN Ultrasound Procedure Report* Data structure (SR Template) for encoding observations, such as measurements, and details of the associated obstetric/gynecological ultrasound procedure.	Final	High	Moderate	Moderate
DICOM Mammo CAD	*DICOM Mammography CAD SR* Data structure (SR Template) for CAD observations and details of the associated medical imaging procedure.	Final	High	Moderate	Moderate
DICOM KOS	*DICOM Key Object Selection* Data structure (SR Template) for identifying specific DICOM instances and encoding details such as why they have been selected.	Final	Moderate	Moderate	Moderate
IHE KIN	*IHE Key Image Note Profile* Data structure to reference one or more images, flagging them as significant, and add notes. Profiles DICOM KOS.	Final	Moderate	Low	Moderate
HL7 ORU	*HL7 Observation Result* Data structure for encoding imaging results such as a textual diagnostic report and associated metadata.	Final	Universal	High	High
HL7 CDA R2	*Clinical Document Architecture, Release 2* Syntax for constructing clinical documents. CDA templates define specific contents for specific types of documents.	Final	Moderate	Moderate	Moderate
Legacy content standards					
	None listed.				
Emerging content standards					
DICOM Part 20	*Imaging Reports using HL7 Clinical Document Architecture* Data structure (CDA Templates) for encoding diagnostic imaging reports including coded measurements and findings. Profiles HL7 CDA R2.	Final	Low	Pilot	Low
IHE MRRT	*IHE Management of Radiology Report Templates Profile* HTML5 Format for encoding templates used to drive the report authoring process.	Trial	Low	Pilot	Low

^a   Reflects ECG management systems in an imaging context. ECG acquisition devices are more likely to use proprietary formats or alternate standards.

See A.3 for terms.

Table 2 *(continued)*

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
Rad Report	*RSNA Radiology Reporting Templates* A library of templates used to capture radiology report content.	Final	Low	Low	Low
DICOM "Non-Core" Image IODs	*DICOM Image Information Object Definitions ("Non-Core")* Data structure for encoding image pixels and key metadata, including patient id and demographics, imaging technique, procedure details, order and workflow information.	Final	Low	Low	Moderate
DICOM Enhanced Image IODs	*DICOM Enhanced Image Information Object Definitions* Data structure for encoding multi-frame images and extended key metadata in a single object, including patient id and demographics, imaging technique, procedure details, frame organization, order and workflow information.	Final	Low	Low	Moderate
DICOM Encapsulated STL	*DICOM Encapsulated STL IOD* Data structure for encoding an STL 3D model in an encapsulating DICOM instance along with key metadata, including patient id and demographics, and 3D model usage.	Final	Low	Pilot	Low
DICOM ECG IODs	*DICOM Electrocardiogram IODs* Data structure for encoding ECG data and key metadata, including patient id and demographics, acquisition and procedure details, order and workflow information.	Final	Low [a]	Low [a]	Low
DICOM RRDSR	*DICOM Radiopharmaceutical Radiation Dose SR* Data structure (SR Template) for encoding details of radiopharmaceuticals administered for a medical imaging procedure.	Final	Low	Pilot	Low
DICOM IVUS SR	*DICOM IVUS Report* Data structure (SR Template) for encoding observations, such as measurements, and details of the associated intravascular ultrasound procedure.	Final	Low	Low	Moderate
DICOM Cardiac Cath SR	*DICOM Cardiac Catheterization Report* Data structure (SR Template) for encoding observations, such as measurements, and details of the associated cardiac catheterization procedure.	Final	Low	Low	Moderate
DICOM CT/MR Cardiovascular SR	*DICOM CT/MR Cardiovascular Analysis Report* Data structure (SR Template) for encoding observations, such as measurements, and details of the associated cardiovascular CT or MR procedure.	Final	Low	Low	Moderate
DICOM Stress Testing SR	*DICOM Stress Testing Report* Data structure (SR Template) for encoding observations, such as measurements, and details of the associated SPECT, PET, or Echo cardiac stress procedure.	Final	Low	Low	Moderate
DICOM Breast Imaging SR	*DICOM Breast Imaging Report* Data structure (SR Template) for encoding observations, such as measurements, and details of the associated x-ray or ultrasound breast imaging procedure.	Final	Low	Pilot	Moderate

[a]   Reflects ECG management systems in an imaging context. ECG acquisition devices are more likely to use proprietary formats or alternate standards.

See A.3 for terms.

Table 2 *(continued)*

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
DICOM Chest CAD	*DICOM Chest CAD SR* Data structure (SR Template) for CAD observations and details of the associated medical imaging procedure.	Final	Low	Low	Moderate
DICOM Colon CAD	*DICOM Colon CAD SR* Data structure (SR Template) for CAD observations and details of the associated medical imaging procedure.	Final	Low	Low	Moderate
^a Reflects ECG management systems in an imaging context. ECG acquisition devices are more likely to use proprietary formats or alternate standards. See A.3 for terms.					

5.3.2.1   DICOM "Core" Image IODs

SDO: DICOM [9], See PS3.3, Section A

The "Core" Image IODs include CT, MR, XA, XRF, US, MG, DX, CR, NM, PET, Breast Tomosynthesis, Intra-Oral X-ray, and Secondary Capture. While most of these IODs contain images of a particular imaging modality, the Secondary Capture object is used for things like screenshots, clinical result screens, or digitized physical films and typically is missing spatial information or procedure details.

DICOM "Core" Image objects are exchanged between systems (like scanners, PACS and workstations) using DICOM protocols like DICOM C-STORE and WADO-RS. Products claim support for Storage SOP Classes that pair these IODs with the Storage Service.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.2   DICOM Ophthalmic Photography 8-bit IOD

SDO: DICOM [9], See PS3.3, Section A

DICOM Ophthalmic Photography 8-bit image objects are exchanged between systems (like fundus cameras, PACS and workstations) using DICOM protocols like DICOM C-STORE and WADO-RS. Products claim support for Storage SOP Classes that pair these IODs with the Storage Service. There is a related Ophthalmic Photography 16-bit IOD which is much less-widely used.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.3   DICOM Ophthalmic Tomography Image IOD

SDO: DICOM [9], See PS3.3, Section A

DICOM Ophthalmic Tomography Image objects are exchanged between systems (like OCT scanners, PACS and workstations) using DICOM protocols like DICOM C-STORE and WADO-RS. Products claim support for Storage SOP Classes that pair these IODs with the Storage Service.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.4　DICOM "Visible Light" Image IODs

SDO: DICOM [9], See PS3.3, Section A

The "Visible Light" IODs include still image and video objects for endoscopy, microscopy, and medical photography. DICOM Visible Light Image objects are exchanged between systems (like scanners, PACS and workstations) using DICOM protocols like DICOM C-STORE and WADO-RS. Products claim support for Storage SOP Classes that pair these IODs with the Storage Service.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.5　DICOM Encapsulated Documents

SDO: DICOM [9], See PS3.3, Section A.45

Instances of Encapsulated PDF IODs might contain scanned paper documents or PDF renderings of other electronic documents. This is often used to include documents associated with an imaging procedure (such as consent forms, order paperwork, etc.) in the DICOM study folder together with the images. It is sometimes also used for renderings of reports that might include diagrams, charts or other graphics.

DICOM Encapsulated PDF objects are exchanged between systems (like admission systems, scanners, PACS and workstations) using DICOM protocols like DICOM C-STORE and WADO-RS. Products claim support for Storage SOP Classes that pair these IODs with the Storage Service.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.6　DICOM GSPS

SDO: DICOM [9], See PS3.3, Section A.33.1

Systems such as modalities, analysis workstations, and display stations might create and store DICOM Grayscale Presentation State instances so that subsequent displays and print composers can present the referenced instances in the same way. Note that the relative layout of multiple instances on the same screen is addressed by DICOM Hanging Protocols, not by DICOM GSPS.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.7　DICOM SR

SDO: DICOM [9], See PS3.16

DICOM Structured Reporting IODs include the Basic Text, Enhanced, Comprehensive, and Extensible. Other application-specific SR IODs and Templates are listed separately. DICOM SR IODs are used to complement the Image IODs by conveying a wide variety of related data, such as measurements and other metadata.

