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Health Informatics - Service architecture - Part 1: Enterprise viewpoint

Informatique de santé - Service architecture - Partie 1 : Point de vue d'entreprise

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Contents

Foreword

This document (prEN 12967-1:2006) has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by NEN.

This document is currently submitted to the CEN Enquiry.

This document will supersede ENV 12967-1:1998.

This three part draft European standard is a major revision of the ENV 12967-1 that was produced under a mandate given to CEN by the European Commission and the European Free Trade Association.

This multi-part standard under the general heading: Health informatics – Service architecture consists of the following parts:

Part 1: Enterprise viewpoint

Part 2: Information viewpoint

Part 3: Computational viewpoint

Parts 1, 2 and 3 are jointly replacing the European prestandard ENV 12967-1: 1997 Medical informatics – Healthcare Information System Architecture (HISA) - Part 1: Healthcare middleware layer .

Introduction

Healthcare organisational structure consists of networks of centres (hospital cooperations within e.g. counties, individual hospitals, clinics etc.) distributed over the territory, characterised by a high degree of heterogeneity and diversity, from organisational, logistic, clinical, technological 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 (e.g. unit of laboratory analyses, unit of surgery), with specific needs and characteristics, nevertheless needing to share common information and to operate according to integrated workflows. 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. This integration requirement is not only related to the need for improving clinical treatments to the subject of care but is also demanded by the urgent necessity of all 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 large number of databases and applications, mutually isolated and incompatible, which are already available on the market and operational in healthcare organisations to support specific needs of users, cannot be underestimated. Even within the same centre, healthcare information systems are frequently fragmented across a number of applications, data and functionalities, isolated and scarcely consistent with each other.

Under the present circumstances, the main need for care delivery organisations is to integrate and to make available the existing information assets, to make possible the integration and interoperability of existing applications, thereby protecting investments. During integration activities, continuity of service needs to be achieved whilst gradual migration of existing proprietary, monolithic systems towards the new concepts of openness and modularity occurs. The cost-effectiveness of the solutions, especially when projected on the scale of the whole healthcare organisation, represents another crucial aspect to be evaluated carefully.

The goal can be achieved through a unified, open architecture based on a middleware independent from specific applications and capable of integrating common data and business logic and of making them available to diverse, multi-vendor applications through many types of deployment. According to the integration objectives at organisational level, all aspects (i.e. clinical, organizational and managerial) of the healthcare structure must be supported by the architecture, that must be able therefore to comprise all relevant information and all business workflows, structuring them according to criteria and paradigms independent from specific sectorial aspects, temporary requirements or technological solutions.

Standards and technological solutions already exist and will continue being defined for supporting specific requirements, both in terms of *in situ* user operations and with respect to movement of information. The architecture must be able to accommodate such requirements by allowing the specific models to be integrated with the complete information assets of the healthcare organisation and the communication messages to be “services” extracting or importing data from/to the common information as shown in Figure 1.

On the basis of these considerations, the purpose of this standard is twofold:

- to identify a methodology to describe healthcare information systems through a language, notation and paradigms suitable to facilitate the planning, design and comparison of systems;

- to identify the fundamental architectural aspects enabling the openness, integration and interoperability of healthcare information systems.

The architecture is therefore intended as a basis both for working with existing systems as well as for the planning and construction of new systems.

