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Health informatics — Service architecture —

Part 1: Enterprise viewpoint

Informatique de santé — Architecture de service —

Partie 1: Point de vue d'entreprise

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 12967-1 was prepared by Technical Committee ISO/TC 215, *Health informatics*, based on the European Standard EN 12967-1:2007 with minor editorial amendments.

ISO 12967 consists of the following parts, under the general title *Health informatics — Service architecture*:

— *Part 1: Enterprise viewpoint*

— *Part 2: Information viewpoint*

— *Part 3: Computational viewpoint*

Introduction

The healthcare organizational structure consists of networks of centres (hospital cooperations within, for example, counties, individual hospitals, clinics, etc.) distributed over the territory, characterized by a high degree of heterogeneity and diversity, from organizational, logistic, clinical, technological and even cultural perspectives. The structure of individual centres evolves from a vertical, aggregated organization towards the integration of a set of specialized 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 effectively support 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 organization, at local and territorial levels. 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 optimize 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 organizations 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.

In the present circumstances, the main need for care delivery organizations is to integrate and to make available the existing information assets, and 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 organization, represents another crucial aspect to be evaluated carefully.

The goal can be achieved through a unified, open architecture based on 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 organizational level, all aspects (i.e. clinical, organizational and managerial) of the healthcare structure must be supported by the architecture, which must therefore be able 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 to be defined for supporting specific requirements, both in terms of *in situ* user operations and with respect to the 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 organization and the communication messages to be "services" extracting or importing data from/to the common information shown in Figure 1.

On the basis of these considerations, the purpose of ISO 12967 is twofold:

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

— 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 and for the planning and construction of new systems.

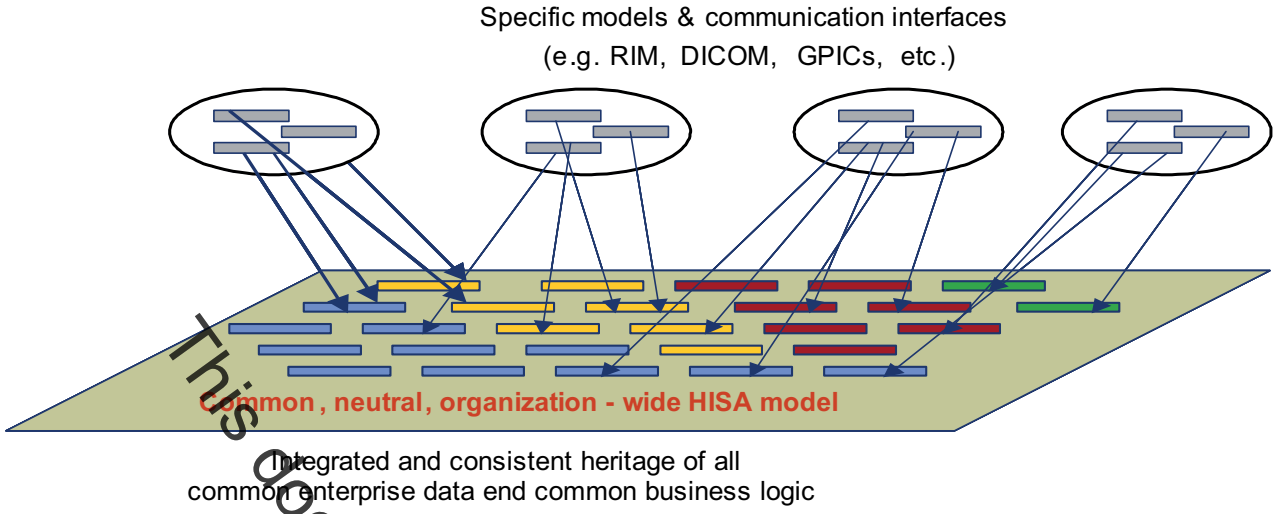

Figure 1 — Complementarity and positioning of the architecture with other standards and models

It is pointed out that ISO 12967 does not aim to define a unique model for clinical, organizational, 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, ISO 12967 does not aim to represent a final, complete set of specifications. On the contrary, it formalizes only fundamental aspects, identified as common in all countries and considered to be currently essential in any advanced healthcare information system. Specifications are formalized, avoiding any dependency on specific technological products and/or solutions.

ISO 12967, therefore, is an open framework that, according to the specification methodology and preserving the compatibility with previous versions, can be extended during time according to the evolution of the healthcare organization both in the individual (national and local) contexts and through international standardization initiatives.

A European pre-standard, ENV 12967-1, developed according to such rationale during 1993 to 1997 and published in 1998, was the basis for implementations of middleware products and implemented integrations in healthcare regions in several countries. In 2000, the CEN/TC 251 Short Strategic Study on Health Information Infrastructure 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. European standardization initiatives have delivered a number of object-oriented domain models and message descriptions that include an architecture for the Electronic Health Record (ISO 13606). Cooperation between CEN and HL7 was started in the year 2000, and on the basis of the CEN modelling principles and the HL7 Reference Information Model, this led to the definition of a set of “General Purpose Information Components” (GPICs) usable for developing messages.

The formal major revision of the pre-standard to a European standard was started in 2003 and in 2007 this led to the publication of the EN 12967 Parts 1 to 3 series on which ISO 12967 is based.

The following characteristics of ISO 12967 can be highlighted as follows.

