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Health informatics — Functional and structural roles

Informatique de santé — Rôles fonctionnels et structurels

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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.

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*.

This corrected version incorporates the following correction:

— 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 http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02005L0036-20140117&from=EN).

Annex A provides ISOCO-08 sample mapping while Annex B provides sample certificate profile for regulated healthcare professionals.

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

There are no normative references in this document.

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
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]

3.3
attribute certificate
data structure, digitally signed by an Attribute Authority, that binds some attribute values with *identification* (3.12) about its holder

[SOURCE: ISO/IEC 9594-8:2014, 3.5.1]

3.4
authorization
granting of privileges, which includes the granting of privileges to access data and functions

Note 1 to entry: Derived from ISO 7498-2: the granting of rights, which includes the granting of access based on access rights.

[SOURCE: ISO 22600-1:2014, 3.6]

3.5
certification authority
CA
certificate issuer; an authority trusted by one or more relying parties to create, assign and manage certificates

Note 1 to entry: Optionally, the certification authority can create the relying parties' keys [ISO 9594-8]. The CA issues certificates by signing certificate data with its private signing key.

Note 2 to entry: Authority in the CA term does not imply any government authorization, only that it is trusted. Certificate issuer can be a better term but CA is used very broadly.

[SOURCE: ISO 22600-1:2014, 3.8]

3.6
delegation
conveyance of privilege from one *entity* (3.8) that holds such privilege, to another entity

[SOURCE: ISO 22600-1:2014, 3.10]

3.7
delegation path
ordered sequence of certificates which, together with authentication of a *privilege asserter's* (3.19) identity, can be processed to verify the authenticity of a privilege asserter's privilege

[SOURCE: ISO 22600-2:2014, 3.15]

3.8
entity
any concrete or abstract thing of interest

Note 1 to entry: While in general, the word entity can be used to refer to anything, in the context of modelling it is reserved to refer to things in the universe of discourse being modelled.

3.9
functional role
role (3.21) which is bound to an act

Note 1 to entry: Functional roles can be assigned to be performed during an act.

Note 2 to entry: Functional roles have been specified in this document.

Note 3 to entry: Functional roles correspond to the ISO/HL7 21731 RIM participation.

Note 4 to entry: See also *structural role* (3.26).

3.10
healthcare organization
officially registered organization that has a main activity related to healthcare services or health promotion

EXAMPLE Hospitals, Internet healthcare website providers, and healthcare research institutions.

Note 1 to entry: The organization is recognized to be legally liable for its activities but need not be registered for its specific *role* (3.21) in health.

[SOURCE: ISO 17090-1:2013, 3.1.4]

3.11
healthcare professional
healthcare personnel having a healthcare professional entitlement recognized in a given jurisdiction

Note 1 to entry: The healthcare professional entitlement entitles a healthcare professional to provide healthcare independent of a *role* (3.21) in a *healthcare organization* (3.10).

EXAMPLE GP, medical consultant, therapist, dentist, etc.

3.12
identification
performance of tests to enable a data processing system to recognize entities

3.13
non-regulated healthcare personnel
person employed by a *healthcare organization* (3.10), but who is not a regulated health professional

EXAMPLE Massage therapist, music therapist, etc.

[SOURCE: ISO 17090-1:2013, 3.1.5, modified]

3.14
organization employee
person employed by a *healthcare organization* (3.10) or a *supporting organization* (3.27)

EXAMPLE Medical records transcriptionists, healthcare insurance claims adjudicators, and pharmaceutical order entry clerks.

3.15
policy
set of legal, political, organizational, functional and technical obligations for communication and cooperation

[SOURCE: ISO 22600-1:2014, 3.13]

3.16
policy agreement
written agreement where all involved parties commit themselves to a specified set of policies

[SOURCE: ISO 22600-1:2014, 3.14]

3.17
principal
human users and objects that need to operate under their own rights

[SOURCE: OMG Security Services Specification: 2001]

3.18
privilege
capacity assigned to an *entity* (3.8) by an authority according to the entity's attribute

Note 1 to entry: Per OASIS Extensible Access Control Markup Language (XACML) V2.0, privilege, permissions, authorization, entitlement and rights are replaced by the term 'rule'.

[SOURCE: ISO 22600-1:2014, 3.17]

3.19
privilege asserter
privilege holder using their *attribute certificate* (3.3) or public-key certificate to assert *privilege* (3.18)

[SOURCE: ISO 22600-2:2014, 3.27]

3.20
privilege verifier
entity (3.8) verifying certificates against a privilege policy

[SOURCE: ISO 22600-2:2014, 3.30]

3.21
role
set of competencies and/or performances that are associated with a task

[SOURCE: ISO 22600-2:2014, 3.33]

3.22
role assignment certificate
certificate that contains the role attribute, assigning one or more *roles* (3.21) to the certificate holder

[SOURCE: ISO 22600-2:2014, 3.34]

3.23
role certificate
certificate that assigns *privileges* (3.18) to a *role* (3.21) rather than directly to individuals

Note 1 to entry: Individuals assigned to a role, through an *attribute certificate* (3.3) or public-key certificate with a subject directory attributes extension containing that assignment, are indirectly assigned the privileges contained in the role certificate.

3.24
role specification certificate
certificate that contains the assignment of *privileges* (3.18) to a *role* (3.21)

[SOURCE: ISO 22600-2:2014, 3.35]

3.25
sponsored healthcare provider
health services provider who is not a regulated professional in the jurisdiction of his/her practice, but who is active in his/her healthcare community and sponsored by a regulated *healthcare organization* (3.10)

EXAMPLE Drug and alcohol education officer who is working with a particular ethnic group, or a healthcare aid worker in a developing country.

[SOURCE: ISO 17090-1:2013, 3.1.10]

3.26
structural role
role (3.21) specifying relations between entities in the sense of competence, often reflecting organizational or structural relations (hierarchies).

Note 1 to entry: Structural roles have been specified in this document.

Note 2 to entry: Structural roles correspond to the ISO/HL7 21731 RIM role.

Note 3 to entry: See also *functional role* (3.9).

3.27
supporting organization
officially registered organization which is providing services to a *healthcare organization* (3.10), but which is not providing healthcare services

EXAMPLE Healthcare financing bodies such as insurance institutions, suppliers of pharmaceuticals and other goods.

[SOURCE: ISO 17090-1:2013, 3.1.11]

3.28
supporting organization employee
person employed by a *supporting organization* (3.27)

4 Abbreviated terms

AA	Attribute Authority
CA	Certification Authority
GCM	Generic Component Model
HL7	Health Level 7
ILO	International Labour Organization
NIST	National Institute for Standards
PKI	Public Key Infrastructure
PMI	Privilege Management Infrastructure
RBAC	Role-Based Access Control
UML	Unified Modeling Language
XACML	eXtensible Access Control Markup Language
XML	eXtensible Markup Language

5 Modeling roles in an architectural context

5.1 Roles within the Generic Component Model

For embedding components meeting functional requirements and services needed in a system, the components of that system have to be managed in its architectural context. Therefore, requirements analysis, design, and deployment of those components have to be developed and managed based on a reference architecture following a unified process.