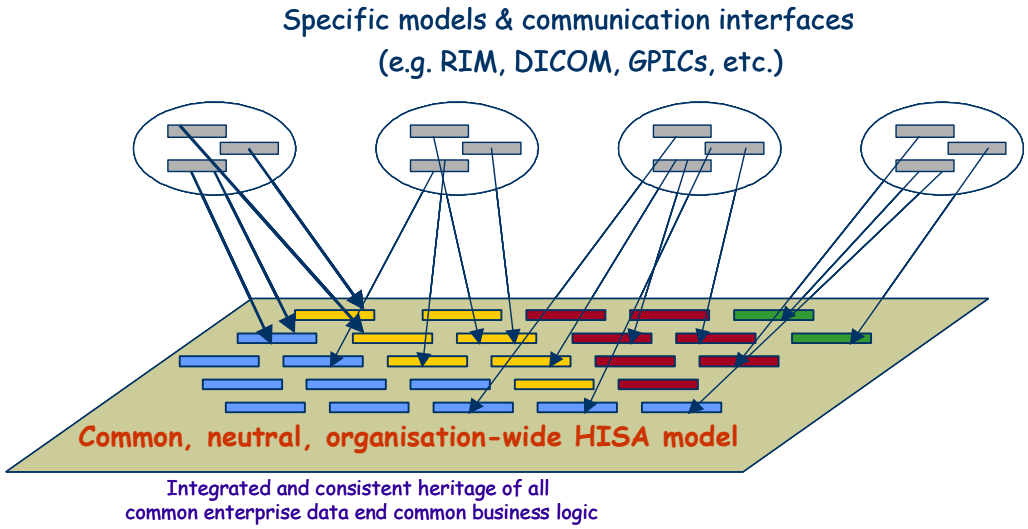

Figure 1. Complementarity and positioning of the architecture with other standards and models

It is pointed out that this standard does not aim at defining a unique model for clinical, organisational, managerial or administrative activities, but rather defines a set of workflows, information and services common to all healthcare information systems, relevant for any healthcare sector and usable by any application also for facilitating the mutual interworking.

Similarly, the standard does not aim to represent a final, complete set of specifications. On the contrary, it formalizes only fundamental aspects, identified as common in all European countries and considered to be –today- essential in any advanced healthcare information system. Specifications are formalized, avoiding any dependency on specific technological products and/or solutions.

The standard, therefore, is an open framework that -according the specification methodology and preserving the compatibility with previous versions- can be extended during the time according to the evolution of the healthcare organisation both in the individual –national and local- contexts and through international standardization initiatives.

A European pre-standard, ENV 12967-1, was developed according to such rationale during 1993-1997 and has been the basis for several implementations of middleware products and implemented integrations in healthcare regions. In year 2000 the CEN/ TC 251 Short Strategic Study: Health Information Infrastructure (2000-08-04) also identified a number of other new architectures and health infrastructure initiatives as well as the requirements and possibilities for alignment with the large body of information model standards developed by CEN for various communication purposes. Furthermore, European standardisation initiatives have delivered a number of object oriented domain models and message descriptions that include an architecture for the Electronic Health Record (ENV 13606). Cooperation between CEN and HL7 has also started, that, on the basis of the CEN modelling principles and HL7 Reference Information Model, has led to the definition of a set of “General Purpose Information Components”, usable for developing messages across information systems.

The present EN evolves and refines the ENV 12967-1 pre-standard taking into account the outcomes from its practical utilisations of during the past years, as well as the other above-mentioned initiatives occurred in CEN. With such a view, the following qualifying aspects can be highlighted:

- The architecture is described according to the methodology of ISO/IEC 10746 *Information technology - Open Distributed Processing – Reference model,* to provide a formal, comprehensive and non ambiguous specification suitable to serve as term of reference in the planning, design and implementation of healthcare information systems.

- The scope of the architecture comprises the support to the activities of the healthcare organisation: as a whole, from the clinical, organisational and managerial point of view. It therefore does not detail peculiarities of specific sectors, but provides an overarching comprehensive information and services framework suitable to accommodate all sectorial requirements.

- According to its scope, the architecture is intrinsically compatible, complementary and synergistic with other models and standards –such as HL7 and GPICS- defined in the scenario of the healthcare IT during the past years to support specific healthcare areas and communications across healthcare information systems. Moreover, specific information objects and services are explicitly foreseen in the architecture to facilitate the implementation of views and communication mechanisms based on such standards.

- In order to protect investments made by industrial and healthcare organisations on the basis of the pre-standard, the current specification is compatible, as much as possible, with the model and provisions defined in the ENV, by extending and refining them according to the new requirements.

1 Scope

This European standard provides guidance for the description, planning and development of new systems as well as for the integration of existing information systems, both within one enterprise and across different healthcare organisations through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the middleware), distinct from individual applications and accessible throughout the whole information system through services, as shown in figure 1.1

