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Health informatics — Interoperability and integration reference architecture – Model and framework

Informatique de santé — Architecture de référence d'interopérabilité et d'intégration — Modèle et cadre

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Contents

Page

Foreword

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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).

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

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].

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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.), 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.

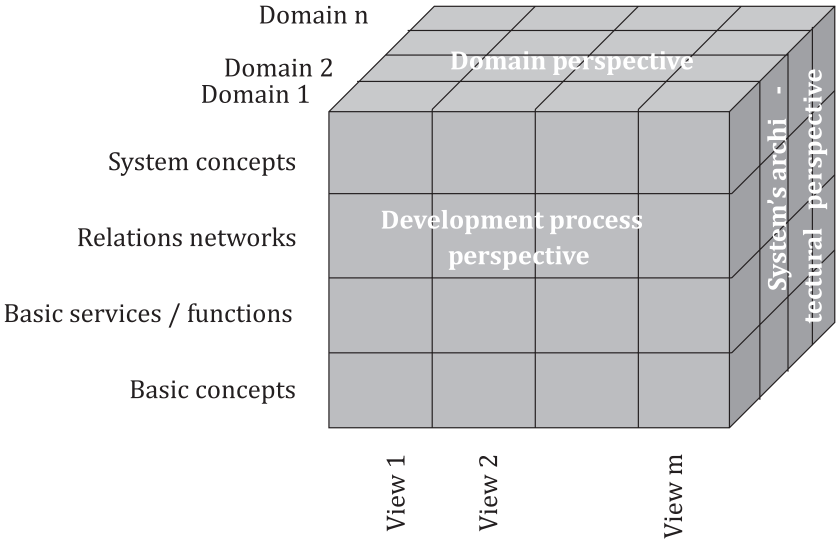

Figure 1 — Generic Reference Architecture model

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].

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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. 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.

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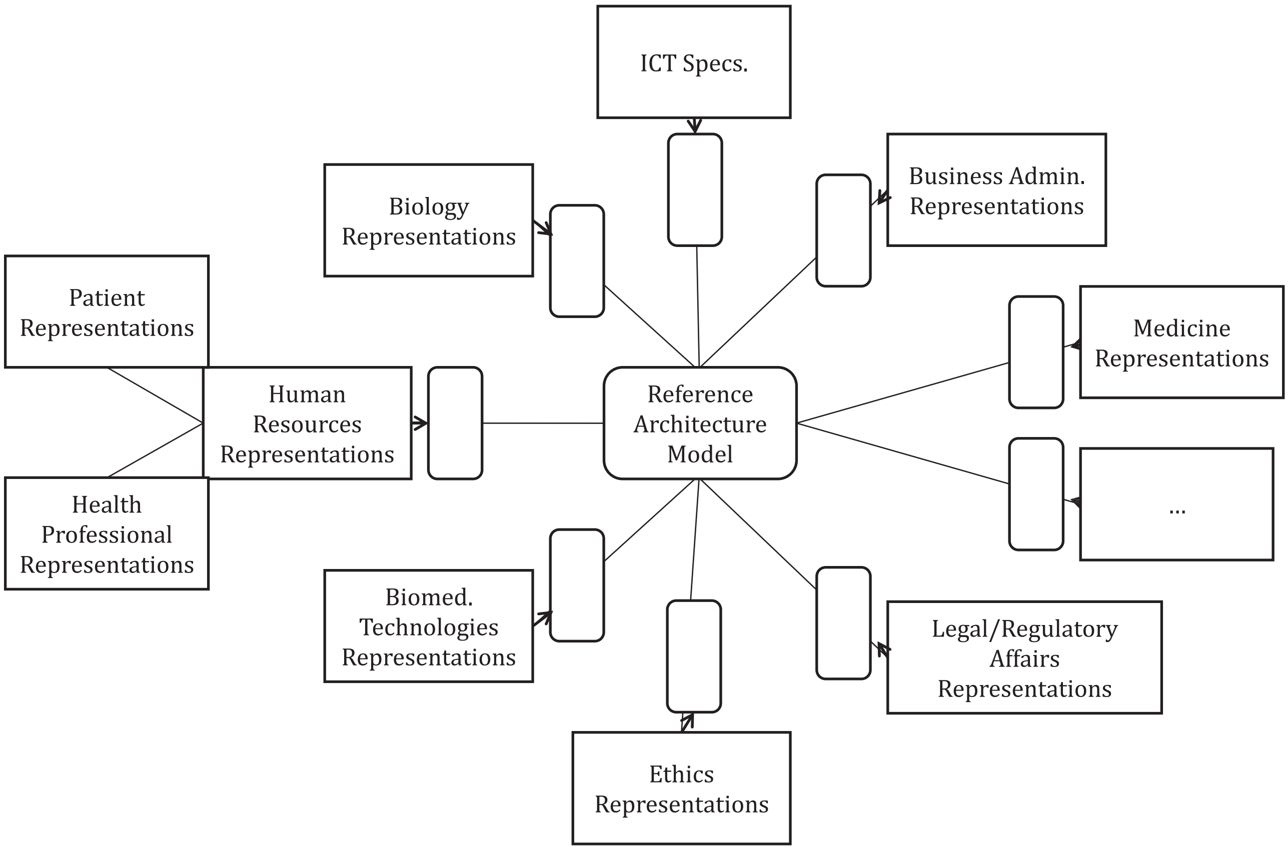

Figure 2 — Overview of this document's interoperability approach

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.

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

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

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3.1
architecture
set of rules to define the structure of a *system* (3.25) and the interrelationships between its parts

[SOURCE: ISO/IEC 10746-2:2009, 6.6, modified — "(of a system)" removed from term.]

3.2
axiom
statement that is taken to be true, to serve as a premise for further reasoning

[SOURCE: ISO/IEC/PRF 21838-1:—[7)], 3.9, modified — Note to entry removed.]

3.3
business viewpoint
viewpoint (3.28) that is concerned with the purpose, scope and policies governing the activities of the specified *ecosystem* (3.10)

3.4
class
type
general *entity* (3.11)

[SOURCE: ISO/IEC/PRF 21838-1:—, 3.2, modified — "type" added as second preferred term, note to entry removed.]

3.5
collection
group of *particulars* (3.19)

[SOURCE: ISO/IEC/PRF 21838-2:—[8)], 3.4, modified — Notes to entry removed.]

3.6
concept
unit of knowledge created by a unique combination of characteristics

Note 1 to entry: Concepts are not necessarily bound to particular natural languages. They are, however, influenced by the social or cultural background which often leads to different categorizations.

Note 2 to entry: As a knowledge component, a concept can be specialized and generalized as components can.

[SOURCE: ISO 1087:2019, 3.2.7, modified — Note 2 to entry replaced.]

3.7
definition
representation of a concept by a descriptive statement which serves to differentiate it from related concepts

[SOURCE: ISO 1087:2019, 3.3.1]

3.8
domain
collection (3.5) of *entities* (3.11) of interest to a certain community or discipline

[SOURCE: ISO/IEC/PRF 21838-1:—, 3.17, modified — Example and note to entry removed.]

7) Under preparation. Stage at the time of publication: ISO/IEC/PRF 21838-1:2021.

8) Under preparation. Stage at the time of publication: ISO/IEC/PRF 21838-2.2:2021.

3.9
domain ontology
ontology (3.18) whose *terms* (3.26) represent *classes* or *types* (3.4) and, optionally, certain *particulars* (3.19) (called 'distinguished individuals') in some *domain* (3.8)

[SOURCE: ISO/IEC/PRF 21838-1:—, 3.18]

3.10
ecosystem
structured *systems* (3.25) and communities that are governed by general rules

3.11
entity
object
item that is perceivable or conceivable

Note 1 to entry: The terms 'entity' and 'object' are catch-all terms analogous to 'something'. In terminology circles 'object' is commonly used in this way. In ontology circles, 'entity' and 'thing' are commonly used.

[SOURCE: ISO/IEC/PRF 21838-1:—, 3.1]

3.12
expression
word or group of words or corresponding symbols that can be used in making an assertion

Note 1 to entry: Expressions are divided into natural language expressions and expressions in a formal language.

[SOURCE: ISO/IEC/PRF 21838-1:—, 3.5]

3.13
formal language
language that is machine readable and has well-defined semantics

[SOURCE: ISO/IEC/PRF 21838-1:—, 3.10, modified — Note removed.]

3.14
formal theory
collection (3.5) of *definitions* (3.7) and *axioms* (3.2) expressed in a *formal language* (3.13)

[SOURCE: ISO/IEC/PRF 21838-1: —, 3.11, modified — Note removed.]

3.15
instance
particular (3.19) that instantiates some *universal* (3.27)

[SOURCE: ISO/IEC/PRF 21838-2:—, 3.6, modified — Example removed.]

