INTERNATIONAL STANDARD

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Health informatics — Service architecture (HISA) —

Part 1: Enterprise viewpoint

Informatique de santé — Architecture de service —

Partie 1: Point de vue de l'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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 12967-1:2009), which has been technically revised. The main changes compared to the previous edition are as follows:

— use of terms, definitions and concepts from ISO 13940:2015 (Contsys), with textual alignment throughout the document including figures, to the extent possible and beneficial;

— reference to further standards, such as HL7® and FHIR®;

— addition of abstraction layers supplementing the viewpoint descriptions;

— introduction of example functions from ISO/HL7 10781 supporting the use case examples of this document;

— addition of Annex C, Cross-Domain Interoperability, in line with the current (2020) ongoing ISO Interoperability and Integration Reference Architecture standardization initiative;

— updates to the Bibliography.

A list of all parts in the ISO 12967 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The healthcare organizational structure consists of networks of centres (hospitals of different types and sizes and outpatient clinics for primary and secondary care within a geographical area) 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.

A further aspect is related to quality management (see bibliography), where information management is an integrated part of quality management and the strategic and operative approaches for these two managerial aspects need to be co-ordinated to be effective. Clinical processes are comprehensive. Systematic and structured information management including medical knowledge management is required for high-level quality in effective healthcare systems.

The aims 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 should be supported by the architecture, which should 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.

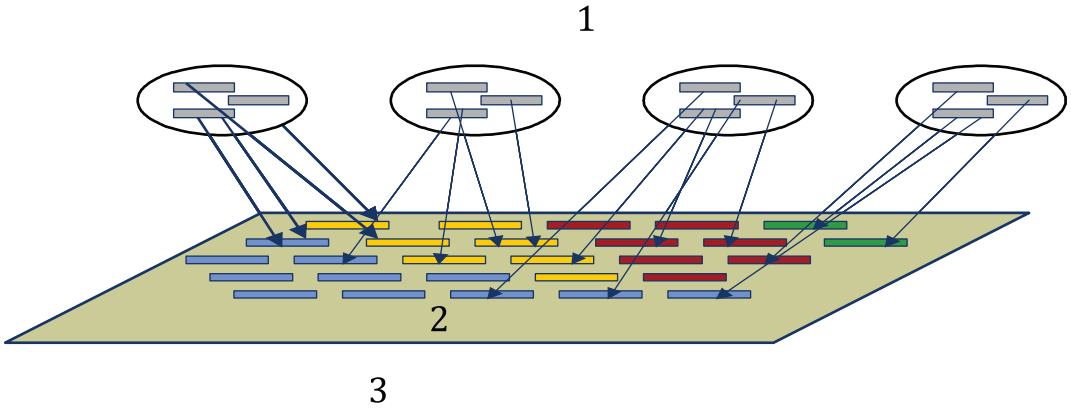
Standards and technological solutions already exist and will continue to be defined for supporting specific requirements, both in terms of in situ user operations and with respect to the movement of information. The architecture should be able to accommodate such requirements by allowing the specific models to be integrated with the complete information assets of the healthcare organization and e.g. 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 the ISO 12967 series 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.



Key

1 specific models and communication interfaces (e.g. CDA, FHIR, ISO 13606, DICOM)

2 common, neutral, organisation-wide HISA model

3 integrated and consistent heritage of all common enterprise data and common business logic

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

It is pointed out that the ISO 12967 series 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, the ISO 12967 series 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.

In line with the above, HISA neither explicitly addresses major trends within healthcare in 2020 such as "Patient Engagement" or "Patient Registries/Patient Data Hubs". HISA nevertheless also supports these trends and might very well be used in connection herewith, providing further support for information exchange, to the benefit of the patient, or for structured and systematic information management regarding research, clinical databases, knowledge application and quality improvement.

The ISO 12967 series, 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, 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 (all parts)], and a concept model of healthcare (ISO 13940:2015). In the last ten years ISO, HL7 and CEN have increasingly collaborated and both the ISO 13606 (all parts) and ISO 13940:2015 have undergone major systematic

reviews as ISO standards. Besides these ISO standards, HL7 Service-Aware Interoperability Framework (SAIF) has served as a source of inspiration, the Australian E-health Interoperability Framework (eHIF, see bibliography) and a conference paper from 2016 "Digital Health Interoperability Frameworks: Use of RM-ODP Standards" as sources of input for this revision (see bibliography).

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 12967-1 to EN 12967-3 series on which the ISO 12967 series is based, currently serving as the basis for this revision.

The following characteristics of the ISO 12967 series 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. (Annex A provides short informative background information regarding the ISO/IEC 10746 (all parts) and Open Distributed Processing).

