**ISO 23903:####(X)**

ISO TC 251/WG 1

Secretariat: ANSI

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

# Contents

# 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 251, Health informatics.

# 0 Introduction

## 0.1 Preface

This International Standard 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 standard 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 specification provides a motivational overview of the Interoperability 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 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 “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 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, information and communication technologies (ICT) get closer 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].

**Table 1. Interoperability levels**

| Information Perspective | Organization Perspective |
|---|---|

[1] personalized, preventive, predictive, participative precision medicine

| 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<br>Coordination |
| Organization/ Service | Common business process | Knowledge sharing at business concept level<br>Agreed cooperation |
| Knowledge based | Multi-domain processes | Knowledge sharing at domain level<br>Cross-domain cooperation |
| Skills based | Individual engagement in multiple domains | Knowledge sharing in individual context<br>Moderated end-user collaboration |

## 0.3 Motivation for the Interoperability 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 advance from the data model, the information model, and the 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 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 [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 [7]. The mathematical concept representation as Meta Reference Architecture 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.

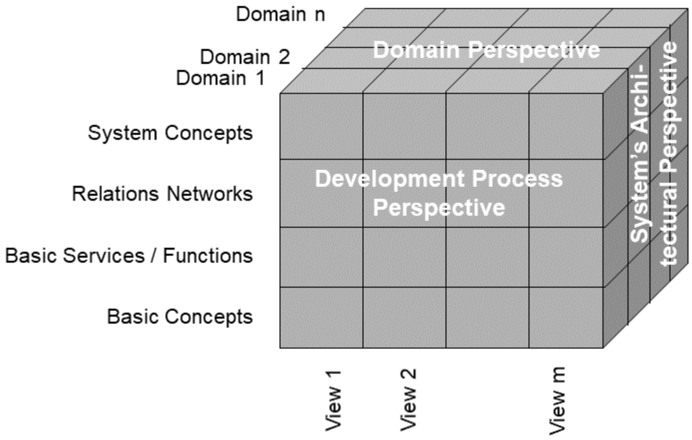


**Figure 1. Generic Reference Architecture model**

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 able to represent any aspect or domain of interest is needed. 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 level, 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 behavioural 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].

# 1 Scope

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 Reference Architecture, by that way providing a standardized interface to that specification. In this way, the methodology offered in this standard 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 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 Reference Architecture instance. In this way, the Interoperability 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 4 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 standard’s Interoperability Reference Architecture.

 

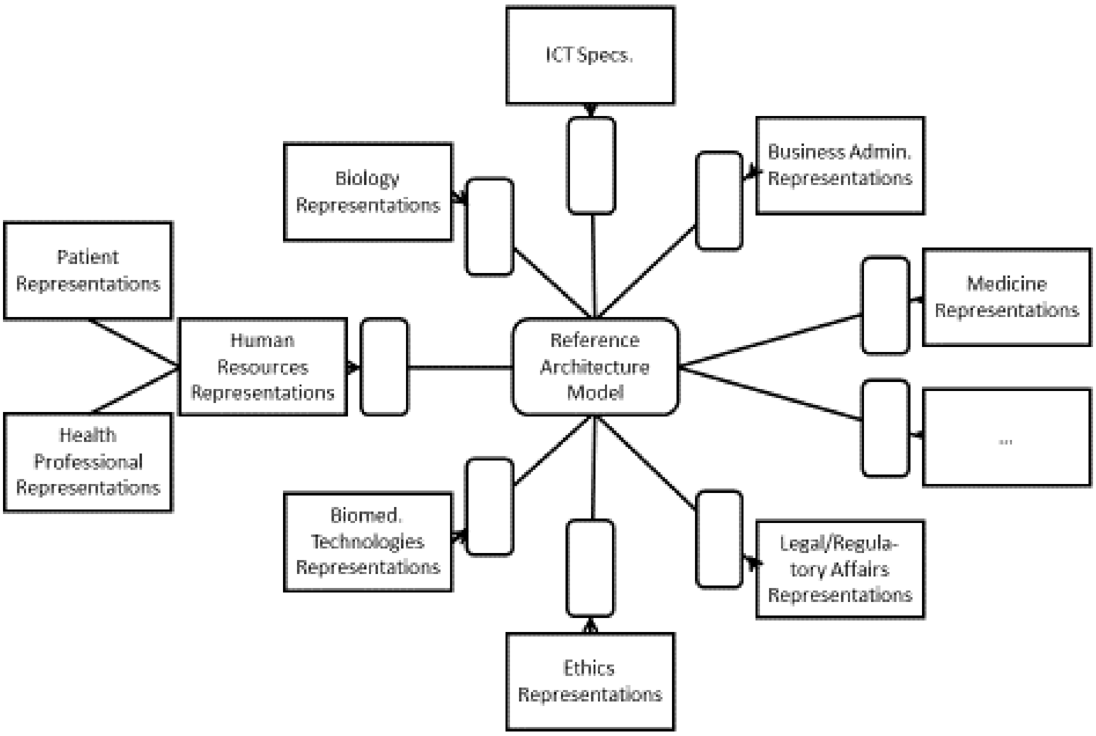


**Figure 4. Overview of this standard's interoperability approach**

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. In summary, this Standard specifies advanced interoperability of ICT-supported business systems. The Interoperability Reference Architecture Model supports ontology harmonization or knowledge harmonization to enable interoperability between existing systems, standards and solutions of 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.

## 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 CD 21838-1 Information technology – Top-level ontologies – Part 1: Requirements

ISO/IEC CD 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**

**model**

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

NOTE 1: 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.

[SOURCE: Lankhorst M. Enterprise Architecture at Work. The Enterprise Engineering Series. Berlin Heidelberg: Springer-Verlag; 2009]

**3.2**

**system**

an ordered composition of interrelated elements

NOTE 1: Systems can be composed (aggregated) to super-systems or decomposed (specialized) to sub-systems.

NOTE 2: A system groups structurally and/or functionally interrelated components, which are separated from the environment defining components by system boundaries.

**3.3**

**system architecture**

describes the system's elements (components), their functions and interrelations

**3.4**

**reference architecture**

a reference model for a class of architectures

**3.5**

**system policy**

rules for selecting components and functions as well as constraints of the relations according to a business case

NOTE 1: Policies define the intended behaviour of a systems.

**3.6**

**ecosystem**

structured systems and communities that are governed by general rules

NOTE 1: Ecosystems are controlled both by external and internal factors.

NOTE 2: The World Health Organization (WHO) described an ecosystem as combined physical and biological components of an environment, forming complex sets of relationships and function as a unit as they interact with their physical environment [SOURCE: World Health Organization. Ecosystem. http://www.who.int/globalchange/ecosystems/en/].