DICOM SR objects are exchanged between systems (like acquisition devices, analysis workstations, PACS, displays, and clinical databases) using DICOM protocols like DICOM C-STORE and WADO-RS. Products claim support for Storage SOP Classes that pair these IODs with the Storage Service.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.8   DICOM CT RDSR

SDO: DICOM [9], See PS3.16 Template TID 10011

DICOM CT RDSR objects are exchanged are exchanged between CT scanners, archives, dose reporting systems and dose registries. RDSR capability has been available on virtually all new CT scanners since 2012.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.9   DICOM X-Ray RDSR

SDO: DICOM [9], See PS3.16, Template TID 10001

DICOM X-Ray RDSR objects are exchanged between x-ray modalities that perform mammography, angiography, fluoroscopy and projection radiography, and archives, dose reporting systems and dose registries.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.10   DICOM Basic Diagnostic SR

SDO: DICOM [9], See PS3.16, Template TID 2000

DICOM Basic Diagnostic SR objects are exchanged between reporting workstations and report archives. Some systems are capable of converting these reports into HL7 result messages and/or HL7 CDA documents (as described in DICOM Part 20).

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.11   DICOM Echo SR

SDO: DICOM [9], See PS3.16, Template TID 5200

DICOM Echo SR objects are exchanged between image acquisition or post-processing systems and reporting or medical record systems.

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.12   DICOM Vascular SR

SDO: DICOM [9], See PS3.16, Template TID 5100

DICOM Vascular SR objects are exchanged between image acquisition or post-processing systems and reporting or medical record systems.

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.13   DICOM OB/Gyn SR

SDO: DICOM [9], See PS3.16, Template TID 5000

DICOM OB/Gyn SR objects are exchanged between image acquisition or post-processing systems and reporting or medical record systems.

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.14 DICOM Mammo CAD SR

SDO: DICOM [9], See PS3.16, Template TID 4000

DICOM Mammo CAD SR objects are exchanged between mammography computer-aided detection and diagnosis systems and reporting or medical record systems.

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.15 DICOM KOS

SDO: DICOM [9], See PS3.16, Template TID 2010

DICOM Key Object Selection SR objects are produced by modalities, QA or review workstations, and PACS to flag relevant DICOM instances, e.g. for QA follow-up, routing to specialists, etc.

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.16 IHE KIN

SDO: IHE Radiology [13], See Volume 1

IHE KIN lets users flag images as significant (e.g. for referring, for surgery, for QA review, for teaching file, etc.) and add notes.

Implementations making use of these objects shall conform to the IHE Radiology Technical Framework.

Tooling: Free and commercial validators, exist and IHE provides testing and associated tooling.

5.3.2.17 HL7 ORU

SDO: HL7 [14], See Observation Reporting in the relevant v2.x release

ORU messages, triggered by events such as R01, encode result details from an imaging procedure and convey them between image archives, imaging reporting systems, and record systems (like EMRs, practice management systems, and personal health record systems) using HL7v2 messaging.

Implementations making use of these messages shall conform to HL7 V2.3.1, and/or HL7 V2.5.1.

NOTE   This does not preclude conforming to other versions of the standard.

Tooling: Free and commercial validators and toolkits exist.

5.3.2.18 HL7 CDA R2

SDO: HL7 [15]

CDA documents containing text, images, sounds, and other multimedia content are exchanged between record systems (like EMRs, practice management systems and personal health record systems) using HL7v2 messaging or IHE XD* infrastructure.

Implementations making use of these objects shall conform to HL7 CDA R2.

NOTE   This does not preclude conforming to other versions of the standard.

Tooling: Free and commercial validators and toolkits are available.

5.3.2.19 DICOM Part 20

SDO: DICOM [9], See PS3.20

Imaging reports are exchanged between reporting systems and record systems (like Report Repositories and EMRs). The coded content can support automated analysis and clinical decision support. PS3.20 describes how DICOM SR coded content, such as measurements or results from CAD or clinical analysis, can be transcoded into the CDA report document. The Part 20 Imaging Report template is closely aligned with the US Consolidated CDA Diagnostic Imaging Report template, however there are some differences.

Implementations making use of these objects shall conform to DICOM PS3 and HL7 CDA R2.

5.3.2.20 IHE MRRT

SDO: IHE Radiology [13], See MRRT

MRRT templates are exchanged between template archives and report creation systems and used to drive the process of collecting the necessary information from the reading radiologist for the particular type of imaging procedure. Templates can also be exchanged with other sites or radiology community libraries such as Rad Report. MRRT templates do not define the structure of the resulting diagnostic report instances that are created. That is covered by report formats such as DICOM Part 20.

Implementations making use of these objects shall conform to the IHE Radiology Technical Framework.

Tooling: Template editors (TREX) exist and IHE provides testing and associated tooling.

5.3.2.21 Rad Report

SDO: RSNA [16]

Many of the templates are available in the IHE MRRT format, as well as in simple text. The library is managed by a set of joint RSNA/ESR advisory panels. Templates downloaded from the library can be imported to some reporting systems. Otherwise sites compose templates inside their reporting system using the downloaded content as a guide.

Implementations making use of these objects shall conform to the RSNA Radiology Reporting Templates.

5.3.2.22 DICOM "Non-Core" Image IODs

SDO: DICOM [9], See PS3.3, Section A

The "Non-Core" group does not reflect any underlying immaturity or architectural grouping of image IODs, but rather just lower levels of adoption and deployment at the time this document was published.

The "Non-Core" Image IODs include IODs for Ophthalmic Measurements, Pathology, Whole Slide Microscopy, Parametric Maps, Segmentation, and Breast Projection.

DICOM "Non-Core" Image objects are exchanged between systems (like scanners, PACS and workstations) using DICOM protocols like DICOM C-STORE and WADO-RS. Products claim support for Storage SOP Classes that pair these IODs with the Storage Service.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.23 DICOM Enhanced Image IODs

SDO: DICOM [9], See PS3.3, Section A

The Enhanced Image IODs include Enhanced CT, Enhanced MR, Enhanced MR Color, Enhanced XA, Enhanced XRF, X-Ray 3D Angiographic, X-Ray 3D Craniofacial, Enhanced PET, Enhanced US, and Legacy Converted Enhanced IODs for CT, MR and PET.

DICOM Enhanced Image objects are exchanged between systems (like scanners, PACS and workstations) using DICOM protocols like DICOM C-STORE and WADO-RS. Products claim support for Storage SOP Classes that pair these IODs with the Storage Service.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.24 DICOM Encapsulated STL

SDO: DICOM [9], See PS3.3, Section A.85

Instances of Encapsulated STL IODs contain 3D models of things like anatomical structures, implants, surgical guides, etc. Typically, the models are associated with imaging that was used to render or design the 3D model.

DICOM Encapsulated STL objects are typically exchanged between creation systems (like 3D workstations or design software), archives where they are stored and managed, and printing software that manages interfacing with the manufacturing devices.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Some validators, toolkits, sample objects, and reference implementations are available.

5.3.2.25 DICOM ECG IODs

SDO: DICOM [9], See PS3.3, Section A.34.3, A.34.4, A.34.5

The ECG IODs include 12-Lead ECG, General ECG, and Ambulatory ECG.

DICOM ECG objects are exchanged between acquisition systems (typically associated with an imaging acquisition like ultrasound or angiography), archives, and display or analysis systems, using DICOM protocols like DICOM C-STORE and WADO-RS. Products claim support for Storage SOP Classes that pair these IODs with the Storage Service.

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Various free and commercial validators, toolkits, sample objects, and reference implementations are available.

5.3.2.26 DICOM RRDSR

SDO: DICOM [9], See PS3.16 Template TID 10021

DICOM RRDSR objects are exchanged between and PET/SPECT scanners (to support decay compensation and uptake computations), and then to archives, clinical analysis software, dose reporting systems and dose registries (to support QA, dose management and clinical analysis).

Implementations making use of these objects shall conform to DICOM PS3.

