



SLOVENSKI STANDARD

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Medical informatics - Healthcare Information System Architecture (HISA) - Part 1: Healthcare Middleware Layer

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Healthcare Middleware Layer

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ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology
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ICS 11.020; 35.240.70

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English version

Medical Informatics - Healthcare Information System Architecture (HISA) - Part 1: Healthcare Middleware Layer

This European Prestandard (ENV) was approved by CEN on 5 January 1998 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.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

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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 "Medical 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 implement this European Standard: 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, C, D, E and F are informative.

Non-technical readers are advised to start analysis of the document with Annex C which provides an introduction to the objectives of the architecture and the technical background underlying its specification.

Introduction

Healthcare organisational structure in all European countries consists of networks of centres distributed over the territory, characterised by a high degree of heterogeneity and diversity, from organisational, logistic, clinical and even cultural perspectives. The structure of individual centres is evolving from a vertical, aggregated organisation towards the integration of a set of specialised functional areas, with specific needs and characteristics. Such a situation determines two main needs which conflict with each other in a certain way. On the one hand it is necessary to support effectively the specific requirements of each unit or user in the most appropriate and cost-effective way whilst on the other hand it is vital to ensure the consistency and integration of the overall organisation, both at local and territorial level.

The large number of applications, mutually isolated and incompatible, that are already available on the market and installed and operational in healthcare organisations, effectively supporting specific needs of users cannot be underestimated. Under the present circumstances, the main need is to make possible the integration and interoperability of already existing applications thereby securing investments already made and allowing continuity of the service whilst facilitating a gradual migration of existing proprietary, monolithic systems towards the new concepts of openness and modularity. The cost-effectiveness of the solutions, especially when projected on the scale of the whole organisation, represents another crucial aspect to be evaluated carefully.

Such objectives are not only related to the need for improving clinical treatments to the subject of care but are also demanded by the urgent necessity of all European countries to control and optimise the current level of expenditure for health, whilst ensuring the necessary qualitative level of services to all subjects of care. The purpose of the standard architecture is to identify a set of common services used within healthcare information systems, supporting specific requirements of the target organisation, as well as being capable of co-operating and interworking according to the requirements of the organisation as a whole.

The architecture is intended as a basis both for the comparison, evolution and integration of existing systems as well as for the planning and high-level design of new open and modular systems, capable of providing consistent and integrated support to the clinical, organisational and managerial requirements of healthcare organisations.

The standard architecture aims at presenting a practical tool, usable by different types of users, involved with different responsibilities during the whole life-cycle of the information system:

Suppliers

who plan and design high-level consistent information systems, meeting the actual requirements of healthcare organisations and capable of interworking in a generic information systems:

Consumers at managerial level

- to plan the implementation and evolution of the Healthcare Information System at strategic level according to organisational goals and requirements;
- to validate the compliance of different solutions with respect to the needs of the organisation;
- to facilitate the selection of different but integratable products;

Consumers at operational level

- to provide an active contribution to the technicians in the specification of the requirements for the system;
- to assess the basic compliance of individual solutions with their specific requirements.

General aims

- to provide a comprehensive and consistent, even if preliminary, framework for the integration of the two main foci of development, research and standardisation activities: patient treatment and management of the organisation;
- to define the scope of a set of subsequent fundamental standards, each capable of detailing the various components of the architecture to a level permitting the physical connection of different products in an open environment.

It should be stressed that this European Prestandard does not aim to recognise a unique model for clinical, organisational, managerial or administrative activities, but rather defines a set of healthcare-specific information and services common to all healthcare information systems, usable by any application, to manage mutual interworking.

This European Prestandard is a foundation standard and may require further standards as indicated in Annex C. In particular, further future standards detailing the aspects related to the description, formalisation and composition of the services should extend the specifications of this standard. These future standards should increase the level of accuracy and compliability suitable for the formalisation of the mechanisms according to which different software products may interact in a generic physical environment.

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Healthcare Information System Architecture (HISA) - Part 1: Healthcare Middleware Layer

1. Scope

This European Prestandard establishes general principles for the architecture of healthcare information systems as well as the scope of a set of Healthcare Common Services, provided by the middleware layer of the healthcare information system. These services are fundamental in any generic information system for supporting the requirements of the management of the information related to the treatment of the subject of care.

This European Prestandard is independent of any specific technological environment and does not imply, either directly or indirectly, the adoption of any specific organisational, design or implementation solution.

This European Prestandard is applicable to the information systems of any type of healthcare organisation.

The specification of the characteristics of the identified Healthcare Common Services is limited to the sole formalisation of their external behaviour, in terms of their function and of the information to be made available to the rest of the system. Such behaviour is defined at the conceptual level only, through formalisms and notations suitable to identify the scope of the services.