3.16
interoperability
ability of a *system* (3.25) or a product to work with other *systems* (3.25) or products without special effort on the part of the customer

Note 1 to entry: Under traditional ICT focus, interoperability is ability of two or more systems or components to exchange information and to use the information that has been exchanged[29].

[SOURCE: IEEE Standards Glossary]

3.17
model
unambiguous, abstract conception of some parts or aspects of the real world corresponding to the modelling goals

Note 1 to entry: The relevant stakeholders 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 should be used iteratively, where 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[30].

3.18
ontology
collection (3.5) of *terms* (3.26), *relational expressions* (3.24) and associated natural-language *definitions* (3.7) together with one or more *formal theories* (3.14) designed to capture the intended interpretations of these *definitions* (3.7)

Note 1 to entry: An ontology defines a set of representational primitives with which to model a domain of knowledge or discourse. The representational primitives are typically classes (or sets), attributes (or properties), and relationships (or relations among class members). The definitions of the representational primitives include information about their meaning and constraints on their logically consistent application[31].

[SOURCE: ISO/IEC/PRF 21838-1:—, 3.14, modified — Note to entry replaced.]

3.19
particular
individual *entity* (3.11)

Note 1 to entry: In contrast to classes or types, particulars are not exemplified or instantiated by further entities.

[SOURCE: ISO/IEC/PRF 21838-1:—, 3.3]

3.20
policy
set of legal, political, organizational, functional, and technical obligations for communication and cooperation

Note 1 to entry: Policies define the intended behaviour of systems.

[SOURCE: ISO 22600-1:2014, 3.13 modified — Note to entry added.]

3.21
primitive
expression (3.12) for which no non-circular *definition* (3.7) can be provided

[SOURCE: ISO/IEC/PRF 21838-2:—, 3.1]

3.22
reference architecture
reference model for a *class* (3.4) of *architectures* (3.1)

3.23
relation
way in which *entities* (3.11) are related

[SOURCE: ISO/IEC/PRF 21838-1:—, 3.4, modified — Notes to entry removed.]

3.24
relational expression
expression (3.11) used to assert that a *relation* (3.22) obtains

[SOURCE: ISO/IEC/PRF 21838-1:—, 3.6, modified — Example and notes removed.]

3.25
system
combination of interacting elements organized to achieve one or more stated purposes

Note 1 to entry: A system groups structurally and/or functionally interrelated components (elements). Systems can be composed (aggregated/generalized) to super-systems or decomposed (specialized) to sub-systems.

[SOURCE: ISO/IEC/IEEE 15288:2015, 4.1.46, modified — Note 1 to entry replaced, notes 2 and 3 to entry removed.]

3.26
term
expression (3.12) that refers to some *class* (3.4) or to some *particular* (3.19)

[SOURCE: ISO/IEC/PRF 21838-1:—, 3.7, modified — Note to entry removed.]

3.27
universal
type
entity (3.11) that has indefinitely many *instances* (3.15)

[SOURCE: ISO/IEC/PRF 21838-2:—, 3.2, modified — Example and note to entry removed.]

3.28
viewpoint
form of abstraction achieved using a selected set of architectural concepts and structuring rules, in order to focus on particular concerns within a system

[SOURCE: ISO/IEC 10746-2:2009, 3.2.7, modified — "(on a system)" removed from term.]

4 Abbreviations

EHR	Electronic Health Record
HL7®	Health Level Seven®
UML	Unified Modelling Language
RM-ODP	Reference Model of Open Distributed Processing

5 Overview on standard system architecture

Acknowledging the different perspectives on a business system and its individual and shared context provided by different disciplines or domains involved in the business case, the business system is composed of subsystems represented by those domain-specific perspectives based on the domain-specific methodologies, terminologies and ontologies. Examples of such subsystems are clinical care, administration, legal/regulatory affairs, security, privacy, training, etc. Like any system, domains can be composed to super-domains or de-composed to subdomains. For correctly and consistently interrelating components of those subsystems in a way that enables the intended system behaviour for meeting the use-case-specific business objectives, an abstract, domain-independent system architecture with generic system components at different levels of granularity shall be defined, enabling the composition/decomposition of any salient system. While the generic system with its generic components and relations is represented using a domain neutral top-level ontology [see ISO/IEC 21838 (all parts)], the business system and use-case-specifically instantiated systems discussed as follows are represented using domain ontologies at lower level. At the first granularity level, the domain specific subsystems (Level of Business Concepts) are specialized into sub-subsystems representing the perspectives of specialized disciplines or subdomains within one domain, deploying their specialized methodologies, terminologies and ontologies (Level of Relations Networks). Examples of such subdomains within the clinical domain are microbiology, pathology, cardiology, ophthalmology, etc. Those subdomains are furthermore specialized into subdomain- and use-case specific services (Level of Aggregations) and tasks (Level of Details). The architectural components and their relationships are represented using the corresponding domain or subdomain ontologies respectively. In this way, services and tasks can be interrelated across domains by interrelating the corresponding components and mapping their concepts, thereby inheriting the related specializations/generalization within the domains/subdomains. For representing the business system's policies, ISO 22600 (all parts), which is the standardization of the policy ontology of PONDER[32], shall be used[33]. For managing and harmonizing different ontologies represented using different representation styles and languages, the OMG® Ontology Definition Metamodel (ODM™)9), V1.1 shall be deployed.

Deploying systems theory, especially its white box approach, the GRA (see 0.3) adopts, but goes beyond, IEEE 1471:2000,[14] which has been later on superseded by ISO/IEC/IEEE 42010:2011.[34] Not being limited to ICT systems, a multi-domain real world business system view has been added, transforming IEEE 1471, ISO/IEC/IEEE 42010 as well as the software development standard ISO/IEC 10746 (all parts) into a three-dimensional approach. This real world business system view formally represents the domains' knowledge spaces, so enabling the correct selection and constraining of components, their functions and relations, that way supporting correct knowledge-level interoperability and systems integration. Only at this viewpoint, correctness and consistency of concepts represented in ICT specifications and standards can be justified.

6 Interoperability and Integration Reference Architecture for ICT Supported Systems

6.1 Interoperability and Integration Reference Architecture domains and granularity levels

Adopting the philosophy of ISO/IEC 10746 (all parts), this document fills a gap for real world interoperability by extending the viewpoints defined in ISO/IEC 10746-1:1998 by an ICT-independent Business View. This way, it corresponds to the OMG® approach for representation, management, interoperability, and application of business semantics. The latter allows for formal multi-domain knowledge representation, interchange and harmonization by providing relationships between symbols in the logical "universe" and individuals in the "real world". Figure 3 presents the Interoperability and Integration Reference Architecture business viewpoint with its domain and its composition/decomposition dimension.

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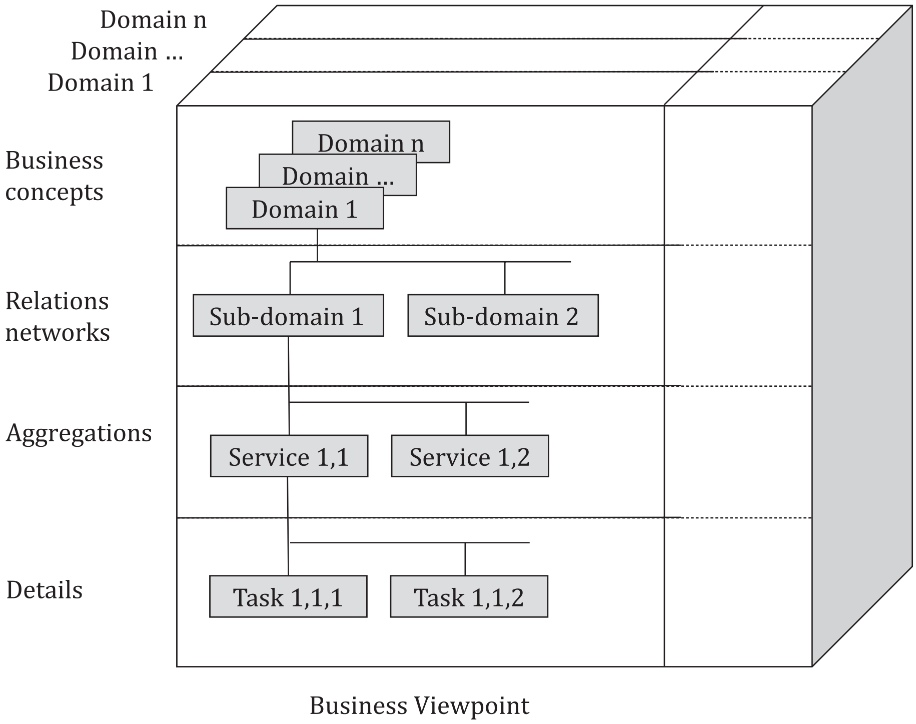


Figure 3 — Interoperability and Integration Reference Architecture domains and granularity levels

6.2 Interoperability and Integration Reference Architecture model for ICT supported systems

By combining that model with ISO/IEC 10746 (all parts) and its viewpoints and representational means, the development, implementation and maintenance process of interoperable health and social ecosystems is added to the approach, completing the Interoperability and Integration Reference Architecture with its three dimensions system domains, system component composition, and system viewpoints after RM-ODP (Figure 4).

