BS EN ISO 12052:2017

BSI Standards Publication

Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management (ISO 12052:2017)

National foreword

This British Standard is the UK implementation of EN ISO 12052:2017. It is identical to ISO 12052:2017. It supersedes BS EN ISO 12052:2011, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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English Version

Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management (ISO 12052:2017)

Informatique de santé - Imagerie numérique et communication en médecine (DICOM) incluant le déroulement des opérations et la gestion des données (ISO 12052:2017)

Medizinische Informatik - Digitale Bildverarbeitung und Kommunikation in der Medizin (DICOM) inklusive Workflow und Datenmanagement (ISO 12052:2017)

This European Standard was approved by CEN on 12 September 2017.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 12052:2017) has been prepared by Technical Committee ISO/TC 215 “Health informatics” in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2018, and conflicting national standards shall be withdrawn at the latest by March 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 12052:2011.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 12052:2017 has been approved by CEN as EN ISO 12052:2017 without any modification.

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Foreword

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

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

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

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

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 12052:2006), of which it constitutes a minor revision.

The changes made are as follows:

— Clause 1, 6.18, 6.19, 6.20 and Clause 7 have been revised;

— informative material has been added to the Introduction.

0 Introduction

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

0.1 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 American College of Radiology (ACR) and the National Electrical Manufacturers Association (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 databases that can be interrogated by a wide variety of devices distributed geographically.

ACR-NEMA standards Publication No. 300-1985, 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.

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

— 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 offline 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 offline 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 must structure 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 specialities.

0.2 Principles

0.2.1 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 specialities 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 may 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 should not contradict DICOM requirements, as that would make it impossible to comply with both DICOM and the Profile.

0.2.2 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 may 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 may involve retirement of sections of the DICOM standard.

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.

0.2.3 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 may be exchanged across many systems and many organizational contexts, and over time. While minor changes may 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.

0.2.4 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. 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 Conformance Statement, in accordance with a consistent pro forma structure, facilitating comparison of products for interoperability.

0.2.5 Consistency of information model

A large number of information objects defined in the DICOM standard follow 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.

INTERNATIONAL STANDARD **ISO 12052:2017(E)**

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

1 Scope

This document, within the field of health informatics, 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.

This document facilitates interoperability of medical imaging equipment by specifying:

— for network communications, a set of protocols to be followed by devices claiming conformance to this document;

— 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 this document, 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 that is to be supplied with an implementation for which conformance to this document is claimed.

This document 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 this document;

— a testing/validation procedure to assess an implementation's conformance to this document.

This document pertains to the field of medical informatics. Within that field, it addresses the exchange of digital information between medical imaging equipment and other systems. Because such equipment may interoperate with other medical devices and information systems, the scope of this document needs to overlap with other areas of medical informatics. However, this document does not address the full breadth of this field.

This document has been developed with an emphasis on 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. However, it is also applicable to a wide range of image and non-image related information exchanged in clinical, research, veterinary, and other medical environments.

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

2 Normative references

There are no normative references in this document.