Tooling: Free and commercial SR validators, sample objects, and reference implementations are available.

5.3.2.27 DICOM IVUS SR

SDO: DICOM [9], See PS3.16, Template TID 3250

DICOM IVUS Report objects are exchanged between procedure recording systems and reporting or medical record systems.

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.28 DICOM Cardiac Cath SR

SDO: DICOM [9], See PS3.16, Template TID 3800

DICOM Cardiac Catheterization Report objects are exchanged between procedure recording systems and reporting or medical record systems.

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.29 DICOM CT/MR Cardiovascular SR

SDO: DICOM [9], See PS3.16, Template TID 3900

DICOM CT/MR Cardiovascular Analysis Report objects are exchanged between analysis systems and reporting or medical record systems.

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.30 DICOM Stress Testing SR

SDO: DICOM [9], See PS3.16, Template TID 3300

DICOM Stress Testing Report objects are exchanged between procedure recording systems and reporting or medical record systems.

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.31 DICOM Breast Imaging SR

SDO: DICOM [9], See PS3.16, Template TID 4200

DICOM Breast Imaging Report objects are exchanged between procedure recording systems and reporting or medical record systems.

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.32 DICOM Chest CAD SR

SDO: DICOM [9], See PS3.16, Template TID 4100

DICOM Chest CAD SR objects are exchanged between computer-aided detection and diagnosis systems and reporting or medical record systems.

Implementations making use of these objects shall conform to DICOM PS3.

5.3.2.33 DICOM Colon CAD SR

SDO: DICOM [9], See PS3.16, Template TID 4120

DICOM Colon CAD SR objects are exchanged between computer-aided detection and diagnosis systems and reporting or medical record systems.

Implementations making use of these objects shall conform to DICOM PS3.

5.4 Technical interoperability

5.4.1 Information exchange standards

Information exchange standards define how content is transferred from one system to another. That content might, in turn, use a particular content standard and/or data standard. The core of an information exchange standard is generally a messaging or transport protocol.

Messaging and transport protocols include those for point-to-point communication, document-based submission; secure e-mails and mHealth applications.

Table 3 lists the portfolio of preferred, legacy, and emerging information exchange standards for clinical imaging.

Table 3 — Preferred, legacy, and emerging information exchange standards

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
Preferred information exchange standards				
DICOM DIMSE Services	*DICOM Storage Service and Query/Retrieve Service* Protocols to move (push/pull-to) DICOM instances (IODs) and query for patients/studies/images.	Final	Universal	Universal	High
HL7 ADT	*HL7v2 Messaging – Patient Administration* Messages to transmit patient details such as new or updated demographics and visit information.	Final	Universal	Universal	High
HL7 OMG	*HL7v2 Messaging – Order Management* Messages to transmit procedure order details and creation, revision, completion, cancellation, etc.	Final	Moderate	Moderate	Moderate
IHE XDS-I.b	*IHE Cross-enterprise Document Sharing for Imaging Profile* Transactions to share images, diagnostic reports and related information across a group of care sites. Extends IHE XDS.b.	Final	High	[a]	Moderate
IHE XDS.b	*IHE Cross-Enterprise Document Sharing Profile* Transactions to submit, index, query, and retrieve documents stored in a distributed set of document repositories with a centralized registry.	Final	High	[a]	Moderate
IHE XCA-I	*IHE Cross-Community Access for Imaging Profile* Transactions to share images, diagnostic reports and related information between communities. Extends IHE XCA.	Final	Moderate	Low	Moderate
IHE XCA	*IHE Cross-Community Access Profile* Transactions to query and retrieve documents stored in another community via a gateway.	Final	Moderate	Moderate	Moderate
DICOMweb	DICOM RESTful Services Protocols (REST-based) to pull (WADO-RS) and push (STOW-RS) DICOM instances, and to query (QIDO-RS) for patients/studies/images.	Final	Moderate	Low	Moderate
DICOM Part 10	*DICOM Media Storage and File Format* File format and media organization rules for reading/writing DICOM instances from/to physical media such as CDs, DVDs, and USB devices.	Final	High	High	High
[a] *Moderate in the EU and Canada, Low but rising in the* US, *Low elsewhere* See A.3 for terms				

Table 3 *(continued)*

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
IHE PDI	*IHE Portable Data for Imaging Profile* Transaction for exchanging imaging data on digital media. Profiles DICOM Part 10.	Final	Universal	Universal	High
Legacy information exchange standards					
DICOM WADO-URI	*DICOM URI Service* Protocol (HTTP-based) to pull DICOM instances. Superseded by WADO-RS.	Final	Moderate	Moderate	Moderate
HL7 ORM	*HL7 Order Entry* Messages to transmit procedure order details and creation, revision, completion, cancellation, etc. Superseded by HL7 OMG.	Final	High	High	High
Emerging information exchange standards					
IHE WIA	*IHE Web-based Image Access Profile* Transactions to pull DICOM images or renderings and query for studies, series, and images. Profiles DICOM QIDO-RS and WADO-RS	Trial	Low	Low	Moderate
a *Moderate in the EU and Canada, Low but rising in the* US, *Low elsewhere*					
See A.3 for terms					

5.4.1.1 DICOM DIMSE Services

SDO: DICOM [9], See PS3.4 Annex B and Annex C

DICOM DIMSE Services are fundamental to using DICOM instances, thus virtually every device that interacts with DICOM data implements one or more DIMSE Services.

The DICOM Storage Service uses the C-STORE message. The DICOM Query/Retrieve Service uses the C-FIND and C-MOVE messages. Systems use DICOM C-STORE to push DICOM instances to other devices, DICOM C-FIND to query about DICOM instances on another device that match a filter, and DICOM C-MOVE to request that a copy of instances on another system be sent. It is the DICOM Storage Service that is most typically paired with Information Object Definitions (IODs) to create a Service-Object Pair (SOP) Class to which implementations claim conformance.

Implementations making use of these services shall conform to DICOM PS3.

Tooling: Free and commercial tools, validators, and a variety of open source reference implementations are available.

5.4.1.2 HL7 ADT

SDO: HL7 [14], See Patient Administration in the relevant v2.x release

ADT messages are generally passed as unsolicited updates from a Patient Administration system to other systems in the hospital including imaging systems such as the RIS (which incorporates the information into DICOM Modality Worklists) and the PACS/VNA (which handle reconciliation of things like demographic updates and patient merges). A variety of ADT messages communicate events such as patient account creation, admissions, demographic changes, discharge, transfers, etc. The messages carry details such as patient identifiers, demographics, insurance, inpatient status, location, visit details, and might describe procedures associated with the visit.

In the US, the underlying implementation of many products is v2.3.1, while in Europe and Japan many products are based on v2.5.1. That being said, products often include requested features from later HL7

versions and the products should have basic interoperability between versions. Several IHE profiles include specific options related to those versions.

Implementations making use of these messages shall conform to HL7 V2.3.1, and/or HL7 V2.5.1.

NOTE   This does not preclude conforming to other versions of the standard.

Tooling: Free and commercial validators and toolkits exist.

5.4.1.3   HL7 OMG

SDO: HL7 [14], See Order Management in the relevant v2.x release

OMG messages are generally exchanged as unsolicited updates between systems associated with the order, but most often between order placers and order fillers (i.e. EMR, CPOE, RIS, and PACS). The messages carry details such as patient identifiers, demographics, visit, and insurance, as well as details of the order including order ids, accession #, ordering physician, and the type of procedure ordered.

In the US, many products implement the v2.3.1 ORM instead (see below), while in Europe and Japan many products are based on the v2.5.1 OMG. That being said, products often include requested features from later HL7 versions and the products should have basic interoperability between versions. Several IHE profiles include specific options related to those versions.

Implementations making use of these messages shall conform to HL7 V2.5.1.

NOTE   This does not preclude conforming to other versions of the standard.

Tooling: Free and commercial validators and toolkits exist.

