DICOM Correction Proposal

STATUS	Draft Final Text
Date of Last Update	2016/01/11
Person Assigned	Harry Solomon
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Submission Date	2014/04/28

Correction Number CP-1415
Log Summary: Update PS3.1 front matter
Name of Standard PS3.1 2015c PS3.2–20 2015c (Foreword and Normative References)
Rationale for Correction PS3.1 is the core of ISO 12052, and is the public face of DICOM through ISO. For the next revision of 12052, DICOM should update PS3.1 to present a comprehensive and up to date description that addresses common questions of a variety of interested parties. ISO now provides free public access to the introductory front matter published in all ISO standards through its Online Browsing Platform (OBP). PS3.1 should have its front matter updated to be most effective in that forum. The content of the Principles section is based on presentations by current and past chairs of the DSC to various stakeholders. Normative References are updated. Text that is simply rearranged is shown with strikethrough and underline, but not boldface. New text is shown with underline and boldface. *[Comment: AGFA: In section 1.42 change or rephrase the "deprecated for new implementations". Perhaps replace it with "not recommended for new implementations". The word "deprecated" is usually used just in reference to specifications and product features. It reads oddly and may be confusing to translate when used as implementation guidance. "not recommended" may be too strong, so alternative phrasing may be appropriate - ACCEPTED - use "discouraged" instead.]* *[Comment: GE: change "denoted by" to "denoted as" - REJECTED – Accepted Toshiba revision of section.]* *[Comment: McKesson - Section 1.2 (previously in section 5) contains text which mentions PACS. It is unclear why PACS is called out, but other systems aren't (modalities, CAD, viewers, archives, etc.). I recognize this text predates the CP, but this might be an opportunity to update it – ACCEPTED – line struck]* *[Comment: Toshiba – multiple revisions – mostly ACCEPTED]*
Correction Wording:

Foreword

The DICOM Standards Committee is an independent, international standards development organization comprising biomedical professional societies whose specialties include the use of medical imaging, manufacturers of medical imaging equipment and related information systems, and government agencies, trade associations, and other standards development organizations with an interest in standardization of medical imaging information and related data. Membership is open to all organizations with a material interest in the work of the Committee. The Committee collaborates closely with other standards

development organizations in the fields of Healthcare Informatics and Electrical Equipment in Medical Practice. The Secretariat of the Committee is the National Electrical Manufacturers Association and its Medical Imaging and Technology Alliance division.

The principal product of the Committee is this Standard, Digital Imaging and Communications in Medicine (DICOM).

This DICOM Standard was developed according to the procedures of the DICOM Standards Committee.

The DICOM Standard is structured as a multi-part document using the guidelines established in [ISO/IEC Directives Part ~~3~~2] ***Rules for the structure and drafting of International Standards***.

The Standard is published as NEMA Standard PS3, and its Parts are identified by the numbering of the NEMA publication (PS3.1, PS3.2, etc.).

~~Introduction~~

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

~~History~~

~~With the introduction of computed tomography (CT) followed by other digital diagnostic imaging modalities in the 1970's, 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 data bases 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.~~

~~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.~~

~~These Standards Publications specified a hardware interface, a minimum set of software commands, and a consistent set of data formats.~~

~~The DICOM Standard~~

~~This Standard, which is currently designated Digital Imaging and Communications in Medicine (DICOM), 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 an off-line media environment. 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 and MOD and logical filesystems such as ISO 9660 and PC File System (FAT16).~~
- ~~It specifies how devices claiming conformance to the Standard react to commands and data being exchanged. The ACR-NEMA Standard was confined to the transfer of data, but DICOM specifies, through the concept of Service Classes, the semantics of commands and associated data.~~

- 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.

- It is structured as a multi-part document. This facilitates evolution of the Standard in a rapidly evolving environment by simplifying the addition of new features. ISO directives that define how to structure multi-part documents have been followed in the construction of the DICOM Standard.

- It introduces explicit Information Objects not only for images and graphics but also for waveforms, reports, printing, etc.

- It specifies an established technique for uniquely identifying any Information Object. This facilitates unambiguous definitions of relationships between Information Objects as they are acted upon across the network.

Current Direction

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 forthcoming from the DICOM Committee member organizations based on input from users of the Standard. These proposals are considered for inclusion in future editions of the Standard. A requirement in updating the Standard is to maintain effective compatibility with previous editions.

Retirement

Part of the maintenance process involves retirement of sections of the Standard, including but not limited to, IODs, Attributes, Service Classes, SOP Classes, Transfer Syntaxes and Protocols.

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 Standard.