With the Generic Component Model (GCM), such reference architecture in conformance with essential standards for distributed, component-based, service-oriented and semantically interoperable information systems has been developed in the mid-1990s (e.g. ISO/IEC 9594-8, ISO/IEC 10746-2, and ISO/IEC 2382-8) and used in the context of several ISO TC 215 and CEN TC 251, as well as HL7 specifications. The model specifies a component-based and service-oriented architecture for any domain. While this document goes beyond security and privacy issues, functional and structural roles are also used to manage privileges and access control. In this restricted context, functional and

structural roles have been specified and modelled in ISO 22600. This document extends scope, services, and deployment of functional and structural roles, nevertheless being based on the architectural approach for semantically interoperable eHealth/pHealth (personal health) information systems[7][8].

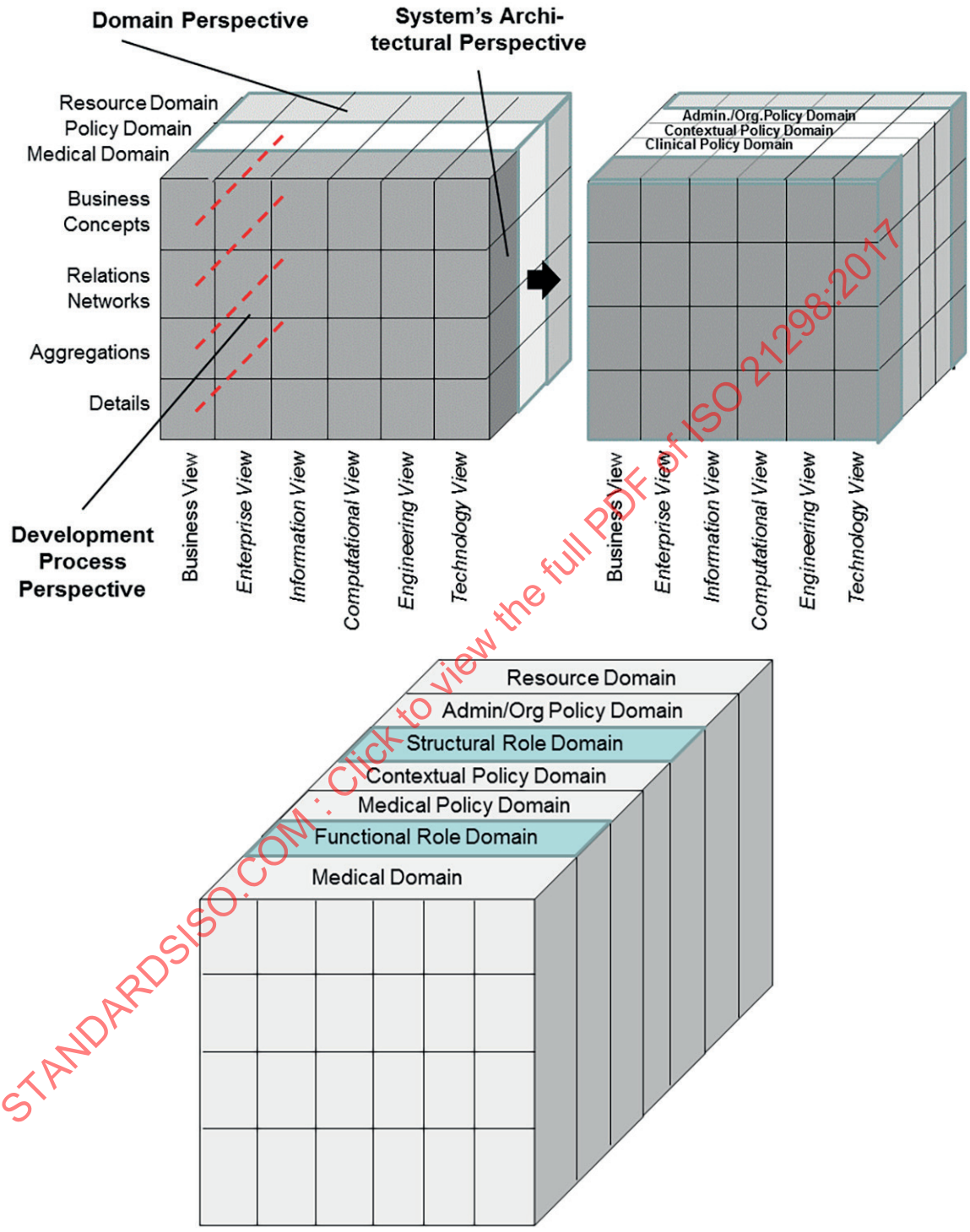
A system architecture defines the system's components, their functions and interrelationships. A system architecture is modelled in three dimensions.

— Components for meeting specific domains' requirements.

— The decomposition and, after detailing the underlying concepts, the composition of those components following corresponding aggregation concepts/rule (e.g. component collaboration, workflow, algorithm). Granularity levels are at least business concepts, relations networks, basic services/functions and basic concepts.

— The different views on that component according to ISO 10746 from the Enterprise View (business case, use case, requirements) through the Information View and the Computational View representing the platform independent logic of the system/component, as well as the Engineering View and Technology View both dealing with platform-specific implementation aspects.

Figure 1 presents the Generic Component Model providing the aforementioned reference architecture, adding a real-world business viewpoint to the ISO 10746 viewpoints.



NOTE Modelled after Reference [8] (modified).

Figure 1 — Representation of the role concepts defined in this standard using the Generic Component Model

The principles established in this document are also applicable to domains other than healthcare. In that case, that domain and its related policy domain have to be entered in Figure 1c.

The development of components, their concept representation and their aggregation are based on constraint modeling. Concepts and rules can be represented using meta-languages such as UML and UML derivatives or the XML languages set.

5.2 Roles and policy aspects

Roles group entities regarding their functions and relations in a business context. Roles should be managed according to all dimensions of a system, represented, for example, by the GCM. They may be expressed by an entity attribute.

For managing relationships between the entities, structural (organizational) and functional roles can be defined. Roles might be assigned to any entity as an actor in a communication or cooperation interrelationship (e.g. person, organization, system, device, application, component, etc.). Because entities are actors in use cases, roles have relationship to actors and therefore to actions. Functional and structural roles are associated with, and defined by, policies.

Policies are defined and applied to rule a system's behaviour. Without separating concerns, i.e. without representing specific perspectives on that system in specific GCM dimensions, policies will be implicitly embedded in the system components specification. They control a system by constraining the system's components (attributes and operations) and their relationships structurally and functionally. This is, for example, done in some simplistic Role-Based Access Control (RBAC) specifications by summarizing those constraints in permission bound to a role and expressed as permission attribute without explicitly defining and binding the driving policy to the corresponding component. In case of conflicting constraints, related access control decision policies have to be deployed. If such policies are not available, the most restrictive constraint is usually applied.

A policy may describe the legal framework including rules and regulations, the organizational and administrative framework, functionalities, claims and objectives, the entities involved, agreements, rights, duties, and penalties defined, as well as the technological solution implemented for collecting, recording, processing and communicating data in information systems.