**3.7**

**domain**

collection of *entities* (3.16) of interest to a certain community or discipline

[SOURCE: ISO/IEC CD 21838-1]

 

**3.8**
**viewpoint**
A viewpoint (on a system) is an abstraction that yields a specification of the whole system related to a particular set of concerns.
[SOURCE: ISO/IEC 10746-1:1998]

**3.9**
**business viewpoint**
viewpoint, which is concerned with the purpose, scope and policies governing the activities of the specified ecosystem

**3.10**
**ontology**
*collection* (3.17) of *terms* (3.22), *relational* expressions (3.25) and associated natural-language definitions together with one or more formal theories designed to capture the intended interpretations of these definitions [SOURCE: ISO/IEC CD 21838-1]
NOTE 1: An ontology defines a set of representational *primitives* (3.19) with which to model a domain of knowledge or discourse. [SOURCE: Ling Liu and M. Tamer Özsu (Eds.), Encyclopedia of Database Systems, Springer-Verlag, 2009]

**3.11**
**domain ontology**
*ontology* (3.10) whose *terms* (3.22) represent *classes* (3.18) or *types* and, optionally, certain *particulars* (3.19) (called 'distinguished individuals') in some *domain* (3.7)
[SOURCE: ISO/IEC CD 21838-1]

**3.12**
**concept**
A concept is a model. It shall be uniquely identifiable, accepted by experts and users, as well as independent.
NOTE 1: A concept as a knowledge component can be specialized and generalized as components can.

**3.13**
**instance**
*particular* (3.20) that instantiates some *universal* (3.21)
[SOURCE: ISO/IEC CD 21838-1]

**3.14**
**interoperability**
ability of a system or a product to work with other systems or products without special effort on the part of the customer [SOURCE: IEEE Standards University]
NOTE 1: 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 [SOURCE: IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries (New York, NY: 1990)].
NOTE 2: In an ecosystem context, interoperability describes motivation, willingness, ability, and capability to cooperate for achieving common goals or business objectives.

**3.15**
**logical interoperability**
ability to derive each and every *axiom* (3.27) of one *formal theory* (3.29) from another
[SOURCE: ISO/IEC CD 21838-1]

**3.16**
**entity / object**
anything perceivable or conceivable
[SOURCE: ISO/IEC CD 21838-1]

**3.17**
**collection**
*particular* (3.20) that instantiates some *universal* (3.21)
[SOURCE: ISO/IEC CD 21838-1]

**3.18**
**class / type**
general *entity* (3.16)
[SOURCE: ISO/IEC CD 21838-1]

**3.19**
**primitive**
expression for which no non-circular definition can be provided
[SOURCE: ISO/IEC CD 21838-2]

**3.20**
**particular**
individual *entity* (3.16)
[SOURCE: ISO/IEC CD 21838-1]

**3.21**
**universal**
*entity* (3.16) that has indefinitely many *instances* (3.12)
[SOURCE: ISO/IEC CD 21838-1]

**3.22**
**term**
*expression* (3.23) that refers to some *class* (3.17) or to some *particular* (3.18)
[SOURCE: ISO/IEC CD 21838-1]

**3.23**
**expression**
word or group of words or corresponding symbols that can be used in making an assertion
[SOURCE: ISO/IEC CD 21838-1]

**3.24**
**relation**
way in which *entities* (3.16) are related
[SOURCE: ISO/IEC CD 21838-1]

 

**3.25**
**relational expression**
*expression* (3.23) used to assert that a *relation* (3.24) obtains
[SOURCE: ISO/IEC CD 21838-1]

**3.26**
**definition**
concise statement of the meaning of an *expression* (3.23)
[SOURCE: ISO/IEC CD 21838-1]

**3.27**
**axiom**
statement that is taken to be true, to serve as a premise for further reasoning
[SOURCE: ISO/IEC CD 21838-1]

**3.28**
**formal language**
language that is machine readable and has a well-defined semantics
[SOURCE: ISO/IEC CD 21838-1]

**3.29**
**formal theory**
collection of *definitions* (3.26) and *axioms* (3.27) expressed in a *formal language* (3.28)
[SOURCE: ISO/IEC CD 21838-1]

# 4 Abbreviations

For the purposes of this document, the following abbreviations apply.

| | |
|---|---|
| **CEN** | Comité Européen de Normalisation (European Committee for Standardization) |
| **EHR** | Electronic Health Record |
| **EU** | European Union |
| **GP** | General Practitioner |
| **HL7** | Health Level Seven |
| **IANA** | Internet Assigned Numbers Authority |
| **IETF** | Internet Engineering Task Force |
| **ISO** | International Organization for Standardization |
| **OID** | Object Identifier |
| **R&D** | Research and Development |
| **RFC** | Request For Comments |
| **UCUM** | Unified Code for Units of Measure |
| **UML** | Unified Modelling Language |
| **XML** | Extensible Mark-up Language |

# 5 Overview

## 5.1 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 behavior for meeting the use case specific business objectives, an abstract, domain-independent system architecture with generic system components at different levels of granularity must 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), 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, the policy ontology of PONDER [15] and its standardization in ISO 22600 shall be used [16]. For managing and harmonizing different ontologies represented using different representation styles and languages, the OMG Ontology Definition Metamodel V1.1 can be deployed.

Deploying systems theory, especially its white box approach, the GRA (Section 0.3) adopts, but goes beyond, IEEE 1471 Recommended Practice for Architectural Description of Software-Intensive Systems, which has been later on superseded by ISO/IEC/IEEE 42010:2011. 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 10746 ODP-RM 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 Reference Architecture for ICT Supported Systems

## 6.1 Interoperability Reference Architecture domains and granularity levels

Adopting the philosophy of ISO 10746 Information Technology – Reference Model – Open Distributed Processing, the standard fills a gap for real world interoperability by extending the viewpoints defined in ISO/IEC 10746 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 2 presents the Interoperability Reference Architecture business viewpoint with its domain and its composition/decomposition dimension.

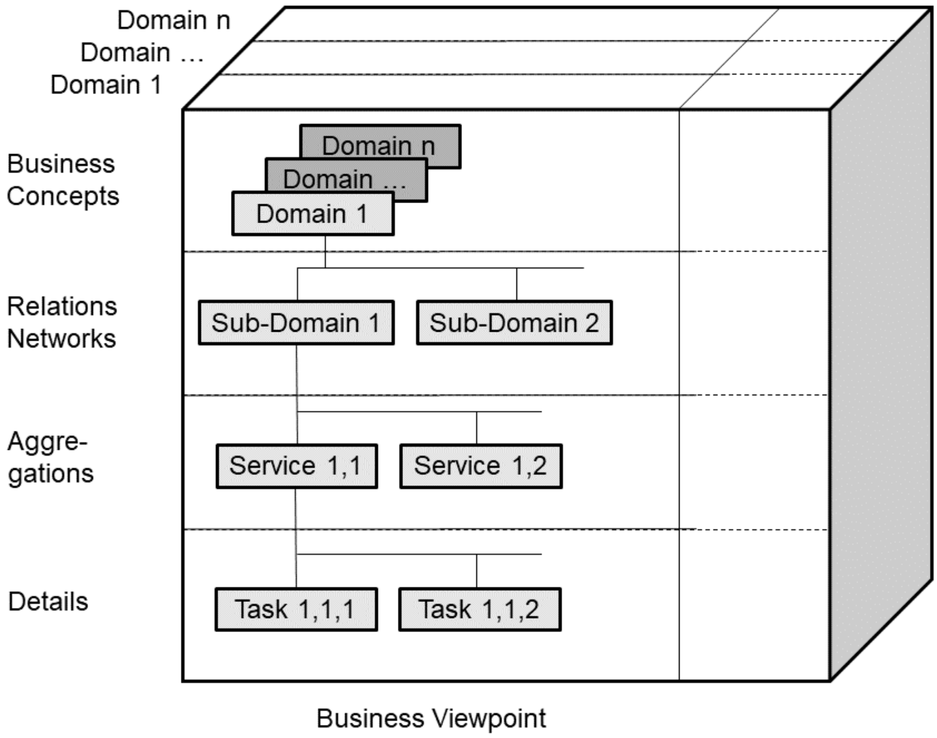


**Figure 2. Interoperability Reference Architecture domains and granularity levels**

## 6.2 Interoperability Reference Architecture model for ICT supported systems

By combining that model with ISO/IEC 10746 Information Technology – Reference Model – Open Distributed Processing (RM-ODP) 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 Reference Architecture with its three dimensions system domains, system component composition, and system viewpoints after RM-ODP (Figure 3).