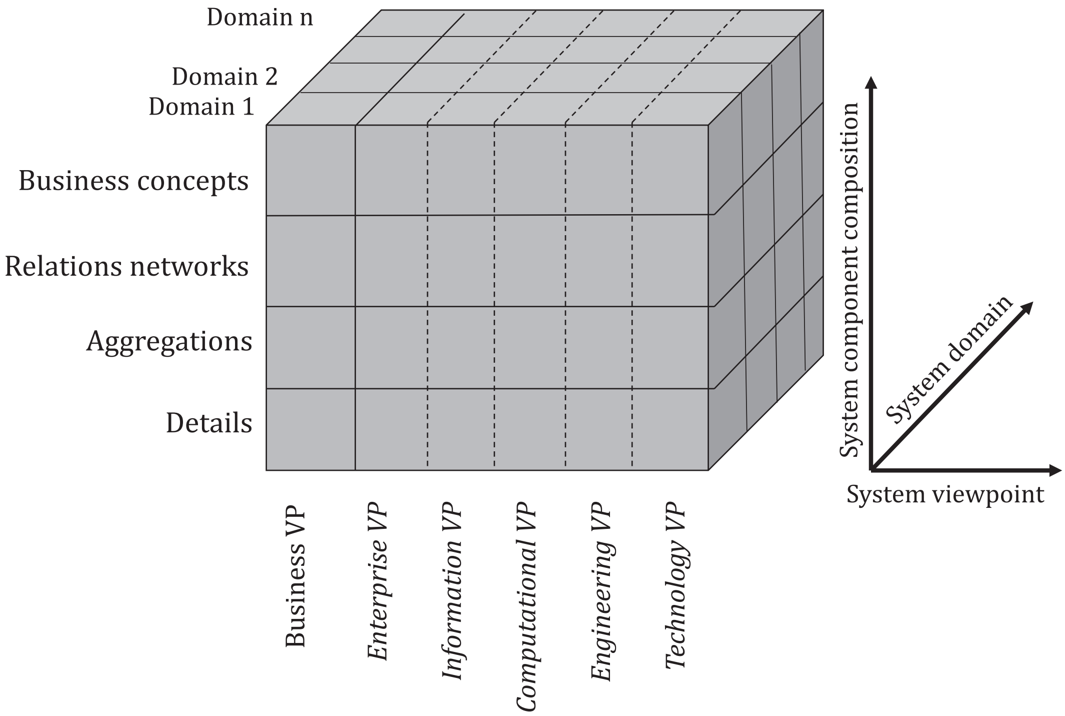


Figure 4 — The Interoperability and Integration Reference Architecture model

Due to the formal, correct and consistent representation of use-case specific context aware business systems and their tool-supported automated transformation into finally implementable solutions, the approach can also be deployed to perform a business system and business objective conformant analysis of existing systems and specifications regarding their appropriateness, correctness and consistency, but also to support an appropriate design of emerging system. As the components presented in the different RM-ODP Viewpoints starting with the Business Viewpoint of the correctly and consistently designed business system architecture, the transformed viewpoint components shall be instantiated, thereby preferably selecting and adapting existing specifications/solutions. In other words, the Interoperability and Integration Reference Architecture guides developers of component system to select and constrain the right elements, e.g. HL7's Fast Healthcare Interoperability Resources (FHIR®[10]) or FHIR® Profiles. Only this way, the correctness of compositions, relations and underlying policies can be ascertained[35]. In consequence, both legacy systems and emerging systems can in this way be correctly and consistently designed or redesigned.

6.3 Interoperability and Integration Reference Architecture framework

6.3.1 Basic requirements

The system's complexity shall be limited to the level needed for representing the intended business case. This might imply the recursive deployment of the modelling process. For each business system component where a specification is to be developed or an integration of existing specification at any system development view (here any view defined in ISO/IEC 10746-1:1998) is intended, the domain this component belongs to as well as its granularity level shall be defined. The business process and use-case-specific representation of that component shall be provided deploying the domain's internationally approved ontology including related logics. In case an ontology does not exist for the domain, an ontology shall be developed following the ISO 21838 (all parts) definitions and procedures.

10) FHIR is a registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

6.3.2 Management of relationships in the Interoperability and Integration Reference Architecture

There are three types of relationships between the components of the Interoperability and Integration Reference Architecture depending on the dimension those relationships are established: specialization/generalization; mapping; transformation (Figure 5).

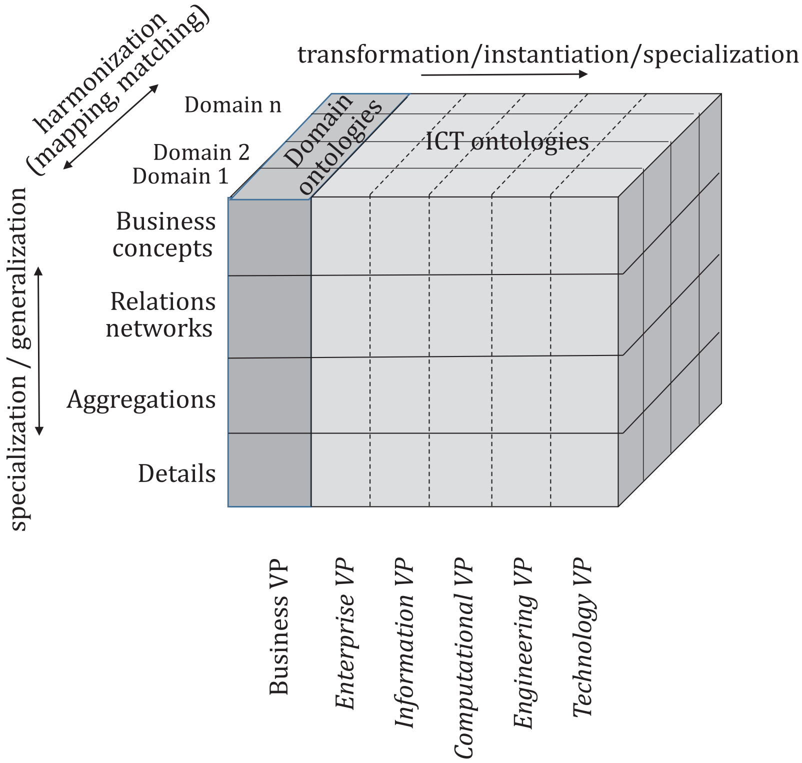


Figure 5 — Relationships in the Interoperability and Integration Reference Architecture Model

Composition/decomposition, i.e. specialization/generalization of components shall be provided for interrelating components between different granularity levels within the one view and the same domain only. For managing the business system's complexity, there might be a need for running the Interoperability and Integration Reference Architecture process recursively.

Harmonization (mapping/matching) shall be provided only between components of different domains within one view and at the same granularity level only.

Transformation (specialized instantiation) shall be provided within one domain at the same granularity level only.

6.3.3 Business process modelling using the Interoperability and Integration Reference Architecture

A business process is a set of related activities and tasks to accomplish agreed objectives. The Interoperability and Integration Reference Architecture allows formally representing business systems structure and behaviour from the perspectives of the multiple domains involved in the business process. This implies a) the natural/logical behaviour of the business system, i.e. the functionality of the systems components and their relations; and b) the intended behaviour, i.e. the defined policies for meeting the business system's objectives. While common domain ontologies describe the natural/logical functionality of the components as part of the related concepts (case a), a specific policy domain represents the set of rules intentionally applied for interrelating the domains in the interest of the business objectives (case b). The policy domain, represented using policy ontologies such as PONDER[32] and its standardization in ISO 22600 (all parts), can be specialized into policy sub-domains such as legal policies, process policies, individual policies of preferences, ethical policies, etc. (Figure 6). This way, the Interoperability and Integration Reference Architecture enables an ontology-based modelling of business processes. Such processes shall be represented by mapping concepts, related operations and logical interrelations of components including applicable constraints at the same level of architectural granularity.