By formally representing a system through a Reference Architecture Model (e.g. the GCM) separating concerns or perspectives in dimensions, policies can be explicitly modelled as specific GCM dimensions (see Figure 1a). So, applicable multiple policies can be automatically harmonized, thereby resolving possible conflicts (policy negotiation).

Policies can be specified and implemented in different ways, including the following:

— in a policy agreement as specified in ISO 22600-1;

— as an attribute;

— as an implicit policy as part of another component;

— as a separate policy element to be combined with another component or used directly;

— as a rule policy combined with another policy;

— as structured expressions (e.g. using XACML).

Further details regarding policy specification and the relationship to privilege management and access control are provided in ISO 22600.

Roles can be instantiated through numerous mechanisms, including directory entries, database variables and certificates, among others. Role assignment certificates may be attribute certificates or public-key certificates. Specific privileges are assigned to a role rather than to an individual through role specification certificates. The indirect assignment enables the privileges assigned to a role to be updated, without impacting the certificates that assign roles to individuals. Role specification certificates should be attribute certificates, and not public-key certificates. If role specification certificates are not used, the assignment of privileges to a role may be done through other means (e.g. may be locally configured at a privilege verifier).

For role and privilege management, the following measurements are possible:

a) any number of roles can be defined by any Attribute Authority;

b) the role itself and the members of a role can be defined and administered separately, by different Attribute Authorities;

c) a privilege, may be delegated;

d) roles may be assigned any suitable lifetime.

Further discussion regarding assignment of multiplicity of structural and functional roles is addressed in 5.5 and 5.6, respectively. Further details regarding the expression of roles through digital certificates are provided in ISO 17090. Further details regarding the representation of roles as a directory entry are provided in ISO 21091.

Functional and structural roles are associated with and defined by policies.

5.3 Roles in privilege management

Privileges can be assigned to an individual by a role assignment, or directly, following a corresponding access control model such as Discretionary Access Control (DAC). A role can be expressed in public key certificates, attribute certificates or in a directory entry as described in ISO 17090 and ISO 21091. If the role assignment certificate is a public-key certificate, the **role** attribute is contained in the **subjectDirectoryAttributes** extension. In the latter case, any additional privileges contained in the public-key certificate are privileges that are directly assigned to the certificate subject, not privileges assigned to the role. If the role assignment certificate is an attribute certificate, the **role** attribute is contained in the **attributes** component of the attribute certificate.

Thus, a privilege asserter may present a role assignment certificate to the privilege verifier demonstrating only that the privilege asserter has a particular role (e.g. “manager” or “purchaser”). The privilege verifier may know *a priori*, or may have to discover by some other means, the privileges associated with the asserted role in order to make a pass/fail authorization decision. The role specification certificate can be used for this purpose.

A privilege verifier should have an understanding of the privileges specified for the role. The assignment of those privileges to the role may be done within the Privilege Management Infrastructure (PMI) in a role specification certificate or outside the PMI (e.g. locally configured). If the role privileges are asserted in a role specification certificate, mechanisms for linking that certificate with the relevant role assignment certificate for the privilege asserter are provided in this document. A role specification certificate cannot be delegated to any other entity. The issuer of the role assignment certificate may be independent of the issuer of the role specification certificate and these may be administered (expired, revoked, and so on) entirely separately. The same certificate (attribute certificate or public-key certificate) can be a role assignment certificate, as well as contain assignment of other privileges directly to the same individual. However, a role specification certificate should be a separate certificate.

NOTE The use of roles within an authorization framework can increase the complexity of path processing because such functionality essentially defines another delegation path which must be followed. The delegation path for the role assignment certificate can involve different AAs and can be independent of the AA that issued the role specification certificate (see, for example, ISO 22600-2).

5.4 Relations of this standard to related privilege management specifications

The role concepts defined in this document are referenced and reused in many International Standards created, for example, by ISO, CEN, HL7 International, dedicated to privilege management solutions. Examples are ISO 22600, Reference [9] and Reference [10].

Starting point for privilege management solutions is frequently a role-based access control (RBAC) as defined at the US National Institute for Standards (NIST). Considering functional roles in addition to the commonly used structural roles, this RBAC can be refined as specified in Reference [10]. An intermediate

solution for flexible and scalable automated security and privacy management, Reference [10] has been standardized in 2013 by HL7 International. A sophisticated solution is specified in ISO 22600. The latter solution defines the rules required for assuring security and privacy as ontology-based, explicit policies. Those policies flexibly consider contextual and environmental conditions, as well as individual preferences at any level of granularity, thereby supporting comprehensive interoperability. The specifications mentioned here can be accessed at HL7 International on www.hl7.org.

5.5 Structural roles

5.5.1 General

In general, two types of roles can be distinguished: structural roles and functional roles. Structural roles reflect the structural/organizational aspects of relationships between entities (e.g. person-person or person-organization relationships, as happening in employment context, organizational hierarchies, responsibilities, etc.). They enable certain services within the generic structure-function relationship. Many structural roles may be assigned to a single entity reflecting the same entity's relationship to several other entities and/or different context constraints (e.g. structural roles of a person as head physician, director of a healthcare establishment, specialized ophthalmologist, etc.).

Where structural roles reflect human or organizational categories, the structural roles may represent prerequisites, skills, or competencies of entities associated with the roles as identified or guaranteed by the organizations which scope these roles to interact within their particular functional role. Concepts and functions bound to a structural role are depending on the underlying policy. Therefore, structural roles differ from policy domain to policy domain within and across organizational boundaries, and especially between different jurisdictions and countries.

Structural roles persist with the persistence of the relationship between those entities and the related policies despite whether the assigned responsibilities and functions are performed or not.

As structural roles comprise rather complex business processes, structural roles usually relate to higher levels of complexity in the Generic Component Model (see Figure 1).

5.5.2 Structural roles of healthcare professions from the International Labour Organization for trans-jurisdiction mapping

It is clear that each jurisdiction operates under its own classification of regulated and non-regulated structural roles. These roles can be mapped into a group of structural roles.

One group of structural roles useful for mapping trans-jurisdiction authorizations and access rights is the International Standard Classification of Occupations 2008 (ISCO-08), an occupational classification that is a tool for organizing all jobs in an establishment, an industry or a country into a clearly defined set of groups according to the tasks and duties undertaken in the job. In order to enable international interoperability, the following structural roles shall be used where more specific structural roles known to the communicating parties are unavailable. When referencing this vocabulary, the vocabulary identification for this list of coded values shall be referenced by the following OID:

Structural Role vocabulary identification: iso (1) standard (0) functional and structural roles (21298) structural role vocabulary (1)

This structural role vocabulary is reflected in the CodedData of the hcRole attribute as described in ISO 17090. An example is provided in Annex A to further clarify this usage.

This structural role vocabulary may be used for international interoperability for the coding system indicated in the HCProfessional object class, HCProfession attribute as described by ISO 21091.

This structural role vocabulary may be used for recording the internationally recognized role of the individual involved in health related transactions in associated audit logs.

This vocabulary is freely available from the International Labour Organization (ILO) and is therefore not replicated in this document. Annex A provides an example of possible mappings for several national regulated healthcare professions.