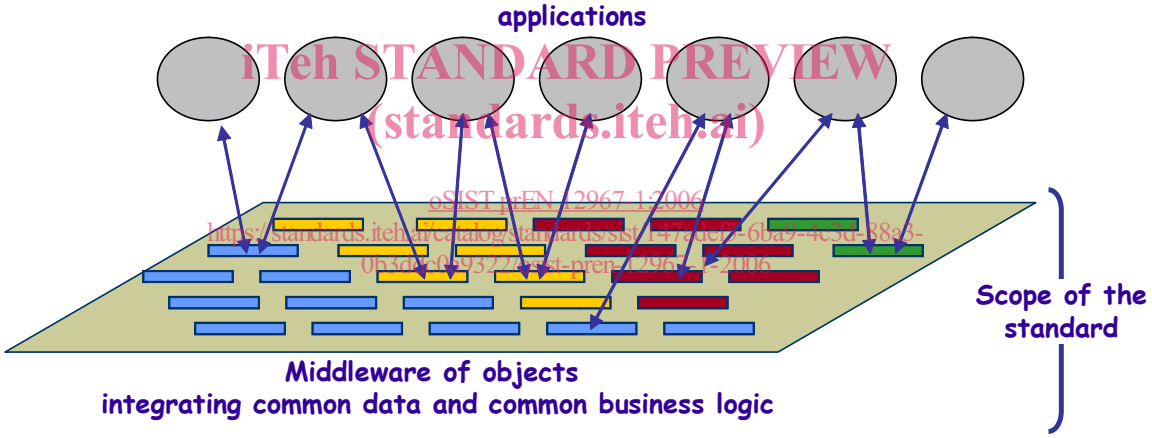

Figure 1.1

The architectural principles are formalised according to the ISO/IEC 10746 criteria and are therefore structured through the following three viewpoints:

a) The Enterprise Viewpoint that specifies a set of fundamental common requirements at enterprise level with respect to the organisational purposes, scopes and policies that must be supported by the information and functionalities of the middleware. It also provides guidance on how one individual enterprise (e.g. a regional healthcare authority, a large hospital or any other where this model is applicable) may specify and document additional specific business requirements, with a view of achieving a complete specification, adequate for the characteristics of that enterprise.

b) The Information Viewpoint that specifies the fundamental semantics of the information model to be implemented by the middleware to integrate the common enterprise data and to support the enterprise requirements formalised in the Enterprise Viewpoint. It also provides guidance on how one individual enterprise may extend the standard model with additional concepts, needed to support local requirements in terms of information to be put in common.

c) The Computational Viewpoint that specifies the scope and characteristics of the services that must be provided by the middleware for allowing the access to the common data as well as the execution of the

business logic supporting the enterprise processes identified in the Information and Enterprise viewpoints. It also provides guidance on how one individual enterprise may specify additional services, needed to support local specific requirements in terms of business logic to be put in common.

The standard is also independent from, and does not imply either explicitly or implicitly, any specific technological solution or product for its deployment. Accordingly, the formalisation of the architecture according to two lower levels of the ODP reference model, the Engineering and Technology viewpoints is outside the scope of this standard.

The language and notations used here for specifying the architecture are based on UML (Unified Modelling Language) complemented by case studies and other paradigms widely utilised by other standards in health informatics. The level of the specification is complete and non-ambiguous enough to allow its implementation into the specific physical and technological scenarios adopted by the various healthcare organisations and vendors. For this exercise it is recommended to follow the methodology formalised by the Engineering and Technology viewpoints of the ISO ODP Reference model.

The standard is organised in three parts:

- Part 1 (this part) specifies the overall characteristics of the architecture, formalises the specification methodology and the conformance criteria, details the Enterprise Viewpoint of the architecture

- Part 2 specifies the Information Viewpoint of the architecture

- Part 3 specifies the Computational viewpoint of the architecture

Each document is self-consistent and is independently utilisable for the intended purposes also by different types of users (Part 1 being more oriented to the managerial level, Parts 2 and 3 being more dedicated to the design activities). Nevertheless, it should be understood that they represent three aspects of the same architecture. Mutual references therefore exist between the different parts and evolutions of the individual documents shall be carried out according to the defined methodology to preserve the overall integrity and consistency of the specification.

2 Normative references

This European Standard 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 Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

prEN 13940-1:2005	Health Informatics – System of concepts to support continuity of care – Part 1: Basic concepts
EN 14822-1:2005	Health Informatics – General purpose information components – Part 1: Overview
EN 14822-2:2005	Health Informatics – General purpose information components – Part 2: Non Clinical
EN 14822-3:2005	Health Informatics – General purpose information components – Part 3: Clinical
CEN/TS 14796:2004	Health Informatics – Data types
prEN_13606-1	Health informatics – Electronic health record communication – Part 1: Reference model
prEN_13606-4	Health informatics – Electronic health record communication – Part 4: Security
ENV 12967-1: 1997	Medical Informatics – Healthcare Information System Architecture Part 1 (HISA) – Healthcare Middleware Layer (to be removed in the end !)