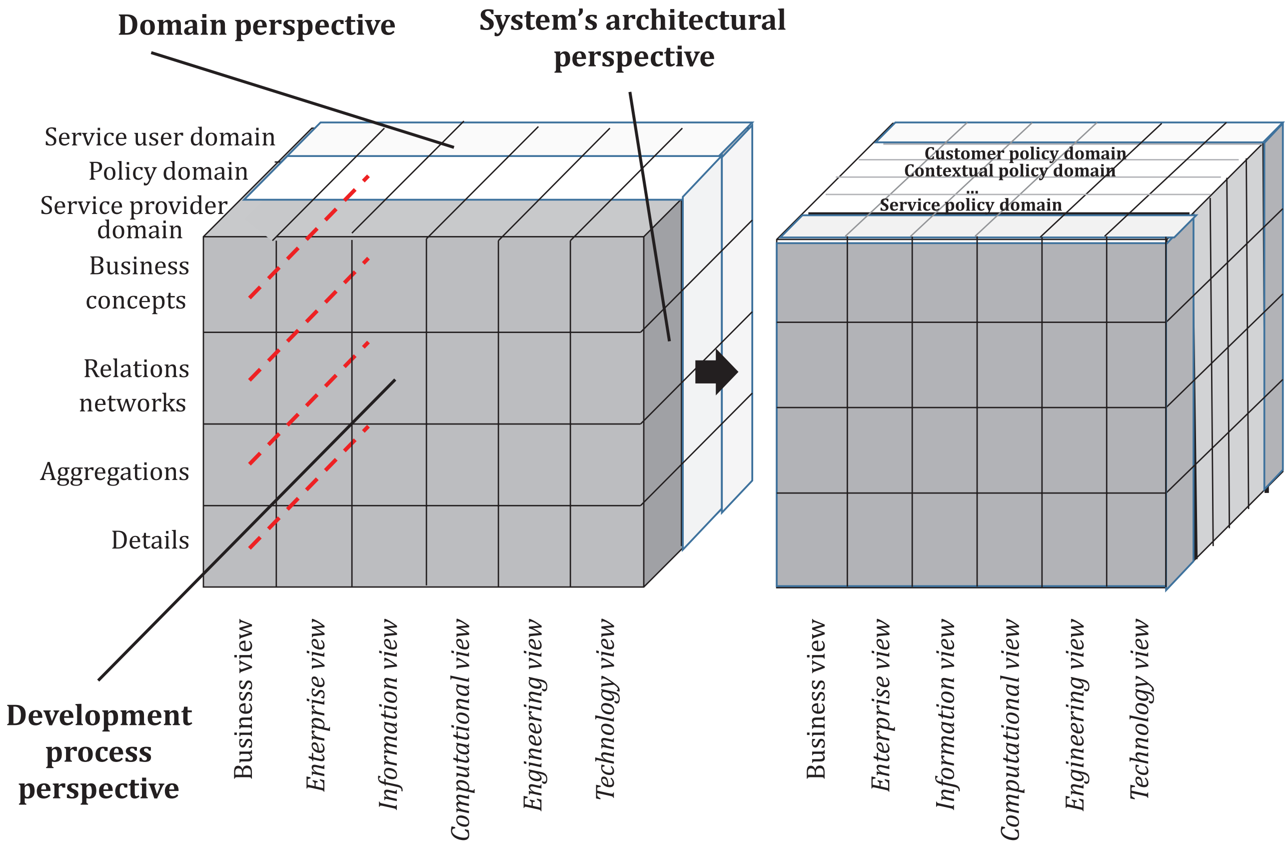


Figure 6 — Specialization of policy domains according to ISO 22600-2:2014 and ISO 21298:2017

This document enables the formal and explicit representation of processes beyond and within the ICT perspective. It covers living systems' evolution as well as manufacturing, but also software development processes. While the first group of non-IT processes is represented by the Generic Reference Architecture (Figure 1), the latter is formalized by the Interoperability and Integration Reference Architecture extending ISO/IEC 10746 (all parts) as well as ISO/IEC/IEEE 15288:2015.[36] It includes the entire software development process lifecycle from computation-independent business process analysis through requirements engineering, system design, information modelling, implementation and maintenance up to the deployment in the real world business system (Figure 4). This way, the Interoperability and Integration Reference Architecture enables ICT views based modelling of business processes. Such processes shall be represented by transforming concepts, related operations and logical interrelations of components including applicable constraints at the same level of architectural granularity through all the views of the Standard. Contrary to classic software engineering processes including ISO/IEC 10746 (all parts), the Interoperability and Integration Reference Architecture model and framework represents the concepts, contexts, relations and constraints from all contributing domains in all ICT views. Therefore, after each transformation to the following view, all transformed concepts, contexts, relations and constraints represented in the related ICT ontology shall be mapped first before performing the next transformation (Figure 5).

Annex A
(informative)

Cross-domain interoperability for security and privacy aware EHR communication

This annex demonstrates the integration of two domain specific standards addressing two interrelated issues such as the use case EHR communication in accordance to security and privacy constraints. As an example, the ISO 13606-1[18] Reference model and the HL7® Composite Security and Privacy Domain Analysis Model[19] are reengineered and combined in an Interoperability and Integration Reference Architecture model instance. Figure A.1 illustrates the process of integrating the two specifications.

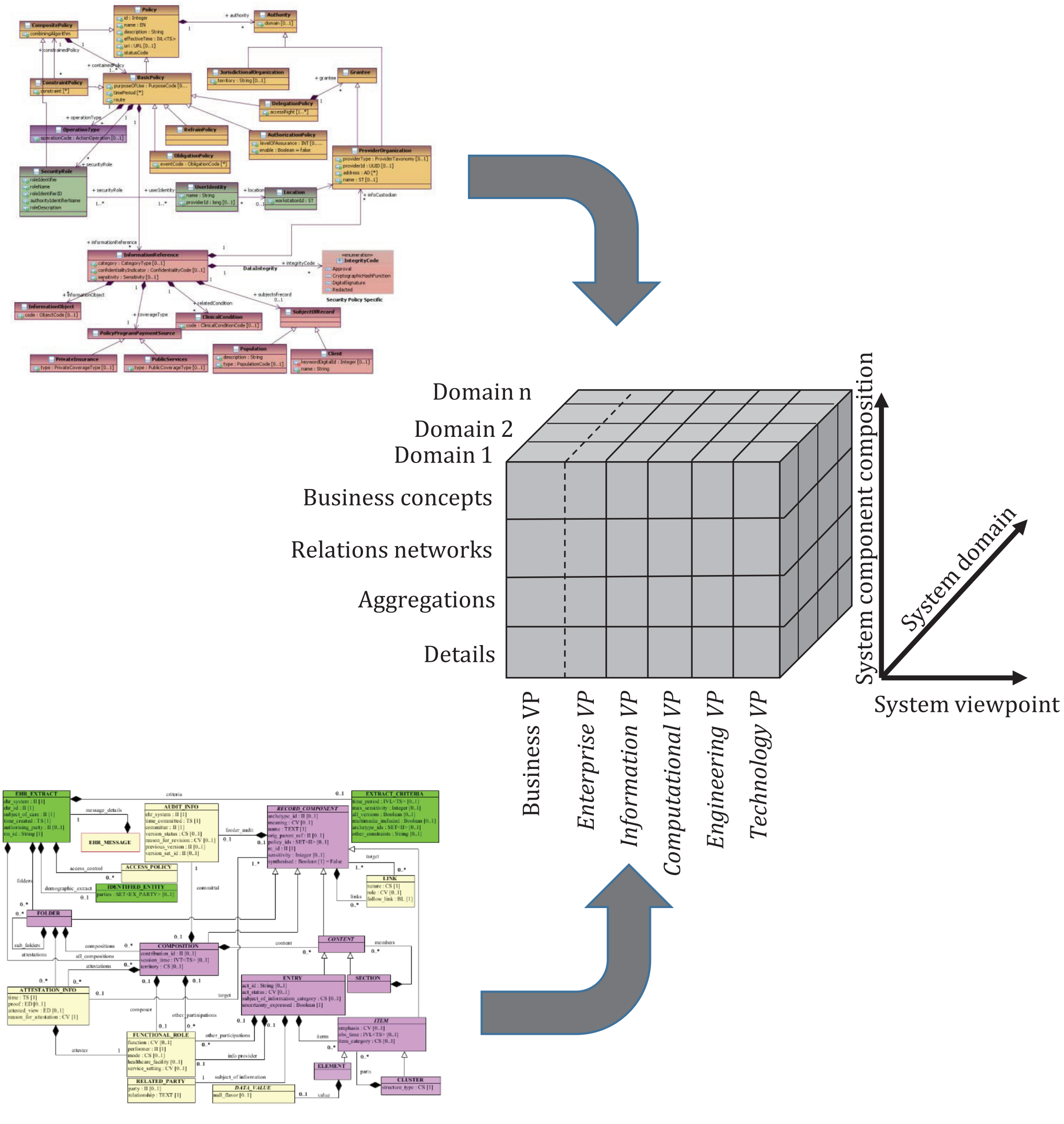


Figure A.1 — Example for model harmonization by re-engineering the HL7® Composite Security and Privacy Domain Analysis Model and the ISO 13606-1 Reference model

The resulting Interoperability and Integration Reference Architecture instance model is shown in Figure A.2 thereby just considering the domains addressed in that use case.