 

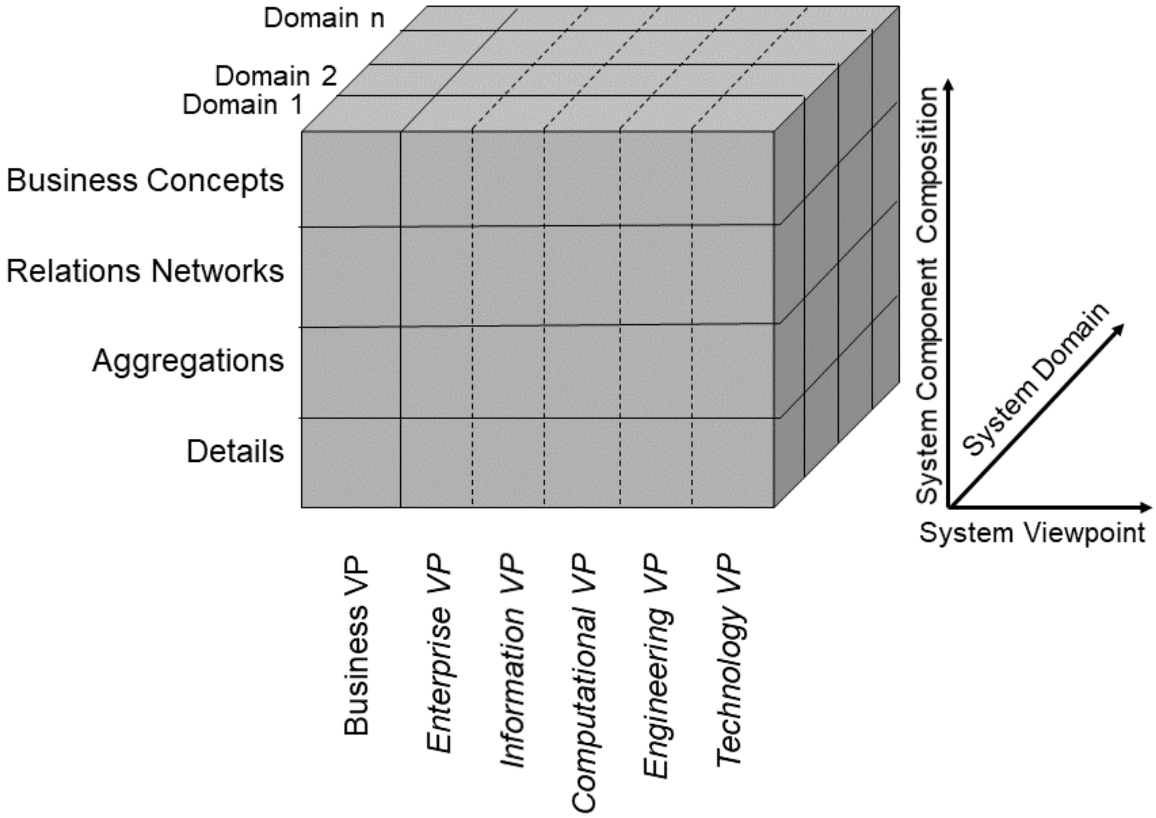


**Figure 3. The Interoperability Reference Architecture Model**

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 have to be instantiated, thereby preferably selecting and adapting existing specifications/solutions. In other words, the Interoperability Reference Architecture guides developers of component system to select and constrain the right elements, e.g. Fast Healthcare Interoperability Resources (FHIR) or FHIR Profiles. Only this way, the correctness of compositions, relations and underlying policies can be ascertained [14]. In consequence, both legacy systems and emerging systems can in this way be correctly and consistently designed or redesigned.

## 6.3 Interoperability Reference Architecture framework

The system's complexity shall be limited to the level needed for representing the intended business case. This may imply the recursive deployment of the modeling process. For each business system component a specification is to be developed or an integration of existing specification at any system development view – here any ISO 10746 view – 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 CD 21838 definitions and procedures.

### 6.4 Management of relationships in the Interoperability Reference Architecture

There are three types of relationships between the components of the Interoperability Reference Architecture depending on the dimension those relationships are established: specialization/generalization; mapping; transformation (Figure 4).

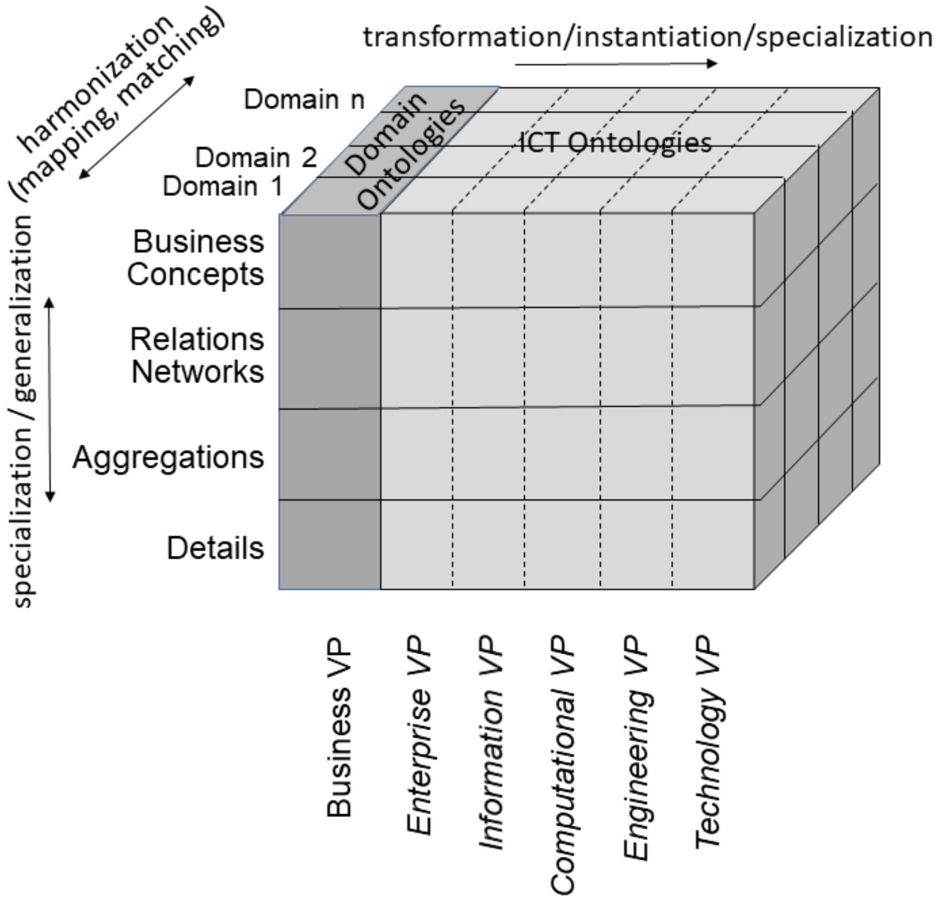


**Figure 4. Relationships in the Interoperability Reference Architecture Model**

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, the might be a need for running the Interoperability 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.