— The architecture is described according to the methodology of ISO/IEC 10746 (all parts), to provide a formal, comprehensive and non-ambiguous specification suitable to serve as a 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 organization as a whole, from the clinical, organizational and managerial point of view. It therefore does not detail specificities of different subdomains, but provides an overarching comprehensive information and services framework to accommodate requirements.

— The architecture is intrinsically compatible, complementary and synergistic with other models and standards, such as HL7 RIM, the derived GPICs and the Electronic Health Record Architecture ISO 13606. A separate mapping document between this HISA standard and HL7 RIM was produced during the ISO process. Specific information objects and services are explicitly foreseen in the architecture to facilitate the implementation of views and communication mechanisms based on such standards.

— Many of the basic concepts of ISO 12967 are aligned with EN 13940, *Health informatics — System of concepts to support continuity of care* that, in June 2008, it was agreed to process also as an International Standard.

ISO 12967 consists of three parts:

— Part 1 (this part) specifies the overall characteristics of the architecture, formalizes the specification methodology and the conformance criteria, and provides details of 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 part is self-consistent and is also independently utilizable for the intended purposes by different types of users (this part being more oriented to the managerial level, Parts 2 and 3 being more dedicated to the design activities). Nevertheless, it must 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 must be carried out according to the defined methodology to preserve the overall integrity and consistency of the specification.

The overall architecture is formalized according to ISO/IEC 10746 (all parts) and is therefore structured through the following three viewpoints.

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

   Enterprise viewpoint is specified in this part of ISO 12967.

b) Information viewpoint: 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 formalized in this part of ISO 12967. It also provides guidance on how one individual enterprise can extend the standard model with additional concepts needed to support local requirements in terms of information to be put in common.

   Information viewpoint is specified in ISO 12967-2.

c) Computational viewpoint: specifies the scope and characteristics of the services that must be provided by the middleware for allowing access to the common data as well as the execution of the business logic supporting the enterprise processes identified in the information viewpoint and in this part of ISO 12967. It also provides guidance on how one individual enterprise can specify additional services needed to support local specific requirements in terms of common business logic to be implemented.

   Computational viewpoint is specified in ISO 12967-3.

Health informatics — Service architecture —

Part 1: Enterprise viewpoint

1 Scope

This part of ISO 12967 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 organizations, 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 2.

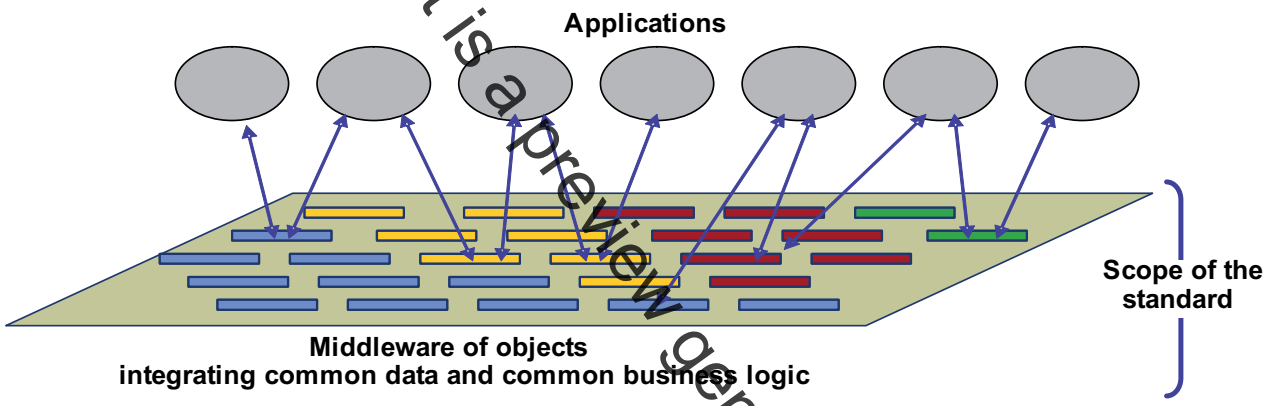

Figure 2 — Scope

This part of ISO 12967 is also independent from, and does not imply either explicitly or implicitly, any specific technological solution or product for its deployment. Accordingly, the formalization of the architecture according to two lower levels of the ODP reference model, the engineering and technology viewpoints, is outside the scope of this part.

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 utilized 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 organizations and vendors. For this exercise, it is recommended to follow the methodology formalized by the Engineering and Technology viewpoints of the RM ODP Reference model[1)].

1) For more introductory material on RM-ODP and many guideline documents see www.rm-odp.net.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 System concepts

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

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

3.1.3
information service
ability of the system to provide a defined set of output information based on a defined set of input information

NOTE 1 The term information service is consistently used in this part of ISO 12967 for the services provided by the information system.

NOTE 2 The healthcare information services (HCIS) are the healthcare related services provided by healthcare information systems.

3.1.4
viewpoint on a system
abstraction that yields a specification of the whole system related to a particular set of concerns

3.1.5
middleware
enabling technology of enterprise application integration (EAI) describing a piece of software that connects two or more software applications so that they can exchange data

NOTE 1 Common programming interfaces between applications are considered as middleware. For example, Open Database Connectivity (ODBC) enables applications to make a standard call to all the databases that support the ODBC interface.

NOTE 2 HISA services belong to the parts of the architecture that are middleware, and they address basic aspects dealing with the fundamental openness and sharing of information and business logic for the healthcare organization. In this part of ISO 12967, the usage of the term “middleware” is in the context of HISA, related to the services.