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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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Contents

Page

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.

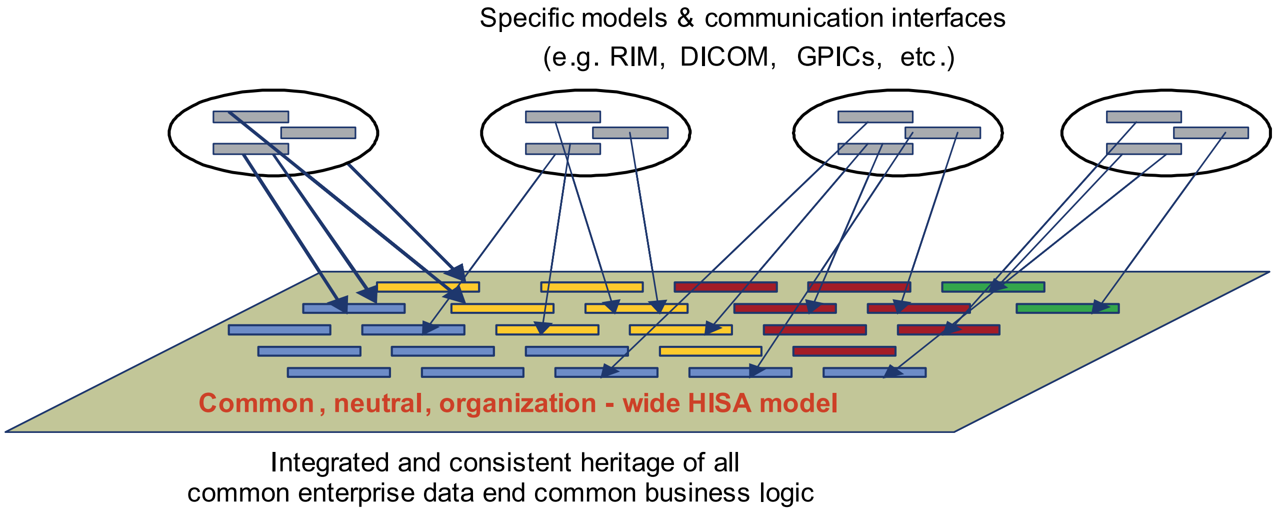

Figure 1 — Complementarity and positioning of the architecture with other standards and models

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.

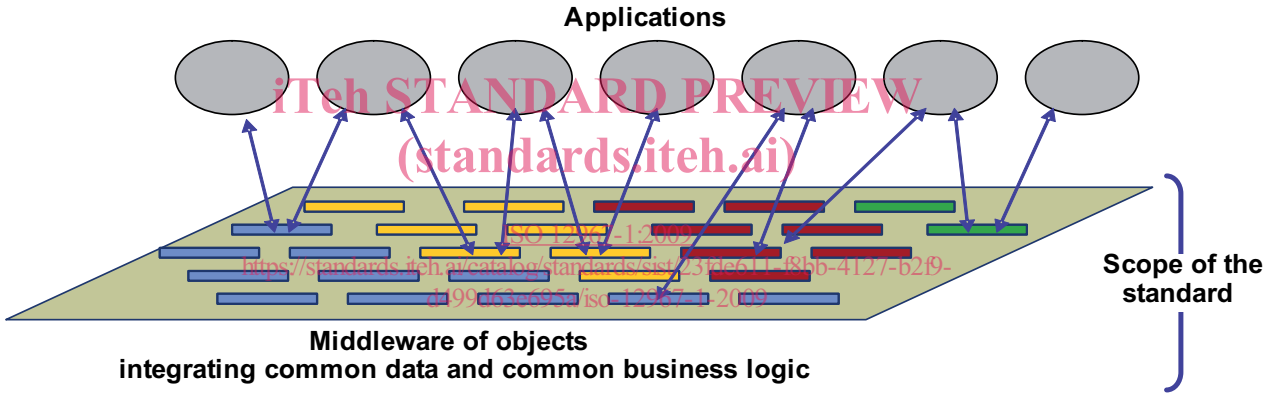

Figure 2 — Scope

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.

3.1.6
enterprise application integration
EAI
use of software and computer systems architectural principles to integrate a set of enterprise computer applications

3.2 Concepts relating to organization

3.2.1
organization
group of people and facilities with an arrangement of responsibilities, authorities and relationships

[ISO 9000:2005]

NOTE 1 The arrangement is generally orderly.

NOTE 2 An organization can be public or private.

NOTE 3 This part of ISO 12967 deals with healthcare organizations ranging from hospital cooperations within, for example, counties, in individual hospitals, individual clinics, etc. encompassing only specific subsets of normal hospital services.

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

NOTE 1 The arrangement is generally orderly.

NOTE 2 A formal expression of the organizational structure is often provided.

NOTE 3 The scope of an organizational structure can include relevant interfaces to external organizations.

3.3 Community concepts

3.3.1
community
configuration of objects formed to meet an objective

NOTE The objective is expressed as a contract, which specifies how the objective can be met

3.3.2
federation
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 they are met.

NOTE 2 In the text of ITU-T Rec. X.903 (in ISO/IEC 10746-3:1996) the terms purpose and objective are synonymous. The enterprise language systematically uses the term, objective, and emphasizes the need for expressing objective in measurable terms.