 

# 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 example, the ISO 13606-1 Reference Model and the HL7 Composite Security and Privacy Domain Analysis Model are reengineered and combined in an Interoperability Reference Architecture model instance. Figure A1 illustrates the process of integrating the two specifications.

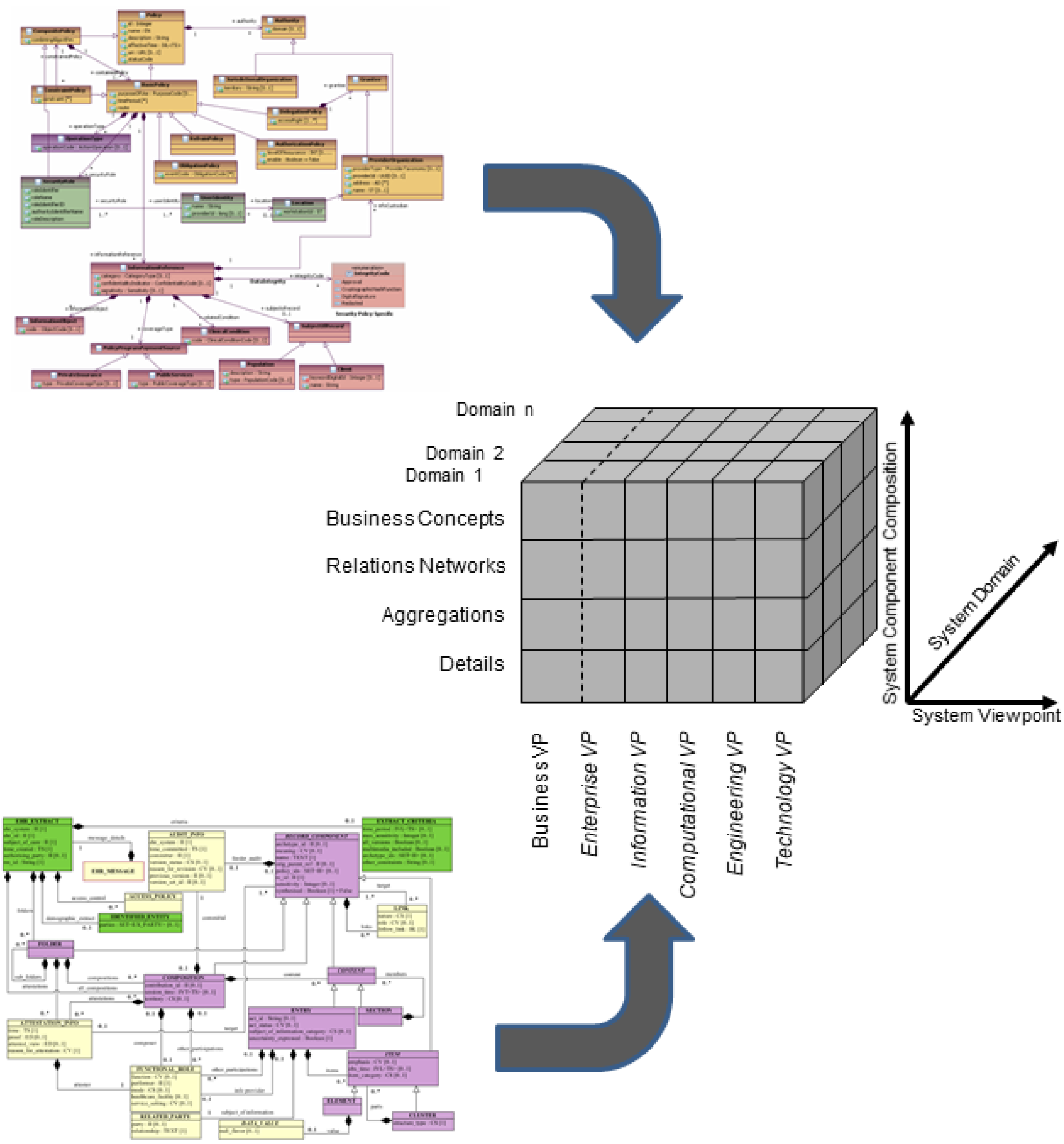


**Figure A1. Example for model harmonization by re-engineering the HL7 Composite Security and Privacy Domain Analysis Model and the ISO 13606 Reference Model**

The resulting Interoperability Reference Architecture instance model is shown in Figure A2 thereby just considering the domains addressed in that use case.

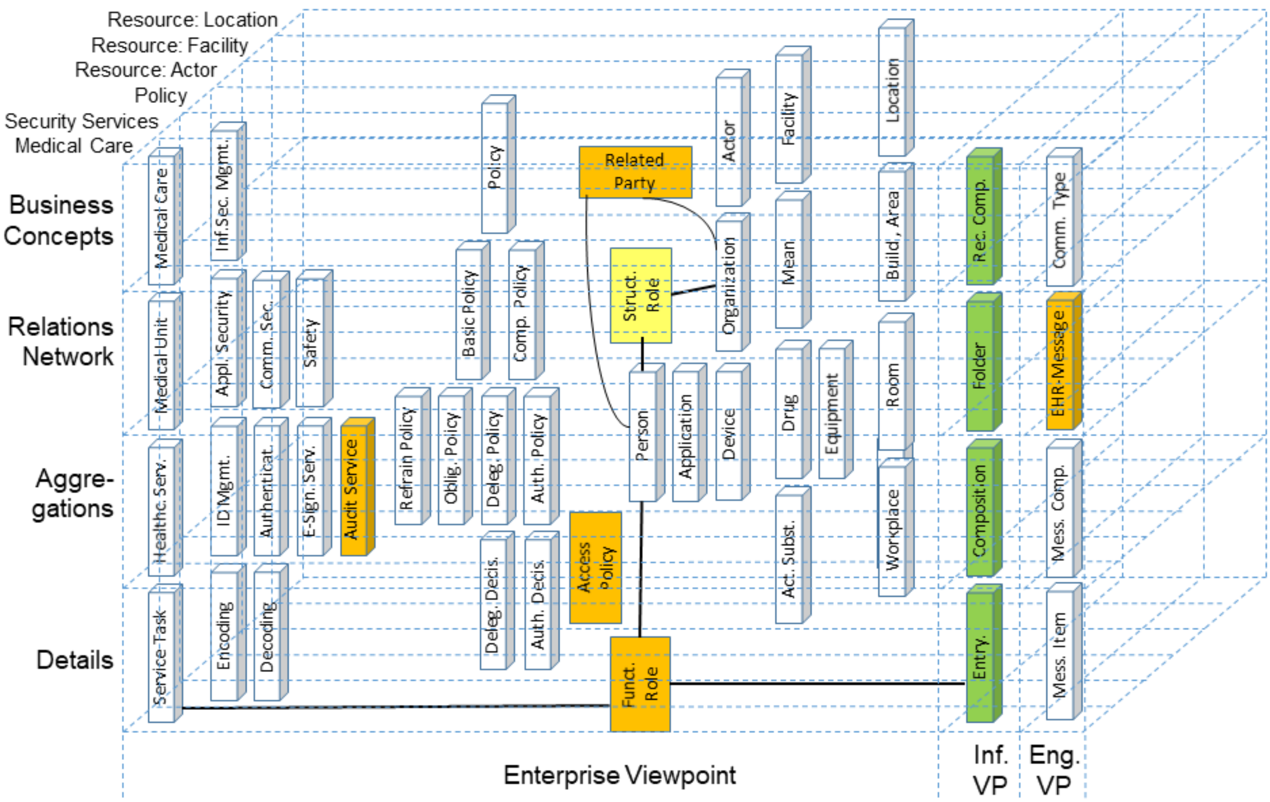


**Figure A2. Reengineering the ISO 13606 Reference Model in the context of the HL7 Composite Security and Privacy Domain Analysis Model**

The figure shows a mixture of different viewpoints not considered in the standard, so requiring essential advancements and transformations of the ISO 13606 Reference Model. Furthermore, there is a vast amount of explicit knowledge missing in ISO 13606 but necessary for the harmonization challenge as demonstrated by the non-colored components, which complete the architectural model. Just the ISO 13606 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 with other specifications such as HL7 v2 and v3 – a permanent challenge Standards Development Organizations are faced with – can be easily performed.