When a jurisdiction or domain uses this document, it will need to map its healthcare specialties to the internationally recognized structured vocabulary identified to assure compatibility. Policy mapping shall be used to negotiate the specifics of these roles between jurisdictions. If there are any interpretation differences between two parties entering into an exchange, then these differences should be reconciled through policy agreement (see ISO 22600-1 as an example of a policy model).

This vocabulary shall be used to specify the structural role associated with the following Healthcare Person regulatory status classification (Table 1):

> Regulatory status vocabulary identification: iso (1) standard (0) Healthcare Person regulatory status (21298) regulatory status (2) for roles defined in this standard.

Table 1 — Vocabulary for specifying structural roles associated with healthcare person regulatory status

Reg_status_id	Reg_status_name	Description
01	healthcare professional	Healthcare personnel having a healthcare professional entitlement recognized in a given jurisdiction NOTE The healthcare professional entitlement entitles a healthcare professional to provide healthcare independent of a role in a healthcare organization. EXAMPLES GP, medical consultant, therapist, dentist, nurse, radiographer, etc. (EN 13940)
02	non-regulated healthcare personnel	Person employed by a healthcare organization, but who is not a regulated health professional (ISO 17090-1) EXAMPLES Receptionist or secretary who organizes appointments or a business manager who is responsible for validating a subject of care's health insurance.
03	sponsored healthcare provider (NOTE: This category is used to reflect healthcare professionals under training)	Health services provider who is not a regulated professional in the jurisdiction of his/her practice, but who is active in his/her healthcare community and sponsored by a regulated healthcare organization (ISO 17090-1) EXAMPLES A drug and alcohol education officer who is working with a particular ethnic group or a healthcare aid worker in a developing country.
04	supporting organization employee	Person employed by a supporting organization (ISO 17090-1) EXAMPLES Medical records transcriptionists, healthcare insurance claims adjudicators and pharmaceutical order entry clerks.

5.5.3 Healthcare specialties

Structural roles may be classified by healthcare specialty. Healthcare specialties may be associated with medical doctors, nursing, other healthcare professions, and supporting roles.

It is clear that each jurisdiction operates under its own classification of healthcare specialties. The informative value set below can be used to map these specialties for trans-jurisdiction semantic interoperability. A jurisdiction may map to the node of the SNOMED-CT tree that most accurately describes the specialty. Where there is not an exact match, then the mapping should be applied to the value that most closely matches the specialty of the jurisdiction.

The following healthcare specialties value set may be used for such sub-classification to enable international interoperability using the OID structure:

Healthcare specialty value set identification: iso (1) standard (0) healthcare specialty value set functional and structural roles (21298) healthcare specialty (3).

Value Set Name: Healthcare Specialties (ISO 21298)

Value Set OID: 1.0.21298.3

Value Set Description: Healthcare specialty classification supporting structural roles.

Value Set Type: Intensional (code values extracted using a rule)

Intensional Rule for Value set: Value set includes all concepts that are children of the nodes in the SNOMED-CT tree of concepts exemplified in Table 2.

Table 2 — Intensional Value set root nodes for specifying structural roles associated with healthcare specialities

Concept code	Concept name	Code system
394658006	Clinical specialty (qualifier value)	SNOMED-CT
394733009	Healthcare specialty (qualifier value)	SNOMED-CT

When a jurisdiction or domain uses this document, it will need to map its healthcare specialties to the internationally recognized structured vocabulary identified to assure compatibility. Policy mapping shall be used to negotiate the specifics of these specialties between jurisdictions. If there are any interpretation differences between two parties entering into an exchange, then these differences should be reconciled through policy agreement (see ISO 22600-1 as an example of a policy model).

5.6 Functional roles

Functional roles are bound to the realization/performance of actions performed by an entity. Regarding the healthcare business process, functional roles can be defined in relation to the care or administrative process. One entity may perform as a single functional role in a single act only. In a security and privacy context, these functional roles may be bound to policies representing different levels of authorizations and access rights. Because the functional role is bound to the action, once the action has been completed, the corresponding relationship between the entity and the functional role associated with the action ends.

The assignment of a structural role is an activity performed by two interacting entities playing action-bound functional roles (see 6.2.).

As functional roles comprise rather business functions, services or simply transactions (basic business concepts), functional roles relate to lower levels of complexity in the Generic Component Model (Figure 1).

Further details regarding the role engineering process and related policies can be found in ISO 22600.

One set of functional roles useful for modelling authorizations and access rights is the following list which shall be used for international interoperability where more specific functional roles are unavailable (Table 3):

Functional roles coded values vocabulary Identification: iso (1) standard (0) functional and structural roles (21298) functional role vocabulary (4)

Table 3 — Vocabulary for specifying high-level functional roles

role_ identifier	role_name	Description
01	Subject of care	Recipient of care services, e.g. patient
02	Subject of care proxy	e.g. parent, guardian, carer, or other legal representative NOTE Some jurisdictions may use different terms to describe this role (e.g. Subject of care proxy).
03	Personal healthcare professional	Healthcare professional with the closest relationship to the subject of care, often the subject of care's GP
04	Privileged healthcare professional	Healthcare professional nominated by the subject of care OR Nominated by the healthcare facility of care (if there is a nomination by regulation, practice, etc. such as an emergency override)
05	Directly involved healthcare professional	Healthcare professional involved in providing direct care to the subject of care
06	Indirectly involved healthcare professional	Healthcare professional indirectly involved in caring the subject of care (teaching, research, etc.)
07	Supporting healthcare party	Party supporting service provision to the subject of care

This identifies a high-level list of functional roles to enable interoperable exchanges across jurisdictional or domain boundaries. This can be applied to manage the creation, access, processing, and communication of health information. More granular functional roles may be asserted within a domain or jurisdiction or may be agreed upon for communications between such domains or jurisdictions.

Additionally, functional roles can be grouped according to the relation to the information created, recorded, entered, processed, stored, and communicated:

— composer;

— committer;

— certifier;

— signer;

— authorizer;

— subject of information;

— information provider.

Examples for low-level functional roles (aggregations or even details in the GCM) are

— prescriber,

— observer,

— diagnostician, and

— therapist.

These may be aggregated in relation to a process (admission, care of a certain subject, etc.). Examples for functional roles of healthcare professionals are

— caring doctor (responsible doctor),

— member of diagnostic team,

— member of therapeutic team,

— consulting doctor,

— admitting doctor,

— family doctor, and

— functional specific nurse.

6 Formally modelling roles

6.1 Roles within the Generic Component Model

In the context of an entity to entity interrelationship mediated by a common act, roles are used to qualify the association between those entities, therefore established as association classes. For harmonization with the HL7's modeling approach where association classes could not be expressed (before moving towards UML after introducing the Model Interchange Framework MIF), roles have been introduced as HL7 RIM classes, qualifying the Entity-Act association through Functional Roles at the Act side and Structural Roles at the Entity side.

Structural roles correspond to the ISO/HL7 21731 RIM Role_Class, while the functional roles correspond to the ISO/HL7 21731 Participation_Class. The relationship between entities mediated by structural roles has been expressed at the ISO/HL7 21731 RIM Role_Relationship_Class. Security and privacy related specifications provided by HL7 International such as Reference [9], Reference [10] or Reference [11] refer to the definitions provided in this document.