— 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 CDA, HL7 FHIR, ISO 13940:2015 (Contsys) and ISO 13606 (all parts). A separate mapping document between ISO 12967-2 and HL7 RIM was produced during the process for the first version of this ISO 12967 series. 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 concepts and principles shared with ISO 13606 (all parts), ISO 13940:2015 (Contsys) and the ISO 12967 series are aligned, originally stemming from CEN. But as the standards also reflect different, although complementary, scopes, purposes and objectives, as investigated during a joint "concurrent use" initiative, differences do exist.

Each part in the ISO 12967 series is self-consistent and is also independently utilizable for the intended purposes by different types of users (this document 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 should be carried out according to the defined methodology to reserve 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 should 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 document.

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 document. 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 should 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 document. 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.

Annex C includes an explanation of ISO 23903:—[1)] and its relevance in regard to the ISO 12967 series, for integration with other standards such as ISO 13940.

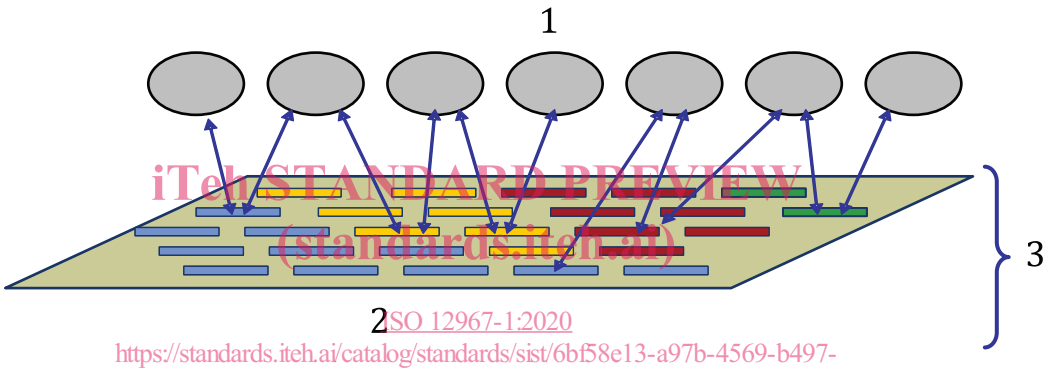
1) Under preparation. Stage at the time of publication ISO/DIS 23903:2020.

Health informatics — Service architecture (HISA) —

Part 1: Enterprise viewpoint

1 Scope

This document provides guidance and requirements 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.



Key

1 applications
2 middleware of objects integrating common data and common business logic
3 scope of ISO 12967-1

Figure 2 — Scope

This document 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 document.

The language and notations used here for specifying the architecture are based on UML (Unified Modeling 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. Accordingly, methodology formalized by the Engineering and Technology viewpoints of the RM ODP Reference Model can be followed for the implementation.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 (all parts), *Information technology — Open Distributed Processing — Reference model*

ISO 12967-2:2020, *Health informatics — Service architecture — Part 2: Information viewpoint*

ISO 12967-3:2020, *Health informatics — Service architecture — Part 3: Computational viewpoint*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1 Healthcare

3.1.1
healthcare
care activities, services, management or supplies related to the health of an individual

Note 1 to entry: This includes more than performing procedures for subjects of care. It includes, for example, the management of information about patients, health status and relations within the healthcare delivery framework and may also include the management of clinical knowledge.

[SOURCE: ISO 13940:2015, 3.1.1]

3.1.2
health issue
representation of an issue related to the health of a subject of care as identified by one or more healthcare actors

[SOURCE: ISO 13940:2015, 6.3]

3.1.3
healthcare matter
representation of a matter related to the health of a subject of care and/or the provision of healthcare to that subject of care, as identified by one or more healthcare actors

[SOURCE: ISO 13940:2015, 6.2]

3.1.4
health state
physical and mental functions, body structure, personal factors, activity, participation and environmental aspects as the composite health of a subject of care

[SOURCE: ISO 13940:2015, 6.5]

3.1.5
health condition
observed or potential observable aspects of the health state at a given time

[SOURCE: ISO 13940:2015, 6.4]

3.1.6
observed condition
health condition observed by a healthcare actor

[SOURCE: ISO 13940:2015, 6.4.1]

3.2 System concepts

3.2.1
information service
ability of the system to provide a defined set of output information based on a defined set of input information

Note 1 to entry: The term information service is consistently used in this document for the services provided by the information system.

Note 2 to entry: The healthcare information services are the healthcare related services provided by healthcare information systems.