As the underlying methodology of the Interoperability 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 views for analyzing, designing, implementing and maintaining the related ICT solution.

The presented approach has been successfully deployed in several cross-domain ISO specifications, such as ISO 22600 Health informatics - Privilege management and access control, ISO 21298 Health informatics - Functional and structural roles, HL7 Composite Security and Privacy Domain Analysis Model. Its feasibility has been practically demonstrated for automatically harmonizing HL7 v2.x and HL7 v3 specifications [18, 19] or for automatically designing inter-domain Web services to facilitate multi-disciplinary approaches to Type 2 Diabetes Care management [20, 21]. The approach also allows a comparative analysis and evaluation of ICT Enterprise Architectures [14].

# 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 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 has to 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)" [13, 18]. That way, it enables the mutual transformation of those communications standards for the sake of interoperability of existing solutions. The resulting Interoperability Reference Architecture instance model is shown in Figure B1 thereby just considering the domains addressed in that use case.

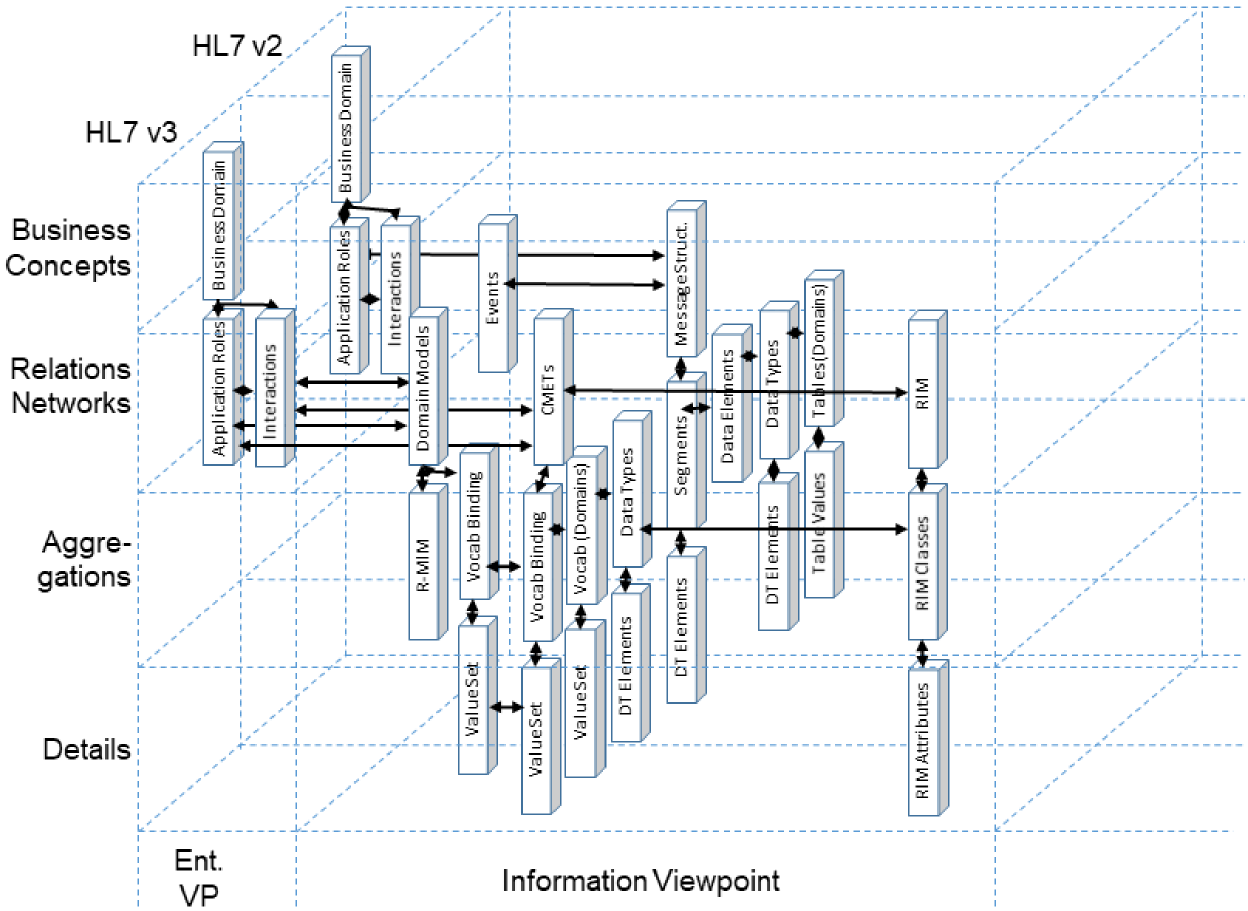


**Figure B1. Reengineering the development process model of HL7 v2 and HL7v3 for integrating the two communication standards**

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 details.

As the underlying methodology of the Interoperability 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 views for analyzing, designing, implementing and maintaining the related ICT solution.

The presented approach has been successfully deployed in several cross-domain ISO specifications, such as ISO 22600 Health informatics - Privilege management and access control, ISO 21298 Health informatics - Functional and structural roles, HL7 Composite Security and Privacy Domain Analysis Model. Its feasibility has been practically demonstrated for automatically designing inter-domain Web services to facilitate multi-disciplinary approaches to Type 2 Diabetes Care management [20, 21]. The approach also allows a comparative analysis and evaluation of ICT Enterprise Architectures [14].

# Annex C
(informative)
# Integration of Standards in the ISO 12967 Health Information Services Architecture Framework

Bound to the Interoperability Reference Architecture Framework, inter-domain relationships have to happen at the same level of granularity [5]. To get there, intra-domain specializations/generalizations have to be performed. In summary, the Interoperability 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, 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 ISO Interoperability Reference Architecture.

