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Zdravstvena informatika - Referenčna arhitektura medobratovalnosti in integracije - Model in okvir (ISO/DIS 23903:2020)

Health Informatics - Interoperability and Integration Reference Architecture - Model and Framework (ISO/DIS 23903:2020)

Medizinische Informatik - Interoperabilitätsreferenzarchitektur (ISO/DIS 23903:2020)

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Health informatics — Interoperability and Integration Reference Architecture – Model and Framework

ICS: 35.240.80

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Foreword

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This document was prepared by Technical Committee ISO/TC 251, Health informatics.

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, the DIS 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 DIS 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 to be interpreted and applied by its users, who may 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[1)] 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, defined by IEEE as the “ability of two or more systems or components to exchange information and to use the information that has been exchanged”, has evolved during the last 30 years from structured messaging (e.g. EDI, HL7 messaging) over sharing concepts (e.g. openEHR Archetypes, EN/ISO 13940 ContSys concepts) – 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 have to 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[4].

1) Personalized, preventive, predictive, participative precision medicine.

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
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.), have 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.[5] For achieving the latter, the relevant stakeholders shall 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 requires meeting design principles such as orthogonality, generality, parsimony, and propriety[6].

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 specific representation styles.

The alternative is an abstract domain-independent representation of systems using Universal Type Theory and corresponding logics. The mathematical concept representation using a Meta Reference Architecture according to the Barendregt Cube with Parameters[7] 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 behavior 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 the next sections.

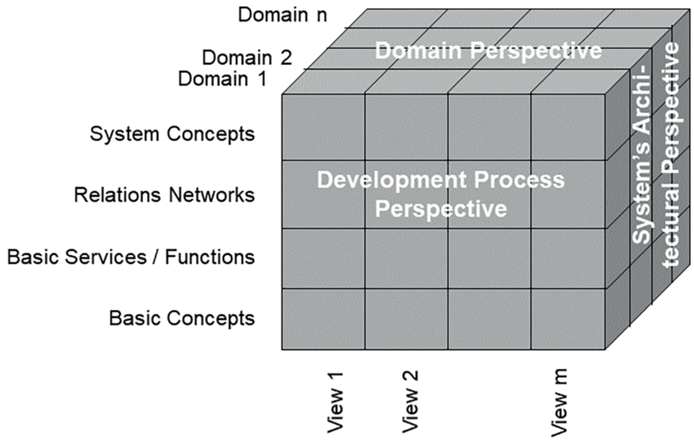

Figure 1 — Generic Reference Architecture model

To represent advanced interoperability and integration settings, different domain-specific representations must be 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.[8,9] Top level ontologies are specified in ISO 30401, health domain ontologies are SNOMED International's SNOMED-CT or specific ontologies such as the Open Biomedical Ontologies (OBO), including the Gene Ontology,[10] maintained by the OBO Foundry[11].

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 system analysis or design has 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 behavioral or functional aspects of systems. According to IEEE 1471, 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 behavior 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[12].

In the seventies and eighties of the last century, a data level interoperability approach was developed by defining the application and technology agnostic standard data exchange format EDI in order to transform proprietary formats into the standard format and vice versa. Thus standards arose such as ISO 9735 EDIFACT, or its healthcare-specific pendant ISO/HL7 27931:2009 *Data Exchange Standards – Health Level Seven Version 2.5* – An application protocol for electronic data exchange in healthcare environments. The latter defines a generic system architecture for knowledge level interoperability.

It allows consistently transforming and interrelating any domain specific subsystem's structure and behavior (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 DIS 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 Reference Model and the *HL7 Composite Security and Privacy Domain Analysis Model* 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 methodology and creating an adequate HL7 v2 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)[13] 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 *Health Informatics Service Architecture*, while Annex D presents the approach in context of ISO 13972 *Clinical Information Models*. Finally, Annex E presents the Reference Architecture Stack the ISO/IEC JTC1 AG8 project "Meta Reference Architecture and Reference Architecture for Systems Integration" is looking for, completely derived from this DIS's Interoperability and Integration Reference Architecture.

