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

Informatique de santé — Imagerie numérique et communication dans la 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 12052 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

ACR (the American College of Radiology) and NEMA (the National Electrical Manufacturers Association) formed a joint committee in 1983 to develop a Standard for Digital Imaging and Communications in Medicine. The third release of this work received the name DICOM, for Digital Imaging and Communications in Medicine. This DICOM Standard was developed according to the NEMA Procedures in liaison with other Standardization Organizations including ISO/TC/215, CEN TC251 in Europe and JIRA in Japan, with review also by other organizations including IEEE, HL7 and ANSI in the USA. Several countries have been actively involved in the development of the DICOM Standard — in particular Canada, Germany, France, Italy, Japan, Korea, Taiwan and the United States of America. Contributions were received from more than 20 other countries. DICOM is used in most healthcare institutions worldwide where patient imaging is performed. Most imaging devices and imaging related information systems products support it.

Within health informatics, this International Standard addresses the exchange of digital images and related information between both medical imaging equipment and systems concerned with the management of that information.

This International Standard facilitates interoperability of systems claiming conformance. In particular, it:

— addresses the semantics of commands and associated data; for devices and systems to interact, there must be standards on how they are expected to behave in response to commands and associated data, not just the information which is to be moved between devices and systems;

— is explicit in defining the conformance requirements of implementations of this International Standard; in particular, a conformance statement has to specify enough information to determine the functions for which interoperability can be expected with another system claiming conformance;

— facilitates operation in a networked environment and in the area of media interchange;

— is structured to accommodate the introduction of new services, thus facilitating support for future medical imaging applications.

Even though this International Standard has largely facilitated the implementations of Picture Archiving and Communication Systems (PACS) solutions and integrated digital imaging departments, use of this International Standard alone does not guarantee that all the goals of such solutions will be met. This International Standard facilitates interoperability of systems claiming conformance in a multi-vendor environment, but does not, by itself, guarantee interoperability.

This International Standard has been developed with an emphasis on diagnostic medical imaging as practiced in radiology, cardiology and other imaging disciplines.

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

1 Scope

Within the field of health informatics this International 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.

This International Standard is intended to facilitate interoperability of medical imaging equipment and information systems by specifying:

— a set of protocols to be followed by systems claiming conformance to this International Standard.

— the syntax and semantics of commands and associated information data models that ensure effective communication between implementations of this International Standard;

— information that shall be supplied with an implementation for which conformance to this International Standard is claimed.

This International Standard does not specify:

— the implementation details of any features of this International Standard on a device or systems for which conformance is claimed;

— the overall set of features and functions to be expected from a larger system implemented by integrating a group of devices and systems each claiming conformance to this International Standard;

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

Within health informatics both medical imaging systems and equipment concerned with the management and communication of medical image data may also be required to interoperate with systems in other areas of health informatics. The communication of these data with these other areas may be in the scope of other standards.

2 Terms and definitions

For the purposes of this document, the terms and definitions in DICOM Standard, PS 3 apply.

3 Symbols and abbreviations

For the purposes of this document, the following abbreviations apply.

— **ACSE** Association Control Service Element

— **DICOM** Digital Imaging and Communications in Medicine

— **OSI** Open Systems Interconnection

— **PACS** Picture Archiving and Communication Systems

— **TCP/IP** Transmission Control Protocol/Internet Protocol

4 Requirements

4.1 Provisions

This International Standard references, normatively and in its entirety, the publicly available specification known as the "Digital Imaging and Communications in Medicine (DICOM) Standard, PS 3".

4.2 Conformance

A claim of conformance to this International 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, PS 3.2 (Part 2) which includes, but is not limited to, a list of all data IOD items communicated by the product and confirmation that their content conforms to the specifications of DICOM PS 3.

5 Overview of the content of the DICOM standard

5.1 Document structure

DICOM consists of the following parts:

PS 3.1: Part 1: Introduction and Overview

PS 3.2: Part 2: Conformance

PS 3.3: Part 3: Information Object Definitions

PS 3.4: Part 4: Service Class Specifications

PS 3.5: Part 5: Data Structure and Semantics

PS 3.6: Part 6: Data Dictionary

PS 3.7: Part 7: Message Exchange

PS 3.8: Part 8: Network Communication Support for Message Exchange

PS 3.9: Retired

PS 3.10: Part 10: Media Storage and File Format for Data Interchange

PS 3.11: Part 11: Media Storage Application Profiles

PS 3.12: Part 12: Media Formats and Physical Media for Data Interchange

PS 3.13: Retired

PS 3.14 Part 14: Grayscale Standard Display Function

PS 3.15: Part 15: Security and Systems Management Profiles

PS 3.16: Part 16: Content Mapping Resource

PS 3.17: Part 17: Explanatory Material

PS 3.18: Part 18: Web Access to persistent DICOM Objects

These parts of the DICOM Standard are related but independent documents. A brief description of each part is provided in 5.2 to 5.18.