The use of the retired features is deprecated in new implementations, in favor of those alternatives remaining in the standard.

1 Scope and Field of Application

PS3.1 provides an overview of the entire Digital Imaging and Communications in Medicine (DICOM) Standard. It describes the history, scope, goals, and structure of the Standard. In particular, it contains a brief description of the contents of each part of the Standard.

1.1 Scope of DICOM

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 Standard.
- The syntax and semantics of Commands and associated information that can be exchanged using these protocols.
- For media communication, a set of media storage services to be followed by devices claiming conformance to the 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 that must be supplied with an implementation for which conformance to the Standard is claimed.

The DICOM Standard does not specify:

- The implementation details of any features of the 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 DICOM conformance.
- A testing/validation procedure to assess an implementation's conformance to the Standard.

1.2 Field of Application

The DICOM Standard pertains to the field of Biomedical and Healthcare 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 Standard needs to overlap with other areas of medical informatics. However, the DICOM Standard does not address the breadth of this field.

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

1.3 History

With the introduction of computed tomography (CT) followed by other digital diagnostic imaging modalities in the 1970's, 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 data bases 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 ACR-NEMA 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.

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

- It is applicable to a networked environment. The ACR-NEMA Standard was applicable in a point-to-point environment only. 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 file system. DICOM supports operation in an off-line media environment using industry standard media such as **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 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 implementer 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 specialties.

1.4 Principles

1.4.1 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 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 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.

1.4.2 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 Standard, and may be submitted to the Secretariat**. Supplements and corrections to the 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 Standard. **Once changes are consolidated into an updated edition of the Standard, the individual change documents are not maintained; readers are directed to use the consolidated edition of the Standard.**

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

The maintenance process may involve retirement of sections of the 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 Standard. The use of the retired features is discouraged for new implementations, in favor of those alternatives remaining in the standard.

1.4.3 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 is defined to create a new instance, which is assigned a new globally unique object identifier.

1.4.4 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 Standard. Conformance requirements and conformance claims are therefore referenced to the identifier of the SOP Class, and never referenced to an edition of the Standard.

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

1.4.5 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.

2 Normative References

[ISO/IEC Directives Part ~~3~~**2**] ISO/IEC. ~~**1989.**~~ ***Rules for the structure and*** *drafting* ~~***and Presentation***~~ *of International Standards*. **Sixth edition, 2011**

[ACR/NEMA 300] ACR/NEMA. ~~1988~~. *Digital Imaging and Communications*. 1988.

[ISO/**IEC** 8822] ISO/**IEC**. ~~1988.~~ *Information Processing Systems - Open Systems Interconnection - Connection Oriented Presentation Service Definition*. **1994.**

[ISO/**IEC** 8649] ISO/**IEC**. ~~1988.~~ *Information Processing Systems - Open Systems Interconnection - Service Definition for the Association Control Service Element*. **1996. (withdrawn 2012)**

…

5 ~~Goals of~~ The DICOM ~~Standard~~ Communication Model

The DICOM Standard facilitates interoperability of devices claiming conformance. In particular, it:

- Addresses the semantics of Commands and associated data. For devices to interact, there must be standards on how devices are expected to react to Commands and associated data, not just the information that is to be moved between devices.
- Addresses the semantics of file services, file formats and information directories necessary for off-line communication.
- Is explicit in defining the conformance requirements of implementations of the Standard. In particular, a conformance statement must specify enough information to determine the functions for which interoperability can be expected with another device claiming conformance.
- Facilitates operation in a networked environment.
- Is structured to accommodate the introduction of new services, thus facilitating support for future medical imaging applications.
- Makes use of existing international standards wherever applicable, and itself conforms to established documentation guidelines for international standards.

~~Even though the DICOM Standard has the potential to facilitate implementations of PACS solutions, use of the Standard alone does not guarantee that all the goals of a PACS will be met. This Standard facilitates interoperability of systems claiming conformance in a multi-vendor environment, but does not, by itself, guarantee interoperability.~~

~~This Standard has been developed with an emphasis on diagnostic medical imaging as practiced in radiology, cardiology and related disciplines; however, it is also applicable to a wide range of image and non-image related information exchanged in clinical and other medical environments.~~

Figure 5-1 presents the general communication model of the Standard, which spans both network (on-line) and media storage interchange (off-line) communication. …

In each Part of the Standard, update the Foreword as follows:

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In each Part of the Standard, update Normative References as follows:

[ISO/IEC Directives Part ~~3~~**2**] ISO/IEC. ~~**1989.**~~ ***Rules for the structure and*** *drafting* ~~***and Presentation***~~ *of International Standards*. **Sixth edition, 2011**