The aforementioned Generic Component Model specifies a component-based and service-oriented architecture for any domain. Within that domain, the component model can be appropriately applied by decomposing it from Business Concepts level over Relations Network, Basic Services/Functions down to Basic Concepts. Thus, a business process is refined considering the workflows and resulting activities and functions up to the transactions performed. Dedicating roles to the different business process levels is called Role Engineering (Figure 1). Starting with this computation-independent model of real systems, the different views of open distributed systems are considered according to ISO 10746. Further details of the modelling approach and policy-driven role-based access control can be found in ISO 22600.

6.2 Developing the role model

6.2.1 Relationships and transformation

Expressing this in principle using UML, the many-to-many relationships between entities and acts can be transformed according to Figure 2 by qualifying them through action-specific structural and functional roles.

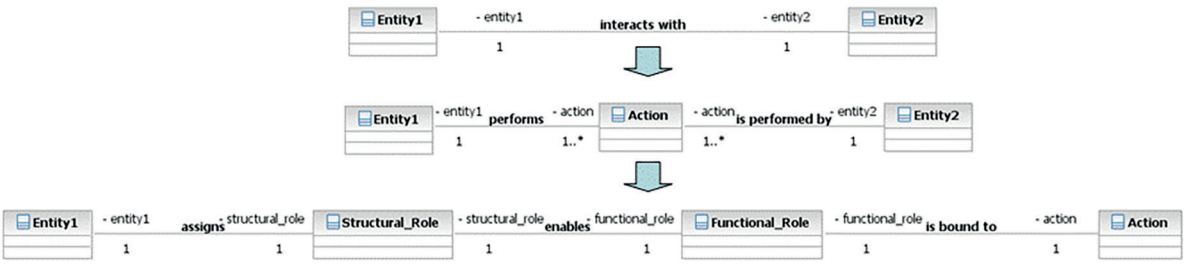


Figure 2 — Development of the role model

6.2.2 Assignment of structural roles

A relationship between two (or more) entities may be the result of a contractual agreement act between the entities playing specific functional roles (see Figure 3). Such a contract could define the structural role as being, for instance, a head physician. Another example would be an Entity-Entity relationship for education whereby a special qualification is granted, as well as a certification act resulting in a certificate certifying this qualification as a structural role.

This structural role constrains another Entity-Entity relationship influencing the functional role played by the entities involved in an activity. Structural roles are established as an act between entities according to specific act-related functional roles. This is depicted in Figure 3, which in principle describes the assignment process and the deployment process of structural roles.

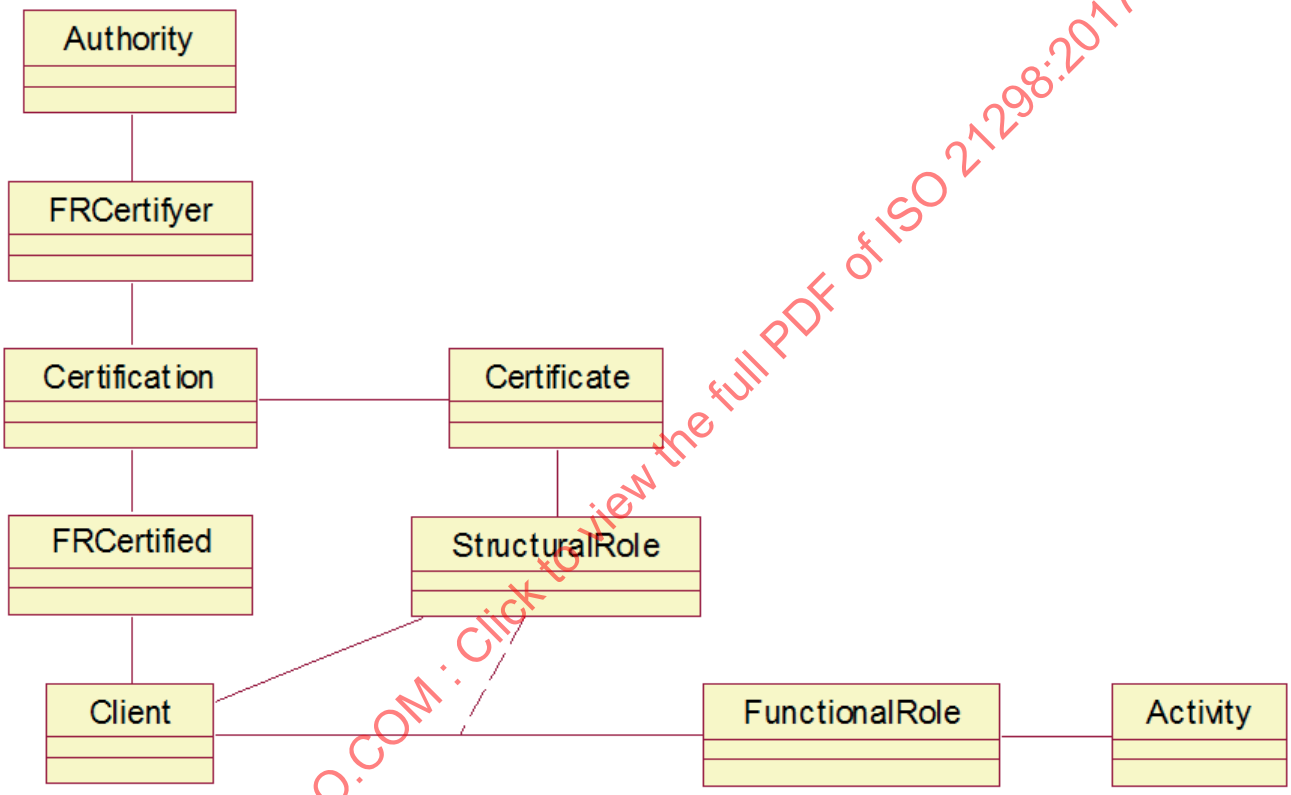


Figure 3 — Establishment of a structural role within an act according to specific functional roles

Considering both structural roles and functional roles in the same context, structural roles provide the prerequisites/competencies for entities to perform interactions (an act) within their specific functional roles. Qualifications, skills, etc. are influencing both the assignment of the structural roles and the performance of activities according to their functional roles.

6.2.3 Generic role specification

Figure 4 in principle describes a role using XML.

```
<role>
      <role_identifier/>
      <role-name/>
      <role-authority>
            <authority_identifier/>
            <authority_name/>
      </role-authority>
      <role-description>
      …
      </role_description>
</role>
```

Figure 4 — Role specification

Table 4 describes the Role attributes.

Table 4 — Role attributes

Attribute	Type	Remarks
role_identifier	SET <II>	Set of InstanceIndentifier
role_name	CS	CodedSimpleValue
authority_identifier_ID	OID	ISO ObjectIdentifier
authority_identifier_name	ST	String
role_description	CD	ConceptDescription

As shown in Figure 4, role_description provides a typed concept description, e.g. representing typed rules (policies), thereby enabling flexibility and extensibility by preserving interoperability. As policies describe any legal, social, ethical, functional, and technical implication of a system's and its components' security, privacy and safety, policies are used to describe the related dimensions in the Generic Component Model, i.e. constraints on considered components, their functions and interrelations. In that context, the medical domain of, e.g. creating, storing, processing, retrieving, and communicating Electronic Health Records (EHR) has to be combined with the ethico-legal domain, fixing requirements and conditions for the operation of such an EHR system. Therefore, all classes in the interaction chain reflecting certain domains' perspectives have to be connected to corresponding policy classes ruling the former classes' behavior. ISO 22600 has introduced a policy model meeting the requirements of the Generic Component Model (Figure 5). More details about modelling and use of policies in the security, privacy, and safety context can be found in ISO 22600.