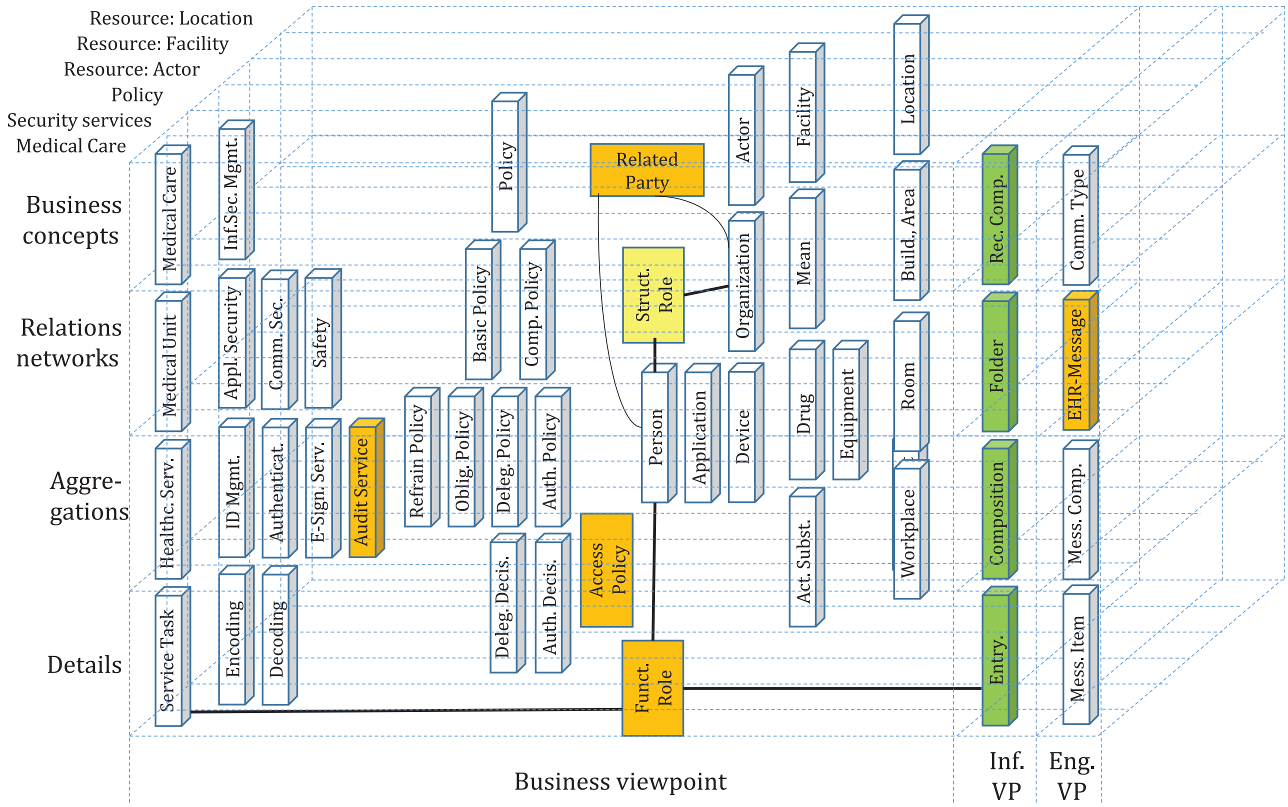


Figure A.2 — Reengineering the ISO 13606-1 Reference Model in the context of the HL7® Composite Security and Privacy Domain Analysis Model

Figure A.2 shows a mixture of different viewpoints not considered in the document, so requiring essential advancements and transformations of the ISO 13606-1 Reference model. Furthermore, there is a vast amount of explicit knowledge missing in ISO 13606-1 but necessary for the harmonization challenge as demonstrated by the non-colored components, which complete the architectural model. Just the coloured ISO 13606-1 components presented in three-dimensional cuboids represent valid architectural components in the reference architecture model. The others (colored rectangles) have to be transferred into valid components. In that way, the harmonization of ISO 13606-1 with other specifications such as HL7 v2® and HL7 v3® – a permanent challenge standards development organizations are facing – can be easily performed.

As the underlying methodology of the Interoperability and Integration Reference Architecture model and framework assures its formal correctness, consistency and completeness, the described process can be automated. The same holds for transforming the cross-domain, harmonized, consistent informational representation of the complex business system into the different ISO/IEC 10746 (all parts) views for analysing, designing, implementing and maintaining the related ICT solution.

The presented re-engineering and formalization approach has been successfully deployed in several cross-domain standards, such as ISO 22600 (all parts), ISO 21298,[37] HL7® Composite Security and Privacy Domain Analysis Model.[19] Its feasibility has been practically demonstrated for automatically harmonizing HL7 v2.x® and HL7 v3® specifications[38][39] or for automatically designing inter-domain Web services to facilitate multi-disciplinary approaches to Type 2 Diabetes Care management[40][41]. The approach also allows a comparative analysis and evaluation of ICT Enterprise Architectures[23].

Annex B
(informative)

Interoperability between different communication standards

This annex demonstrates the integration of different communication standards by transforming the development methodology of HL7 v2® and HL7 v3® in an Interoperability and Integration Reference Architecture instance. While there is a standardized methodology for HL7 v3® communication, such clearly defined methodology is missing for HL7 v2®. Therefore, HL7 v2® must be transformed into such a methodology model. The outcome including the ontological representation of those two architectures and their harmonization process using a related domain ontology "Communication Standards Ontology (CSO)"[20][38]. That way, it enables the mutual transformation of those communications standards for the sake of interoperability of existing solutions. The resulting Interoperability and Integration Reference Architecture instance model is shown in Figure B.1 thereby just considering the domains addressed in that use case.

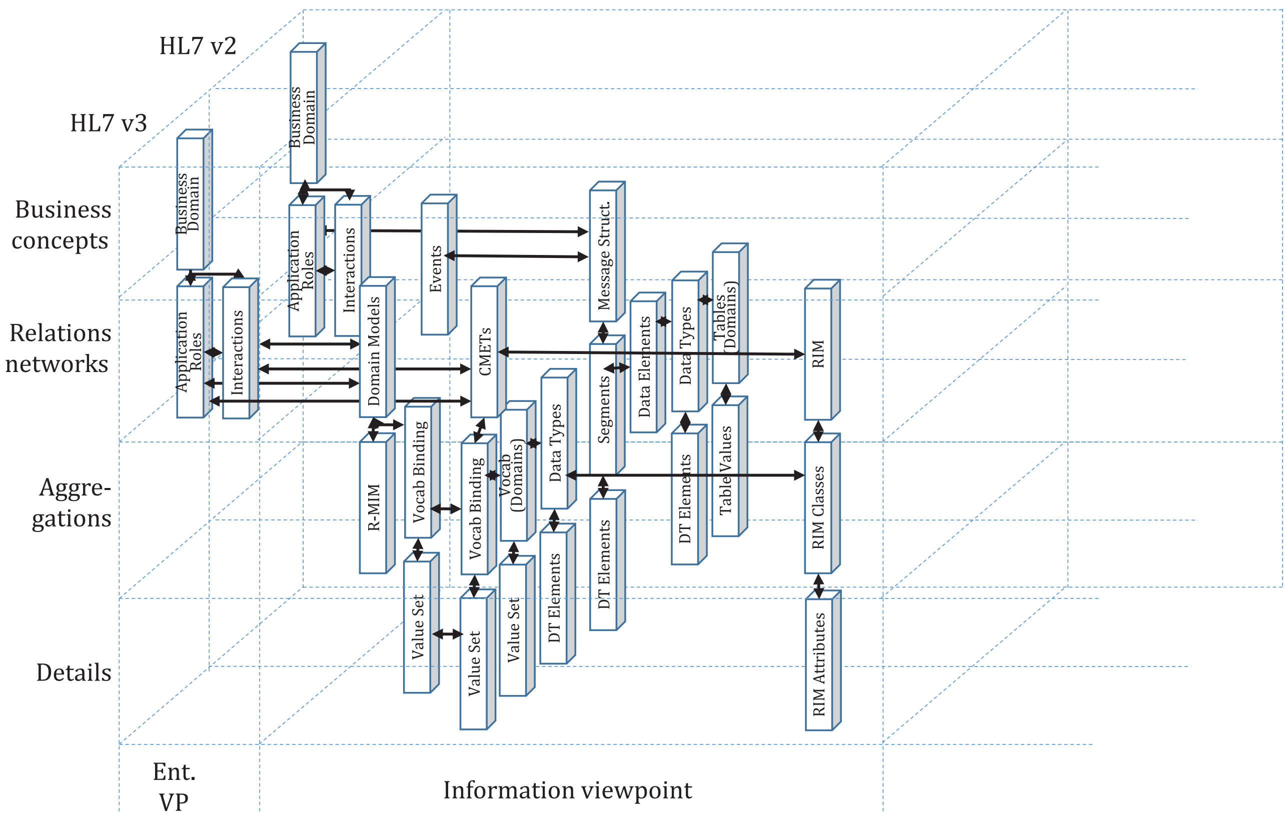


Figure B.1 — Re-engineering the development process model of HL7 v2® and HL7v3® for integrating the two communication standards

The HL7® communication standards are specified as technology and application agnostic. For bridging between the two standards, just a transformation of the related information models is necessary. Therefore, just the Information Viewpoint is considered in detail.