DICOM Standard, PS 3 is available in print or in electronic form from the DICOM web site at: http://dicom.nema.org/.

5.2 PS 3.2: Conformance

PS 3.2 of the DICOM Standard defines principles that implementations claiming conformance to that Standard shall follow.

— Conformance requirements: PS 3.2 specifies the general requirements which shall be met by any implementation claiming conformance. It references the conformance sections of other parts of the Standard.

— Conformance statement: PS 3.2 defines the structure of a conformance statement. It specifies the information which shall be present in a conformance statement. It references the conformance statement sections of other parts of the Standard.

PS 3.2 does not specify a testing/validation procedure to assess an implementation's conformance to the Standard.

Figures 1 and 2 depict the construction process for a conformance statement for both network communication and media exchange. A conformance statement consists of the following parts:

— set of information objects, which is recognized by this implementation;

— set of service classes, which this implementation supports;

— set of communications protocols or physical media, which this implementation supports;

— set of security measures, which this implementation supports.

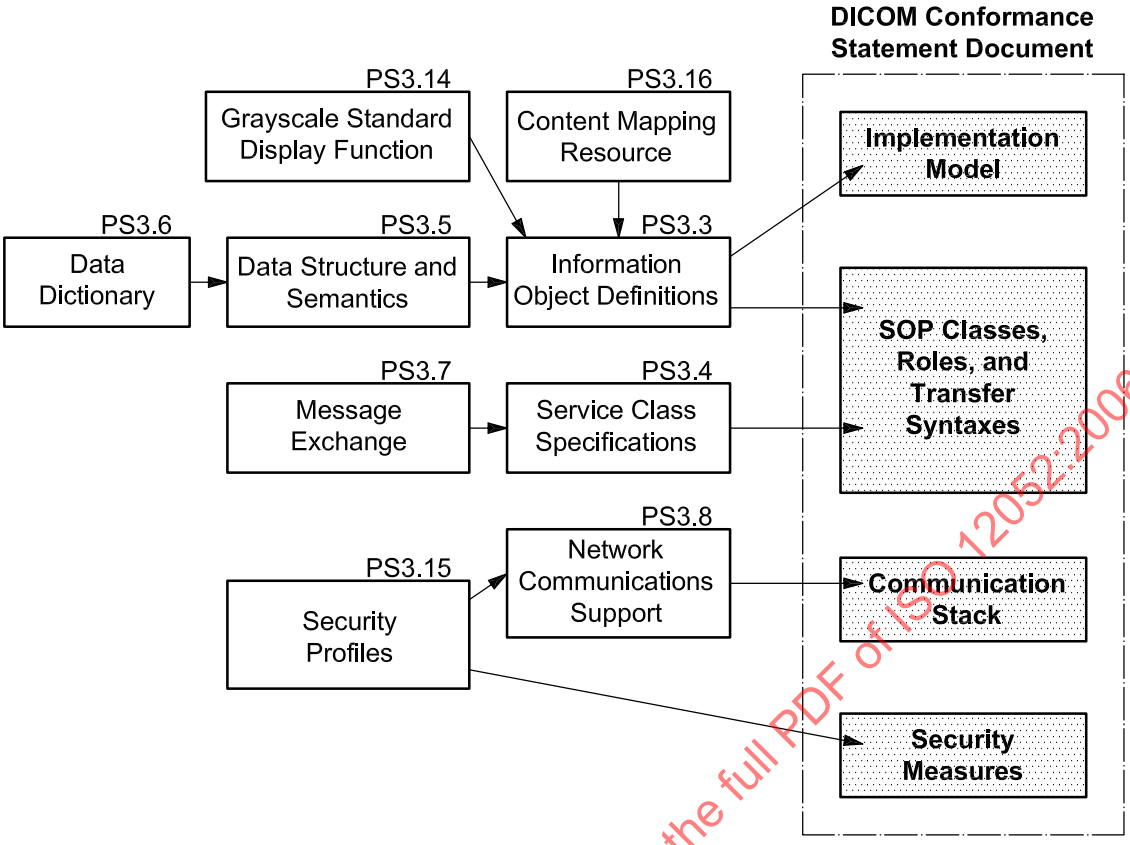

Figure 1 — Construction process for a network conformance statement

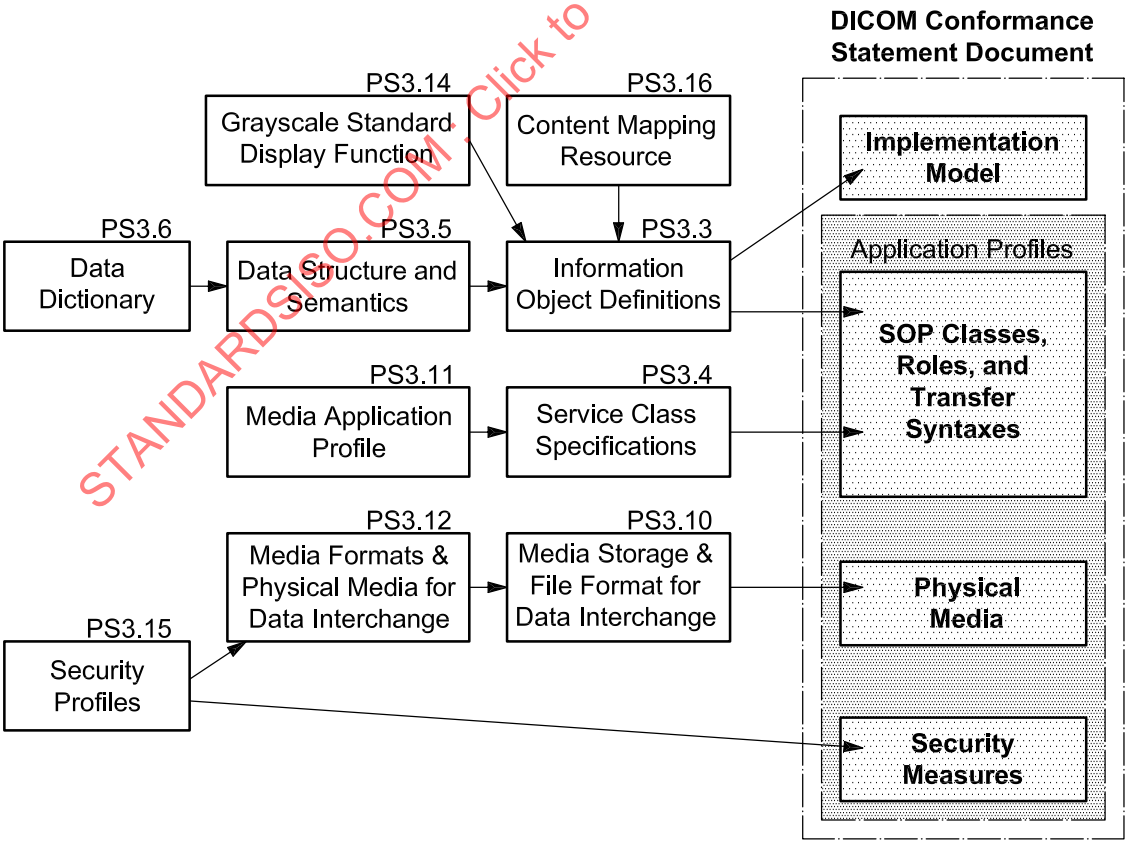

Figure 2 — Construction process for a media conformance statement

5.3 PS 3.3: Information Object Definitions

PS 3.3 of the DICOM Standard specifies a number of Information Object Classes which provide an abstract definition of real-world entities applicable to communication of digital medical images and related information (e.g., waveforms, structured reports, radiation therapy dose, etc.). Each Information Object Class definition consists of a description of its purpose and the Attributes which define it. An Information Object Class does not include the values for the Attributes which comprise its definition.

Two types of Information Object Class are defined: normalized and composite.

Normalized Information Object Classes include only those attributes inherent in the real-world entity represented. For example the study Information Object Class, which is defined as normalized, contains study date and study time Attributes because they are inherent in an actual study. Patient name, however, is not an attribute of the study Information Object Class because it is inherent in the patient on which the study was performed and not the study itself.

Composite Information Object Classes may additionally include Attributes which are related to but not inherent in the real-world entity. For example, the Computed Tomography Image Information Object Class, which is defined as composite, contains both attributes which are inherent in the image (e.g. image date) and attributes which are related to but not inherent in the image (e.g. patient name). Composite Information Object Classes provide a structured framework for expressing the communication requirements of images where image data and related data need to be closely associated.