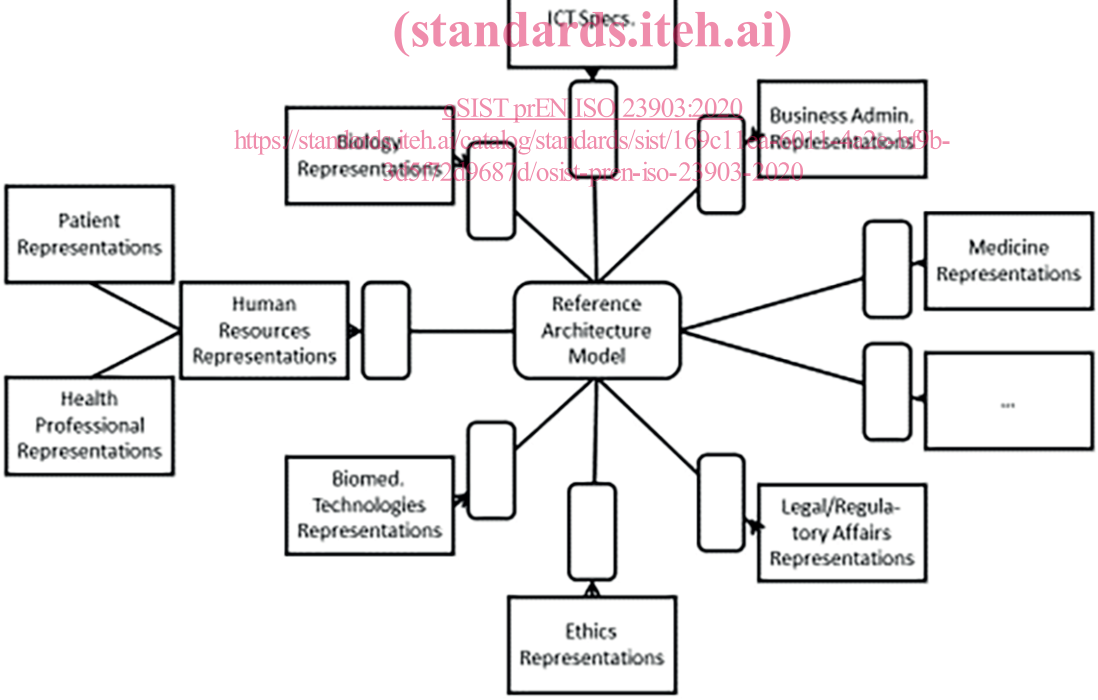

Figure 2 — Overview of this document's interoperability approach

Bound to the GCM Framework, inter-domain relationships must happen at the same level of granularity.[14] To get there, intra-domain specializations/generalizations have to be performed.

Health informatics — Interoperability and Integration Reference Architecture – Model and Framework

1 Scope

This DIS 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 DIS 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 analyzing, designing, integrating, and running any type of systems. For realizing advanced interoperability, flexible, scalable, business-controlled, adaptive, knowledge-based, intelligent health and social ecosystems must 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) and Web Ontology Language (OWL) – specifically OWL 2 (WWW Consortium), languages for modeling and integrating business processes like Business Process Modeling Language (BPML) (OMG), but also OMG's Unified Modeling Language (UML, also specified as ISO/IEC 19505) based representation styles for the different ISO/IEC 10746 views are outside the scope of this document.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 10746-2:2009, *Information technology — Open distributed processing — Reference model: Foundations*

ISO/IEC 10746-3:2009, *Information technology — Open distributed processing — Reference model: Architecture*

ISO/IEC 10746-4:1998, *Information technology — Open distributed processing — Reference model: Architectural semantics*

ISO 22600-1:2014, *Health informatics — Privilege management and access control — Part 1: Overview and policy management*

ISO 22600-2:2014, *Health informatics — Privilege management and access control — Part 2: Formal models*

ISO 22600-3:2014, *Health informatics — Privilege management and access control — Part 3: Implementations*

ISO/IEC/DIS 21838-1, *Information technology — Top-level ontologies — Part 1: Requirements*

ISO/IEC/DIS 21838-2, *Information technology — Top-level ontologies — Part 2: Basic formal ontology*

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:

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

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

3.1
axiom
statement that is taken to be true, to serve as a premise for further reasoning

[SOURCE: ISO/IEC CD 21838-1, 3.9]

3.2
business viewpoint
viewpoint, which is concerned with the purpose, scope and policies governing the activities of the specified ecosystem

3.3
class/type
general *entity* (3.9)

[SOURCE: ISO/IEC CD 21838-1, 3.2]

3.4
collection
group of particulars (3.19)

[SOURCE: ISO/IEC CD 21838-2, 3.4]

3.5
concept
A concept is a model. It shall be uniquely identifiable, accepted by experts and users, as well as independent.

Note 1 to entry: A concept as a knowledge component can be specialized and generalized as components can.

3.6
definition
concise statement of the meaning of an *expression* (3.11)

[SOURCE: ISO/IEC CD 21838-1, 3.8]

3.7
domain
collection of *entities* (3.10) of interest to a certain community or discipline

[SOURCE: ISO/IEC CD 21838-1, 3.17]

3.8
domain ontology
ontology (3.18) whose *terms* (3.27) represent *classes* (3.3) or *types* and, optionally, certain *particulars* (3.19) (called 'distinguished individuals') in some *domain* (3.7)

[SOURCE: ISO/IEC CD 21838-1, 3.18]