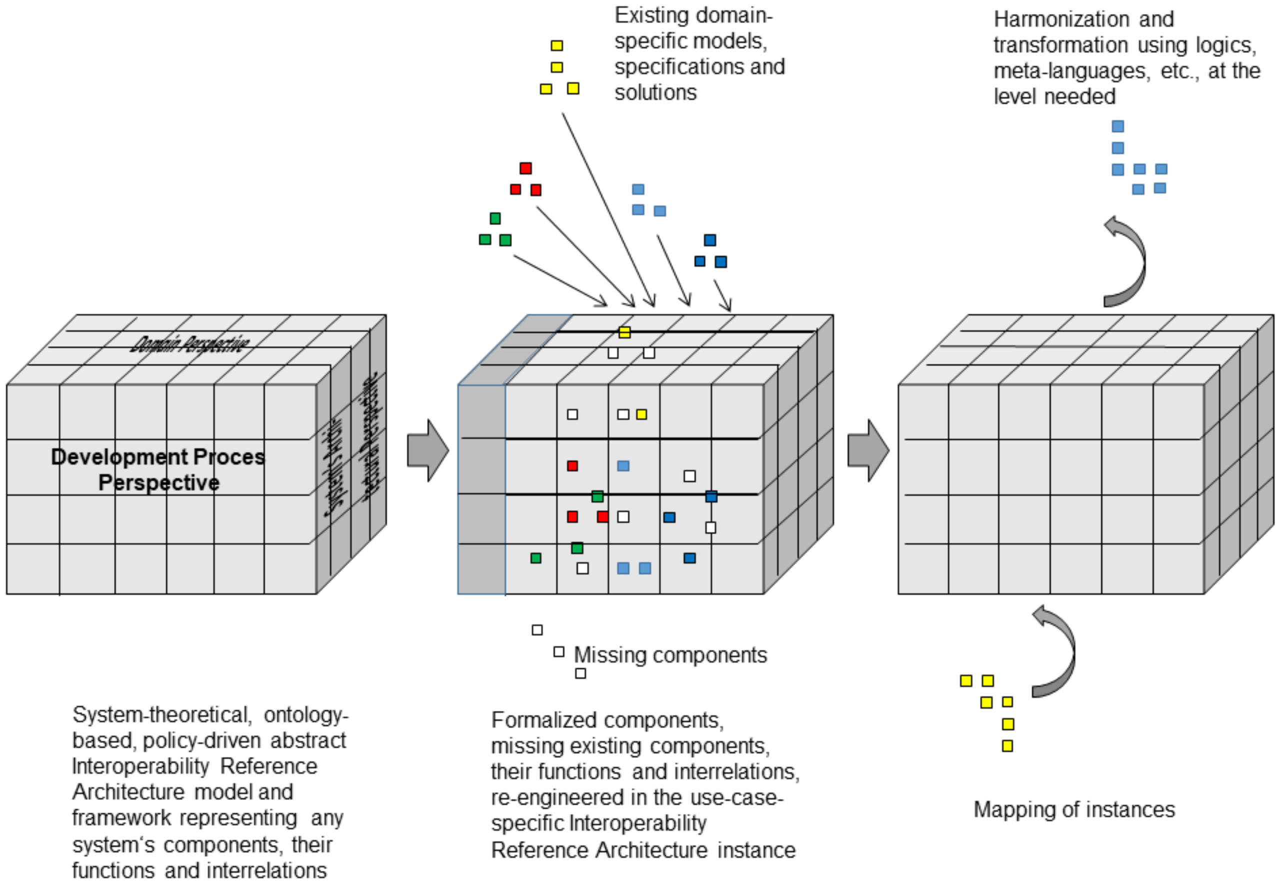


**Figure C1 — Integration of standards and specifications using GCM Reference Architecture Model**

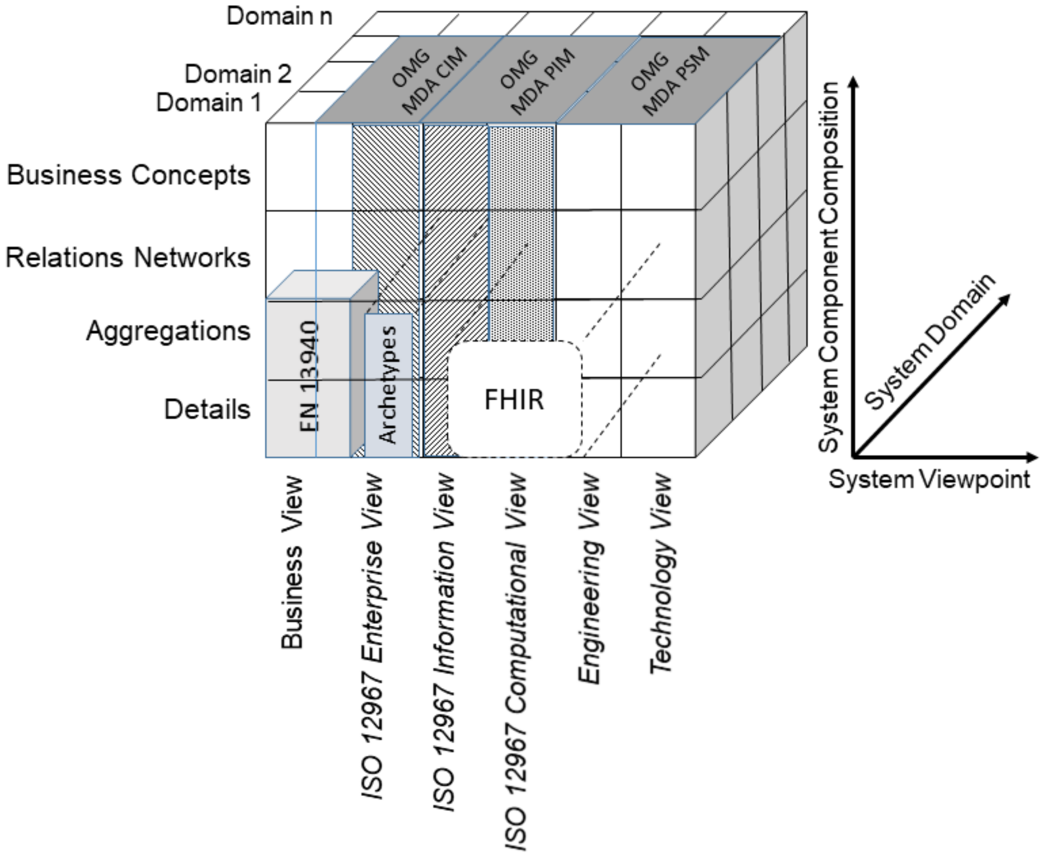


**Figure C2 — Integration of standards and specifications explicitly mentioned in the standard at hand, using the Interoperability Reference Architecture Model**

As an example, re-engineering of parts of HISA ISO 12967 (red text) and Contsys ISO 13940 (green text) into an Interoperability Reference Architecture instance, is shown in Figure C.3. The figure shows a mixture of Enterprise and Information viewpoints. Contsys 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 Contsys is what goes on in the domain in terms of detailed concepts and how to support this. The HISA Enterprise Viewpoint is at a high level of abstraction without detailed concepts, describing and diagrammatically illustrating what goes on in healthcare. The focus of HISA is the service architecture, supporting healthcare from an IT perspective. The required models, classes and attributes of HISA described in the 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 Contsys.