3.2.2
middleware
enabling technology of enterprise application integration describing a piece of software that connects two or more software applications so that they can exchange data

Note 1 to entry: 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 to entry: 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 document, the usage of the term "middleware" is in the context of HISA, related to the services.

3.2.3
enterprise application integration
use of software and computer systems architectural principles to integrate a set of enterprise computer applications

3.2.4
object
model of an entity, characterized by its behaviour and its state, encapsulated and distinct from other objects

Note 1 to entry: This definition is about "object" in the architectural sense [in line with the ISO/IEC 10746 (all parts)]. This does not preclude the use of the word in the natural language sense as an entity itself, where e.g. a "process object" of a healthcare/clinical process is the health state of a subject of care.

[SOURCE: ISO/IEC 10746-2:2009, 8.1, modified — shortened.]

3.2.5
enterprise object
object modelling an enterprise entity

3.2.6
class
abstraction of the knowledge and behaviour of a set of similar things

Note 1 to entry: Class in UML is a description of a set of objects that share the same attributes, operations, methods, relationships, and semantics.

[SOURCE: ISO/IEC/IEEE 24765:2017, 3.577, modified — Note 1 to entry substituted.]

3.3 Concepts relating to organization

3.3.1
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

Note 1 to entry: An organization can be public or private.

Note 2 to entry: The scope of an organizational structure can include relevant interfaces to external organizations.

[SOURCE: ISO 9000:2015, 3.2.1, modified — Note 1 to entry has been simplified and Note 2 to entry substituted.]

3.3.2
healthcare actor
organization or person participating in healthcare

[SOURCE: ISO 13940:2015, 5.2, modified — Note 1-3 to entry omitted.]

3.3.3
healthcare provider
healthcare actor that is able to be assigned one or more care period mandates

[SOURCE: ISO 13940:2015, 5.2.3, modified — Note 1-3 to entry omitted.]

3.3.4
subject of care
healthcare actor with a person role; who seeks to receive, is receiving, or has received healthcare

Note 1 to entry: Among synonyms are patient and subject of healthcare

[SOURCE: ISO 13940:2015, 5.2.1, modified — Note 1 to entry substituted and Examples omitted.]

3.3.5
healthcare organization
healthcare provider having an organization role

[SOURCE: ISO 13940:2015, 5.2.3.1, modified — Note 1-4 to entry and Examples omitted.]

3.3.6
role
function or position

[SOURCE: ISO 13940:2015, 3.3.5]

3.4 Community concepts

3.4.1
community
configuration of objects formed to meet an objective

Note 1 to entry: The objective is expressed as a contract, which specifies how the objective can be met.

3.4.2
federation
community of domains

3.4.3
objective
practical advantage or intended effect, expressed as preferences about future states

Note 1 to entry: Some objectives are ongoing, some are achieved once they are met.

3.5 Behaviour concepts

3.5.1
resource
asset that is utilized or consumed during the execution of a process

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

Note 2 to entry: 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).

[SOURCE: ISO 13940:2015, 3.4.1, modified — Note 1-2 to entry substituted.]

3.5.2
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: An important objective for health care today is its ability to be organized in integrated processes to ensure continuity of care. The processes may be considered within a single organization or across organizations.

Note 2 to entry: Inputs to a process are generally outputs of other processes.

Note 3 to entry: The health care process is provided in the health care enterprise.

Note 4 to entry: Processes in an organization are generally planned and carried out under controlled conditions to add value.

Note 5 to entry: A process where the conformity of the resulting output cannot be readily or economically verified is frequently referred to as a “special process”.

Note 6 to entry: When a demand for care is accepted by a health care provider, a care mandate is established stating the mission and authorization for the health care provider to provide health care services to the subject of care. This care mandate is the basis for decisions about which health care activities are to be performed, what the objective is for the health care process and the receptacle for objective evidence provided by the clinical process. Through verification, the quality of each health care activity or series of health care activities can be assessed giving prerequisites for possible rework, repair, scrap or concession (see respective definitions in ISO 9000:2015, 3.12.8, 3.12.9, 3.12.10, and 3.12.5). The mandate finally reaches a point where the total requirement for the health care process has been fulfilled and the care mandate can be terminated.

Note 7 to entry: In the clinical process, the health 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 8 to entry: Processes can be influenced by events. Such an event does not occur within the process in question, but is the conception by the 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.

[SOURCE: ISO 9000:2015, 3.4.1, modified — Note 1 to entry substituted, Note 2 to entry simplified, Note 3 to entry substituted, Note 6 to entry substituted, Note 7 and 8 to entry added.]

3.5.3
step
abstraction of an action, used in a process, that might leave unspecified objects that participate in that action