This European Prestandard is limited to the identification of a set of common services capable of supporting that part of the information system related to the treatment of the subjects of care. The support for requirements specific to the management and administration of the healthcare infrastructure is not explicitly addressed by this European Prestandard. Due to the intrinsic integration of the organisation, services and information provided by the Healthcare Common Services identified, this European Prestandard does not explicitly exclude administrative and managerial requirements.

This European Prestandard does not specify the characteristic of any application or sub-system and, in particular, a healthcare record system of the healthcare information system. The services defined in this European Prestandard are used by the information system, including healthcare record systems, for the management of elementary information, relevant and common to the whole healthcare organisation.

This European Prestandard does not specify all possible classes of information and services which are necessary or useful in all possible healthcare information systems, but only as a fundamental set which is considered to be of major relevance.. The set of services and information classes identified in this European Prestandard is not exhaustive. It may be extended in individual installations, according to specific requirements, depending on the particular nature of the information system, as well as on national and local needs.

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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	Vocabulary of terminology
ISO/IEC	7498-1	1994	Information technology - Open Systems Interconnection - Basic Reference Model: The Basic Model
ISO	10241	1992	International terminology standards - preparation and layout
ENV	12017	1995	Medical Informatics - Medical Informatics Vocabulary
prENV	12265	1996	Medical Informatics - Electronic Healthcare Record Architecture
prENV	12443	1996	Medical Informatics - Healthcare Information Framework

3. Definitions

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

3.1 concept

unit of thought constituted through abstraction on the basis of properties common to a set of objects [ISO1087]

3.2 data concept

entity or relationship defined within the structural view of the Healthcare Common Services

3.3 healthcare actor

person entrusted with the direct or indirect provision of healthcare services

3.4 healthcare information system architecture

structure of, and interrelationships with as well as relationship to the organisation and business context to be supported

3.5 Healthcare Common Services (HCS)

group of services provided by the healthcare middleware layer of the architecture to support the rest of the system with functions relating to the management of functionalities and of information common to the whole healthcare organisation and peculiar to the healthcare business domain

3.6 object

part of the perceivable or conceivable universe [ISO1087]

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3.7 property

attribute of a phenomenon, body or substance that may be distinguished qualitatively [ENV1614]

3.8 software module

self-consistent set of computer executable programs, identifiable through a non-ambiguous criterion defined by its creator or user

3.9 service

function provided by one layer of the healthcare information system

NOTE: Each service may be invoked by any module of the information system through a formal mechanism, to be documented in the specific installation according to a formal and unambiguous syntax, depending on the programming languages and technological environment adopted.

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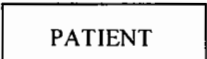
4. Symbols and abbreviations

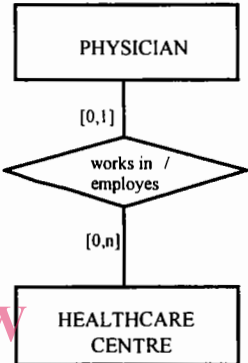
The structure of the data exchanged by each Healthcare Common Service is described at the conceptual level, through the use of the following information object meta-types:

- entity;
- relationship;
- hierarchy;
- subset;
- attribute.

These information object meta-types are defined below, together with their respective graphical notations where applicable.

For the purpose of this European Prestandard, references to entities are in capitals. To improve readability in the text, entity names are sometimes shown in plural form.

<p>ENTITY autonomous and self-consistent object of the domain of interest, with a set of common properties called attributes</p> <p>NOTE: Graphically, an entity is represented by a rectangle.</p>	
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<p>RELATIONSHIP fact that connects two entities</p> <p>NOTE 1: Graphically, a relationship is represented by a diamond, connected to the involved entities.</p> <p>NOTE 2: A relationship is bi-directional; it defines a mutual link between the connected concepts. The diamond contains two names, specifying the meaning of the relationship with respect to each entity.</p> <p>NOTE 3: A relationship has a cardinality with respect to each connected entity, which specifies the minimum and maximum number of occurrences of that relationship which may be related to any generic instance of the entity.</p> <p>NOTE 4: Cardinalities are shown close to the relationship and beside the line connecting the entity with the relationship.</p> <p>NOTE 5: Relationships may have specific properties, which relate to the fact itself and do not depend on the entities which are connected through the relationship. These properties are called <i>attributes</i>.</p>	
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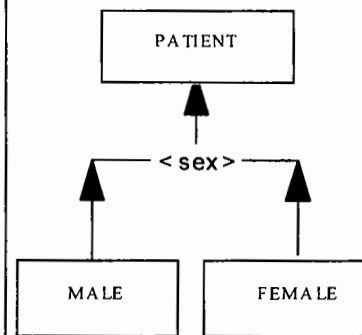
HIERARCHY

classifies one entity, by introducing a partition based on one set of discriminating attributes

NOTE: Graphically, the classification hierarchy is described through a set of arrows linking all sub-entities to the originating entity. The discriminating attribute is written on the line connecting all sub-entities.