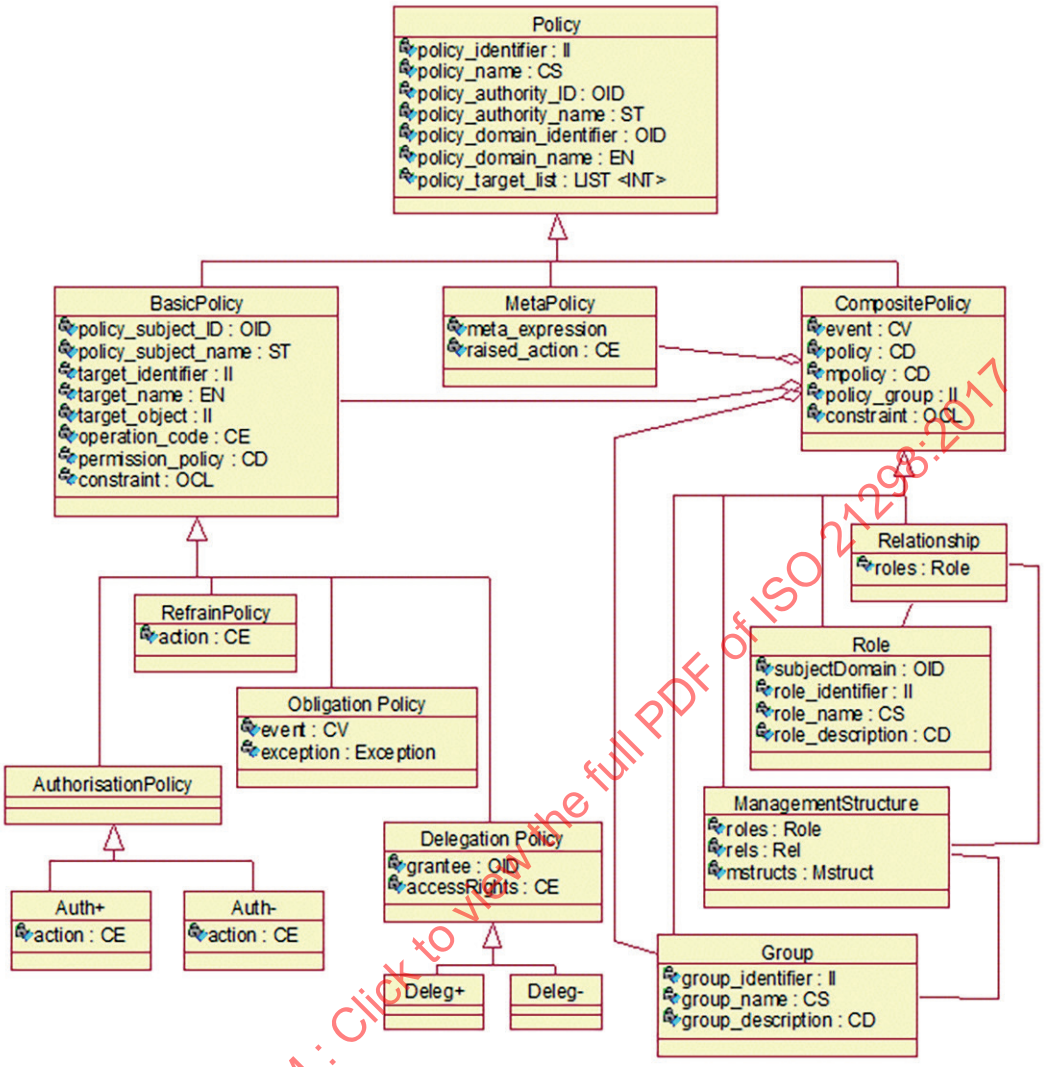


Figure 5 — Policy model (after ISO 22600)

As components representing different domain relations, granularity levels, or viewpoints of a system and its components can be aggregated, the resulting component presents structure and behaviour of the component under consideration under the constraints of the interfering component and the corresponding association. Assuming simple constraining rules, attributes of the interfering class can be expressed as additional attribute in the considered component's class. Combined with certain constraining operations, an additional attribute and related constraints for its instances can be defined, reducing the system's complexity. An example for such component composition using UML could be the aggregation of a functional role component and the related policy component resulting in a combined role_policy_class representing the policy rules by a simple permission attribute in an "extended role class" as defined in the NIST RBAC approach. Such simplification demonstrates the applicability of the models offered in this standard and the related specifications, even if the richness of the approach goes far beyond.

Simple policies widely introduced and used in the security domain are, for example, separation of duties, other administrative, organizational, or time constraints, etc. For example, authorization restrictions may be applied by policy that requires constraints related to the following:

— cardinality;

— time of day;

— static and dynamic separation of duties.

See 5.1 for an overview of the relationship between roles and policies, as well as ISO 22600 for details regarding policy and privilege management.

6.3 Relationships between structural and functional roles

In general, two types of roles can be distinguished: structural roles and functional roles. Structural roles reflect the structural aspects of relationships between entities. Structural roles describe prerequisites, skills, or competencies for acts. Functional roles reflect functional aspects of relationships between entities. Functional roles are bound to the realization/performance of acts.

Considering both structural roles and functional roles in the same context, structural roles provide the prerequisites/skills/competencies for entities to perform interactions (an act) within their specific functional roles.

In the Generic Component Model described in ISO 22600, the component specification and the aggregation rules are defined by policies through constraint modelling. This can lead to a great level of complexity due to the large number of specializations and different grouping rules.

Direct semantic interoperability can be achieved within a common policy domain or where multiple policy domains express the same policy to implement the underlying business rules. Otherwise, interoperability has to be provided through policy bridging (negotiation of policy agreements). The highest achievable level of the harmonization of the roles is determined by the highest commonality within the underlying business rules and the policies used to implement those rules. For instance, within a company or within one administrative domain (e.g. a Physicians' Chamber's area), it would be possible to implement a common policy leveraging consistent structural roles. At some lower level of complexity, such role definition could be harmonized in one or several countries. Globally, ideally we would all operate with common professions (structural roles) and policies, only functional roles as a least common denominator can be harmonized.

While ignoring explicit policy definitions and binding, the HL7 RBAC Task Force provided a role engineering example by defining functional and transactional permissions for US-related structural roles[10].