5.4.1.4   IHE XDS-I.b

SDO: IHE Radiology [13], See Volume 1

IHE XDS-I.b is implemented by systems involved in cross-enterprise sharing of images and reports, including PACS/VNA, EMR, patient record portals, and radiology viewers. The profile adds imaging study related metadata and image retrieval transactions not included in IHE XDS.b.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.1.5   IHE XDS.b

SDO: IHE ITI [17], See Volume 1

IHE XDS.b is implemented by systems involved in cross-enterprise sharing of medical record documents, including EMRs and patient record portals. The profile addresses cross-indexing different patient IDs for the same patient at different institutions participating in document sharing. XDS.b serves as the basis upon which XDS-I.b is built.

Implementations making use of these transactions shall conform to the IHE IT Infrastructure Technical Framework.

5.4.1.6   IHE XCA-I

SDO: IHE Radiology [13], See Volume 1

IHE XCA-I is implemented primarily by the initiating and responding gateway systems in each community that is sharing images and reports. Within the community, there are many different ways that images could be managed and provided to the gateways to fulfill their required behaviors, although there is an expectation that sites will consider using XDS-I.b since the technology and concepts are well-aligned.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.1.7 IHE XCA

SDO: IHE ITI [17], See Volume 1

IHE XCA is implemented primarily by the initiating and responding gateway systems in each community that is sharing medical documents. Within the community, there are many different ways that documents could be managed and provided to the gateways to fulfill their required behaviors, although there is an expectation that sites will consider using XDS.b since the technology and concepts are well-aligned.

Implementations making use of these transactions shall conform to the IHE IT Infrastructure Technical Framework.

5.4.1.8 DICOMweb

SDO: DICOM [9], See PS3.18

The DICOMweb services use RESTful web technology but mirror the information model of the DICOM DIMSE Services which makes it possible to proxy between DIMSE and Web Services in either direction. Such proxiability facilitates mixed environments and non-disruptive migration to the new technology.

Within the DICOMweb Studies service, the Store transaction, also refered to as STOW-RS, corresponds to DICOM C-STORE; the Retrieve transaction, also referred to as WADO-RS, corresponds to DICOM C-MOVE or C-GET; and the Query transaction, also referred to as QIDO-RS, corresponds to DICOM C-FIND.

It is expected that new or lightweight applications such as medical photography software, smartphone applications, distributed viewers, and AI clinical analysis, will increasingly adopt DICOMweb due to the more familiar API style and development model. Servers such as PACS and VNAs will likely implement both DICOMweb and DIMSE Services for the foreseeable future to support a diverse set of clients including larger modalities that would not particularly benefit from re-developing existing software.

Implementations making use of these services shall conform to DICOM PS3.

Tooling: Free and commercial tools, validators, and a variety of open source reference implementations are available.

5.4.1.9 DICOM Part 10

SDO: DICOM [9], See PS3.10

DICOM Part 10 is implemented by devices that write or read media containing DICOM instances. This includes modalities (particularly those used in isolated offices), servers (such as PACS and VNAs), and import/export workstations used to provide patients with copies of their imaging record or to import prior imaging the patient has brought with them. Typically, media contains a single imaging study, or a small number of studies for the same patient. The primary use of Part 10 is for exchange of data, as opposed to long term archival.

Implementations making use of these services shall conform to DICOM PS3.

Tooling: Free and commercial tools, validators, and a variety of open source reference implementations are available.

5.4.1.10 IHE PDI

SDO: IHE Radiology [13], See Volume 1

IHE PDI is implemented by devices that write or read media containing DICOM instances. The profile defines specific options including support for DVD and USB media, HTML content, data encryption, and inclusion of a basic viewer or decryption software on the media.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

Tooling: Free and commercial tools, validators, and a variety of open source reference implementations are available.

5.4.1.11 DICOM WADO-URI

SDO: DICOM [9], See PS3.18, Chapter 9

Although HTTP-based, WADO-URI is not RESTful (which WADO-RS is). For example, the data to be retrieved is specified via parameters rather than a resource path. WADO-URI has been implemented by a variety of servers (PACS/VNA) and primarily browser-based viewing clients. This usage was promoted by the IHE XDS-I.b Profile.

Implementations making use of this service shall conform to DICOM PS3.

5.4.1.12 HL7 ORM

SDO: HL7 [14], See Order Entry in the relevant v2.x release

ORM messages are generally exchanged as unsolicited updates between systems associated with the order, but most often between order placers and order fillers (i.e. EMR, CPOE, RIS, and PACS). The messages carry details such as patient identifiers, demographics, visit, and insurance, as well as details of the order including order ids, accession #, ordering physician, and the type of procedure ordered.

In the US, many products implement the v2.3.1 ORM instead (see below), while in Europe and Japan many products are based on the v2.5.1 OMG. That being said, products often include requested features from later HL7 versions and the products should have basic interoperability between versions. Several IHE profiles include specific options related to those versions.

Implementations making use of these messages shall conform to HL7 V2.5.1.

NOTE   This does not preclude conforming to other versions of the standard.

Tooling: Free and commercial validators and toolkits exist.

5.4.1.13 IHE WIA

SDO: IHE Radiology [13], See WIA Supplement

IHE WIA is implemented by image servers (PACS/VNA) and devices that query/retrieve images, typically for viewing, but also for processing.

An earlier draft of IHE WIA Profile was called the Mobile Access to Health Documents for Imaging Profile (MHD-I). WIA includes specifications for integrating with the IHE MHD [17] and/or IHE XDS.b Profiles but that is not mandatory and WIA can be used standalone.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

Tooling: Free and commercial tools, validators, and a variety of open source reference implementations are available.

5.4.2   Privacy and security standards

Privacy and security standards define technological safeguards or tools used to protect information (including PII) from unauthorized access, modification or destruction, and to protect systems from unauthorized use or disruption (including cyberattacks).

Table 4 lists the portfolio of preferred, legacy, and emerging privacy and security standards for clinical imaging.

Table 4 — Preferred, legacy, and emerging privacy and security standards

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
Preferred privacy and security standards					
DICOM Audit	*DICOM Audit Trail Message Profiles* Messages (format, content, and transmission protocol) for specific events related to the access of medical imaging data and related activity by users and devices.	Final	Moderate	Moderate	Moderate
DICOM Deidentification	*DICOM Attribute Confidentiality Profiles* Behaviors and options for modifying DICOM instances to maintain the confidentiality of the associated patient, individuals, and organizations.	Final	Moderate	Moderate	Moderate
IHE ATNA	*IHE Audit Trail and Node Authentication Profile* Messages to create medical record access audit trails. Also profiles certificate-based authentication to secure connections between systems.	Final	Moderate	Moderate	Moderate
IHE ATNA – Radiology Option	*IHE Audit Trail and Node Authentication – Radiology Audit Trail Option* ATNA audit message trigger events and codes associated with IHE Radiology transactions. Profiles IHE ATNA	Final	Moderate	Low	Low
IHE BPPC	*IHE Basic Patient Privacy Consents Profile* Format for encoding privacy consent policies for individual patients. Behaviors for enforcing consent policies.	Final	Moderate	Low	Moderate
DICOM TLS	*DICOM Secure Transport Connection Profiles* Profiles how to establish and use Transport Layer Security (TLS) connections for DICOM protocol communications (both DIMSE and DICOMweb).	Final	Moderate	Moderate	Moderate
Legacy privacy and security standards					
	None listed.				
Emerging privacy and security standards					
	None listed.				
See A.3 for terms					

5.4.2.1   DICOM Audit

SDO: DICOM [9], See PS3.15 Sections A.5, A.6, A.7

Audit messages are sent from devices that interact with DICOM data (such as modalities, archives, processing workstations, media creators, and display systems) to an audit server using syslog messages.

Implementations making use of these services shall conform to DICOM PS3.

5.4.2.2   DICOM Deidentification

SDO: DICOM [9], See PS3.15 Annex E

DICOM instances are de-identified by modifying specific attributes as described in the Confidentiality Profile. Depending on selected confidentiality options (for example to maintain the longitudinal relationship between related data timestamps needed for correct clinical analysis) and on object definition requirements, the handling of each attribute is defined, e.g. to add a random offset to the value, to blank the value, or to remove the attribute entirely.

Deidentification might be performed by systems including data creators, archives, importers, exporters, teaching file composers, and standalone DICOM cleaners.