 

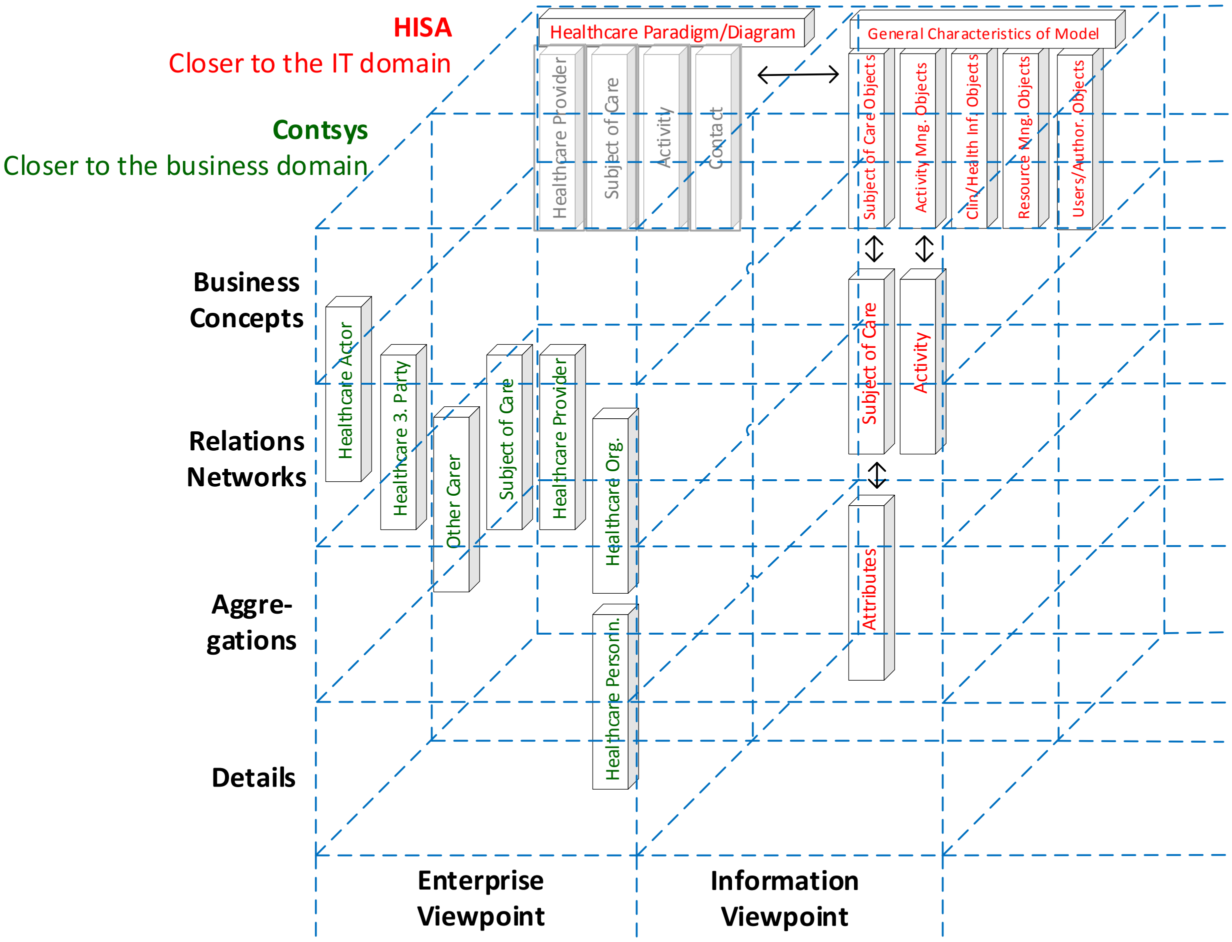


**Figure C3 — Re-engineering example of selected parts of HISA ISO 12967 and Contsys ISO 13940**

# Annex D
(informative)
# Deployment of the Interoperability Reference Architecture Approach in ISO 13972 Clinical Information Models

As ISO 13972 deals with modelling methodologies, the Interoperability Reference Architecture has been fundamentally integrated in the standard instead of referring to it by an Annex. Figure D1 details the placement of the standard's information models in comparison to well known HL7 information model standards.

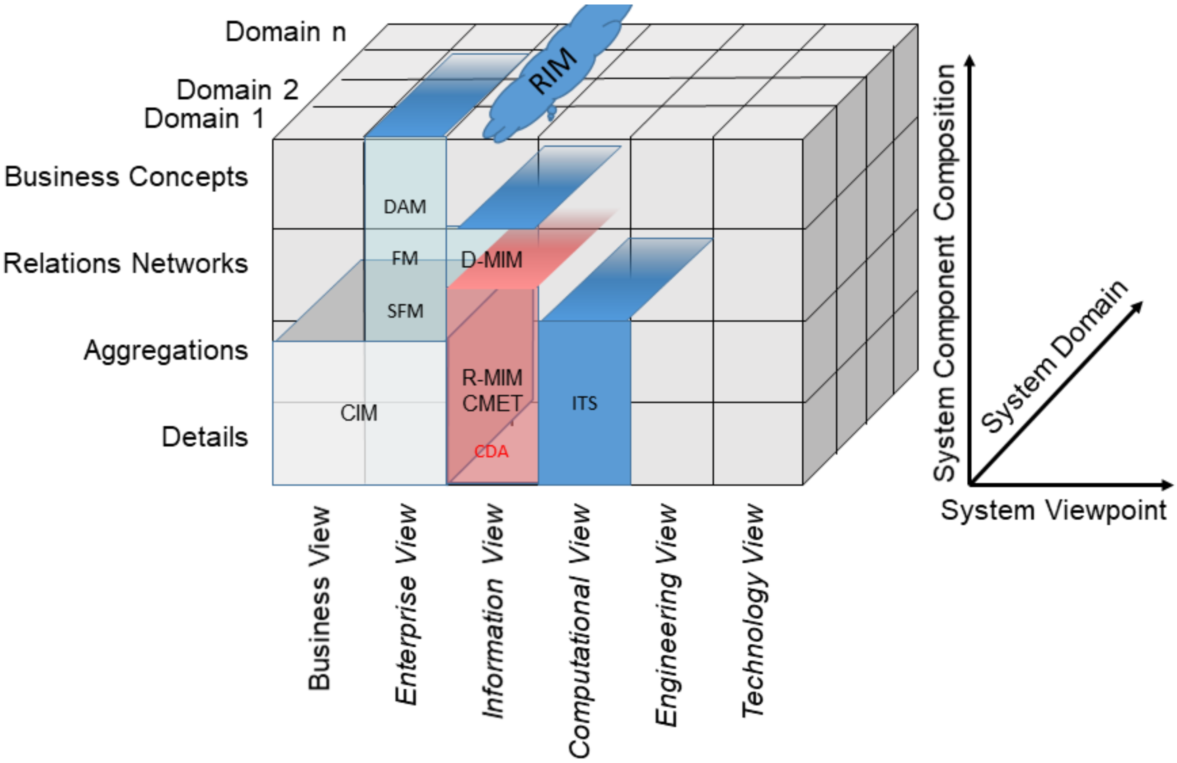


**Figure D1 — Placing the ISO 13972 Clinical Information Models and well known HL7 information models in the Interoperability Reference Architecture Model**

# Annex E
(informative)
# Reference Architecture Stack intended by the ISO/IEC JTC1 AG8 project “Meta Reference Architecture and Reference Architecture for Systems Integration"

This Annex demonstrates 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 standard’s Interoperability Reference Architecture. The intended ISO/IEC JTC1 AG8 project “Meta Reference Architecture and Reference Architecture for Systems Integration" Reference Architecture Stack coomprises: Meta Reference Architecture (Meta RA), Generic RA, Domain Specific RA (DSRA), Solution RA, Solution Architecture (Solution A), Implementation A, Deployment A.