ISO/IEC 10746-1:1998	Information technology – Open Distributed Processing – Reference model: Overview
ISO/IEC 10746-2:1996	Information technology – Open Distributed Processing – Reference model: foundations
ISO/IEC 10746-3:1996	Information technology – Open Distributed Processing – Reference model: Architecture
ISO/IEC 10746-4:1998	Information technology – Open Distributed Processing – Reference model: Architectural semantics
ISO/IEC 15414	Information technology – Open Distributed Processing – Reference model: Enterprise language
ISO/IEC 19793	Information technology – Open distributed processing – Use of UML for ODP system specifications
ISO 9000:2000	Quality management systems – Fundamentals and vocabulary

3 Terms and definitions

For the purposes of this European Standard the following terms and definitions apply.

3.1 System concepts

3.1.1
scope (of a system)
the behaviour the system is expected to exhibit towards the enterprise it serves.

3.1.2
field of application (of a specification)
the properties the environment of the ODP system must have for the specification of that system to be viable

3.1.3
information service
the ability of the system to provide a defined set of output information based on a defined set of input information. The term information service is consistently used in this standard for the services provided by the information system

Note: The healthcare information services (HCIS) are the healthcare related services provided by healthcare information systems

3.1.4
viewpoint
A viewpoint (on a system) is an abstraction that yields a specification of the whole system related to a particular set of concerns.

3.2 Concepts relating to organisation

3.2.1
organisation
group of people and facilities with an arrangement of responsibilities, authorities and relationships [ISO 9000]

NOTE 1: The arrangement is generally orderly.

NOTE 2: An organisation can be public or private.

NOTE 3: This standard deals with healthcare organisations, ranging from hospital cooperations within e.g. counties, over individual hospitals, to individual clinics etc. encompassing only specific subsets of normal hospital services

3.2.2
organisational structure
arrangement of responsibilities, authorities and relationships between people

NOTE 1: The arrangement is generally orderly.

NOTE 2: A formal expression of the organisational structure is often provided

NOTE 3: The scope of an organisational structure can include relevant interfaces to external organisations

3.3 Community concepts

3.3.1
community
a configuration of objects formed to meet an objective. The objective is expressed as a contract which specifies how the objective can be met

3.3.2
federation
a community of domains

3.3.3
objective
practical advantage or intended effect, expressed as preferences about future states

NOTE 1: Some objectives are ongoing, some are achieved once met.
NOTE 2: In the text of ITU-T Rec. X.903 | ISO/IEC 10746-3 [3-5] the terms, purpose and objective, are synonymous. The enterprise language systematically uses the term, objective, and emphasises the need of expressing objective in measurable terms.

3.3.4
community object
a composite enterprise object that represents a community. Components of a community object are objects of the community represented

3.4 Behaviour concepts

3.4.1
actor (with respect to an action)
an enterprise object that participates in the action

NOTE - It may be of interest to specify which actor initiate that action.

3.4.2
artefact (with respect to an action)
an enterprise object that is referenced in the action

NOTE – An enterprise object that is an artefact in one action can be an actor in another action.

3.4.4
resource
an enterprise object which is essential to some behaviour and which requires allocation or may become unavailable

NOTE 1: Allocation of a resource may constrain other behaviours for which that resource is essential.

NOTE 2: A consumable resource may become unavailable after some amount of use or after some amount of time (in case a duration or expiry has been specified for the resource)..

3.4.5
interface role
a role of a community identifying behaviour which takes place with the participation of objects that are not members of that community

3.4.6
process
set of interrelated or interacting activities which transforms inputs into outputs [ISO 9000]

NOTE 1 Inputs to a process are generally outputs of other processes

NOTE 2 Processes in an organization (3.3.1) are generally planned and carried out under controlled conditions to add value.

NOTE 3 A process where the conformity (3.6.1) of the resulting product (3.4.2) cannot be readily or economically verified is frequently referred to as a “special process”

NOTE 4 An important objective for health care today is its ability to be organised in integrated processes to ensure continuity of care. The processes may be considered within a single organization or across organisations.

NOTE 5 The health care process (3.8.2) consists of three parallel processes: the clinical **process** (3.8.3) which is managed by a **management process** (3.8.4) running in parallel, and a **communication process** (3.8.5) dealing with information and resource flow.