Implementations making use of these services shall conform to DICOM PS3.

Tooling: Free and commercial tools, validators, and reference implementations are available.

5.4.2.3   IHE ATNA

SDO: IHE ITI [17], See Volume 1

IHE ATNA is implemented by any system that needs to authenticate partner systems, establish secure network connections or record security audit logs. Sites will need some form of certificate management, and an audit server to store the audit messages.

Implementations making use of these transactions shall conform to the IHE IT Infrastructure Technical Framework.

Tooling: General purpose tools for certificates and syslog are available, as well as IHE testing tools specifically for ATNA.

5.4.2.4   IHE ATNA – Radiology Option

SDO: IHE Radiology [13], See Volume 3, Section 5.1

The IHE ATNA – Radiology Option would be implemented by the audit trail server, by imaging systems that submit audit messages (such as modalities, PACS/VNA, reading workstations, etc), and systems that process audit logs.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.2.5   IHE BPPC

SDO: IHE ITI [17], See Volume 1

IHE BPPC is implemented by systems, such as PACS/VNA, that might need to enforce the privacy consent appropriate to the use of imaging data.

Implementations making use of these transactions shall conform to the IHE IT Infrastructure Technical Framework.

5.4.2.6   DICOM TLS

SDO: DICOM [9], See PS3.15 Annex B

Participants in DICOM protocol communications might use TLS to secure those communications and potentially to validate the identity of the system with which they are communicating.

Implementations making use of these services shall conform to DICOM PS3.

Tooling: Free and commercial connection validators that support TLS (Transport Layer Security) are available.

5.4.3 Technical workflow standards

Technical workflow standards define interactions between systems, to achieve particular technical tasks. This includes creation of content (data sets encoded using appropriate content standards and data standards), and communication of content (using appropriate information exchange standards). The standard might define particular task management, sequencing, technical pre-requisites for steps, data validation, data quality requirements, privacy and security protocols (using appropriate privacy and security standards).

Table 5 lists the portfolio of preferred, legacy, and emerging technical workflow standards for clinical imaging.

Table 5 — Preferred, legacy, and emerging technical workflow standards

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
Preferred workflow standards					
IHE SWF.b	*IHE Scheduled Workflow.b Profile* Transactions for ordering, scheduling, performing, storing, and viewing Radiology exams. Profiles HL7 Patient and Order Management, DICOM DIMSE, MWL, and Storage Commitment. SWF.b combines and supersedes IHE SWF and IHE PIR.	Final	Moderate	a	Moderate
DICOM MWL	*DICOM Modality Worklist Management Service* Protocol to query for scheduled imaging procedures and associated details about the patient, procedure, order and associated care providers.	Final	Universal	Universal	Moderate
DICOM MPPS	*DICOM Modality Performed Procedure Step SOP Class* Protocol to communicate the creation, update, cancelation or completion of an imaging procedure step (e.g. an acquisition) and associated details like timestamps and a list of DICOM instances produced.	Final	High	Low	Moderate
DICOM Storage Commit	*DICOM Storage Commitment Push Model SOP Class* Protocol to request confirmation that sent DICOM instances have been successfully stored.	Final	High	Moderate	Moderate
IHE CATH	*IHE Cardiac Catheterization Workflow Profile* Transactions for ordering, scheduling, performing, storing, and viewing Cardiac Catheterization procedures. Profiles IHE SWF.	Final	High	Moderate	Moderate
IHE ECHO	*IHE Echocardiography Workflow Profile* Transactions for ordering, scheduling, performing, storing, and viewing digital echocardiography procedures. Profiles IHE SWF.	Final	High	Moderate	Moderate
IHE MAMMO	*IHE Mammography Image Profile* Transactions and behavior to create, exchange, use, and display Mammography images and related data. Profiles DICOM MG Image IOD and C-STORE.	Final	High	Moderate	Moderate
a Moderate in Europe and Japan, Low in US which more commonly uses HL7 2.3.1 and SWF.					
See A.3 for terms					

Table 5 *(continued)*

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
IHE DBT	*IHE Digital Breast Tomosynthesis Profile* Transactions and behavior to create, exchange, use, and display Digital Breast Tomosynthesis images and related data. Profiles DICOM Breast Tomosynthesis Image IOD and C-STORE.	Final	Moderate	Low	Moderate
IHE NMI	*IHE Nuclear Medicine Image Profile* Transactions and behavior to create, exchange, use, and display Nuclear Medicine images and result screens. Profiles some DICOM "Core" IODs and DICOM DIMSE Services.	Final	Moderate	Low	Moderate
IHE REM	*IHE Radiation Exposure Monitoring Profile* Transactions and behavior to create, exchange, analyze, anonymize, and submit radiation dose records to a registry. Profiles DICOM CT RDSR and X-Ray RDSR.	Final	High	Moderate	Moderate
IHE IOCM	*IHE Imaging Object Change Management Profile* Transactions and behavior to flag, delete or sequester DICOM objects due to data retention policies, quality issues, or patient safety issues, and to propagate that information in a distributed storage environment. Profiles DICOM KOS.	Final	Moderate	Moderate	Low
IHE IRWF	*IHE Import Reconciliation Workflow Profile* Transactions and behavior to import images from CDs, hardcopy, etc., reconcile identifiers to match local values, and notify local systems. Will be superseded by IRWF.b.	Final	Moderate	Low	Moderate
DICOM GSDF	*DICOM Grayscale Standard Display Function* Standardizes a display function that maps input values to corresponding grayscale luminances, and describes methods for measuring the characteristic curve of a particular display system	Final	High	High	High
IHE CPI	*IHE Consistent Presentation of Images Profile* Transactions and behavior to maintain consistent intensity and image transformations between different hardcopy and softcopy devices. Profiles DICOM GSPS and GSDF.	Final	High	Moderate	High
IHE TCE	*IHE Teaching File and Clinical Trial Export Profile* Transactions and behavior to flag images and related information for automatic routing to teaching file authoring or clinical trials management systems. Profiles DICOM KOS.	Final	Low	Low	Moderate
Legacy workflow standards					
IHE SWF	*IHE Scheduled Workflow Profile* Transactions for ordering, scheduling, performing, storing, and viewing Radiology exams. Superseded by IHE SWF.b.	Final	High	High	High
a Moderate in Europe and Japan, Low in US which more commonly uses HL7 2.3.1 and SWF.					
See A.3 for terms					

Table 5 *(continued)*

Brief name	Formal name and scope	Standard Maturity	Product Adoption	Site Deployment	Tooling
IHE PIR	*IHE Patient Information Reconciliation Profile* Transactions for reconciling imaging data and records in cases of unidentified or misidentified patients. Used with IHE SWF. Superseded by IHE SWF.b.	Final	High	High	Moderate
Emerging workflow standards					
DICOM UPS	*DICOM Unified Procedure Step Service* Data structure (UPS IOD) for a workitem (procedure step) as scheduled, progress during performance, and results; and a Protocol for creating and updating work items, querying the collective worklists, and tracking progress.	Final	Low	Low	Low
IHE REM-NM	*IHE Radiation Exposure Monitoring for Nuclear Medicine Profile* Transactions and behavior to create, exchange, analyze, anonymize, and submit radiopharmaceutical dose records to a registry. Mirrors IHE REM.	Trial	Low	Pilot	Low
IHE IRWF.b	*IHE Import Reconciliation Workflow.b Profile* Transactions and behavior to import images from CDs, hardcopy, etc., reconcile identifiers to match local values, and notify local systems. Extends IRWF with support for proxy orders.	Final	Low	Pilot	Moderate
a Moderate in Europe and Japan, Low in US which more commonly uses HL7 2.3.1 and SWF. See A.3 for terms					

5.4.3.1 IHE SWF.b

SDO: IHE Radiology [13], See SWF.b Supplement

IHE SWF.b is implemented by systems for registering patients (ADT, EHR), and systems for ordering (EHR, CPOE), scheduling (RIS), acquiring (Modality), storing (PACS/VNA) and displaying data from imaging procedures. For example, it describes how relevant details from HL7 Orders are properly transcoded into DICOM Modality Worklist entries, and how Accession numbers are used to manage studies and closing the order loop.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.2 DICOM MWL

SDO: DICOM [9], See PS3.4 Annex K

The Worklist Service is typically provided by a server such as a RIS, PACS, VNA or EMR component. The service is used primarily by imaging modalities, but has also been used by non-imaging modalities and by IT systems interested in monitoring the departmental workflow.

