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Entwurf

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**Medizinische Informatik –
Servicearchitektur –
Teil 3: Verarbeitungssicht (ISO/DIS 12967-3:2019);
Englische Fassung prEN ISO 12967-3:2019**

Health informatics –
Service Architecture (HISA) –
Part 3: Computational viewpoint (ISO/DIS 12967-3:2019);
English version prEN ISO 12967-3:2019

Informatique de santé –
Architecture de service –
Partie 3: Point de vue informatique (ISO/DIS 12967-3:2019);
Version anglaise prEN ISO 12967-3:2019

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Nationales Vorwort

Dieses Dokument (prEN ISO 12967-3:2019) wurde in der WG 1 „Architecture, Frameworks and Models“ des Technischen Komitees ISO/TC 215 „Health Informatics“ und mit dem Technischen Komitee CEN/TC 251 „Medizinische Informatik“, dessen Sekretariat von NEN (Niederlande) gehalten wird, erarbeitet.

Der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des DIN-Normenausschusses Medizin (NAMED) hat an der Erarbeitung ebenfalls mitgewirkt.

Dieses Dokument enthält unter Berücksichtigung des Präsidialbeschlusses 1/2004 nur die englische Originalfassung von EN ISO 12967-3:2019.

Für die in diesem Dokument zitierten internationalen Dokumente wird im Folgenden auf die entsprechenden deutschen Dokumente hingewiesen:

ISO 9000	siehe	DIN EN ISO 9000:2015-11
ISO 13606-1	siehe	DIN EN ISO 13606-1:2017-06
ISO 13606-4	siehe	DIN EN ISO 13606-4:2017-06

Änderungen

Gegenüber DIN EN ISO 12967-3:2011-06 wurden folgende Änderungen vorgenommen:

- a) Verwendung von Begriffen, Definitionen und Konzepten aus Teil 1 und Teil 2 dieser Normenreihe, die mit ISO 13940:2016 (Contsys) abgestimmt wurden;
- b) Aktualisierung von Texten, Tabellen, Bildern usw. im Zusammenhang mit der Überarbeitung von Teil 1 und Teil 2 dieser Normenreihe, die wiederum an die ISO 13940:2016 angepasst wurden;
- c) Aufnahme von Verweisungen auf weitere Standards, wie z. B. HL7 und FHIR, von denen letzterer im neuen Anhang B im Hinblick auf die HISA-Servicearchitektur behandelt wurde;
- d) Aktualisierung der Literaturhinweise.

Zusammenfassung

HISA spezifiziert grundlegende Anforderungen an die „Informationsinfrastruktur“ und gesundheitsversorgungsspezifische „Servicearchitektur“.

Dieser Teil von ISO 12967 spezifiziert die grundlegenden Merkmale des Verarbeitungsmodells, das durch eine spezifische Architekturschicht des Informationssystems (d. h. die Servicearchitektur) implementiert werden soll, um eine umfassende und integrierte Schnittstelle zur allgemein gültigen Unternehmensinformation zu schaffen und die grundlegenden Geschäftsprozesse der Gesundheitsversorgungsorganisation zu unterstützen, wie in ISO 12967-1 festgelegt. Das Verarbeitungsmodell wird ohne explizite oder implizite Voraussetzung über physische Technologien, Tools oder Lösungen spezifiziert, die für dessen physische Implementierung in den verschiedenen Zielszenarien übernommen wird. Die Spezifikation ist dennoch formell, vollständig und unzweideutig genug, um es Implementierern zu ermöglichen, ein effizientes Design des Systems für die spezifische technologische Umgebung abzuleiten, die für die physische Implementierung ausgewählt wird.

Das Verarbeitungsmodell sorgt für eine konsistente Grundlage zwischen verschiedenen Ingenieurs- und Technologiespezifikationen (einschließlich Programmiersprachen und Kommunikationsmechanismen), da diese mit dem gleichen Verarbeitungsobjektmodell konsistent sein müssen. Diese Konsistenz ermöglicht bereichsübergreifendes Arbeiten und die Übertragbarkeit von Komponenten in der resultierenden Implementierung.

Ziel dieser Spezifikation ist es nicht, eine feststehende, vollständige Spezifikation aller möglichen Schnittstellen, die für jegliche Anforderung jeglichen Gesundheitsversorgungsunternehmens nötig sein könnte, zu repräsentieren. Sie spezifiziert nur einen Satz von Merkmalen hinsichtlich Gesamtorganisation und individueller Verarbeitungsmodelle, die als grundlegend und allen Gesundheitsversorgungsorganisationen gemein erkannt wurden, und die durch das von der Servicearchitektur implementierte Verarbeitungsmodell erfüllt werden.

