SLOVENSKI STANDARD
SIST ENV 12443:2003

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Medicinska informatika ï Okvirne dolo ļ be o informacijah o zdravstvenem varstvu (HIF)

Medical Informatics - Healthcare Information Framework (HIF)

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

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English version

Medical Informatics - Healthcare Information Framework (HIF)

This European Prestandard (ENV) was approved by CEN on 7 November 1996 as a prospective standard for provisional application.

The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into a European Standard.

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

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Foreword

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

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.

Annexes A, B and C are informative.

Introduction

With the rapid growth of informatics applications in healthcare it is becoming increasingly necessary for the existence of standards for standard makers. The Healthcare Information Framework (HIF) is one such standard.

Healthcare informatics has, as its first objective, to give doctors better ways to treat their patients using a quicker, safer and more complete access to information. The information includes that related to the patient (the medical record), to knowledge (knowledge database) and to resources.

This European Prestandard sets out to establish general concepts, requirements, relationships, context and the terminology to be used in subsequent developments of specific standards for healthcare domain specific informatics standards.

The normative portion of this European Prestandard is intended for use by healthcare informatics domain specific standards writers and, in particular, standards writers concerned with Healthcare Reference Architectures. Specific requirements for conformance are defined in Annex A "Conformance to the Healthcare Information Framework." Domain experts may find that an initial review of Annex A provides a useful context for a reading of the overall document. Annex B "Description of the Healthcare Information Framework" provides an informative view of the role of the Healthcare Information Framework. It is intended for reading by healthcare informatics experts who have an interest in standardisation and wish to understand the intent of this document in the arena of healthcare informatics standards development.

This European Prestandard builds upon and embodies the work of the Bangemann committee and, in particular, one of the elements of the key architectural constructs. This element is the technology view which uses the same layering principle.

The writing of this European Prestandard revealed not only the wealth of information available but also the diversity and so to avoid prolonged debate it covers the common ground within the healthcare informatics arena. Subsequent parts to cover new areas of conformance as well as a wider audience to encompass suppliers of components, system integrators and healthcare professionals will eventually be required.

The Healthcare Information Framework (HIF) takes into account that

- heterogeneity is a characteristic of existing healthcare;

- multiple architectures are needed to provide optimised support for different healthcare processes and healthcare users;

- healthcare organisational structures, processes and technologies evolve continuously due to external and internal pressures for change;

- a top-down approach may be used.

The Healthcare Information Framework also takes into account that doctors should finally have access to technology, which is not the case at the moment, and therefore shows how technology should support their work in the future.

1 Scope

This European Prestandard establishes the Healthcare Information Framework (HIF) as a logical mapping between the healthcare environment and informatics applications which support and facilitate clinical and other functions.

This European Prestandard specifies the set of requirements, recommendations and guidelines which apply to developments within CEN/TC 251 which enable consistent development and evolution of healthcare domain specific informatics standards.

This European Prestandard is applicable to, and will be primarily used by, healthcare domain specific informatics standards writers and, in particular, those writing Healthcare Reference Architectures standards.

2 Normative references

This European Prestandard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of any of these publications apply to this European Prestandard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

ISO 1087	1990	Terminology - Vocabulary
ISO 7498	1992	Information processing systems - Open Systems Interconnection - Basic Reference Model
ISO/IEC 2382-1	1993	Information technology - Vocabulary -Part 1: Fundamental terms
ISO/IEC 2382-20	1990	Information technology - Vocabulary - Part 20: System development
ISO/IEC 9646-1	1994	Information technology - Open Systems Interconnection - Conformance testing methodology and framework - Part 1: General concepts

3 Definitions

NOTE: Definitions fall into three categories: those single terms defined in the Shorter Oxford English Dictionary, those terms that are defined within this European Prestandard applicable to other standards and those terms used expressly for the understanding of this European Prestandard.

For the purpose of this European Prestandard, the following definitions apply:

3.1 compatibility

capability of a functional unit to meet the requirements of a specified interface without appreciable modification [ISO/IEC 2382-1]

3.2 concept

unit of thought constituted through abstraction on the basis of properties common to a set of objects [ISO 1087]

3.3 Conceptual Architectural Framework

collective term for: healthcare domain view, technology view and performance requirements view

NOTE: In this European Prestandard the abbreviation "CAF" is used.

