International Standard

ISO 12052

Health informatics — Digital imaging and communication in medicine (DICOM) including workflow and data management

Informatique de santé — Imagerie numérique et communication en médecine (DICOM) incluant le déroulement des opérations et la gestion des données

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Foreword

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

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

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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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 12052:2017), which has been technically revised.

The main changes are as follows:

— updates to Clause 3 to add several terms;

— updates to 6.10 to clarify the relationship of DICOM media interchange to data set specifications in Figure 3;

— updates to 6.21 to describe and reference PS3.21 for transformation between DICOM and NCI AIM;

— updates to 6.22 to describe and reference PS3.22 for real-time communication of DICOM content;

— updates to Clause 7 to clarify references to units of conformance are not acceptable in lieu of a conformance statement document for a product.

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.

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Introduction

0.1 General

Digital Imaging and Communications in Medicine (DICOM) is the standard for the communication and management of medical imaging information and related data.

The DICOM standard facilitates interoperability of medical imaging equipment by specifying:

— for network communications, a set of protocols to be followed by devices claiming conformance to the DICOM standard;

— the syntax and semantics of Commands and associated information which can be exchanged using these protocols;

— for media communication, a set of media storage services to be followed by devices claiming conformance to the DICOM standard, as well as a File Format and a medical directory structure to facilitate access to the images and related information stored on interchange media;

— information to be supplied with an implementation for which conformance to the DICOM standard is claimed.

The DICOM standard does not specify:

— the implementation details of any features of the DICOM standard on a device claiming conformance;

— the overall set of features and functions to be expected from a system implemented by integrating a group of devices each claiming conformance to the DICOM standard;

— a testing/validation procedure to assess an implementation's conformance to the DICOM standard.

The DICOM standard facilitates interoperability of systems claiming conformance in a multi-vendor environment, but does not, by itself, guarantee interoperability.

0.2 History

With the introduction of computed tomography (CT) followed by other digital diagnostic imaging modalities in the 1970s, and the increasing use of computers in clinical applications, the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) recognized the emerging need for a standard method for transferring images and associated information between devices manufactured by various vendors. These devices produce a variety of digital image formats.

The ACR and the NEMA formed a joint committee in 1983 to develop a standard to:

— promote communication of digital image information, regardless of device manufacturer;

— facilitate the development and expansion of picture archiving and communication systems (PACS) that can also interface with other systems of hospital information;

— allow the creation of diagnostic information data bases that can be interrogated by a wide variety of devices distributed geographically.

ACR-NEMA Standards Publication No. 300-1985[4], published in 1985, was designated version 1.0. The Standard was followed by two revisions: No. 1, dated October 1986 and No. 2, dated January 1988. These Standards Publications specified a hardware interface, a minimum set of software commands, and a consistent set of data formats.

ACR-NEMA Standards Publication No. 300-1988, published in 1988, was designated version 2.0. It included version 1.0, the published revisions, and additional revisions. It also included new material to provide command support for display devices, to introduce a new hierarchy scheme to identify an image, and to add data elements for increased specificity when describing an image.

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In 1993, ACR-NEMA Standard 300 was substantially revised and replaced by the standard, designated Digital Imaging and Communications in Medicine (DICOM). It embodies a number of major enhancements to previous versions of the ACR-NEMA Standard:

— It is applicable to a networked environment. The ACR-NEMA Standard was applicable in a point-to-point environment only; for operation in a networked environment a Network Interface Unit (NIU) was required. DICOM supports operation in a networked environment using the industry standard networking protocol TCP/IP.

— It is applicable to off-line media exchange. The ACR-NEMA Standard did not specify a file format or choice of physical media or logical filesystem. DICOM supports operation in an off-line media environment using industry standard media such as CD-R, DVD-R and USB and common file systems.

— It is a service-oriented protocol, specifying the semantics of commands and associated data, and how devices claiming conformance to the DICOM standard react to commands and data being exchanged. Specified services include support for management of the workflow of an imaging department. The ACR-NEMA Standard was confined to the transfer of data with only implicit service requirements.

— It specifies levels of conformance. The ACR-NEMA Standard specified a minimum level of conformance. DICOM explicitly describes how an implementor structures a conformance statement to select specific options.

In 1995, with the addition of DICOM capabilities for cardiology imaging supported by the American College of Cardiology, the ACR-NEMA Joint Committee was reorganized as the DICOM Standards Committee, a broad collaboration of stakeholders across all medical imaging specialties.