Physische Implementierungen müssen Erweiterungen des Normverarbeitungsmodells erlauben, um zusätzliche und lokale Anforderungen zu unterstützen, dabei aber die Konsistenz mit den Vorgaben dieses Teils von ISO 12967 beibehalten. Erweiterungen müssen sowohl die Definition zusätzlicher Eigenschaften der Objekte des Normmodells als auch der Implementierung völlig neuer Objekte beinhalten.

Diese Normspezifikation muss auch über die Zeit hinweg entsprechend der Entwicklung anwendbarer Normierungsinitiativen erweiterbar sein. Die Spezifikation von Erweiterungen muss nach der in Abschnitt 7 von ISO 12967-1:2019 festgelegten Methodik vorgenommen werden, in der ein Satz gemeinsamer Informationsdienste der Gesundheitsversorgung angeführt und deren Erforderlichkeit und Methodik beschrieben werden, mit der dieser angewendet wird.

Diese Informationsdienste sind nur der identifizierbare Minimalsatz entsprechend des Bedarfs des Gesundheitsversorgungsunternehmens und bilden die Servicearchitektur (d. h. die Integrationsplattform), die als Grundlage für Gesundheitsversorgungsanwendungen, z. B. die elektronische Gesundheitsakte oder Patientenverwaltung, dienen.

Nationaler Anhang NA (informativ)

Begriffe

Die Benummerung der folgenden Begriffe und Abkürzungen sind identisch mit der Benummerung in der englischen Fassung.

3 Begriffe

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe.

3.1

Schnittstelle

(en: interface)

Abstraktion des Verhaltens eines Objekts, bestehend aus einem Teilsatz der möglichen Wechselwirkungsmechanismen dieses Objekts, zusammen mit dem Satz der Einschränkungen, die beim Auftreten dieser Wechselwirkung vorliegen

3.2

Verarbeitungsobjekt

(en: computational Object)

von einer Verarbeitungssicht aus betrachtetes Objekt zur Darstellung der funktionalen Zerlegung eines Systems, das einen bestimmten Zustand und ein bestimmtes Verhalten sowie Wechselwirkungen durch Schnittstellen mit weiteren Verarbeitungsobjekten aufweist

Nationaler Anhang NB (informativ)

Literaturhinweise

DIN EN ISO 9000, *Qualitätsmanagementsysteme — Grundlagen und Begriffe*

DIN EN ISO 13606-1, *Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form — Teil 1: Referenzmodell*

DIN EN ISO 13606-4, *Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form — Teil 4: Sicherheit*

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 215, Health informatics.

This second edition is a revision of, cancels and replaces the first edition (ISO 12967-3:2009), which was based on the European Standard EN 12967-3:2007.

ISO 12967 consists of the following parts, under the general title Health informatics — Service architecture:

- *Part 1: Enterprise viewpoint*
- *Part 2: Information viewpoint*
- *Part 3: Computational viewpoint*

The main changes compared to the previous edition of this part (part 3, computational viewpoint) are as follows:

- Use of terms, definitions and concepts from parts 1 and 2 of ISO 12967, in turn aligned with ISO 13490:2016 (Contsys)
- Reference to further standards, such as HL7 and FHIR, the latter of which is treated in new Annex B with respect to the HISA service architecture
- Updating regarding text, tables, etc. related based on the revision of parts 1 and 2 of this 3-part standard, aligned in turn with ISO 13940:2016 Contsys
- Updates to the Bibliography

Introduction

ISO 12967 is a multi-part standard that provides guidance for the description, planning and development of new systems as well as for the integration of existing information systems, both within one enterprise and across different healthcare organizations through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the service architecture), distinct from individual applications and accessible throughout the whole information system through information services, as shown in Figure 1.

