SLOVENSKI STANDARD
SIST ENV 12052:2003

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Medicinska informatika – Komuniciranje z medicinskimi slikami (MEDICOM)

Medical Informatics - Medical Imaging Communication (MEDICOM)

Informatique de santé - Communication d'images médicales (MEDICOM)

Ta slovenski standard je istoveten z: **ENV 12052:1997**

ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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English version

Medical Informatics - Medical Imaging Communication (MEDICOM)

Informatique de santé - Communication d'images médicales (MEDICOM)

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

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Table of Contents

Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 "Medical informatics", the secretariat of which is held by SIS.

This European Prestandard has been prepared under a mandate (BC-IT-214) given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

0 Introduction

0.1 History

The increased use of data processing and telecommunication capabilities has made possible the transmission of medical image and related data within and between institutions. Early work in this area led to the development of a large number of private image formats and communication methods. The further expansion of medical image interchange is hampered by the lack of a standard format for specifying image objects and standard means for on-line or off-line communication of medical image objects.
In order to accomplish standardised communication of medical image and related data by either on-line or off-line means a complete stack of standards is required.
This European Pre-standard references DICOM (various Parts of NEMA PS3). DICOM results from a complete redesign of the ACR-NEMA Standards Publication No. 300-1988 which was designated ACR-NEMA V2.0.
DICOM, or Digital Imaging and Communications in Medicine Version 3.0 embodies a number of major enhancements:

a) It is applicable to a networked environment. DICOM supports operation in a networked environment using standard networking protocols such as OSI and TCP/IP;

b) It specifies how devices claiming conformance to DICOM shall react to commands and data being exchanged. Previous versions were confined to the transfer of data, but DICOM specifies, through the concept of Service Classes, the semantics of commands and associated data;

c) It specifies a structured approach to conformance. Previous versions specified only a minimum level of conformance. DICOM explicitly describes how an implementor must structure a Conformance Claim to select specific options. This will also allow purchasers of equipment with a DICOM interface to specify the functions and options they expect for their environment;

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

e) It introduces explicit Information Objects not only for images and graphics but also for studies, reports, etc.;

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

0.2 CEN Standardisation on Communication in Medical Imaging

CEN/TC 251/WG 4 contributed to the development and review of DICOM. By basing this Standard on DICOM, CEN expects to facilitate world-wide harmonisation of Medical Image Communication Standards with existing industry standards and accelerate the emergence of internationally approved standards in this area. In this harmonisation process CEN's strategy is to ensure that applicable ISO/IEC Standards are used and integrated.

0.3 Future Directions

It is anticipated that this Standard will be an evolving standard and that proposals for enhancements will be forthcoming from the member organisations based on input from users of this Standard. These proposals will be considered for future versions of the Standard. A major objective in updating the Standard is to maintain effective compatibility with previous versions.
In the preparation of this Standard, suggestions and comments from users, vendors, and other interested parties have been sought, evaluated, and included. Inquiries, comments, and proposed or recommended revisions should be submitted to CEN/TC 251.
This Standard references a number of specifications which have been initially published by NEMA. However, they are also maintained by CEN to ensure that their evolution meets European requirements.

1 Scope and Field of Application

This document includes an overview of the Standard. In particular, it contains a brief description of the contents of each of the DICOM Parts referenced by this Standard (see Annex B).
This Standard facilitates inter-operability of medical imaging equipment by specifying:

- A unifying architecture for Communication in Medical Imaging, including a number of strategic directions for the evolution of this architecture;
- For on-line communication, a set of protocols to be followed by devices claiming conformance to the Standard as well as the syntax and semantics of Commands and associated information which can be exchanged over a network interface using these protocols;
- For off-line communication, a set of media storage services to be supported by devices claiming conformance to the Standard as well as a File Format and a medical Media Storage Directory structure to facilitate access to the images and related information stored on an interchange media;
- The conformance requirements of implementations of the Standard. In particular, a Conformance Statement must be provided with every implementation claiming conformance to the Standard. It specifies sufficient information to determine the functions for which inter-operability is expected with another device claiming conformance;

- A framework for the functioning of Registration and Sponsoring Authorities allowing efficient extension of the Standard and ensuring easy availability of Object and Service Class specifications.

This Standard does not specify:

- A testing/validation procedure to assess an implementation's conformance to the Standard;

- The implementation details of any features of the Standard for devices 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 Standard.

This Standard pertains to the field of Medical Informatics. Within that field, it addresses the exchange of digital information between medical imaging equipment. Because medical imaging equipment may inter-operate with other medical devices, the scope of this Standard overlaps with other areas of Medical Informatics. However, this Standard is not intended to address the breadth of the Medical Informatics field, but only the communication in Medical Imaging related aspects.

The Standard makes use of existing international standards wherever applicable, and itself conforms to established documentation guidelines for international standards. In particular the relationship of this Standard to the Image Processing and Interchange (IPI) Standard is described in Annex C.

Even though the Standard has the potential to facilitate implementations of Picture Archiving and Communications Systems (PACS) or Image Management and Communications Systems (IMACS), use of the Standard alone does not guarantee that all the goals of an image archiving and management system will be met. This Standard facilitates inter-operability of systems claiming conformance in a multi-vendor environment, but does not, by itself, guarantee inter-operability.

This Standard has been developed with an emphasis on diagnostic and therapeutic medical imaging. Even though, the image types initially considered are mostly related to radiology; this Standard is applicable to exchange of all types of diagnostic and therapeutic images and the associated image related information. Numerous extensions are envisaged to support future medical imaging applications. The introduction of these extensions is facilitated by ensuring that Service Classes, Information Objects and Data Elements are specified in separate Parts. Such Parts may be rapidly updated through the use of a registration process (See Annex A).

