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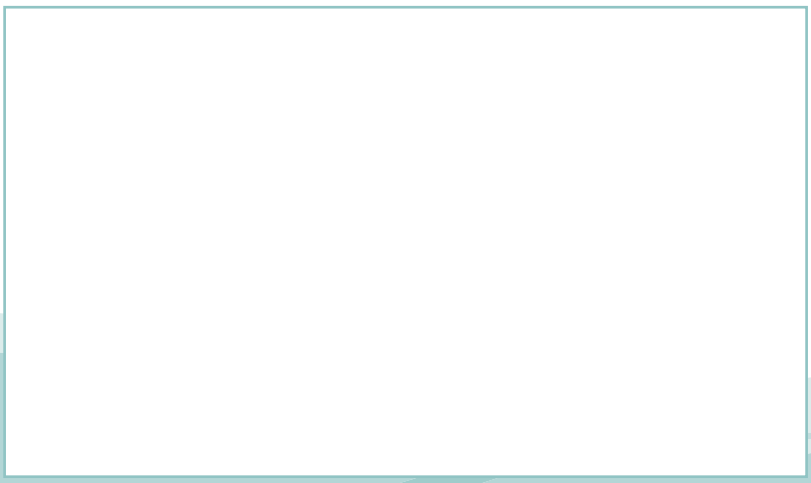
SWEDISH STANDARDS INSTITUTE

Hälso- och sjukvårdsinformatik – DICOM, digital bildhantering – kommunikation, arbetsflöde och dataförvaltning (ISO 12052:2017)

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



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Europastandarden EN ISO 12052:2017 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 12052:2017.

Denna standard ersätter SS-EN ISO 12052:2011, utgåva 1.

The European Standard EN ISO 12052:2017 has the status of a Swedish Standard. This document contains the official version of EN ISO 12052:2017.

This standard supersedes the Swedish Standard SS-EN ISO 12052:2011, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Hälso- och sjukvårdsinformatik, SIS/TK 334.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 12052

September 2017

ICS 35.240.80

Supersedes EN ISO 12052:2011

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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.

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.