SLOVENSKI STANDARD
SIST EN ISO 23903:2021

01-julij-2021

Zdravstvena informatika - Referenčna arhitektura interoperabilnosti in integracije - Model in okvir (ISO 23903:2021, popravljena različica 2021-07)

Health Informatics - Interoperability and Integration Reference Architecture - Model and Framework (ISO 23903:2021, Corrected version 2021-07)

Medizinische Informatik - Interoperabilitäts- und Integrations-Referenzarchitektur - Modell und Framework (ISO 23903:2021, korrigierte Fassung 2021-07)

Informatique de santé - Architecture de Référence d'Interopérabilité et d'Intégration - Modèle et cadre (ISO 23903:2021, Version corrigée 2021-07)

Ta slovenski standard je istoveten z: **EN ISO 23903:2021**

ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN ISO 23903:2021 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23903

April 2021

ICS 35.240.80

English Version

Health Informatics - Interoperability and integration reference architecture - Model and framework (ISO 23903:2021, Corrected version 2021-07)

Informatique de santé - Architecture de référence d'interopérabilité et d'intégration - Modèle et cadre (ISO 23903:2021, Version corrigée 2021-07)

Medizinische Informatik - Interoperabilitäts- und Integrations-Referenzarchitektur - Modell und Framework (ISO 23903:2021, korrigierte Fassung 2021-07)

This European Standard was approved by CEN on 9 March 2021.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 21 July 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 23903:2021 E

Contents

Page

European foreword

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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 23903:2021, Corrected version 2021-07 has been approved by CEN as EN ISO 23903:2021 without any modification.

INTERNATIONAL STANDARD

ISO 23903

First edition
2021-04

Corrected version
2021-07

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

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

Reference number
ISO 23903:2021(E)

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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.

This corrected version of ISO 23903:2021 incorporates the following corrections:

— Figure E.1 has been corrected.

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].

---

1) HL7 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.

2) openEHR is a registered trademark of the openEHR Foundation. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

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