7 Use cases for the use of structural and functional roles in an interregional or international context

An organizational entity, through an authorized representative, assigns a structural role to an employee for whom organizational policy defines his/her privileges and duties. Where this is delivered as a role certificate, the role certificate would be delivered as part of an employment contract that expresses the underlying policy applicable for that role. Such a policy might also refer to other policies to which the subject of the assigned role should conform such as legislation, regulations, etc. This structural role is typically related to certain formal or informal qualifications such a medical license or other clinical credentials. A structural role certificate may be directly bound to a qualification (e.g. certified physician). Alternatively, the structural role may reflect an individual's job or position within the organization (e.g. Head of Cardiology). Based upon the assigned structural role (e.g. Head of Department), the role owner performs in the enterprise context in all business cases according to this structural role. This might cover a series of basic functions (performed under functional roles) such as hiring staff members, assigning structural roles within a policy domain, planning, preparing, controlling processes, planning activities and functions, managing infrastructure, or managing resources such as budgets. Concepts and functions bound to a structural role depend on the underlying policy. Therefore, structural roles differ from policy domain to policy domain within and across organizational boundaries, and especially between different jurisdictions and countries.

For example, in an emergency case such as a traffic accident, a person (living entity) performs according to his/her structural role [e.g. as physician (2211) or nurse (2221)] or following ethical principles or legal challenges without explicit role assignment in the functional role of Healthcare professional (05) in order to care for accident's victims. Once the action associated with the functional role has been performed, the functional role disappears.

Within a clinical workflow, a physician (2211) performs a prescription as part of his/her structural role obligations dedicated to a specific subject of care in a specific case of care. In one policy domain with a common understanding of the different transactions performed in the context of a prescription action/function, the locally defined functional role of prescriber (locally coded) can be communicated and used for semantic interoperability. Because of differences regarding the required transactions to perform a prescription in different jurisdictions, the prescription action/function can be refined towards the transactions involved such as substance administration or signing a prescription. For international semantic interoperability, the functional role would be Healthcare professional (05), and the structural role would by Medical Doctor (2211). Cross-jurisdiction recognized transactions may be agreed upon through the policy agreement process to enable interoperable prescription signing functions at a more detailed functional role level. Coarse-grained roles (e.g. structural roles) require harmonization of underlying policies, while fine-grained roles (functional roles used at the transaction level) are suitable for global communication and cooperation. For establishing a cooperative framework, we leverage the highest level of common policy.

In an RBAC model of an EHR, the member of a therapeutic team, functional role Healthcare professional (05), might include a midwife (2222) in one country, but it might exclude this particular healthcare professional in another country, classifying him or her as another functional role, Health-related professional (06). If interoperability is to be achieved, the privileges and obligations of each different healthcare professional must be examined, and a common consensus must be achieved through policy agreement between these two jurisdictions.

Annex A
(informative)

ISCO-08 sample mapping

Table A.1 provides a sample mapping of multiple national regulated professionals to ISCO-08. Blank cells indicate that there is no regulation of the corresponding ISCO-08 profession in a particular jurisdiction.

Table A.1 — Sample mapping of multiple national regulated professionals to ISCO-08

ISCO-08	SNOMED-CT	Japan	France	Finland	Ontario	Nether-lands	Australia
2211 Generalist medical practitioners (including District medical doctor – therapist, Family medical practitioner, General practitioner, Medical doctor (general), Medical officer (general), Resident medical officer specializing in general practice, Physician (general), Primary healthcare physician)	112247003	'Medical Doctor'	GPs	physician	Physicians and Surgeons	Physicians	Medical practitioner
2212 Specialist medical practitioners (including Anaesthetist, Cardiologist, Emergency medicine specialist, Gynaecologist, Obstetrician, Ophthalmologist, Paediatrician, Pathologist, Preventive medicine specialist, Psychiatrist, Radiologist, Resident medical officer in specialist training, Specialist physician (internal medicine), Surgeon, etc.)	69280009		specialists				
2261 Dentists (including Dental Practitioner, Dental Surgeon, Dentist, Endodontist, Oral and Maxillofacial Surgeon, Oral Pathologist, Orthodontist, Paedodontist, Periodontist, Prosthodontist, Stomatologist	106289002	'Dentist'	Dental surgeons Interns	dentist	Dental Surgeons	Dentists	Dentist Dental specialist
2262 Pharmacists (including Dispensing chemist, Hospital pharmacist, Industrial pharmacist, Retail pharmacist)	46255001	'Pharmacist'	Pharmacists	head dispenser, pharmacist	Pharmacists	Pharmacists	Pharmacists

Table A.1 *(continued)*

ISCO-08	SNOMED-CT	Japan	France	Finland	Ontario	Nether-lands	Australia
2131 Biologists, botanists, zoologists and related professionals (including Animal Behaviourist, Bacteriologist, Biologist, Biotechnologist, Botanist, Cell Geneticist, Marine Biologist, Microbiologist, Molecular Biologist, Molecular Geneticist, Zoologist, Pharmacologist)	31641003						
3213 Pharmaceutical technician (including Pharmaceutical technician, Pharmaceutical assistant)	159040006		Pharma-ceutical Assistant				
3212 Medical and pathology laboratory technicians (including Blood-bank technician, Cytology technician, Medical laboratory technician, Pathology technician)	159285000	'Medical Technologist' 'Clinical Laboratory Technician'		medical laboratory technologist	Medical Laboratory Technician		Medical technologist Clinical laboratory technologist
2119 Forensic science technician	159285000						
3211 Medical imaging and therapeutic equipment technicians (including Diagnostic medical radiographer, Mammographer, Medical radiation therapist, Nuclear medicine technologist, Sonographer)	386626000	'Radiological Technologist'	Radiation Technologist, Manipulateur d'electroradiologie medicale	radiographe	Medical Radiation Technologists		Medical radiation practitioner Diagnostic radiographer Nuclear medicine technologist Radiation therapist Sonographer
2221 Nursing professionals (including Clinical nurse, District nurse, Nurse anaesthetist, Nurse educator, Nurse practitioner, Professional Nurse, Public health nurse, Specialist nurse)	224569005	'General Nurse' 'Public Health Nurse'	Nurses	nurse public health nurse	Nurses	Nurses	Registered nurse
2222 Midwifery professionals (including Professional midwife)	106294002	'Midwife'	Midwifes	midwife	Midwives	Midwives	Midwife
2264 Physiotherapists (including Geriatric physical therapist, Paediatric physical therapist, Orthopaedic physical therapist, Physiotherapist)	36682004	'Physical Therapist'	Physiotherapists	physiotherapist	Physiotherapists	Physiotherapists	Physiotherapist

