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Health Informatics — Interoperability and integration reference architecture — Model and framework

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The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Informatique de santé - Architecture de référence d'interopérabilité et d'intégration - Modèle et cadre (ISO 23903:2021)

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This document (EN ISO 23903:2021) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2021, and conflicting national standards shall be withdrawn at the latest by October 2021.

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The text of ISO 23903:2021 has been approved by CEN as EN ISO 23903:2021 without any modification.

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Foreword

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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).

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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).

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Introduction

0.1 Preface

This document supports the integration of a) specifications from different domains with their specific methodologies, terminologies and ontologies including specific specification style as well as b) systems based on those specifications. Enabling the use-case-specific identification and consistent, formal representation including constraints of necessary components with their specific concepts and their relationships, this document facilitates the deployment of existing standards and systems, the analysis and improvement of specifications under revision as well as the design of new projects.

This document provides an overview of the Interoperability and Integration Reference Architecture (first introduced in the 1990s as the Generic Component Model – GCM[1][2]), providing scope, justification and explanation of key concepts and the resulting model and framework. It contains explanatory material on how this Interoperability and Integration Reference Architecture is interpreted and applied by its users, who might include standards writers and architects of interoperable systems, but also systems integrators.

The ongoing organizational, methodological and technological paradigm changes in health and social care result in health systems transformation toward P5 (personalized, preventive, predictive, participative precision) systems medicine as fully distributed, highly dynamic, strongly integrated, multi-disciplinary (or multi-domain) intelligent ecosystems, comprising both structured systems, communities governed by rules, and combinations thereof[3].

0.2 Interoperability levels

Interoperability (see 3.16) has evolved during the last 30 years from structured messaging (e.g. EDI, HL7®[1)] messaging) over sharing concepts [e.g. openEHR®[2)] Archetypes, ISO 13940[4] (system of concepts to support continuity of care)] – both representing the data/information exchange paradigm – to cooperation at application level (e.g. Web services). All those solutions focus on information and communication technologies (ICT) systems interoperability using ICT terminologies and ontologies for representing data, information, or even concepts and knowledge, thereby distinguishing the three interoperability levels: a) foundational, b) structural, and c) semantic interoperability.

On the move towards digital health, ICT systems get more closely integrated in the real world business process. This move requires supporting advanced, knowledge-level and business process focused interoperability between all principals acting in those ecosystems such as persons, organizations, devices, applications, components, or objects to achieve the common business objectives. As knowledge, methodologies and terminologies of the domains involved in the business case and represented through those domains' ontologies, but also individual contexts, abilities and capabilities are highly different, they must be shared and adapted in advance or dynamically at runtime, enabling adequate cooperation of actors and systems involved. Table 1 summarizes the different interoperability levels[5].

Table 1 — Interoperability levels

Information Perspective		Organization Perspective
Interoperability Level	**Instances**	**Interoperability Level**
Technical	Technical plug&play, signal & protocol compatibility	Light-weight interactions
Structural	Simple EDI, envelopes	Data sharing
Syntactic	Messages and clinical documents with agreed vocabulary	Information sharing

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Information Perspective		Organization Perspective
Interoperability Level	**Instances**	**Interoperability Level**
Semantic	Advanced messaging with common information models and terminologies	Knowledge sharing at IT concept level in computer-parsable form Coordination
Organization / Service	Common business process	Knowledge sharing at business concept level Agreed service function level cooperation
Knowledge based	Multi-domain processes	Knowledge sharing at domain level Cross-domain cooperation
Skills based	Individual engagement in multiple domains	Knowledge sharing in individual context Moderated end-user collaboration

0.3 Motivation for the Interoperability and Integration Reference Architecture

Meeting the objectives of improving safety, quality and efficiency of care with ICT support requires advancing interoperability between computer systems towards a business-process-specific co-operation of actors representing the different domains participating in the business case. For that purpose, the agreed domain knowledge, but also the individual and shared context (language, education, skills, experiences, psychological, social, occupational, environmental aspects, etc.), need to be represented correctly and formally for integration with the ICT system as part of the business system. As the domain experts involved describe specific aspects of that business system in their own specific contexts and using specific terminologies and ontologies, methodologies and frameworks, the resulting informational representations are often quite inconsistent, requiring a peer-to-peer interoperability adaptation process. Adapting existing standardized informational representations of domain-specific use cases to changing contexts or contexts including multiple domains requires another common harmonized informational representation, resulting in permanent revisions of specifications.

