

### SLOVENSKI STANDARD SIST EN ISO 21298:2017

01-julij-2017

Zdravstvena informatika - Funkcionalne in strukturne vloge (ISO 21298:2017, popravljena različica 2017-04)

Health informatics - Functional and structural roles (ISO 21298:2017, Corrected version 2017-04)

Medizinische Informatik - Funktionelle und strukturelle Rollen (ISO 21298:2017, korrigierte Fassung 2017-04)

Informatique de santé - Rôles fonctionnels et structurels (ISO 21298:2017, Version corrigée 2017-04)

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ICS:

35.240.80 Uporabniške rešitve IT v

zdravstveni tehniki

IT applications in health care

technology

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM **EN ISO 21298** 

February 2017

ICS 35.240.80

#### **English Version**

### Health informatics - Functional and structural roles (ISO 21298:2017, Corrected version 2017-04)

Informatique de santé - Rôles fonctionnels et structurels (ISO 21298:2017, Version corrigée 2017-04)

Medizinische Informatik - Funktionelle und strukturelle Rollen (ISO 21298:2017, korrigierte Fassung 2017-04)

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EN ISO 21298:2017 (E)

#### **European foreword**

This document (EN ISO 21298:2017) 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of an identical text or by endorsement, at the latest by August 2017, and conflicting national standards shall be withdrawn at the latest by August 2017.

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

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### iTeh STAN Endorsement notice VIEW

The text of ISO 21298:2017, Corrected version 2017-04 has been approved by CEN as EN ISO 21298:2017 without any modification.

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## INTERNATIONAL STANDARD

ISO 21298

First edition 2017-02 Corrected version 2017-04

### **Health informatics — Functional and structural roles**

Informatique de santé — Rôles fonctionnels et structurels

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#### ISO 21298:2017(E)

#### **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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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 <a href="https://www.iso.org/patents">www.iso.org/patents</a>).

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: <a href="www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

This first edition of ISO 21298 cancels and replaces ISO/TS 21298:2008, which has been technically revised.

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

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replacement of Figure 2.

#### Introduction

This document contains a specification for encoding information related to roles for health professionals and consumers. At least five areas have been identified where a model for encoding role information is needed.

- a) **Privilege management and access control**: role-based access control is not possible without an effective means of recording role information for healthcare actors.
- b) **Directory services**: structural roles are usefully recorded within directories of healthcare providers (see for example, ISO 21091).
- c) **Audit trails**: functional roles are usefully recorded within audit trails for health information applications.
- d) **Public key infrastructure (PKI)**: The ISO 17090 series allows for the encoding of healthcare roles in certificate extensions, but no structured vocabulary for such roles is specified. This document identifies such a coded vocabulary.
- e) **Purpose of use**: A role specification determines for what purposes healthcare information can be used. Purposes of use are tied to specific roles in many cases (see for example, ISO 21091).

In addition to these security-related applications, there are several other possible applications of this standard, such as follows.

- **Clinical care provision**: finding and identifying the right professional for a health service.
- Support of care: billing of healthcare services.
- **Communication management**: directing healthcare-related messages by means of a specific role.
- **Health service management and quality assurance**: defining the purpose of use for specific data.

This document is complementary to other relevant standards that also describe and define roles for the purpose of access control. It extends the model through the separation of role and policy. This separation allows for a richer and more flexible capability to instantiate business rules across multiple domains and jurisdictions. Backward compatibility with ANSI International Committee for Information Technology Standards (INCITS) and HL7 RBAC (Role-Based Access Control) is provided through simplification by combining policy and role into a single construct.

The role concepts defined in this document are referenced and reused in many international standards created, for example, by ISO, CEN, HL7 International. Examples are ISO 22600, Reference [9], Reference [10] and Reference [11].

The European Commission and the EU Parliament have established a Professional Qualifications Directive (2005/36/EC) defining medical specialties (see <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02005L0036-20140117&from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02005L0036-20140117&from=EN</a>).

 $\underline{\text{Annex A}}$  provides ISOCO-08 sample mapping while  $\underline{\text{Annex B}}$  provides sample certificate profile for regulated healthcare professionals.

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#### **Health informatics** — Functional and structural roles

#### 1 Scope

This document defines a model for expressing functional and structural roles and populates it with a basic set of roles for international use in health applications. Roles are generally assigned to entities that are actors. This will focus on roles of persons (e.g. the roles of health professionals) and their roles in the context of the provision of care (e.g. subject of care).

Roles can be structural (e.g. licensed general practitioner, non-licensed transcriptionist, etc.) or functional (e.g. a provider who is a member of a therapeutic team, an attending physician, prescriber, etc.). Structural roles are relatively static, often lasting for many years. They deal with relationships between entities expressed at a level of complex concepts. Functional roles are bound to the realization of actions and are highly dynamic. They are normally expressed at a decomposed level of fine-grained concepts.

Roles addressed in this document are not restricted to privilege management purposes, though privilege management and access control is one of the applications of this document. This document does not address specifications related to permissions. This document treats the role and the permission as separate constructs. Further details regarding the relationship with permissions, policy, and access control are provided in ISO 22600.

### 2 Normative references tandards.itch.ai)

There are no normative references in this document.

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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 <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>
- ISO Online browsing platform: available at <a href="http://www.iso.org/obp">http://www.iso.org/obp</a>

#### 3.1

#### access control

means of ensuring that the resources of a data processing system can be accessed only by authorized entities in authorized ways

[SOURCE: ISO/IEC 2382-8:2015, 2126294]

#### 3.2

#### attribute certificate authority

#### AA

authority which assigns privileges by issuing attribute certificates (3.3)

[SOURCE: ISO/IEC 9594-8:2014, 3.5.2, modified]