The Scheduled Procedure Steps (SPS) communicated in the Worklist Service often have one or more corresponding Performed Procedure Steps (PPS) communicated in the Modality Performed Procedure Step SOP Class.

Implementations making use of these services shall conform to DICOM PS3.

Tooling: Free and commercial tools, validators, and reference implementations are available.

5.4.3.3　DICOM MPPS

SDO: DICOM [9], See PS3.4 Annex F

The creation and update of DICOM Performed Procedure Steps is typically driven by modality systems. The PPS information is typically recorded and propagated by server systems like the RIS and PACS/VNA. The information might be used to prune acquisition worklists, trigger subsequent steps in workflow, or as data for departmental workflow analytics.

Implementations making use of these services shall conform to DICOM PS3.

Tooling: Free and commercial tools, validators, and reference implementations are available.

5.4.3.4　DICOM Storage Commit

SDO: DICOM [9], See PS3.4 Annex J

In the DICOM Storage Commitment Push Model, the sender of a DICOM instance, such as a modality or a processing workstation, requests that the server, such as a PACS or VNA, return a commitment that the server will commit to storing the listed instances. Confirmation is often used by the requesting system to determine that the local copy of the instance can now be deleted. Conversely, lack of confirmation might trigger a resend of the instances. The period of time that the server is committing to store the instance is not defined by DICOM, but rather will be determined by product design and factors such as local retention policies, etc.

Implementations making use of these services shall conform to DICOM PS3.

Tooling: Free and commercial tools, validators, and reference implementations are available.

5.4.3.5　IHE CATH

SDO: IHE Cardiology [18], See Volume 1

IHE CATH is implemented by systems for ordering (EHR, CPOE), scheduling (RIS), acquiring (imaging modalities, ECG, hemodynamic, and procedure record systems), storing (PACS/VNA) and displaying data from imaging procedures in the cardiac cath. lab. In addition to the functions of IHE SWF, on which it is based, IHE CATH also addresses coordinating the collection of acquisition devices used in a single procedure.

Implementations making use of these transactions shall conform to the IHE Cardiology Technical Framework.

5.4.3.6　IHE ECHO

SDO: IHE Cardiology [18], See Volume 1

IHE ECHO is implemented by systems for ordering (EHR, CPOE), scheduling (RIS), acquiring (modalities), storing (PACS/VNA) and displaying data from echocardiography imaging procedures. In addition to the functions of IHE SWF, on which it is based, IHE CATH also addresses dealing with issues that arise from echo devices being mobile and intermittently connected to the network.

Implementations making use of these transactions shall conform to the IHE Cardiology Technical Framework.

5.4.3.7　IHE MAMMO

SDO: IHE Radiology [13], See Volume 1

IHE MAMMO is implemented by devices that schedule (RIS), acquire (modality), store (PACS/VNA), process (CAD), display or print mammography procedure images. The Profile was written to take into account a number of MQSA requirements.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.8 IHE DBT

SDO: IHE Radiology [13], See Volume 1

IHE DBT is implemented by devices that schedule (RIS), acquire (modality), store (PACS/VNA), process (CAD), display or print breast tomosynthesis images.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.9 IHE NMI

SDO: IHE Radiology [13], See Volume 1

IHE NMI is implemented by devices that acquire (modality), store (PACS/VNA), process (reconstruction or clinical workstations), or display nuclear medicine procedure images. The Profile is intended to supplement the IHE SWF or SWF.b Profiles but can be used independently.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.10 IHE REM

SDO: IHE Radiology [13], See Volume 1

IHE REM is implemented by devices that deliver and/or detect x-ray radiation (imaging modalities, etc.), archive radiation records (PACS, VNA, etc.), perform analytics on radiation dose data, or serve as registries. Radiopharmaceutical dose monitoring is addressed by the IHE REM-NM Profile.

The high adoption and moderate deployment reflect usage in CT. In Angiography, mammography, and radiography, adoption is increasing, but still low to moderate.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.11 IHE IOCM

SDO: IHE Radiology [13], See Volume 1

IHE IOCM is implemented by archives of DICOM instances (PACS, VNAs, XDS Repositories), consumers of DICOM instances (displays, processing workstations), importers, and systems that initiate change requests like QA workstations and PACS administration consoles.

The intention of using DICOM KOS instances as the mechanism to encode changes is that even systems that do not implement the profile will be able to store and make available the KOS and its contents so that downstream systems and users can still be made aware of the intended changes.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.12 IHE IRWF

SDO: IHE Radiology [13], See Volume 1

IHE IRWF is implemented by systems that import imaging studies from media, such as CDs and DVDs, archive systems (PACS, VNAs), departmental systems (RIS), and EHRs that need notification of

imported studies. The importer obtains local demographics from enterprise systems using IHE PIX [17] or IHE PDQ [17].

The IHE IRWF specification is superseded by IHE IRWF.b but will not be re-categorized as Legacy until IHE IRWF.b has seen greater deployment.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.13 DICOM GSDF

SDO: DICOM [9], See PS3.14

Systems, such as image display monitors and printers producing films that are placed on lightboxes, implement the characteristic curve measurement methods so they can be calibrated to the Grayscale Standard Display Function [9], resulting in perceptually consistent presentation of images.

Implementations making use of these services shall conform to DICOM PS3.

Tooling: Various free and commercial tools are available.

5.4.3.14 IHE CPI

SDO: IHE Radiology [13], See Volume 1

IHE CPI is implemented by systems that display diagnostic images such as softcopy display stations (stand-alone or integrated with a HIS, RIS or PACS), archives with displays (PACS/VNA), hardcopy devices that print film or paper, and some modalities. The profile addresses consistency of image manipulations including user annotations, shutters, flip/rotate, display area, and zoom.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.15 IHE TCE

SDO: IHE Radiology [13], See Volume 1

IHE TCE is implemented by flagging systems (reading workstations, PACS, VNAs) that flag images for teaching file or clinical trial use, routing systems (DICOM routers, PACS, VNAs, QA stations), storage systems (PACS, VNAs, research data repositories), and processing systems (teaching file authoring software, clinical trial systems). The profile specifically addresses anonymization and pseudonymization (reversible) methods and behavior.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.16 IHE SWF

SDO: IHE Radiology [13], See Volume 1

IHE SWF has been superseded by IHE SWF.b. IHE SWF profiles HL7 2.3.1 and depends on being paired with IHE PIR to handle certain exception cases.

IHE SWF is implemented by systems for registering and managing patients (ADT, EHR), and systems for ordering (EHR, CPOE), scheduling (RIS), acquiring (Modality), storing (PACS/VNA) and displaying data from imaging procedures. For example, it describes how relevant details from HL7 Orders are properly transcoded into DICOM Modality Worklist entries, and how Accession numbers are used to manage studies and closing the order loop.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.17 IHE PIR

SDO: IHE Radiology [13], See Volume 1

IHE PIR has been superseded by IHE SWF.b. IHE PIR profiles HL7 2.3.1.

IHE PIR is implemented by systems for registering and managing patients (ADT, EHR), and systems for ordering (EHR, CPOE), scheduling (RIS), acquiring (Modality), and storing (PACS/VNA) data from imaging procedures. It describes how, when, and where, reconciliation details are captured, propagated and applied to imaging data.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.18 IHE REM-NM

SDO: IHE Radiology [13], See REM-NM Supplement

IHE REM-NM is implemented by devices that capture radiopharmaceutical preparation and administration details (e.g. hot lab workstations), PET and SPECT modalities that need reliable dose details to drive calculations like decay correction or standardized uptake values (SUV), archives that store records (PACS, VNA, etc.), devices that perform analytics on radiation dose data, or serve as registries. Radiopharmaceutical dose monitoring is addressed by the IHE REM-NM Profile.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.4.3.19 DICOM UPS

SDO: DICOM [9], See PS3.4 Annex CC

DICOM Unified Procedure Step (UPS) is implemented by a worklist server, and by clients that create and/or perform work items (schedulers, workflow managers, processing workstations, reporting workstations, acquisition devices) and clients that monitor work items (dashboards, workflow managers, EMRs, business analytics).