Modelling systems for multi-domain interoperability requires the advancement from the data model, information model, and ICT domain knowledge perspective to the knowledge perspective of the business domains[6]. For achieving the latter, the relevant stakeholders are responsible to define the provided view of the model as well as the way of structuring and naming the concepts of the problem space. First capturing key concepts and key relations at a high level of abstraction, different abstraction levels can be used iteratively. Thereby, the first iteration is performed in a top-down manner to guarantee the conceptual integrity of the model. This demands meeting design principles such as orthogonality, generality, parsimony, and propriety.[7] ISO 30401[8] defines the requirements for knowledge management systems in organizations to meet business objectives.

It is impossible to represent the highly complex, highly dynamic, multi-disciplinary/multi-domain healthcare system by one domain‘s terminology/ontology or – even worse for the reasons mentioned right before - by exclusively using ICT ontologies and ICT specific representation styles.

The alternative is an abstract, domain-independent representation of systems using Universal Type Theory[9] and corresponding logics. The mathematical concept representation using a Meta Reference Architecture according to the formal theory of the Barendregt Cube with Parameters[9] in combination with systems engineering methodologies allows representing any system architecturally (i.e. the system’s components, their functions and internal as well as external relations) by generically describing its composition/decomposition and behaviour from the perspectives of all domains of relevance in a specific business case. A third dimension describes the system’s development process such as evolution for living systems, manufacturing for technical systems, or a software development process, resulting in a generic system model or Generic Reference Architecture presented in Figure 1. Details regarding the dimensions of the model are explained in Clause 5 and Clause 6.

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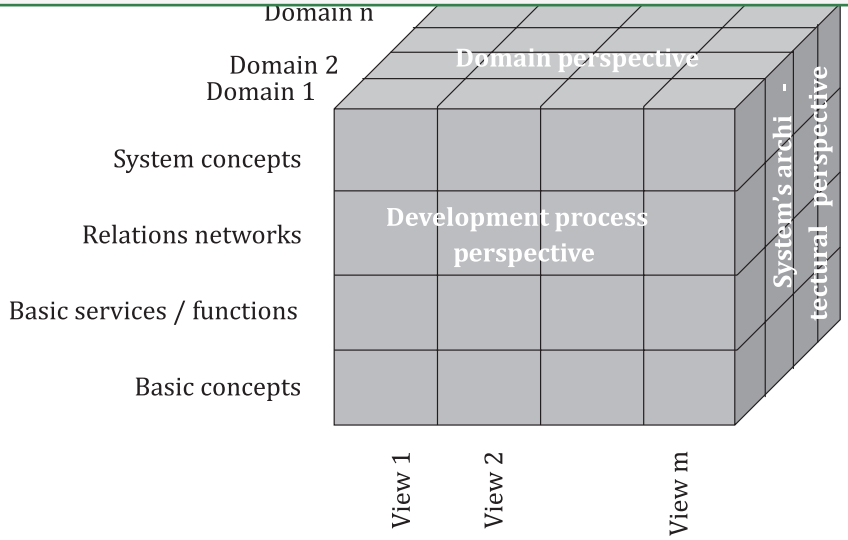

Figure 1 — Generic Reference Architecture model

To represent advanced interoperability and integration settings, different domain-specific representations are linked to the same real world component. Therefore, an abstract and generic reference architecture is needed which is able to represent any aspect or domain of interest. For correctly and formally representing the concepts and relations of the domain-specific subsystems involved in that business case, those subsystems are represented by their corresponding approved domain ontologies, resulting in a system-theoretical, architecture-centric, top-level ontology driven approach[10][11]. Requirements for top level ontologies are specified in ISO 21838 (all parts). Health domain ontologies are SNOMED-CT®[3] or specific ontologies such as the Open Biomedical Ontologies (OBO), including the Gene Ontology,[12] maintained by the OBO Foundry[13].

As we can consistently model and compute only systems of reasonable complexity, the Generic Reference Architecture model (Figure 1) can be used recursively at different granularity levels, so representing, e.g. the continuum of real-world systems from elementary particles to the universe. The concepts of the system's components and their relations are represented in appropriate expressions in natural or formal languages up to the basic level of primitives. The system analysis or design needs to address partial systems when considering higher granularity levels of the system in question.