3.3.4
community object
composite enterprise object that represents a community

NOTE The components of a community object are objects of the community represented.

3.4 Behaviour concepts

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

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

3.4.2
artefact with respect to an action
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.

3.4.3
resource
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).

3.4.4
interface role
role of a community identifying behaviour which takes place with the participation of objects that are not members of that community

3.4.5
process
set of interrelated or interacting activities which transforms inputs into outputs

[ISO 9000:2005]

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

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

NOTE 3 A process where the conformity of the resulting product 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 organized in integrated processes to ensure continuity of care. The processes may be considered within a single organization or across organizations.

NOTE 5 The health care process is provided in the health care enterprise.

NOTE 6 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 [ISO 9000:2005 definitions 3.6.7, 3.6.9, 3.6.10, and 3.6.11, respectively]. 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 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 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.

NOTE 9 ISO 10746-1 defines process as: a collection of steps taking place in a prescribed manner and leading to an objective.

3.4.6
step
abstraction of an action, used in a process, that may leave unspecified objects that participate in that action

3.4.7
service
number of processes, involving the organization in the provision of specific objectives

NOTE 1 This definition regards the services provided in the organization, with or without an electronic information system, whereas the definition of “Information service” regards the information (input/output) provided by the system.

NOTE 2 The healthcare services are the services taking place within a healthcare organization

3.4.8
workflow
number of services, involving the organization in the provision of more complex objectives, according to agreed procedural rules

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

3.5 Policy concepts

3.5.1
policy
set of rules related to a particular purpose

NOTE 1 A rule can be expressed as an obligation, an authorization, permission or a prohibition

NOTE 2 Not every policy is a constraint. Some policies represent an empowerment.

NOTE 3 This definition may be refined by adding authorization.

3.5.2
authorization
prescription that a particular behaviour must not be prevented

NOTE Unlike permission, an authorization is an empowerment

3.5.3
violation
action contrary to a rule

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

3.6 Accountability concepts

3.6.1
party
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 Examples of parties include enterprise objects representing natural persons, legal entities, governments and their parts, and other associations or groups of natural persons.

3.6.2
commitment
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
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
action that assigns authority, responsibility or a function to another object

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

3.6.5
evaluation
action that assesses the value of something

NOTE 1 For example, the act by which an ODP system assigns a relative status to something, according to an 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
act that establishes a rule

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

3.6.7
agent
enterprise object (authority, responsibility, function, etc.) that has been delegated by and acts for another enterprise object (in exercising the authority, carrying out the responsibility, performing the function, etc.)

NOTE 1 An agent may be a party or may be the ODP system or one of its components. Another system in the environment of the ODP system may also be an agent.

NOTE 2 The delegation may have been direct, by a party, or indirect, by an agent of the party having authorization from the party to so delegate.

3.6.8
principal
party that has delegated (authority, a function, etc.) to another

3.6.9
contracting party with respect to a contract
party that agrees to a contract

4 Symbols and abbreviations

ECG	Electrocardiogram
EHR	Electronic Health Record
HISA	Health Informatics Service Architecture
ODP	Open Distributed Processing
SOA	Service Oriented Architecture
UML	Unified Modelling Language

5 Methodology for the specification of the architecture

This clause describes the methodology adopted by this part of ISO 12967 for the specification of the architecture. The same methodology shall be used by healthcare enterprises and industrial vendors for describing the characteristics of HISA-conformant systems. The scope of the methodology is the specification of the contents of the documents that will be delivered for describing the architecture. The formalization of the process according to which a system is identified, planned, designed and implemented is outside the scope of this part of ISO 12967; the ODP approach described in this clause may nevertheless provide guidance for the definition of such a process.

Subclause 5.1 provides an overview on the viewpoint-based ODP methodology. Subclause 5.2 specifies how this is used in HISA (for the enterprise, information and computation viewpoints themselves) and how the characteristics of HISA-conformant systems should be described.

5.1 Viewpoints for the specification of the architecture

The methodology defined by ISO/IEC 10746 (all parts) shall be used for the specification of a healthcare service architecture that shall be structured through five viewpoints, individually specifying a particular set of concerns of the whole system:

- **Enterprise viewpoint**, which is concerned with the purpose, scope and policies governing the activities of the specified system within the organization of which it is a part;
- **Information viewpoint**, which is concerned with the kinds of information handled by the system and constraints on the use and interpretation of that information;
- **Computational viewpoint**, which is concerned with the functional decomposition of the system into a set of objects that interact through formalized interfaces;
- **Engineering viewpoint**, which is concerned with the infrastructure required to support system implementation and distribution;
- **Technology viewpoint**, which is concerned with the choice of technology to support system implementation and distribution.

For each viewpoint there is an associated viewpoint language that can be used to express a specification of the system from that viewpoint. The object modelling concepts give a common basis for the viewpoint languages and make it possible to identify relationships between the different viewpoint specifications and to assert correspondences between the representations of the system in different viewpoints.

This part of ISO 12967 formalizes the enterprise, information and computational viewpoints illustrated in Figure 3. Systems conformant to HISA shall be described by means of the same three viewpoints, complemented with the specification of the infrastructural and technological characteristics. Such aspects should be described according to the criteria defined by the ODP engineering and technology viewpoints.

NOTE An actual implementation of the HISA services could be described as a Service Oriented Architecture (SOA), e.g. in the form of web services.