Table A.1 *(continued)*

ISCO-08	SNOMED-CT	Japan	France	Finland	Ontario	Nether-lands	Australia
2269 Health professionals not elsewhere classified (including Arts therapist, Dance and movement therapist, Occupational therapist, Podiatrist, Recreational therapist, etc.)	309398001	'Occupational Therapist'	Occupational Therapist Podiatrist Psychomotrician	occupational therapist protected occupational title: podiatrist, protected occupational title: chiropodist	Occupational Therapists Chiropodists		Occupational therapist Podiatrist Medical laboratory scientist Clinical scientist
2267 Optometrists and ophthalmic opticians (including Ophthalmic Optician, Optometrist, Orthoptist)	28229004	'Orthoptist'	Orthoptists Optician	optician	Optometrist Opticians		Optometrist Orthoptist
2266 Audiologists and speech therapists (including Audiologist, Language therapist, Speech therapist, Speech, Pathologist)	159026005	'Speech Therapist'	Speech and language pathologist	speech therapist	Audiologists and Speech-Language Pathologists	Speech Pathology, Audiologist	Audiologists Speech pathologist
3214 Medical and dental prosthetic technicians (including Dental technician, Denturist, Orthotic technician, Orthotist, Prosthetic technician, Prosthetist)	309428008	'Dental Technician' Prosthetics and Orthc-tic' 'Artificial limb fitter'	Audioprothesist Prothésiste dentaire/ technicien dentaire Prosthetist, Orthotist	dental technician	Dental Technologists		Audiometrist Dental prosthetist Dental technician Orthotist/ prosthetist
3221 Nursing associate professionals (including Associate professional nurse, Assistant nurse, Enrolled nurse, Practical nurse)	224576000						Enrolled nurse
3222 Midwifery associate professionals (including Assistant midwife, Traditional midwife)	309452001						Mothercraft nurse
2265 Dieticians and nutritionists (including Clinical dietician, Food service dietician, Nutritionist, Public health nutritionist, Sports nutritionist)	159033005	'National Registered 'Dietitian'	Dieticians	dietitian	Dieticians		Dietician Nutritionist

Table A.1 *(continued)*

ISCO-08	SNOMED-CT	Japan	France	Finland	Ontario	Nether-lands	Australia
2635 Social work and counselling professionals (including Addictions counsellor, Bereavement counsellor, Child and youth counsellor, Family counsellor, Marriage counsellor, Parole officer, Probation officer, Social worker, Women's welfare organizer)	106328005	'Certified Social Worker'	Assistant en service social				Social worker Welfare support worker
5321 Healthcare assistants, Nursing aide (including Birth assistant (clinic or hospital), Nursing aide (clinic or hospital), Patient care assistant, Psychiatric aid, etc.)	224577009	'Certified Care Worker'					Nursing support worker Personal care assistant Aged or disabled care worker.
5322 Home-based personal care workers (including Home care aide, Home birth assistant, Nursing aide (home), Personal care provider, etc.)	224577009						
2240 Paramedical practitioner (including Advanced care paramedic, Clinical officer (paramedical), Feldscher, Primary care paramedic, Surgical technician)	397897005						
3258 Ambulance workers (including Ambulance officer, Ambulance paramedic, Emergency medical technician, Emergency paramedic)	409971007	'Emergency Medical Technician'		protected occupational title: hospital and ambulance attendant		Ambulance Officers and Paramedics, Intensive Care Ambulance Paramedic	Intensive care ambulance paramedic Ambulance officer
2634 Psychologists (including Clinical Psychologist, Educational Psychologist, Organizational Psychologist, Psychotherapist, Sports psychologist)	59944000	'Psychiatric Social Worker'	Psychologue	psychologist	Psychologists	Healthcare Psychologists, Psychotherapists	Psychologist Clinical Psychologist

Table A.1 *(continued)*

ISCO-08	SNOMED-CT	Japan	France	Finland	Ontario	Nether-lands	Australia
2149 Engineering professionals not elsewhere classified (including Biomedical engineer, Explosive ordnance engineer, Marine salvage engineer, Materials engineer, Optical engineer, Safety engineer, etc.)	106269003	'Clinical Engineer'					Biomedical engineer
3255 Physiotherapy technicians and assistants (including Acupressure therapist, Electrotherapist, Hydrotherapist, Massage therapist, Physiotherapy technician, Physical rehabilitation technician, Shiatsu therapist, etc.)	309404006	'Masseur'		protected occupational title: trained masseur protected occupational title: physiotherapy assistant	Massage Therapists		Massage therapist Therapy aide Physiotherapist's assistant
3251 Dental assistants and therapists (including Dental assistant, Dental hygienist, Dental therapist)	26042002	'Dental Hygienist'		dental hygienist	Dental Hygienists		Dental hygienist Dental therapist
5329 Personal care workers in health services not elsewhere classified (including Dental aid, First-aid attendant, Hospital orderly, Medical imaging assistant, Pharmacy aid, Phlebotomist, Sterilization aid)	184152007						Dental assistant Dental nurse Phlebotomist Therapy aide
1120 Managing directors and chief executives (including Chief executive, Managing director, Regional manager)	265911003						Chief executive officer General manager
1342 Health service managers (including Clinical director, Community healthcare coordinator, Director of nursing, Hospital matron, Medical administrator)	224579007						Medical administrator, Nursing clinical director, Health service manager Nurse manager

Table A.1 *(continued)*

ISCO-08	SNOMED-CT	Japan	France	Finland	Ontario	Nether-lands	Australia
1343 Aged care service managers (Aged care home director, Community aged care coordinator, Nursing home director, Retirement village coordinator)	224608005						
1344 Social welfare managers (including Community centre manager, Family services manager, Housing services manager, Welfare Centre Manager, etc.)	158932008	'Care Manager'					
3254 Dispensing opticians (including Contact lens optician, Dispensing optician, etc.)	159023002						Optical dispenser
3259 Health associate professionals not elsewhere classified (including Chiropractors, Osteopath, Naprapaths)	106288005			protected occupational title: trained chiropractor protected occupational title: trained osteopath protected occupational title: naprapath	Chiropractors		Chiropractor Osteopath
3413 Religious associate professionals (including Faith healer, Lay preacher, Monk, Nun)	54503009						
2230 Traditional and complementary medicine practitioners (including Acupuncturist, Ayurvedic practitioner, Chinese herbal medicine practitioner, Homeopath, Naturopath, Unani practitioner)	225423004						Acupuncturist Chinese herbal medicine practitioner Chinese herbal dispenser Naturopath Homeopath

Table A.1 *(continued)*

ISCO-08	SNOMED-CT	Japan	France	Finland	Ontario	Nether-lands	Australia
3230 Traditional and complementary medicine associate professionals (including Bonesetter, Herbalist, Witch doctor, Village healer, Scraping and cupping therapist)	224609002						
5321 Healthcare assistants (including Birth assistant (clinic or hospital), Nursing aide (clinic or hospital), Patient care assistant, Psychiatric aid)	224577009		Aide soignant	protected occupational title: assistant nurse		Nursing Assistant	
3256 Medical assistant (including Advanced care paramedic, Clinical officer (paramedical), Feldscher, Primary care paramedic, Surgical technician)	22515006						
2263 Environmental and occupational health and hygiene professionals	307969004						
2133 Environmental protection professional	265926001						
3257 Environmental and occupational health inspectors and associates (including Health inspector , Occupational health and safety inspector Occupational health and safety inspector , Sanitarian, Sanitary inspector, Workplace health and safety)	45956004						Environmental Health Officer Occupational Health and Safety Officer
2111 Physicists and astronomers (including Astronomer, Medical Physicist, Nuclear Physicist, Physicist)	106257006			protected occupational title: hospital physicist			Medical physicist
2352 Special needs teachers (including Learning Disabilities Special Education Teacher, Learning support teacher, Remedial teacher, Teacher of gifted children, Teacher of the hearing impaired, Teacher of the sight impaired)	281569003						
2250 Veterinarians (including Animal pathologist, Veterinarian, Veterinary epidemiologist, Veterinary intern, Veterinary surgeon)	106290006						