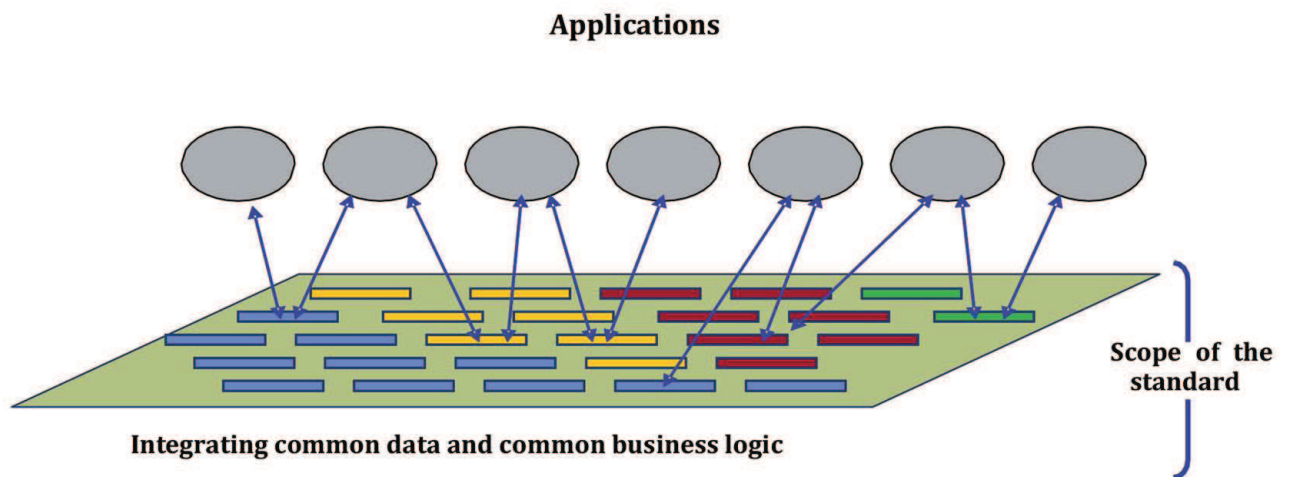


Figure 1 — Scope of this International Standard

The overall architecture is formalized according to ISO/IEC 10746 (all parts)^{[10][11][12][13]} and is therefore structured through the following three viewpoints.

- a) Enterprise viewpoint: specifies a set of fundamental common requirements at enterprise level with respect to the organizational purposes, scopes and policies that must be supported by the information and functionality of the service architecture. It also provides guidance on how one individual enterprise (e.g. a regional healthcare authority, a large hospital or any other organization where this model is applicable) can specify and document additional specific business requirements, with a view to achieving a complete specification, adequate for the characteristics of that enterprise.

Enterprise viewpoint is specified in ISO 12967-1.

- b) Information viewpoint: specifies the fundamental semantics of the information model to be implemented by the service architecture to integrate the enterprise's common data and to support the enterprise requirements formalized in ISO 12967-1. It also provides guidance on how one individual enterprise can extend the standard model with additional concepts needed to support local requirements in terms of information to be put in common.

Information viewpoint is specified in ISO 12967-2.

- c) Computational viewpoint: specifies the scope and characteristics of the information services that must be provided by the service architecture for allowing access to the common data as well as for the execution of the business logic supporting the enterprise processes identified in the information viewpoint and in ISO 12967-1. It also provides guidance on how one individual enterprise can specify additional information services needed to support local specific requirements in terms of common business logic to be implemented.

Computational viewpoint is specified in this part of ISO 12967.

– *Entwurf* –

Health informatics — Service Architecture (HISA) —

Part 3: Computational viewpoint

1 Scope

HISA specifies fundamental requirements for 'information infrastructure' and healthcare specific 'service architecture'.

This part of ISO 12967 specifies the fundamental characteristics of the computational model to be implemented by a specific architectural layer of the information system (i.e. the service architecture) to provide a comprehensive and integrated interface to the common enterprise information and to support the fundamental business processes of the healthcare organization, as defined in ISO 12967-1. The computational model is specified without any explicit or implicit assumption about the physical technologies, tools or solutions to be adopted for its physical implementation in the various target scenarios. The specification is nevertheless formal, complete and non-ambiguous enough to allow implementers to derive an efficient design of the system in the specific technological environment which will be selected for the physical implementation.

The computational model provides the basis for ensuring consistency between different engineering and technology specifications (including programming languages and communication mechanisms) since they must be consistent with the same computational object model. This consistency allows open inter-working and portability of components in the resulting implementation.

This specification does not aim at representing a fixed, complete, specification of all possible interfaces that may be necessary for any requirement of any healthcare enterprise. It specifies only a set of characteristics – in terms of overall organization and individual computational objects, identified as fundamental and common to all healthcare organizations, and that are satisfied by the computational model implemented by the service architecture.

Preserving consistency with the provisions of this part of ISO 12967, physical implementations shall allow extensions to the standard computational model in order to support additional and local requirements. Extensions shall include both the definition of additional properties in the objects of the standard model and the implementation of entirely new objects.