As the underlying methodology of the Interoperability and Integration Reference Architecture model and framework assures its formal correctness, consistency and completeness, the described process can be automated. The same holds for transforming the model into the different ISO/IEC 10746 (all parts) views for analysing, designing, implementing and maintaining the related ICT solution.

The presented re-engineering and formalization approach has been successfully deployed in several cross-domain standards, such as ISO 22600 (all parts), ISO 21298,[37] HL7® Composite Security and Privacy Domain Analysis Model.[19] Its feasibility has been practically demonstrated for automatically harmonizing HL7 v2.x® and HL7 v3® specifications[38][39] or for automatically designing inter-domain Web services to facilitate multi-disciplinary approaches to Type 2 Diabetes Care management[40][41]. The approach also allows a comparative analysis and evaluation of ICT Enterprise Architectures[23].

Annex C
(informative)

Integration of Standards in ISO 12967 (all parts)

Bound to the Interoperability and Integration Reference Architecture Framework, inter-domain relationships have to happen at the same level of granularity[6]. To get there, intra-domain specializations/generalizations have to be performed. In summary, the Interoperability and Integration Reference Architecture Model supports ontology harmonization or knowledge harmonization to enable knowledge level interoperability between existing systems, standards and solutions of any level of complexity without the demand for continuously adapting/revising those specifications.

For designing, specifying and implementing a multi-disciplinary system, first the business view of the use-case-specific real world business system in question according to Figure 2 has to be modelled, thereby representing the architectural components and relations of the business domains involved based in those domains' ontologies. In the development process, the specified model has to be transformed into the different viewpoints of ISO/IEC 10746 (all parts), instantiating the related model components by properly selecting, placing, constraining and interrelating existing specifications (Figure C.1). Figure C.2 shows domain specific standards and specifications to be integrated in the HISA process according to the Interoperability and Integration Reference Architecture, thereby also indicating in the domain dimension whether one or more domains are addressed.

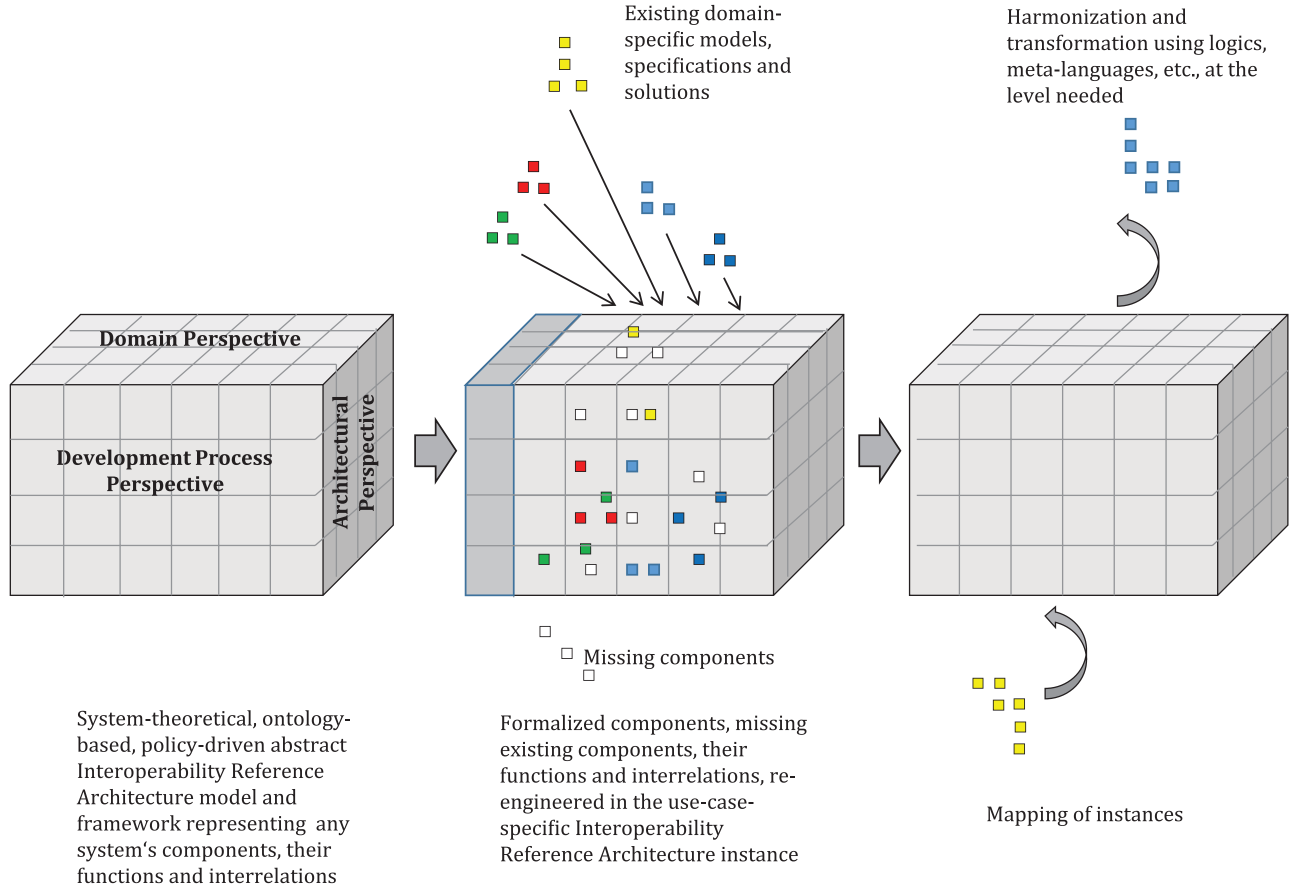


Figure C.1 — Integration of standards and specifications using GCM Reference Architecture Model

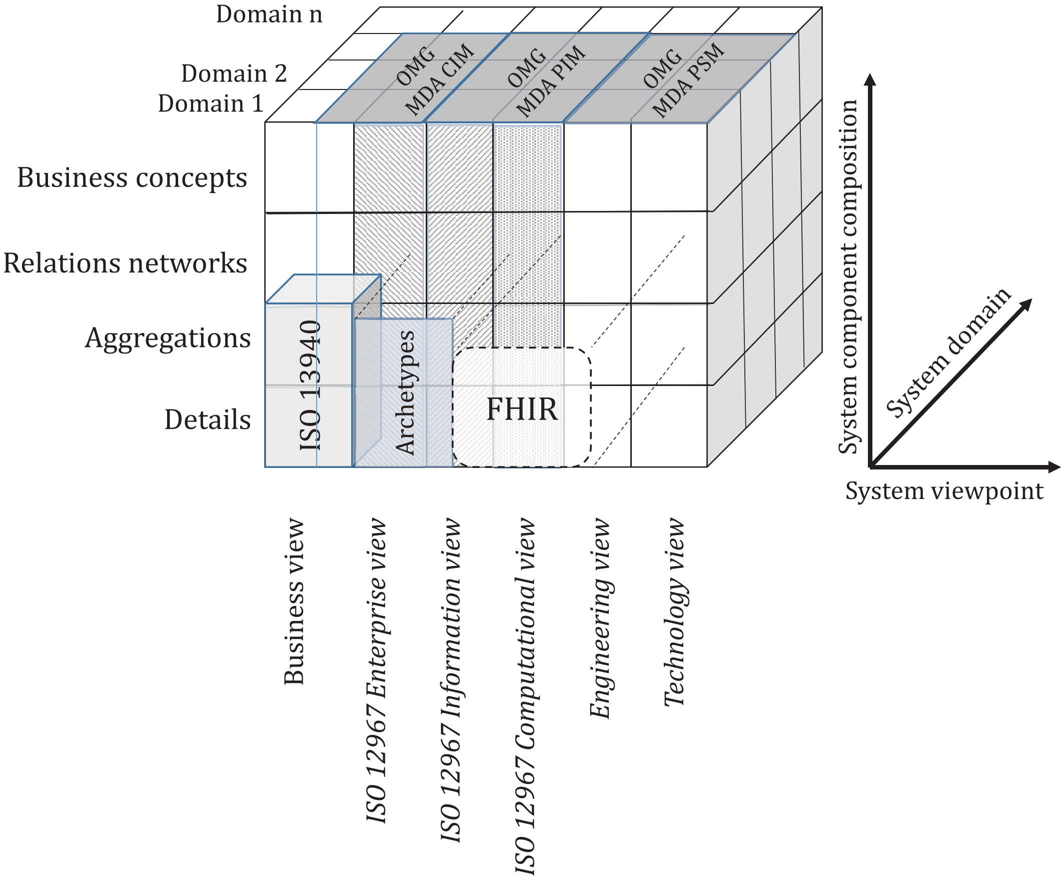


Figure C.2 — Integration of standards and specifications explicitly mentioned in the standard at hand, using the Interoperability and Integration Reference Architecture Model