To simplify the Information Object Class definitions, the attributes of each Information Object Class are partitioned with similar attributes being grouped together. These groupings of attributes are specified as independent modules and may be re-used by other Composite Information Object Classes.

PS 3.3 defines a model of the real-world along with the corresponding information model that is reflected in the Information Object Definitions. Future editions of this International Standard may extend this set of Information Objects to support new functionality.

To represent an occurrence of a real-world entity, an Information Object Instance is created, which includes values for the attributes of the Information Object Class. The attribute values of this Information Object Instance may change over time to accurately reflect the changing state of the entity which it represents. This is accomplished by performing different basic operations upon the Information Object Instance to render a specific set of services defined as a Service Class. These Service Classes are defined in PS 3.4 of the Standard.

5.4 PS 3.4: Service Class Specifications

PS 3.4 of the DICOM Standard defines a number of Service Classes. A Service Class associates one or more Information Objects with one or more commands to be performed upon these objects. Service Class Specifications state requirements for Command Elements and how resulting commands are applied to Information Objects. Service Class Specifications state requirements for both providers and users of communications services.

PS 3.4 of the DICOM Standard defines the characteristics shared by all Service Classes, and how a Conformance Statement to an individual Service Class is structured. It contains a number of normative annexes which describe individual Service Classes in detail.

Examples of Service Classes include the following:

1) Storage Service Class;

2) Query/Retrieve Service Class;

3) Basic Worklist Management Service Class;

4) Print Management Service Class.

PS 3.4 defines the operations performed upon the Information Objects defined in PS 3.3. PS 3.7 defines the commands and protocols for using the commands to accomplish the operations and notifications described in PS 3.4.

5.5 PS 3.5: Data Structure and Semantics

PS 3.5 of the DICOM Standard specifies how DICOM applications construct and encode the Data Set information resulting from the use of the Information Objects and Services Classes defined in PS 3.3 and PS 3.4 of the DICOM Standard. The support of a number of standard image compression techniques (e.g., JPEG lossless and lossy) is specified.

PS 3.5 addresses the encoding rules necessary to construct a Data Stream to be conveyed in a Message as specified in PS 3.7 of the DICOM Standard. This Data Stream is produced from the collection of Data Elements making up the Data Set.

PS 3.5 also defines the semantics of a number of generic functions that are common to many Information Objects. PS 3.5 defines the encoding rules for international character sets used within DICOM.

5.6 PS 3.6: Data Dictionary

PS 3.6 of the DICOM Standard is the centralized registry that defines the collection of all DICOM Data Elements available to represent information, along with elements utilized for interchangeable media encoding and a list of uniquely identified items that are assigned by DICOM.

For each element, PS 3.6 specifies:

— its unique tag, which consists of a group and element number;

— its name;

— its value representation (character string, integer, etc.);

— its value multiplicity (how many values per attribute);

— whether it is retired.

For each uniquely identified item, PS 3.6 specifies:

— its unique value, which is numeric with multiple components separated by decimal points and limited to 64 characters;

— its name;

— its type, either Information Object Class, definition of encoding for data transfer or certain well known Information Object Instances;

— in which part of the DICOM Standard it is defined.

5.7 PS 3.7: Message Exchange

PS 3.7 of the DICOM Standard specifies both the service and protocol used by an application in a medical imaging environment to exchange Messages over the communications support services defined in PS 3.8. A message is composed of a Command Stream defined in PS 3.7 followed by an optional Data Stream as defined in PS 3.5.

PS 3.7 specifies:

— the operations and notifications (DIMSE Services) made available to Service Classes defined in PS 3.4;

— rules to establish and terminate associations provided by the communications support specified in PS 3.8, and the impact on outstanding transactions;

— rules that govern the exchange of Command requests and responses;

— encoding rules necessary to construct Command Streams and Messages.

5.8 PS 3.8: Network Communication Support for Message Exchange

PS 3.8 of the DICOM Standard specifies the communication services and the upper layer protocols necessary to support, in a networked environment, communication between DICOM applications as specified in PS 3.3, PS 3.4, PS 3.5, PS 3.6 and PS 3.7. These communication services and protocols ensure that communication between DICOM applications is performed in an efficient and coordinated manner across the network.

The communication services specified in PS 3.8 are a proper subset of the services offered by the OSI Presentation Service (ISO/IEC 8822) and of the OSI Association Control Service Element (ACSE) (ISO/IEC 8649). They are referred to as the Upper Layer Service, which allows peer applications to establish associations, transfer messages and terminate associations.