NOTE 6 The health care process is provided in the health care enterprising process (3.8.6).

NOTE 7 When a demand for care (3.8.9) is accepted by a health care provider (3.5.3), a care mandate {3.8.10} is established stating the mission and authorisation for the health care provider (3.5.3) to provide health care services (3.8.8) to the subject of care (3.1.1). This care mandate is the basis for decisions about which health care activities (3.8.7) are to be performed, what the objective is for the health care process (3.8.2) and receptacle for objective evidence provided by the clinical process (3.8.3). Through verification the quality (3.10) of each health care activity (3.8.7) or series of health care activities can be assessed giving prerequisites for possible rework, repair, scrap or concession [ISO 9000:2000 concepts 3.6.7, 3.6.9, 3.6.10, and 3.6.11]. The mandate finally reaches a point where the total requirement (3.15) for the health care process (3.8.2) has been fulfilled and the care mandate {3.8.10} can be terminated.

NOTE 8 In the clinical process (3.8.3) the health (3.8.1) may improve, a risk for deterioration of the health may be reduced, or knowledge about the health may be improved, something which increases the possibilities to have a positive influence on the health.

NOTE 9 Processes can be influenced by events. An event does not occur in the own process but is the conception by the own process of an activity executed in another process. An event will probably lead to a change in the decided process strategy or to a result of the process other than the intended one.

NOTE 10: ISO 10746-1 defines process as: a collection of steps taking place in a prescribed manner and leading to an objective

3.4.7
step
an abstraction of an action, used in a process, that may leave unspecified objects that participate in that action

3.4.8
service

a number of processes, involving the organisation in the provision of specific objectives

NOTE 1: This definition regards the services provided in the organisation, with or without an electronic information system, whereas the definition of 'Information service' (3.2.3) regards the information (input/output) provided by the System.

NOTE 2: The healthcare services are the services taking place within a healthcare organisation

3.4.9
workflow
a number of services, involving the organisation in the provision of more complex objectives, according to agreed procedural rules

NOTE 1: In healthcare, workflow will often take place based on three fundamental processes, the clinical process, the information process and the management process, where information, tasks and activities are shifted between these.

3.5 Policy concepts

3.5.1
policy
a set of rules related to a particular purpose. A rule can be expressed as an obligation, an authorization, a permission or a prohibition

NOTE 1: Not every policy is a constraint. Some policies represent an empowerment.

NOTE 2: This definition refines 2-11.2.7 by adding authorization.

3.5.2
authorisation
a prescription that a particular behaviour must not be prevented

NOTE: Unlike a permission, an authorisation is an empowerment

3.5.3
violation
an action contrary to a rule

NOTE: A rule or policy may provide behaviour to occur upon violation of that or some other rule or policy.

3.6 Accountability concepts

3.6.1
party
an enterprise object modelling a natural person or any other entity considered to have some of the rights, powers and duties of a natural person

NOTE 1: Examples of parties include enterprise objects representing natural persons, legal entities, governments and their parts, and other associations or groups of natural persons.

NOTE 2: Parties are responsible for their actions and the actions of their agents.

The following concepts are used to identify actions which involve the accountability of a party.

3.6.2
commitment
an action resulting in an obligation by one or more of the participants in the act to comply with a rule or perform a contract.

NOTE The enterprise object(s) participating in an action of commitment may be parties or agents acting on behalf of a party or parties. In the case of an action of commitment by an agent, the principal becomes obligated.

3.6.3
declaration
an action that establishes a state of affairs in the environment of the object making the declaration

NOTE – The essence of a declaration is that, by virtue of the act of declaration itself and the authority of the object or its principal, it causes a state of affairs to come into existence outside the object making the declaration.

3.6.4
delegation
the action that assigns authority, responsibility or a function to another object

NOTE – A delegation, once made, may later be withdrawn.

3.6.5
evaluation
an action that assesses the value of something.

NOTE 1: For example, the act by which an ODP system assigns a relative status to some thing, according to estimation by the system.

NOTE 2: Value can be considered in terms of usefulness, importance, preference, acceptability etc; the evaluated target may be, for example, a credit rating, a system state, a potential behaviour, etc.

3.6.6
prescription
an act that establishes a rule

NOTE: Specialised meaning in healthcare where a prescription of medicinal products establishes the rule that medication can be given by a pharmacy