0.4 Technical approach

A system is a composition of interrelated components, ordered to accomplish a specific function or a set of functions. Systems can be decomposed into subsystems or composed to form super-systems. There are constructive or structural and behavioural or functional aspects of systems. According to IEEE 1471,[14] the architecture of a system is the fundamental organization of that system embodied in its components, their relationships to each other and to the environment, and the principles guiding its design and evolution. Rules for selecting and constraining components and functions as well as relations according to a business case are called policies. Policies define the intended behaviour of a system. For living systems, factors such as homeostasis, with the attributes of self-organization and self-regulation as well as growth and development, reproduction, with the associated heredity (structure preservation) and mutation (structural change), and higher development through selection of best-adapted variants out of a large number make the description of living systems more complicated than that of technical systems[15].

In the 1970s and 1980s, a data level interoperability approach was developed by defining the application and technology agnostic standard data exchange format EDI (electronic data interchange) in order to transform proprietary data formats into the standard data format and vice versa.

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Thus International Standards arose such as ISO 9735 (EDIFACT),[16] or its healthcare-specific pendant ISO/HL7 27931:2009,[17] an application protocol for electronic data exchange in healthcare environments. This document defines a generic system architecture for knowledge level interoperability. It allows consistently transforming and interrelating any domain specific subsystem's structure and behaviour (e.g. domain specific standards and specifications) by ontologically representing its concepts and relationships at the real world system component's level of granularity in the abstract generic component system. In other words, the domain specific subsystem (e.g. a domain specific standard or specification) is re-engineered using the Interoperability and Integration Reference Architecture, by that way providing a standardized interface to that specification. In this way, the methodology offered in this document maps between domain specific or proprietary systems and their representation as specification or domain specific standard by transforming them into a standard system architecture and vice versa. Annex A demonstrates the integration of two domain specific standards by reengineering the ISO 13606-1[18] Reference Model and the HL7® Composite Security and Privacy Domain Analysis Model[19] and combining them in an Interoperability and Integration Reference Architecture model instance. Annex B demonstrates the integration of different communication standards by reengineering HL7 v3®[4)] methodology and creating an adequate HL7 v2®[4)] methodology and transforming them into an Interoperability and Integration Reference Architecture instance. In this way, the Interoperability and Integration Reference Architecture supports the mutual transformation of those communications standards for the sake of interoperability of existing solutions. For ontologically representing the models, the Communication Standards Ontology (CSO)[20] has been used. Figure 2 correspondingly presents this standard's interoperability approach. Annex C demonstrates the integration of different standards in the light of ISO 12967(all parts)[21], while Annex D presents the approach in context of ISO 13972[22]. Finally, Annex E demonstrates the deployment of this document's Interoperability and Integration Reference Architecture for the representation and harmonization of alternative reference architectures.