3.4 healthcare domain view

abstraction of a set of entities that are uniform in some property or properties such as knowledge, skills, expertise, or the existence of a single controlling influence which governs the whole

3.5 Healthcare Information Framework

collective term for Conceptual Architectural Framework, Healthcare Reference Architectures, their interactions and conformance testing

NOTE: In this European Prestandard the abbreviation "HIF" is used.

3.6 Healthcare Reference Architecture

specialisation of the Conceptual Architectural Framework (CAF) for a particular healthcare domain.

NOTE: In this European Prestandard the abbreviation "HRA" is used.

3.7 interface

shared boundary between two functional units defined by various characteristics pertaining to the functions, physical interconnections, signal exchanges and other characteristics as appropriate [ISO/IEC 2382-1]

3.8 top-down

pertaining to a method or procedure that starts at the highest level of abstraction and proceeds towards the lowest level [ISO/IEC 2382-20]

4 Conceptual Architectural Framework

The Conceptual Architectural Framework (CAF) is the collective term for: healthcare domain view, technology view and performance requirements view. These three views are separate but interrelated:

- healthcare domain view
projection of a specific healthcare domain using the concepts of objects, knowledge, processes and management of change;

- technology view
projection of the information systems supporting the healthcare domain using the three layers of healthcare application, healthcare middleware and healthcare bitways;

- performance requirements view
projection of the user's requirements using the characteristics of functionality, dependability and controllability.

NOTE: The Conceptual Architectural Framework (CAF) translates the reality of the healthcare professional and information processing world into the information technology world.

4.1 Healthcare domain view

The healthcare domain view shall be described by modelling a structured set of concepts which may include

- objects which include patients (subjects of care), agents, resources;
- knowledge structured as repositories;
- healthcare processes.

The specific modelling formalism used shall be declared by the developer of healthcare domain specific informatics standards.

Models of a healthcare domain which embody any of the following concepts at any level of specialisation shall be accompanied by a suitable domain schema and show relationships to any of the following concepts which are embodied :

- patients (subjects of care);
- agents;
- resources;
- healthcare domain processes;
- knowledge concepts.

4.2 Technology view

The technology view is described as three ordered layers:

- healthcare application layer;

- healthcare middleware layer;

- healthcare bitways layer.

The developer of a healthcare domain specific informatics standard shall declare the specific layer(s) used. The interface between the specific layer used and the succeeding layer i.e. healthcare bitways layer to healthcare middleware layer, healthcare middleware layer to healthcare application layer, shall be defined to allow for compatibility.

NOTE: More than one specific layer may be used.

Healthcare application layer

models the data flows required to support healthcare processes

There are applications consisting of application-processes which perform information processing. An aspect of these application-processes and the protocols by which they communicate comprise the healthcare application layer as the highest layer of the ISO/OSI architecture. [ISO 7498]

Healthcare middleware layer

models shared services required to support the application layer

EXAMPLE: healthcare specific common components and generic common components such as electronic mail, file transfer and video services.

NOTE: Healthcare middleware layer is also known as basic services or enabling services.

Healthcare bitways layer

models telematic infrastructure which provides services to the middleware layer

NOTE: Healthcare bitways layer is also known as networking or physical infrastructure.

4.3 Performance requirements view

The performance requirements view shall be described by modelling three fundamental characteristics:

- functionality;
- dependability;
- controllability.

Developers of healthcare domain specific informatics standards shall declare the process by which performance requirements are derived.

Functionality is derived from three characteristics:

- usability;
- performance;
- relationship to environment.

Dependability is derived from three characteristics:

- security;
- reliability;
- safety.

Controllability is derived from three characteristics:

- control ;
- measurement;
- evolution.

5 Healthcare Reference Architectures

A Healthcare Reference Architecture (HRA) is a specialisation of the Conceptual Architectural Framework (CAF) for a particular healthcare domain which conforms to the Healthcare Information Framework (HIF).

The relationship between Healthcare Reference Architectures (HRA) and the Conceptual Architectural Framework (CAF) shall be declared by the developer of a healthcare domain specific informatics standard.

6. Conformance requirements

Developers of healthcare domain specific informatics standards shall declare the process by which conformance is demonstrated.

For the purpose of creating the conformance requirements the following basic principles taken from ISO/IEC 9646-1 shall apply:

- conformance requirements can be

  a) mandatory requirements: these are to be observed in all cases;

  b) conditional requirements: these are to be observed if the conditions set out in the specification apply;

  c) optional requirements: these can be selected to suit the implementation, provided that any requirements applicable to the option are observed.

- conformance requirements can be stated

  a) positively: they state what is required to be done;

  b) negatively: they state what is required not to be done.