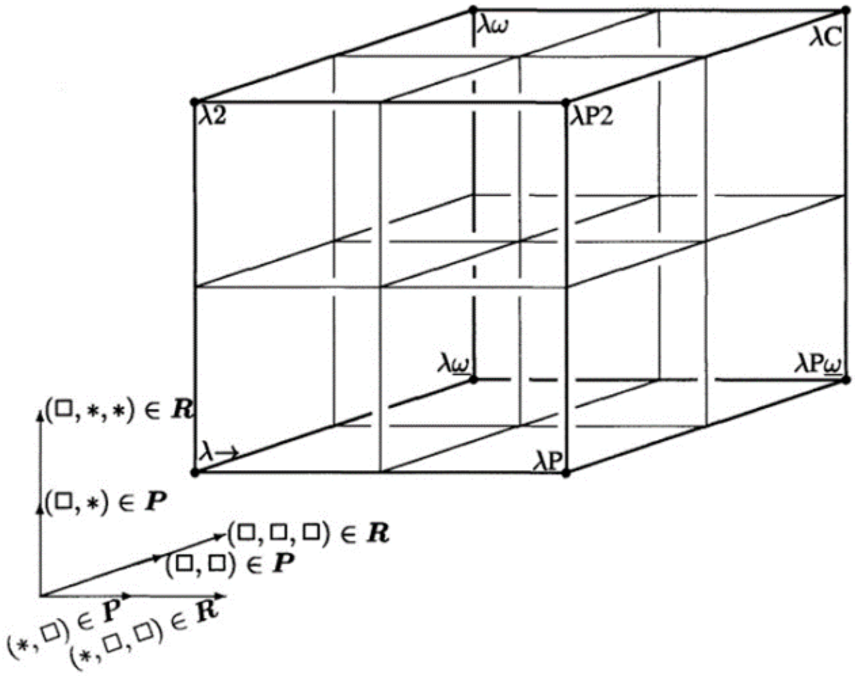


**Figure E1 — Barendregt Cube with Parameters as Meta Reference Architecture of the Interoperability Reference Architecture (after Kamareddine et al [7])**

 

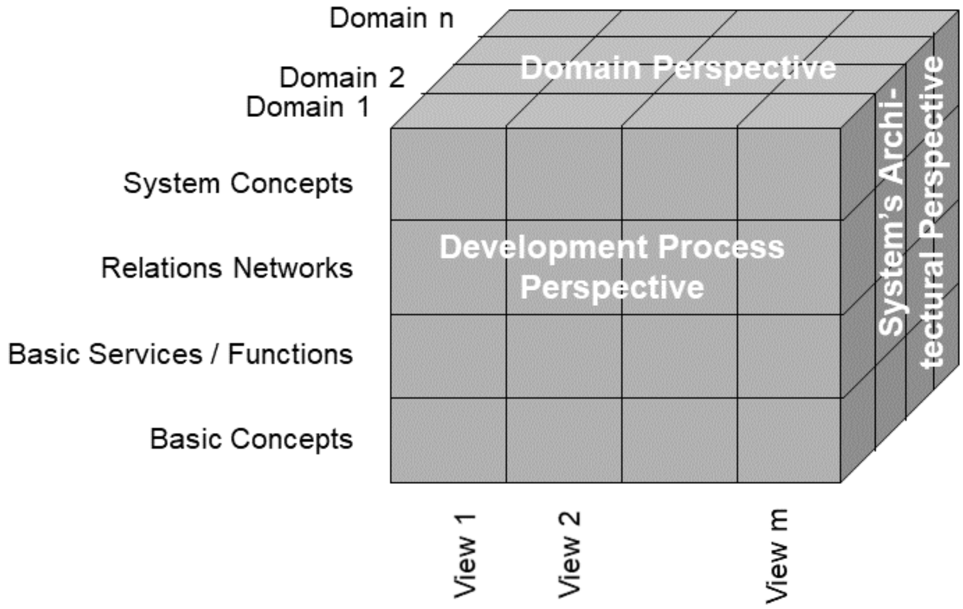


**Figure E2. Generic Reference Architecture (see Section 0.3)**

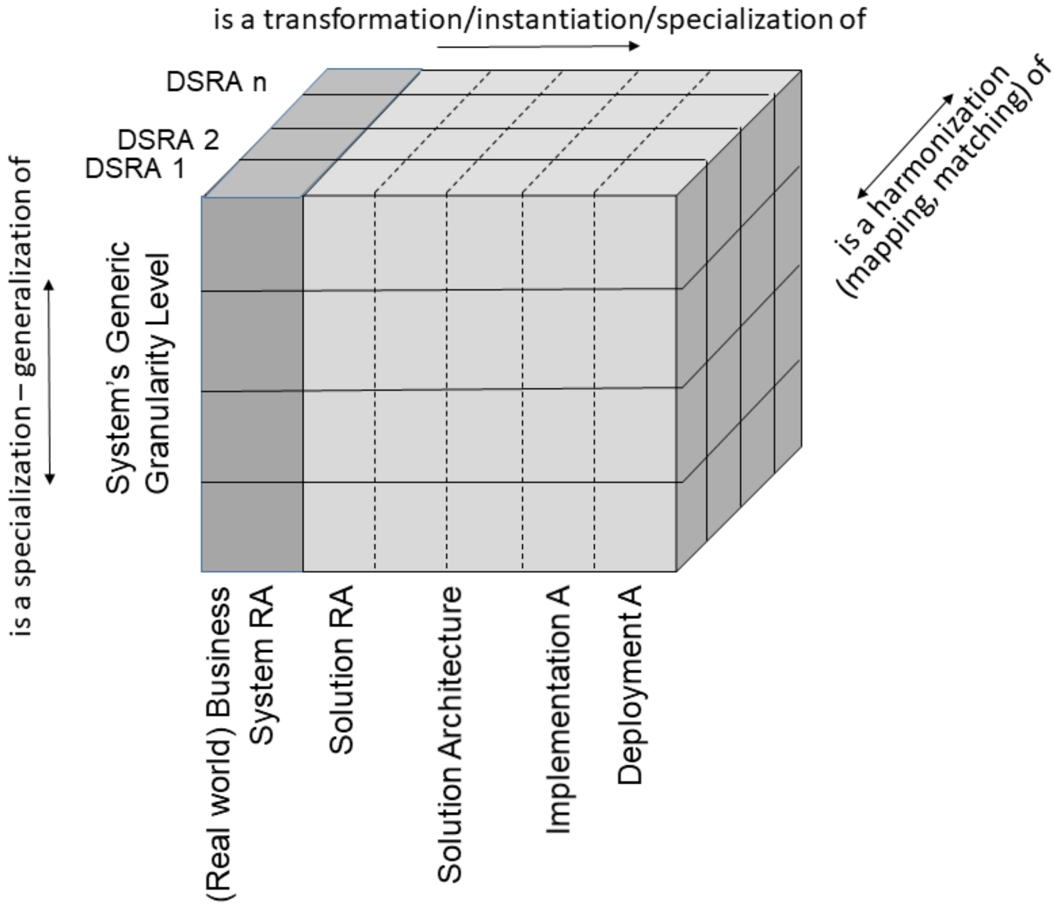

**Figure E3. Rest of the ISO/IEC JTC1 AG8 project “Meta Reference Architecture and Reference Architecture for Systems Integration" Reference Architecture Stack, extended by the (Real World) Business System RA according to the philosophy of this standard**

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