A UPS instance is loosely equivalent to a combined Scheduled Procedure Step (SPS) and Performed Procedure Step (PPS) with additional subscription-based notification capabilities.

Implementations making use of these services shall conform to DICOM PS3.

Low deployment reflects the initial use of UPS in managing planning, verification, and delivery workflow in radiotherapy. Although UPS was designed for general imaging workflow (managing clinical application processing, reporting, etc.), it has not yet been deployed for that.

5.4.3.20 IHE IRWF.b

SDO: IHE Radiology [13], See IHE IRWF.b Supplement

IHE IRWF.b is implemented by systems that import imaging studies from media, such as CDs and DVDs, archive systems (PACS, VNAs), departmental systems (RIS), and EHRs that need notification of imported studies. The importer obtains local demographics from enterprise systems using IHE PIX [17] or IHE PDQ [17].

IHE IRWF.b extends IHE IRWF by making several optional features required and adding some new optional features. See the Options section of the Profile supplement document for details.

Implementations making use of these transactions shall conform to the IHE Radiology Technical Framework.

5.5 Functional interoperability

For future use.

6 Implementation use case guidance

6.1 Overview

A portfolio of standards relevant to the clinical imaging domain is documented in Clause 5 (Portfolio of reference standards). This clause maps those standards to example implementation projects which will be called use cases.

For any given implementation project, the importance of any given standard depends on the scope of that project and the nature of the interoperability needs the project is addressing. Projects typically require the combination of multiple standards. Any given project will need to do its own analysis; however, this clause provides some typical projects to use as templates.

These projects were selected to demonstrate some common project scopes and recognize some common organizational and technical boundaries in HIT. The real world, however, is more fluid and readers can expect that their own project scope might be a subset or superset of one shown here, or might span several of these, or might address a single use case over multiple stages. Similarly, all projects will need to include considerations that go beyond the scope this document can address. This clause is thus informative rather than normative. It is hoped the material will help the reader better identify, understand and apply standards relevant to their project.

Integration planning and projects are frequently scoped based on organizational boundaries and address system interfaces. Figure 2 highlights three organizational interfaces in clinical imaging which will serve as implementation Use Cases.

Device   **Department**

a

b

c

Cross-Enterprise   **Enterprise**
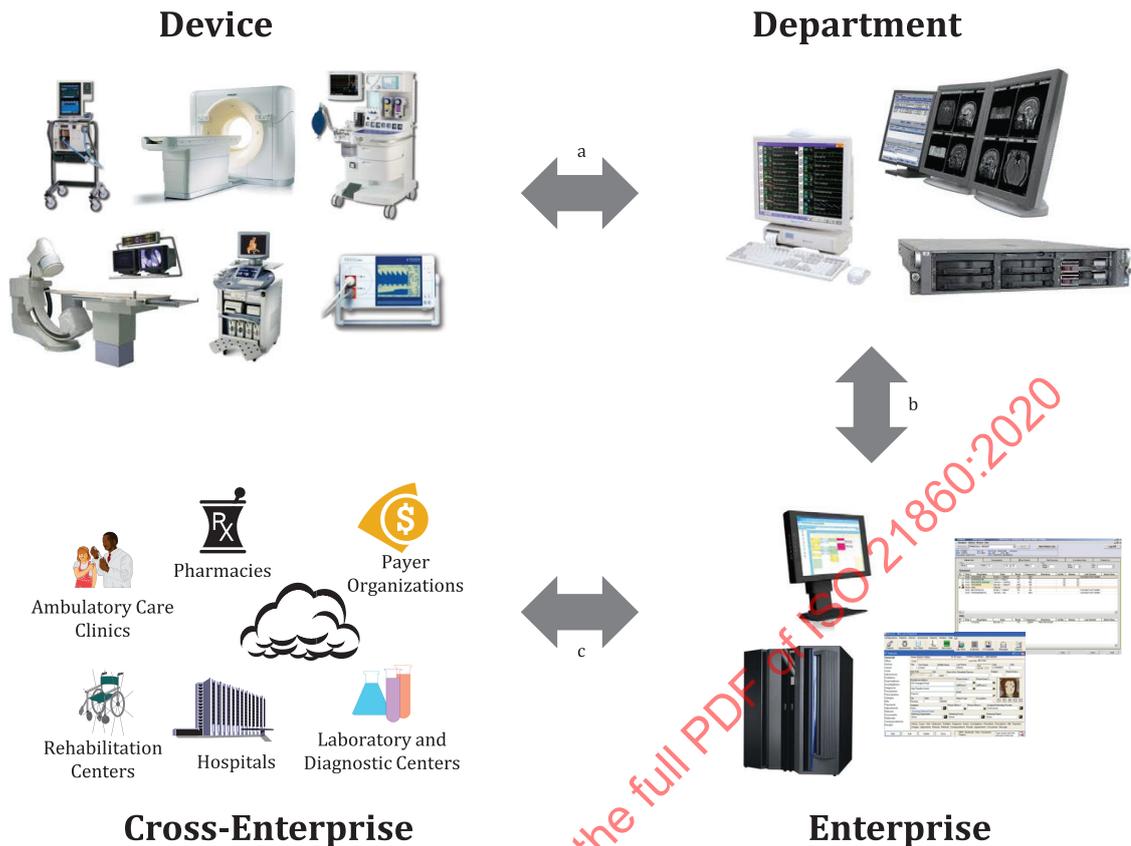
a   Device to Department Integration.

b   Department to Enterprise Integration.

c   Enterprise to Cross-Enterprise Integration.

Figure 2 — Organizational interfaces in clinical imaging

Achieving integration within the department (see 6.2) is sometimes done before integration between the department and the enterprise (see 6.3), and sometimes integration within the department is tackled after integrating departments into the enterprise. Ultimately, it is important to address both so that outputs the departments are providing to the enterprise are consistent and uniform, and so that the inputs the enterprise is providing to the department are likewise well-managed and well-behaved.

NOTE   The content of these use cases focus on clinical imaging. All the systems involved in these use cases, especially those in the enterprise and cross-enterprise space, have important functions that go beyond clinical imaging or for which clinical imaging is not the primary driver. The standards on which those functions in those other Domains are based will be addressed in other RSP documents.

6.2   Device to department integration

This use case is scoped to an image-oriented department (such as radiology or cardiology) and addresses the clinical imaging interfaces between the image acquisition devices and the departmental systems that manage them. This includes:

— managing worklists based on orders for imaging procedures ("encounter-based" imaging is out of scope of this use case)

— coordination of the workflow of capturing images and associated data

— recording images and associated data in a uniform format

— managing images and associated data flow through the process to generate a report, and

— presenting the image and the report for viewing (accessing) to an imaging physician and a patient (his/her legal representative).

Table 6 lists a suggested baseline of key standards for this use case.