Also, this standard specification shall be extendable over time according to the evolution of the applicable standardization initiatives. The specification of extensions shall be carried out according to the methodology defined in Clause 7 of ISO 12967-1:2019, which identifies a set of healthcare common information services, describing their need and the methodology through which they will be used.

These information services are only the minimal set identifiable according to the needs of the healthcare enterprise, and constituting the service architecture (i.e. the integration platform) to serve as the basis for healthcare applications, e.g. EHR or patient administration.

2 Normative references

The following referenced documents are indispensable for the application 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 12967-1:2019, *Health informatics — Service architecture — Part 1: Enterprise viewpoint*

ISO 12967-2:2019, *Health informatics — Service architecture — Part 2: Information viewpoint*

3 Terms and definitions

For the purposes of this document the following terms and definitions apply.

3.1 interface

abstraction of the behaviour of an object which consists of a subset of the possible interaction mechanisms of that object, together with the set of constraints when that interaction occurs

3.2 computational object

object as seen in a computational viewpoint representing the functional decomposition of a system showing a state and behaviour as well as interactions through interfaces with other computational objects

4 Abbreviations

EHR	Electronic Health Record
HISA	Health Informatics - Service Architecture
ODP	Open Distributed Processing
UML	Unified Modelling Language

5 Methodological principles

5.1 General

This part of ISO 12967 encompasses the computational viewpoint, which is concerned in answering HISA design aspects through the functional decomposition of the system into a set of computational objects that interact at interfaces, also enabling distribution. The 'Health Informatics - Service Architecture' will thus be further specified in terms of computational objects, which manage information and provide services, and their interfaces, starting from the clusters of objects identified in ISO 12967-1 and further detailed in ISO 12967-2.

5.2 Clusters of objects

ISO 12967-1 has identified the scope, need for, and use of the HISA standard by both developers and end users. It has described the scope of the business objects from the organization's viewpoint, by summarising the related user activities and requirements through natural language. During this process the main healthcare common clusters of objects have been identified:

1) Subject of care objects

These objects handle the information necessary for supporting the users' activities identified in the "Subject of Care workflow" of ISO 12967-1.

2) Activity management objects

These objects handle the information necessary for supporting the users' activities identified in the "Activity Management workflow" of ISO 12967-1.

3) Healthcare information objects

These objects handle the information necessary for supporting the users' activities identified in the "Healthcare Information workflow" of ISO 12967-1.

4) Users and authorization objects

These objects handle the information necessary for supporting the users' activities related to the management of users and authorizations, as identified in ISO 12967-1.

5) Resources objects

These objects handle the information necessary for supporting the users' activities related to the management of resources, as identified in ISO 12967-1.

6) Classification objects

These objects handle the information necessary for supporting the users' activities related to the management of classifications, coding criteria and dictionaries, as identified in ISO 12967-1.

7) Messaging objects

These objects handle the information necessary for supporting the structuring of data and the communications with other systems through messaging mechanisms, as identified in ISO 12967-1

ISO 12967-2 has formalized the conceptual model of the information being manipulated by the information services, derived from the textual descriptions contained in ISO 12967-1. For each of the clusters of objects, an information model composed of information objects has been identified in ISO 12967-2.

This part of ISO 12967 defines the computational model, composed of computational objects, capable of meeting the requirements described in ISO 12967-1. It is necessary here to identify its relationship to the information model, and the interfaces or access mechanisms it provides to access the information handled by the system, which may also be referred to as 'methods' but more appropriately they are in the following referred to as 'information services'.

The individual information services provided by the computational objects are described illustrating how they allow actual access to the information handled by the system (identifying the interfaces, the constraints, as well as which information of the underlying overall information model is accessed), and eventual parallel actions to be taken.

5.3 Computational language

This part of ISO 12967 is directly concerned with the distribution of processing but not with the interaction mechanisms that enable distribution to occur. The computational specification decomposes the system into objects performing individual functions and interacting at well-defined interfaces.

The heart of the computational language is the computational object model, which constrains the computational specification by defining:

- The form of interface that an object can have;
- the way the interfaces can be bound and the forms of interaction which can take place at them;
- actions an object can perform, in particular the creation of new objects and interfaces.

5.4 The computational objects and interfaces

The computational objects provide the interfaces through which it is possible to access and manipulate the information managed by the information objects described in the information viewpoint. Each cluster itself can be seen as a computational object, providing several interfaces that comprise all interfaces of the information objects belonging to such cluster. The computational objects are defined at the level of the HISA object.