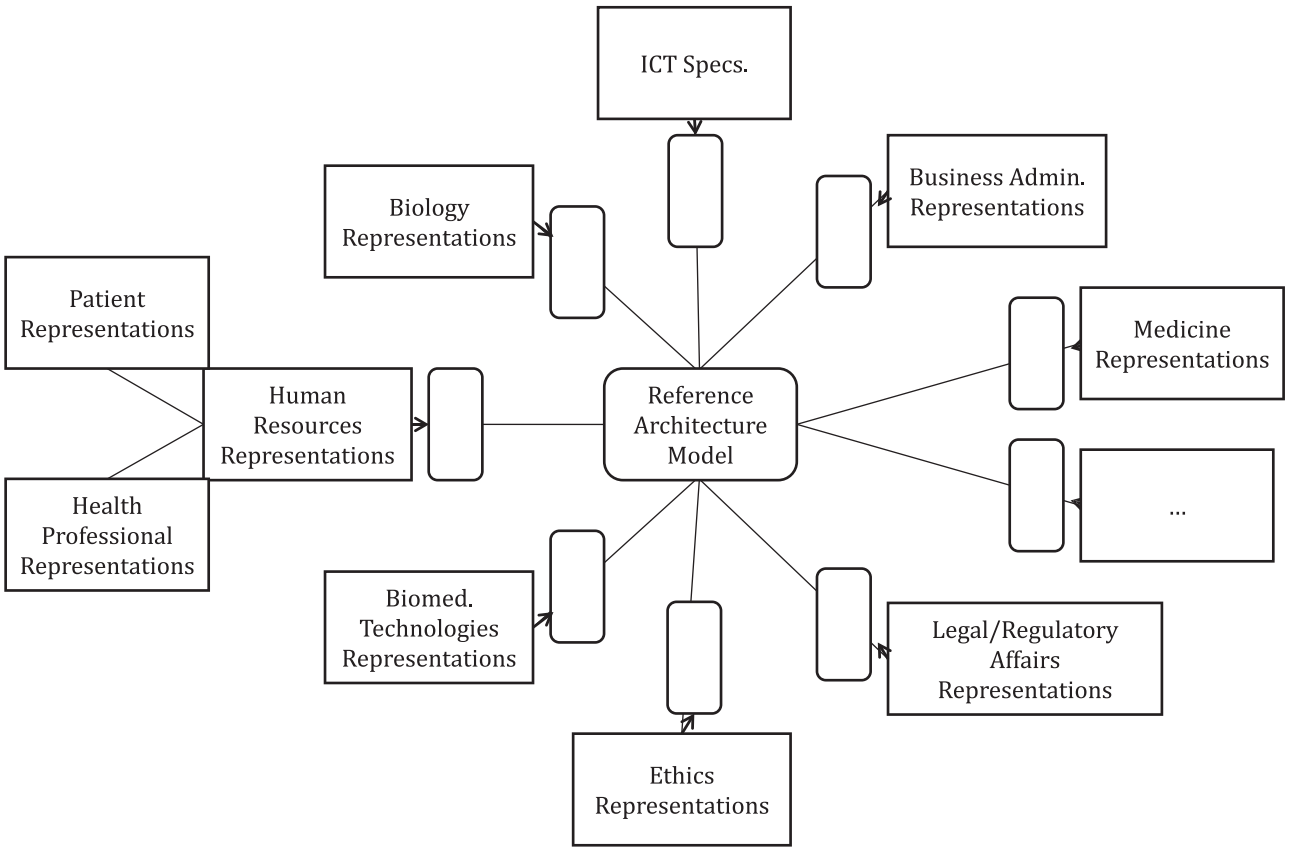

Figure 2 — Overview of this document's interoperability approach

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Bound to the GCM Framework, inter-domain relationships need to happen at the same level of granularity[23]. To get there, intra-domain specializations/generalizations are performed.

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Health Informatics — Interoperability and integration reference architecture — Model and framework

1 Scope

This document enables the advancement of interoperability from the data/information exchange paradigm to knowledge sharing at decreasing level of abstraction, starting at IT concept level (semantic coordination) through business domain concept level (agreed service function level cooperation), domain level (cross-domain cooperation) up to individual context (skills-based end-user collaboration). The document defines a model and framework for a harmonized representation of existing or intended systems with a specific focus on ICT-supported business systems. The Interoperability and Integration Reference Architecture supports ontology harmonization or knowledge harmonization to enable interoperability between, and integration of, systems, standards and solutions at any level of complexity without the demand for continuously adapting/revising those specifications. The approach can be used for analysing, designing, integrating, and running any type of systems. For realizing advanced interoperability, flexible, scalable, business-controlled, adaptive, knowledge-based, intelligent health and social ecosystems need to follow a systems-oriented, architecture-centric, ontology-based and policy-driven approach.

The languages for representing the different views on systems such as ontology languages like Common Logic (CL) (ISO/IEC 24707[24]) and Web Ontology Language (OWL)[25] – specifically OWL 2[26] (World Wide Web Consortium (W3C®[5])), languages for modeling and integrating business processes like Business Process Modeling Language (BPML) (OMG®[6]), but also OMG's Unified Modeling Language (UML, also specified as ISO/IEC 19505[27]) based representation styles for the different ISO/IEC 10746 (all parts) views are outside the scope of this document.

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 22600 (all parts), *Health informatics — Privilege management and access control*

ISO/IEC 21838 (all parts), *Information technology — Top-level ontologies (TLO)*

OMG. *Ontology Definition Metamodel V1.1*

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

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