0.3 Principles

0.3.1 Global applicability and localization

DICOM is a world-wide standard that can be used in every locale. It provides mechanisms to handle data that support cultural requirements, such as different writing systems, character sets, languages, and structures for addresses and person names. It supports the variety of workflows, processes and policies used for biomedical imaging in different geographic regions, medical specialties and local practices.

Localization to meet the requirements of national or local health and workflow policies can be done without deviating from the DICOM standard. Such localization can include specifying code sets (e.g. procedure codes), or profiling data element usage (both specifying locally allowed values, and making elements that are optional in the DICOM standard mandatory for local use).

Localization and profiling can be specified in a number of mechanisms outside the purview of the DICOM Standard. One such mechanism is Integration Profiles from the Integrating the Healthcare Enterprise (IHE) organization. It is important that profiling adhere to the concept of non-contradiction. A profile can add requirements but not contradict DICOM requirements, as that would make it impossible to conform with both DICOM and the profile.

0.3.2 Continuous maintenance

The DICOM Standard is an evolving standard and it is maintained in accordance with the Procedures of the DICOM Standards Committee. Proposals for enhancements are welcome from all users of the DICOM standard, and can be submitted to the Secretariat. Supplements and corrections to the DICOM standard are balloted and approved several times a year. When approved as Final Text, each change becomes official, is published separately, and goes into effect immediately. At intervals, all of the approved Final Text changes are consolidated and published in an updated edition of the DICOM standard. Once changes are consolidated into an updated edition of the DICOM standard, the individual change documents are not maintained; readers are directed to use the consolidated edition of the DICOM standard.

A requirement in updating the DICOM standard is to maintain effective compatibility with previous editions.

The maintenance process can involve retirement of sections of the DICOM standard.

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Retirement does not imply that these features cannot be used. However, the DICOM Standards Committee will not maintain the documentation of retired features. The reader is referred to earlier editions of the DICOM standard.

The use of the retired features is discouraged for new implementations, in favour of those alternatives remaining in the DICOM standard.

0.3.3 Information objects and unique object identification

Many DICOM services involve the exchange of persistent information objects, such as images. An instance of such an information object can be exchanged across many systems and many organizational contexts, and over time. While minor changes can be made to the attributes of an instance to facilitate its handling within a particular organization (e.g. by coercing a Patient ID to the value used in a local context), the semantic content of an instance does not change.

Each instance is identified by a globally unique object identifier, which persists with the instance across all exchanges. Changes to the semantic content of an instance are defined to create a new instance, which is assigned a new globally unique object identifier.

0.3.4 Conformance

Conformance to the DICOM standard is stated in terms of Service-Object Pair (SOP) Classes, which represent Services (such as Storage using network, media, or web) operating on types of Information Objects (such as CT or MR images).

SOP Class specifications in the DICOM standard are only changed in a manner that is intended to be forward and backward compatible for all editions of the DICOM standard. Systems that claim conformance to the same SOP Class are thus compatible across all editions of the DICOM standard. Conformance requirements and conformance claims are therefore referenced to the identifier of the SOP Class, and never referenced to an edition of the DICOM standard.

Each implementation is required to provide a DICOM Conformance Statement, in accordance with a consistent pro forma structure, facilitating comparison of products for interoperability.

0.3.5 Consistency of information model

A large number of information objects defined in the DICOM standard follows a common composite information model with information entities representing Patient, Study, Series, Equipment, Frame of Reference, and the specific instance data type. This information model is a simplification of the real-world concepts and activities of medical imaging; for acquisition modalities, a Study is approximately equivalent to an ordered procedure, and a Series is approximately equivalent to a performed data acquisition protocol element. In other domains, such as Radiotherapy, the Study and Series are less clearly related to real world entities or activities, but are still required for consistency. This simplified model is sufficient for the pragmatic needs of managing imaging and related data collected in routine practice.

New information objects defined in DICOM will typically conform to this existing common information model, allowing reuse of implementations with minimal changes to support the new objects.

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Health informatics — Digital imaging and communication in medicine (DICOM) including workflow and data management

1 Scope

Within the field of health informatics, the DICOM (digital imaging and communication in medicine) standard addresses the exchange of digital images, and information related to the production and management of those images, between both medical imaging equipment and systems concerned with the management and communication of that information, such as Picture Archiving anc Communication System (PACS), Hospital Information System (HIS) and Radiology Information System (RIS).