NOTE: Each instance of the entity belongs to one and only one sub-entity.

EXAMPLE: Classification of the patient is made through the *sex* attribute: a patient is either in the male or in the female sub-entity.

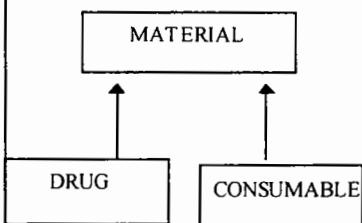


SUBSET

creates a classification in one entity, by identifying a group of instances with common properties, but without determining a partition in the entity.

NOTE: Graphically, a subset is represented with an arrow directly connecting the sub-entity with the entity.

EXAMPLE: Two subsets, DRUG and CONSUMABLE, represent two groups in the whole entity of MATERIAL. A consumable material may also be a drug.



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5. Structure of a healthcare information system architecture

The architecture of any generic healthcare information system shall be described through three co-operative layers [prENV 12443] :

- **Healthcare Application layer**
 models the data flows and functionalities 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/IEC 7498-1];

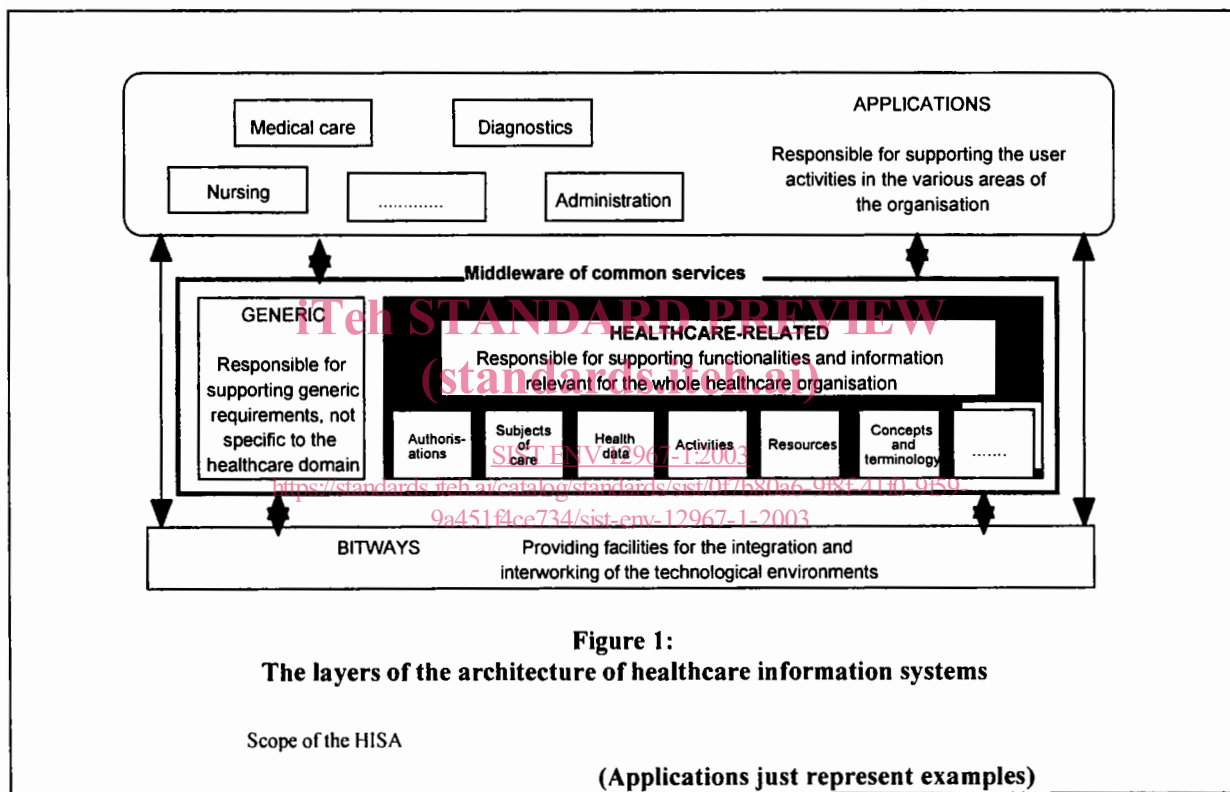
- **Healthcare Middleware layer**
 models shared services required to support the application layer.

NOTE 1: Healthcare middleware layer is also known as basic services or enabling services.

NOTE 2: It consists of a group of services which provide the rest of the system with services common throughout the whole information system.;

- **Healthcare Bitways layer**
 models technological infrastructure which provides services to the middleware layer.