This Standard is based on a general communication architecture for medical imaging presented in Figure 1. It identifies a Medical Imaging Application which uses the communication services offered by an Application Entity. In turn this Application Entity relies on:

- Application Profiles and Transport Profiles for on-line communication. A batch mode and an interactive mode may be distinguished;

- Media Formats and Physical Media for off-line communication.

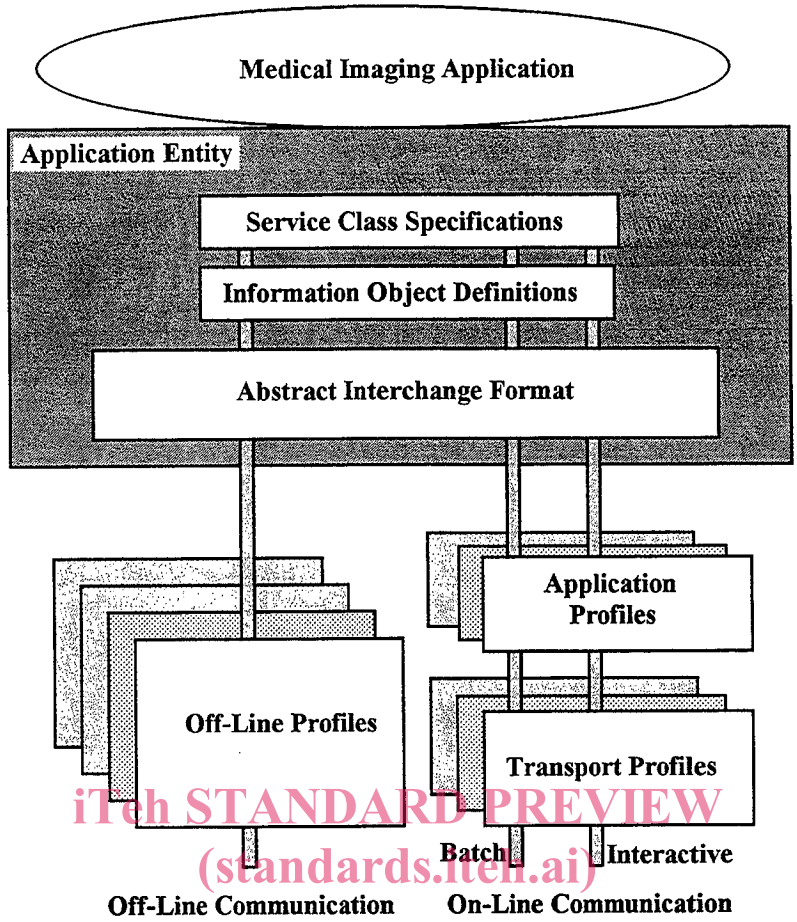

Figure 1. General Communication Architecture for Medical Imaging

2 Normative References

ISO/IEC Directives, 1989 Part 3 - Drafting and presentation of International Standards.

ISO/IEC ISP 11188-3, 1995, Information Technology - International Standardised Profiles - Common Upper Layer Requirements - Part 3: Minimal OSI upper layer facilities

ISO 7498, 1984, Information Processing systems - Open Systems Interconnection - Basic Reference Model

ISO 8822, Information Processing Systems - Open Systems Interconnection - Connection-Oriented Presentation Service Definition.

ISO 8649, Information Processing Systems - Open Systems Interconnection - Service Definition for the Association Control Service Element.

ISO 12087 : 1993, Information technology - Computer Graphics and Image Processing - Functional specification - Image Processing and Interchange.

NEMA PS3-2, 1994, Digital Imaging and Communications in Medicine, Part 2 - Conformance.

NEMA PS3-3, 1994, Digital Imaging and Communications in Medicine, Part 3 - Information Object Definitions.

NEMA PS3-4, 1994, Digital Imaging and Communications in Medicine, Part 4 - Service Class Specifications.

NEMA PS3-5, 1994, Digital Imaging and Communications in Medicine, Part 5 - Data Structure and Encoding.

NEMA PS3-6, 1994, Digital Imaging and Communications in Medicine, Part 6 - Data Dictionary.

NEMA PS3-7, 1994, Digital Imaging and Communications in Medicine, Part 7 - Message Exchange.

NEMA PS3-8, 1993, Digital Imaging and Communications in Medicine, Part 8 - Network Communication Support for Message Exchange.

3 Definitions

For the purpose of this Standard, the following definitions apply:

3.1. Conformance Statement: a formal statement associated with a specific implementation of the Standard. It specifies the Service Classes, Information Objects, and Communication Protocols supported by the implementation

3.2. Data Element: a unit of data defined by a unique tag, name and value characteristics.

3.3. European Registration Secretariat: The part of the Registration Authority responsible for the administrative tasks of registration within Europe. Other registration secretariats may be established in other regions of the world.

3.4. Parent Bodies: The Bodies jointly responsible for establishing and directing the Registration Authority.

3.5. Register Update Order: Document containing approved register update.

3.6. Register Update Request: Document containing requests for register updates.

3.7. Registrable Data: Data as specified by the Parent Bodies for inclusion in a register, such as Data Elements, Transfer Syntaxes, SOP Classes, and approved corrections.

3.8. Registration Authority: The authority responsible for the administrative and technical tasks of registration.

3.9. Service Class: A structured description of a service which is supported by co-operating Application Entities using specific Commands acting on specific class of Information Object

3.10. Service/Object Pair Class: the union of a specific set of DICOM Message Service Element and one related Information Object Definition which completely defines a precise context for communication.

3.11. Transfer Syntax: A set of encoding rules that allow communicating Application Entities to unambiguously negotiate the encoding techniques (e.g., Data Element Structure, byte ordering, compression) they are able to support.