This document is equivalent to part 1 of DICOM. As such, it normatively describes the content of DICOM (Clause 6) and the requirements to make a claim of conformance (Clause 5).

The DICOM standard is applicable to diagnostic medical imaging as practiced in radiology, cardiology, pathology, dentistry, ophthalmology and related disciplines, and image-based therapies such as interventional radiology, radiotherapy and surgery. It is also applicable to a wide range of image and non-image related information exchanged in clinical, research, veterinary, and other medical environments.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

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

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

3.1
attribute
property of an *information object* (3.10)

Note 1 to entry: An attribute has a name and a value which are independent of any encoding scheme.

3.2
command
request to operate on information across a network

3.3
command element
encoding of a parameter of a *command* (3.2) which conveys this parameter's value

3.4
command stream
result of encoding a set of DICOM *command elements* (3.3) using the DICOM encoding scheme

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3.5
conformance statement
formal statement that describes a specific implementation of the DICOM standard

Note 1 to entry: It specifies the service classes, *information objects* (3.10), communication protocols, security profiles, and media storage application profiles supported by the implementation.

3.6
data dictionary
registry of DICOM data elements which assigns a unique tag, a name, value characteristics, and semantics to each *data element* (3.7)

3.7
data element
unit of information as defined by a single entry in the *data dictionary* (3.6)

3.8
data set
exchanged information consisting of a structured set of *attributes* (3.1)

Note 1 to entry: The value of each *attribute* (3.1) in a data set is expressed as a *data element* (3.7).

3.9
data stream
result of encoding a *data set* (3.8) using the DICOM encoding scheme (Data Element Numbers and representations as specified by the *data dictionary* (3.6))

3.10
information object
abstraction of a real information entity (e.g. CT Image, Structured Report) which is acted upon by one or more DICOM *commands* (3.2)

Note 1 to entry: This term is primarily used in DICOM PS3.1, with a few references in DICOM PS3.3. It is an informal term corresponding to a formal term that is introduced in DICOM PS3.3. In all other *parts* (3.14) of the DICOM standard this formal term is known as an Information Object Definition.

3.11
information object class
formal description of an *information object* (3.10) which includes a description of its purpose and the *attributes* (3.1) it possesses

Note 1 to entry: It does not include values for these attributes.

Note 2 to entry: This term is only used in DICOM PS3.1. It is an informal term corresponding to a formal term that is introduced in DICOM PS3.4. This formal term is known as a *service-object pair class* (3.16) or more commonly as a SOP Class.

3.12
information object instance
representation of an occurrence of a real-world entity, which includes values for the *attributes* (3.1) of the *information object class* (3.11) to which the entity belongs

Note 1 to entry: This term is only used in DICOM PS3.1. It is an informal term corresponding to a formal term that is introduced in DICOM PS3.4. This formal term is known as a service-object pair instance or more commonly as a SOP Instance.

3.13
message
data unit of the message exchange protocol exchanged between two cooperating DICOM applications

Note 1 to entry: A message is composed of a *command stream* (3.4) followed by an optional *data stream* (3.9).

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3.14
part
subdivision of the DICOM standard that covers related subject material

3.15
RESTful web service
web service implemented using REST architecture and HTTP

Note 1 to entry: See https://www.ics.uci.edu/~fielding/pubs/dissertation/fielding_dissertation.pdf.

3.16
service class
structured description of a service which is supported by cooperating DICOM applications using specific DICOM *commands* (3.2) acting on a specific class of *information object* (3.10)

3.17
service-object pair class
SOP class
pair of an *information object* (3.10) and either a DICOM message service element (DIMSE) service group, a media storage service, or a web service

4 Abbreviated terms

ACSE	association control service element
API	application programming interface
CT	computed tomography
DICOM	digital imaging and communications in medicine
DIMSE	DICOM message service element
HTTP	hyper-text transfer protocol
IOD	information object definition
OSI	open systems interconnection
PACS	picture archiving and communication systems
REST	representational state transfer
RTP	real-time transport protocol
SMPTE	society of motion picture and television engineers
SOP	service-object pair
STOW-RS	store over the web by RESTful web services
TCP/IP	transmission control protocol/internet protocol
WADO-RS	web access to DICOM objects by RESTful web services

5 Requirements: Conformance

A claim of conformance to the DICOM standard, with regard to a given product, shall only be valid when supported by a DICOM Conformance Statement written in accordance with the provisions of the DICOM standard, PS3.2 (Part 2) which includes, but is not limited to, a list of all data IOD items communicated by

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