NOTE 1: Healthcare bitways layer is also known as networking or physical infrastructure.



Two classes of services shall be identified in the middleware layer of any healthcare information system:

- **Healthcare Common Services** which support the applications with services relating to the management of functionalities and of information common to the whole healthcare information system and peculiar to the healthcare business domain;
- **Generic Common Services** which support the applications with general purpose facilities which are usually common to any information system in any type of business domain.

The scope of this European Prestandard, with respect to the three layers of the architecture, is limited as follows:

- **Application layer**
due to the variety of different healthcare organisations and the dependency of applications on specific local requirements no normative provision is made with respect to the characteristics and scope of individual applications;
- **Middleware layer**
identifies a fundamental set of Healthcare Common Services and formalises their scope and objectives with respect to the overall system, as well as the modalities for their interaction with the rest of the system, both in terms of functionalities provided and of information managed.;
- **Bitways layer**
due to the general applicability of such services in any information system, their specification is outside the scope of this standard.

The scope of this European Prestandard is limited , with respect to the level of specification, as follows:

- The characteristics of the individual services are expressed only in terms of their external behaviour, i.e. functionalities provided and information exchanged, without making, either implicitly or explicitly, any assumption on the actual design or implementation solution.
- The data model presented in the specification of each group of common services only has the purpose of formalising the characteristics of the information, i.e. concepts, attributes and relationships, which are exchanged with the rest of the system. Such models, therefore, do not aim at representing, either explicitly or implicitly, fragments of any possible physical data structure implemented in the system.
- According to the foundation purposes of this European Prestandard, the functionalities of the services are defined only through natural language, adopting terms which are used and familiar in the common practice of information technology. Such a level of formality allows the identification of the scope of the individual services.
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The detailed specification of the interaction mechanisms of individual services, up to the level of allowing different software products to interact in a generic physical environment, is outside the scope of this European Prestandard.
- The services identified by this European Prestandard, as well as their individual characteristics, represent an open set of common properties fundamental for any type of healthcare information system.

NOTE: Both the list of Healthcare Common Services and the properties, i.e. services and data, of each of them may be extended in the actual implementation according to local

requirements as well as to subsequent national and international standards complementing this one.

In order to ensure the modularity and openness of the architecture, this European Prestandard does not define any normative provision with respect to possible interactions between individual services.

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6. Rationale for the identification of the Healthcare Common Services

The purpose of the Healthcare Common Services provided by the healthcare middleware layer shall provide all parts of the healthcare information system with common functionalities to manage those functionalities and information which are common to the whole healthcare information system.

At a high level of abstraction- the essence of any healthcare environment can be described by the following paradigm:

In any healthcare organisation, different types of actors perform activities, using resources, and generating results.

Activities may be either directly or indirectly related to the needs of subjects of care or to general requirements of the organisation..

Depending on the type of activity which is being executed, the results of one activity may represent health characteristics of the subject of care, or simply, other data to be communicated through the healthcare organisation.

When executing one activity, a certain quantity of several resources is also used, such as staff members, consumable materials, physical agents and equipment. The utilisation of each resource has its specific cost, depending on the specific resource involved and on the type of activity performed.

Different types of users are authorised to work with the healthcare information system, and are allowed to perform activities or access various types of information, according to defined criteria, according to national and regional regulations, as well as local rules and the characteristics of the individual activities and data.

Several types of dependencies and relationships may exist among the types of concepts managed by the healthcare information system, relating to both the clinical and organisational aspects

In the healthcare domain view [prENV12443] it is possible to aggregate logically classes of common information into six main groups, identifying for each of them a set of common services, each set referred to as HCS in the following text, responsible for the management of the related concepts:

- Subjects of Care Healthcare Common Services (S-HCS) ;
- Health Characteristic Healthcare Common Services (HC-HCS);
- Activity Healthcare Common Services (A-HCS);
- Resource Healthcare Common Services (R-HCS);
- Authorisation Healthcare Common Services (AU-HCS);
- Concept Healthcare Common Services (C-HCS).

The clustering of the classes of information managed by the healthcare middleware layer and of the related services into the six groups of Healthcare Common Services (HCS) specified in this European Prestandard represents just one possible way of structuring them according to a rationale depending on their main semantic aspects.

For the purpose of conformance to this European Prestandard, the healthcare middleware layer shall provide the healthcare information system with services and information as specified. Different implementations can group the individual information and services of the healthcare middleware layer on the basis of different rationales.

In the following clauses, the external behaviour of each group of Healthcare Common Services (HCS) is formalised. The specification of each group of Healthcare Common Services is structured in three parts:

- **scope**, outlining, in textual form, the main purpose of the services of that group of Healthcare Common Services within the framework of the healthcare information system;