As an example, re-engineering of parts of ISO 12967 (all parts)[21] (red text) and ISO 13940[4] (green text) into an Interoperability and Integration Reference Architecture instance, is shown in Figure C.3. The figure shows a mixture of Enterprise and Information viewpoints. ISO 13940 does not address attributes, but goes far in terms of detailed concept definitions, relations and cardinalities, positioned rather deep in the Enterprise Viewpoint column, approaching an Information Viewpoint description (without attributes). The focus of ISO 13940 is what goes on in the domain in terms of detailed concepts and how to support this. The ISO 12967-1 Enterprise Viewpoint is at a high level of abstraction without detailed concepts, describing and diagrammatically illustrating what goes on in healthcare. The focus of ISO 12967 (all parts) is the service architecture, supporting healthcare from an IT perspective. The required models, classes and attributes described in the ISO 12967-2 Information Viewpoint are as detailed as required, serving generic IT purposes, to appropriately being able to support healthcare according to the Enterprise Viewpoint, not excluding other domain related more specific requirements such as in ISO 13940.

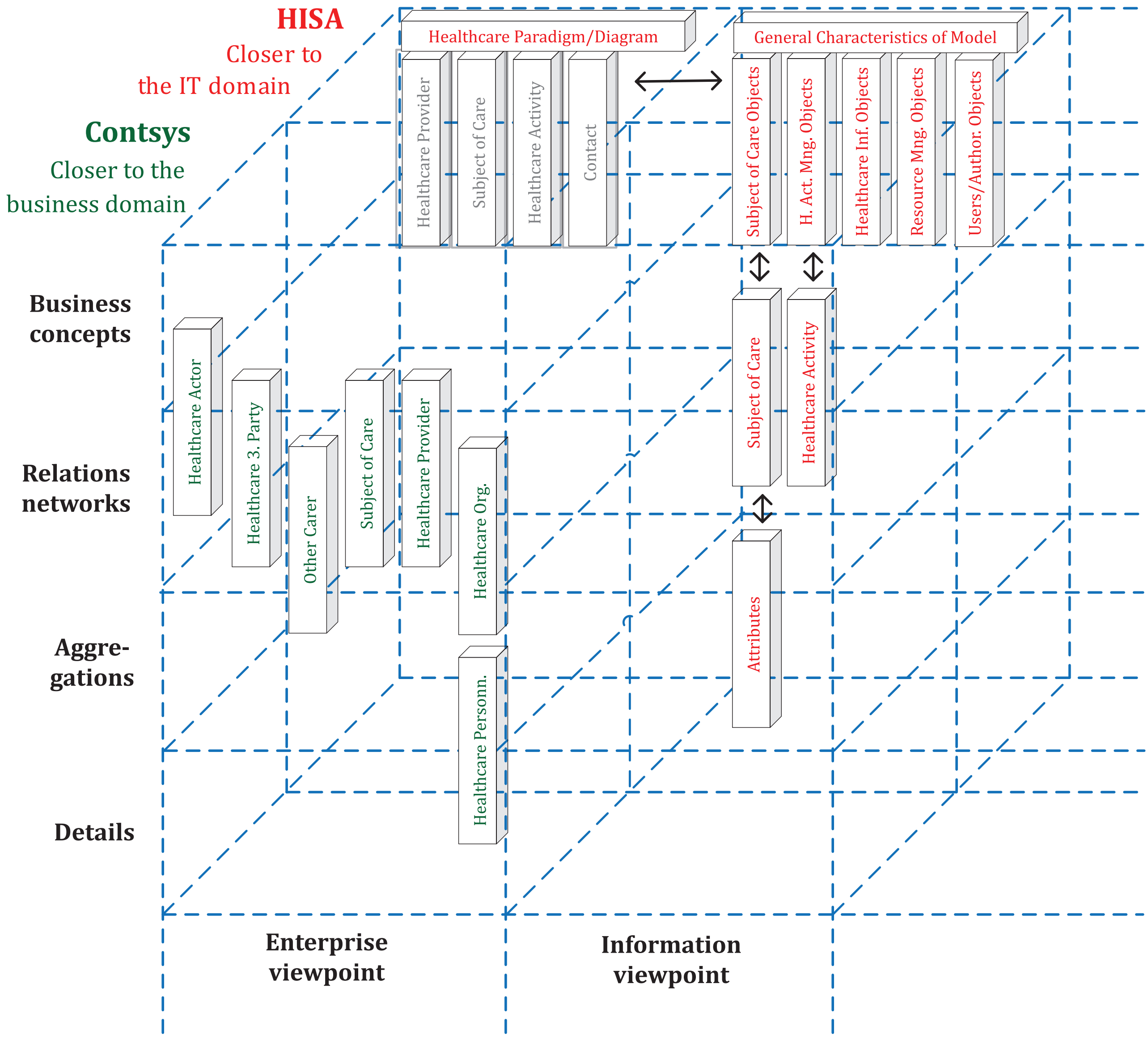


Figure C.3 — Re-engineering example of selected parts of ISO 12967(all parts) (HISA) and ISO 13940 (System of concepts to support continuity of care)

Annex D
(informative)

Deployment of the Interoperability and Integration Reference Architecture Approach in ISO 13972

As ISO 13972 deals with modelling methodologies, the Interoperability and Integration Reference Architecture has been fundamentally integrated in the document instead of referring to it by an annex. Figure D.1 details the placement of the document's information models (CIM) in comparison to well-known HL7® information model standards. The HL7® information model examples represented in Figure D.1 are the ISO/HL7 21731:2014 Reference Information Model (RIM),[42] the business domain specific Domain Analysis Models (DAM), Functional Models (FM) and Service Functional Models (SFM), the message information models Domain Message Information Models (D-MIM), Refined Message Information Models (R-MIM) and Common Message Element Types (CMET), and finally Implementable Technical Specifications (ITS). For details see Reference [43].