Table 6 — Key standards for device to department integration

Brief name	Devices/Systems	Notes
Data standards (See 5.3.1)		
SNOMED CT	RIS, Modalities, Clinical Applications, Reporting Systems	To encode symptoms in imaging orders and worklists; encode anatomy, radiopharmaceuticals, contrast etc., in images and structured data; and encode anatomy, findings and diagnoses in imaging reports.
LOINC	Modalities, Clinical Applications, Reporting Systems	To encode measurements and other observations in structured data and imaging reports.
UCUM	Modalities, Clinical Applications, Reporting Systems Creators	To encode units of measure in images, structured data and imaging reports.
DICOM Codes	Modalities, Clinical Applications, Reporting Systems	To encode many imaging concepts such as modality, imaging technique, etc. Most devices do this as part of supporting DICOM.
DICOM Context Groups	Modalities, Clinical Applications, Reporting Systems	To encode many imaging concepts, such as anatomy, purpose of image reference, etc. Most devices do this as part of supporting DICOM.
Radlex Playbook	RIS, Modalities, PACS, Clinical Applications, Reporting Systems	To encode what procedure is ordered/scheduled/performed in the order, worklist and image objects (and other related records). Although Playbook codes are not widely deployed yet, most imaging products are configurable and any site which does not already have a procedure codeset or which is revising their codeset is strongly advised to consider the RadLex Playbook.
Content standards (See 5.3.2)		
DICOM "Core" Image IODs	Modalities, PACS, Image Displays	To encode images.
DICOM Encapsulated PDFs	RIS, PACS, Displays, Administrative Systems, Report Creators	To handle circulate scanned documents and graphical reports when integrated electronic solutions are not in place.
DICOM SR	PACS, Clinical Applications, Reporting Systems, Clinical Databases	To encode measurements and other clinical analysis data during the clinical imaging workflow.
DICOM CT and X-Ray RDSR	X-ray-based Modalities, PACS, Dose Workstations	To encode radiation exposure data from imaging studies.
DICOM Echo SR	Ultrasound Carts, PACS, Report Creators, Clinical Databases	To encode cardiac measurement sets.
DICOM Mammo CAD	Mammography CAD, PACS, Report Creators	To encode CAD results.
IHE KIN	Modalities, PACS, QA Workstations, Image Displays	To flag images for various purposes (QA Issue, Key Image, etc). Invoking IHE KIN incorporates DICOM KOS.
HL7 CDA R2	Report Creators, Report Repositories	To encode diagnostic imaging reports.
Information exchange standards (See 5.4.1)		
DICOM DIMSE Services	Modalities, PACS, Image Displays, QA Systems, Clinical Systems, 3D Systems, Clinical Databases, Report Creators	To move DICOM data around.
DICOMweb	Lightweight Modalities, PACS, Image Displays, AI Systems	To move DICOM data around using web protocols.
Privacy and security standards (See 5.4.2)		
IHE ATNA with Radiology Option	Modalities, PACS, Image Displays	To ensure secure connections between devices and auditing of PHI access. Invoking IHE ATNA incorporates DICOM Audit.
DICOM TLS	All DICOM systems	To support transport layer security on data connections.

Table 6 *(continued)*

Brief name	Devices/Systems	Notes
Technical workflow standards (See 5.4.3)	
IHE SWF.b	RIS, Modalities, PACS, Image Displays	Developed for Radiology but applicable to scheduled imaging in other departments. Invoking IHE SWF.b incorporates DICOM DIMSE Services, DICOM MWL, DICOM MPPS, and DICOM Storage Commit.
IHE CATH	RIS, Angiography Modalities, Hemodynamic Systems, ECGs, PACS, Image Displays	
IHE ECHO	Ultrasound Modalities, PACS, RIS, Clinical Applications and databases	
IHE MAMMO	Mammography Modalities, CAD, PACS, RIS, Image Displays, Printers	
IHE NMI	Nuclear Medicine Modalities, PACS, Image Displays, Clinical Applications	
IHE REM	X-ray-based Modalities, PACS, Dose Workstations	
IHE REM-NM	Hot Lab Systems, Radiopharmaceutical-based Modalities, PACS, Dose Workstations	
IHE CPI	PACS, Image Displays, Printers	Invoking IHE CPI incorporates DICOM GSDF and DICOM GSPS.
IHE TCE	PACS, Image Displays, Teaching File Authoring systems	

Readers are encouraged to consider the potential benefits of including additional standards (see Clause 5) based on their specific project needs and policies.

6.3   Department to enterprise integration

This use case is scoped to a multi-department enterprise (such as a hospital or large clinic) and addresses the clinical imaging interfaces between the departmental systems and the enterprise systems that manage them (and aggregate their data).

This includes:

— management of clinical imaging orders between the departmental information system (RIS) and the enterprise EHR system

— reporting clinical imaging results (images, measurements, and reports) from the departmental information system to the enterprise EHR system

— presenting the image and the report for viewing (accessing) to the ordering physician and a patient (his/her legal representative) from the enterprise EHR system.

Table 7 lists a suggested baseline of key standards for this use case.

Table 7 — Key standards for department to enterprise integration

Brief name	Devices/Systems	Notes
Data standards (See 5.3.1)	
[a] Historically, the translation of orders into worklists and other administration and workflow tasks in an imaging department were handled by a RIS (Radiology Information System) as a standalone system. In more recent years it has become more common for "departmental information system" services to be addressed as a component of the EHR system.	

Table 7 *(continued)*

Brief name	Devices/Systems	Notes
SNOMED CT	EHR, RIS, Report Repositories	To encode symptoms in imaging orders and worklists; encode anatomy, radiopharmaceuticals, contrast etc, in images and structured data; and encode anatomy, findings and diagnoses in imaging reports.
LOINC	Report Repositories, EHR	To encode measurements and other observations in structured data and imaging reports.
UCUM	Report Repositories, EHR	To encode units of measure in images, structured data and imaging reports.
ICD-10	Report Repositories, EHR	To encode diagnoses.
Radlex Playbook	RIS, PACS, EHR, Report Repositories	To encode what procedure is ordered/scheduled/performed in the order, worklist and image objects (and other related records)
DICOM Codes	RIS, PACS, EHR, Report Repositories	To encode many imaging concepts such as modality, imaging technique, etc.
DICOM Context Groups	RIS, PACS, EHR, Report Repositories	To encode many imaging concepts, such as anatomy, purpose of image reference, etc.
Content standards (See 5.3.2)		
DICOM "Core" Image IODs	PACS, Enterprise Viewers	To encode images.
DICOM Encapsulated PDFs	PACS, Enterprise Viewers, Administrative Systems	This is sometimes used for rendered reports that include tables or graphics, or to convey scanned/printed order or consent documents when a proper electronic system is not in place.
IHE KIN	PACS, Enterprise Viewers	To flag images for various purposes (for Surgery, etc). Invoking IHE KIN incorporates DICOM KOS.
HL7 ORU	PACS, RIS, Report Repositories, EHR	To notify/describe newly available imaging results (images and reports).
HL7 CDA R2	Report Repositories, Enterprise Viewers, EHR	To encode diagnostic imaging reports.
Information exchange standards (See 5.4.1)		
DICOM DIMSE Services	PACS, Enterprise Viewers	To move DICOM data around.
DICOMweb	PACS, Enterprise Viewers	To move DICOM data around using web protocols.
IHE WIA	PACS, Enterprise Viewers, EHR	To access imaging using web protocols. Invoking IHE WIA incorporates some components of DICOMweb.
Privacy and security standards (See 5.4.2)		
IHE ATNA with Radiology Option	PACS, Enterprise Viewers, EHR	To ensure secure connections between devices and audit PHI access. Invoking IHE ATNA incorporates DICOM Audit.
IHE BPPC	PACS, Enterprise Viewers, EHR	To collect consents related to imaging and enforce consent policies.
DICOM TLS	All DICOM systems	To support transport layer security on data connections.
Technical workflow standards (See 5.4.3)		
IHE SWF.b	EHR, RIS, PACS [a]	Developed for Radiology but applicable to scheduled imaging in other departments. The communications between the RIS/PACS and the ADT/HIS (i.e. department to enterprise integration) of IHE CATH and IHE ECHO follow Scheduled Workflow. Invoking IHE SWF.b incorporates HL7 ADT and HL7 OMG.
IHE CPI	PACS, Enterprise Viewers	To provide diagnostic viewing on distributed viewers. Invoking IHE CPI incorporates DICOM GSDF and DICOM GSPS.
IHE IOCM	PACS, VNA	To coordinate studies copied into several archives (radiology, cardiology, patient access portal, etc.)

[a] Historically, the translation of orders into worklists and other administration and workflow tasks in an imaging department were handled by a RIS (Radiology Information System) as a standalone system. In more recent years it has become more common for "departmental information system" services to be addressed as a component of the EHR system.

Readers are encouraged to consider the potential benefits of including additional standards (see Clause 5) based on their specific project needs and policies.