This definition of the Upper Layer Service specifies the use of the DICOM Upper Layer Protocol in conjunction with TCP/IP transport protocols.

The TCP/IP communication protocol specified by PS 3.8 is a general-purpose communication protocol not specific to the DICOM Standard. Figure 3 shows this protocol stack.

5.9 PS 3.9: Retired (Formerly Point-to-Point Communication Support for Message Exchange)

PS 3.9 of the DICOM Standard previously specified the services and protocols used for point-to-point communications in a manner compatible with ACR-NEMA 2.0. It has been retired.

5.10 PS 3.10 Media Storage and File Format

PS 3.10 of the DICOM Standard specifies a general model for the storage of medical imaging information on removable media (see Figure 3). The purpose of this Part is to provide a framework allowing the interchange of various types of medical image and related information on a broad range of physical storage media.

See Figure 3 for understanding how the media interchange model compares to the network model.

PS 3.10 specifies:

— a layered model for the storage of medical images and related information on storage media; this model introduces the concept of media storage application profiles, which specify application specific subsets of the DICOM Standard to which a media storage implementation may claim conformance;

NOTE Such a conformance applies only to the writing, reading and updating of the content of storage media.

— a DICOM file format supporting the encapsulation of any Information Object;

— a secure DICOM file format supporting the encapsulation of a DICOM file format in a cryptographic envelope;

— a DICOM file service providing independence from the underlying media format and physical media.

PS 3.10 defines various media storage concepts:

a) the method of identifying a set of files on a single medium;

b) the method of naming a DICOM file within a specific file system.

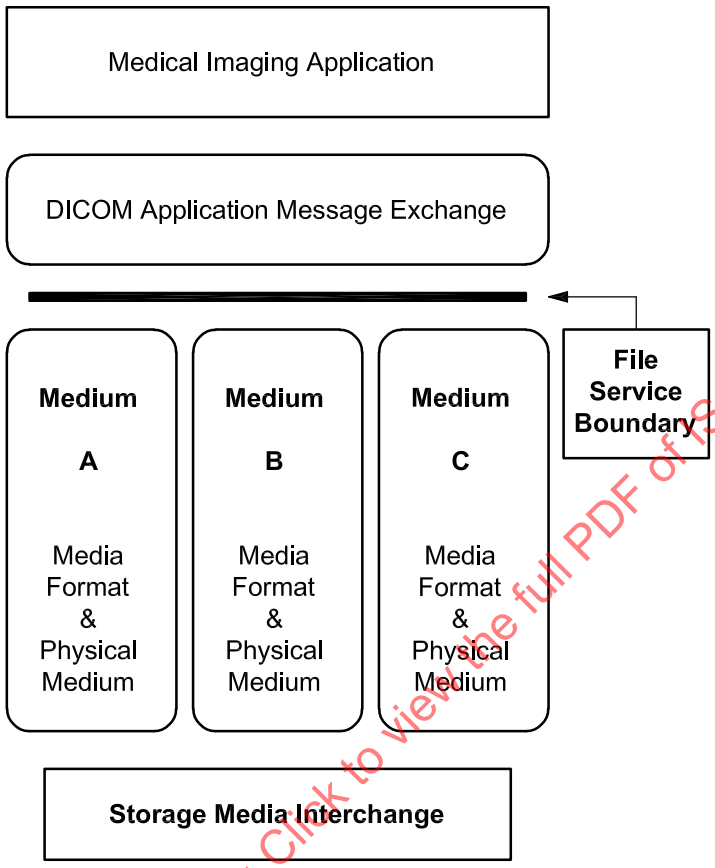

Figure 3 — DICOM Media Communication Model

5.11 PS 3.11: Media Storage Application Profiles

PS 3.11 of the DICOM Standard specifies application-specific subsets of the DICOM Standard to which an implementation may claim conformance. These application-specific subsets will be referred to as Application Profiles in this subclause. Such a conformance statement applies to the interoperable interchange of medical images and related information on storage media for specific clinical uses. It follows the framework, defined in PS 3.10, for the interchange of various types of information on storage media.

An Application Profile annex is organized into the following major parts:

1) the name of the Application Profile, or the list of Application Profiles grouped in a related class;

2) a description of the clinical context of the Application Profile;

3) the definition of the media storage Service Class with the device roles for the Application Profile and associated options;

4) an informative section describing the operational requirements of the Application Profile;

5) a specification of the Information Object Classes and associated Information Objects supported and the encoding to be used for the data transfer;