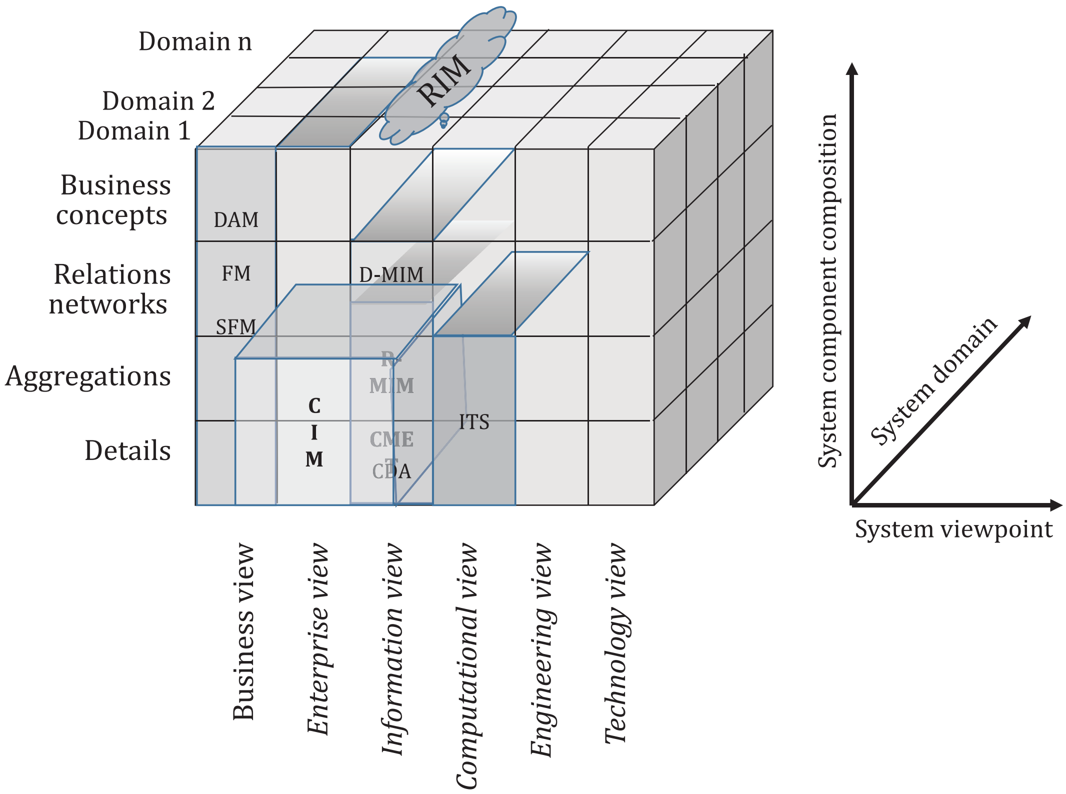
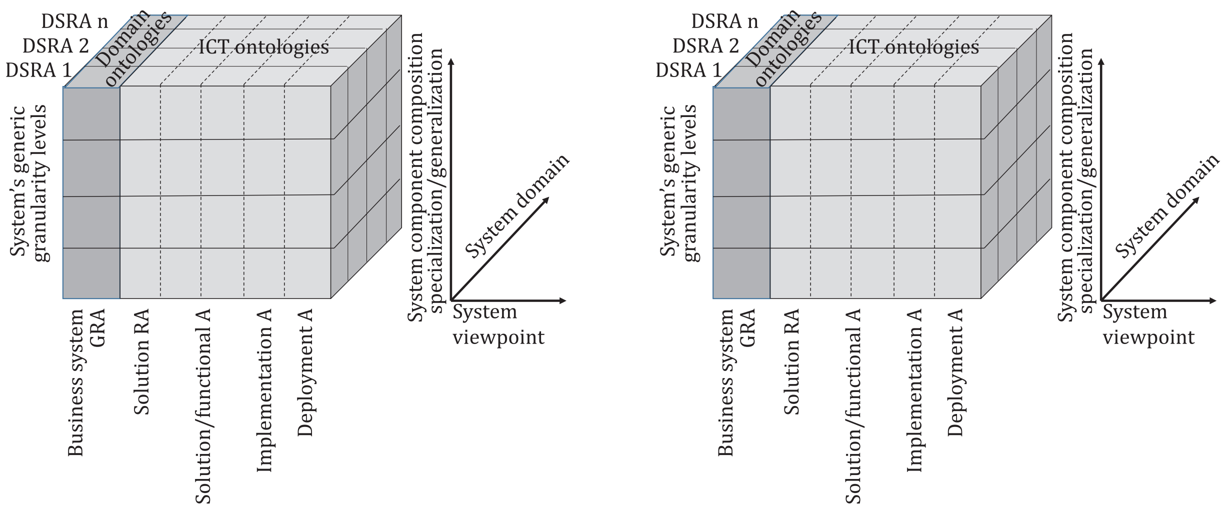


Figure D.1 — Placing the ISO 13972 and well known HL7® information models in the interoperability and integration reference architecture model

Annex E
(informative)

Deployment of the Interoperability and Integration Reference Architecture Approach for the Representation and Harmonization of Alternative Reference Architectures

This annex deploys the Interoperability Reference Architecture Model and Framework defined in this document to represent models and architectural views of other existing reference architectures, exemplified in ISO/IEC 30141:2018[44], ISO/IEC 17789:2014[45], or ISO/IEC 20547-3:2020[46], but also applicable to other reference architectures. Thereby, the Barendregt Cube with Parameters based on Universal Type Theory and Universal Logics[9] in its advancement with systems engineering methodologies towards the Generic Reference Architecture (GRA) model, also deployed for formal concept representation and ontology harmonization in this document, represents a Meta Reference Architecture (Meta-RA). That way, the model and framework specified in this document enables the representation of domain-specific reference architectures (DSRAs), reference architectures (RAs) and architecture (A) models as well as views. Architectures are instances derived from reference architectures in the course of the development process. DSRAs deal with specific knowledge domains such as health, transportation, smart manufacturing, or with specific technology domains such as big data, artificial intelligence, cloud computing. RAs address systems or complex solutions, while architectures describe specific solutions, their implementation and deployment. Alternatively to the ISO/IEC 10746 (all parts) views reused in this document, views such as user view, functional view, implementation view or deployment view have been defined. Figure E.1 represents the DSRAs, RAs, architectures and views of the aforementioned standards in this document's Interoperability Reference Architecture Model and Framework. For integrating those standards' components, they have to be re-engineered by placing them according to domain, granularity level and view, and adapt and interrelate them according to the concepts they represent in the cross-domain business system. The representation of other architecture frameworks such as The Open Group Architecture Framework (TOGAF)[47], the Zachman Framework for Information Systems Architecture, later on generalized towards the Zachman Framework for Enterprise Architecture[48], or the US Federal Enterprise Architecture Framework (FEAF)[49] can be found in Reference [23].



a) Reference architectures and architectures **b) reference architectures and views**

Figure E.1 — Representation of domain reference architectures

ISO 19439:2006[50], referenced by most of the existing reference architectures, provides a framework for enterprise modelling and integration within a software development process. It defines the view, phase and genericity of an enterprise model. While the Interoperability and Integration Reference Architecture defined in this document represents a system of systems belonging to different domains, so enabling cross-domain integration and interoperability, ISO 19439:2006 just supports interoperability between, and integration of different modelling methodologies within one domain. Figure E.2 represents views, genericity levels and phases of enterprise models defined in ISO 19439:2006. Consequently, Meta-RA and Interoperability and Integration Reference Architecture presented in this document define the domain, the composition/decomposition (granularity) and the view dimension to represent multiple domains systems and their development process, thereby combining the ISO 19439:2006 phase and view dimensions analogue to ISO/IEC 10746 (all parts).

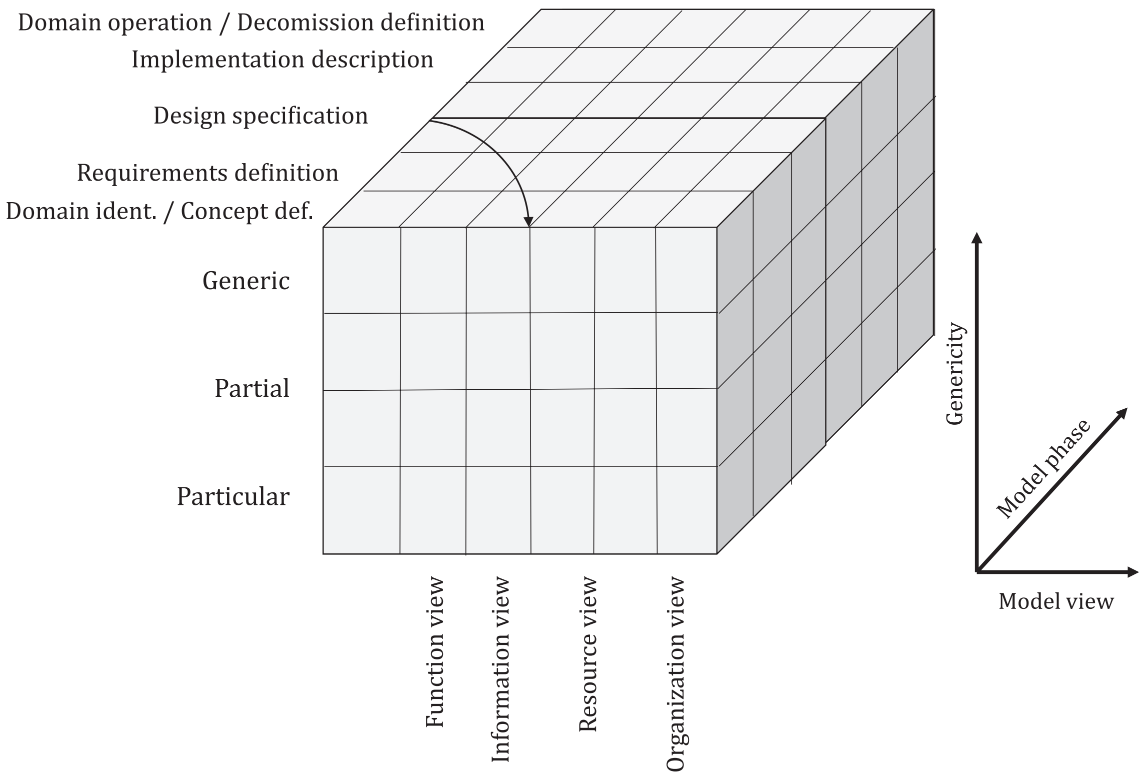


Figure E.2 — Representation of ISO 19439

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