TECHNICAL SPECIFICATION

ISO/TS 21298

First edition
2008-12-01

Health informatics — Functional and structural roles

Informatique de santé — Rôles fonctionnel et structurel

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 21298 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

This Technical Specification contains a specification for encoding information related to roles for health professionals and consumers. At least four 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 health care providers (see, for example, ISO/TS 21091).

c) **Audit trails**: functional roles are usefully recorded within audit trails for health information applications.

d) **Public key infrastructure (PKI)**: The three-part International Standard ISO 17090[9], [10] allows for the encoding of healthcare roles in certificate extensions, but no structured vocabulary for such roles is specified. This Technical Specification identifies such a coded vocabulary.

In addition to these security related applications there are several other possible applications of this Technical Specification, such as:

e) **Search and retrieval**: finding and identifying the right professional for a health service.

f) **Administration**: billing of health care services.

g) **Messaging**: directing healthcare related messages by means of a specific role.

This Technical Specification is complemetary to other relevant standards that also describe and define roles for the purpose of access control. Backward compatibility with ANSI INCITS and HL7 RBAC is provided through simplification by combining the policy and role into a single construct. This Technical Specification extends the model through the separation of the role and policy. This separation allows for a richer and more flexible capability to instantiate business rules across multiple domains and jurisdictions.

Health informatics — Functional and structural roles

1 Scope

This Technical Specification 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) or functional (e.g. a provider who is a member of a therapeutic team, an attending physician, 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 Technical Specification are not restricted to privilege management purposes, though privilege management is one of the applications of this Technical Specification as well as access control. This Technical Specification does not address specifications related to permissions. This Technical Specification treats the role and the permission as separate constructs. Further details regarding the relationship with permissions, policy and access control are provided in ISO/TS 22600-1.

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 17090-2, *Health informatics — Public key infrastructure — Part 2: Certificate profile*

ISO/HL7 21731, *Health informatics — HL7 version 3 — Reference information model — Release 1*

ISO 22600-1, *Health informatics — Privilege management and access control — Part 1: Overview and policy management*

International Labour Organization: *International Standard Classification of Occupations 2008* (ISCO-08)

3 Terms and definitions

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

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

[ISO/IEC 2382-8, definition 08.04]

**3.2
attribute authority
AA**
authority that assigns privileges by issuing attribute certificates

NOTE   Adapted from X.509.

**3.3
attribute certificate**
data structure, digitally signed by an attribute authority, which binds some attribute values with identification about its holder

NOTE   Adapted from X.509.

**3.4
authority**
entity that is responsible for the issuance of certificates

NOTE   Two types are distinguished in this Technical Specification: certification authority which issues public-key certificates and attribute authority which issues attribute certificates.

**3.5
authorization**
granting of rights, which includes the granting of access based on access rights

[ISO 7498-2, definition 3.3.10]

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

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

**3.8
entity**
any concrete or abstract thing of interest

[ISO/IEC 10746-2, definition 6.1]

NOTE   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
identification**
performance of tests to enable a data processing system to recognise entities

[ISO/IEC 2382-8, definition 08.04.12 (as **identitiy authentication**, **identity validation**)]

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

[ISO/IEC 17090-1, definition 3.1.5]

EXAMPLES   Receptionist or secretary who organizes appointments, or a business manager who is responsible for validating patient health insurance.

NOTE   The fact that the employee is not authorized by a body independent of the employer in his professional capacity does not, of course, imply that the employee is not professional in conducting his services.

3.11
policy
set of legal, political, organizational, functional and technical obligations for communication and cooperation

3.12
policy agreement
written agreement in which all involved parties commit themselves to a specified set of policies

3.13
principal
actor able to realize specific scenarios (user, organization, system, device, application, component, object)

3.14
privilege
capacity assigned to an entity by an authority according to the entity's attribute

NOTE   Per OASIS Extensible Access Control Markup Language (XACML) V2.0, privilege, permissions, authorization, entitlement and rights are replaced by the term "rule".

3.15
regulated health professional
person who is authorized by a nationally recognized body to be qualified to perform certain health services

[ISO/IEC 17090-1, definition 3.1.8]

EXAMPLES   Physicians, registered nurses and pharmacists.

NOTE 1   The types of registering or accrediting bodies differ in different countries and for different professions. Nationally recognised bodies include local or regional governmental agencies, independent professional associations and other formally and nationally recognised organizations. They may be exclusive or non-exclusive in their territory.

NOTE 2   A nationally recognized body in this definition does not imply one nationally controlled system of professional registration but, in order to facilitate international communication, it would be preferable for one nationwide directory of recognised health professional registration bodies to exist.

3.16
role
set of competences and/or performances that are associated with a task

3.17
role assignment certificate
certificate that contains the role attribute, assigning one or more roles to the certificate holder

3.18
role certificate
certificate that assigns privileges to a role rather than directly to individuals

NOTE   Individuals assigned to that role, through an attribute certificate or public-key certificate with a subject directory attributes extension containing that assignment, are indirectly assigned the privileges contained in the role certificate.

3.19
role specification certificate
certificate that contains the assignment of privileges to a role

4   Abbreviations

AA   Attribute Authority

XML   eXtensible Markup Language

ILO   International Labour Organization

PKI   Public Key Infrastructure

PMI   Privilege Management Infrastructure

UML   Unified Modelling Language

5   Modelling 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 shall be developed and managed based on a reference architecture following a unified process.

With the generic component model, 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-nineties (see, e.g. References [1], [2], [3]) and used in the context of several ISO/TC 215 and CEN/TC 251 specifications. The model specifies a component-based and service oriented architecture for any domain. While this Technical Specification 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/TS 22600-2. This Technical Specification 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.

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 10746-2[8] 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.
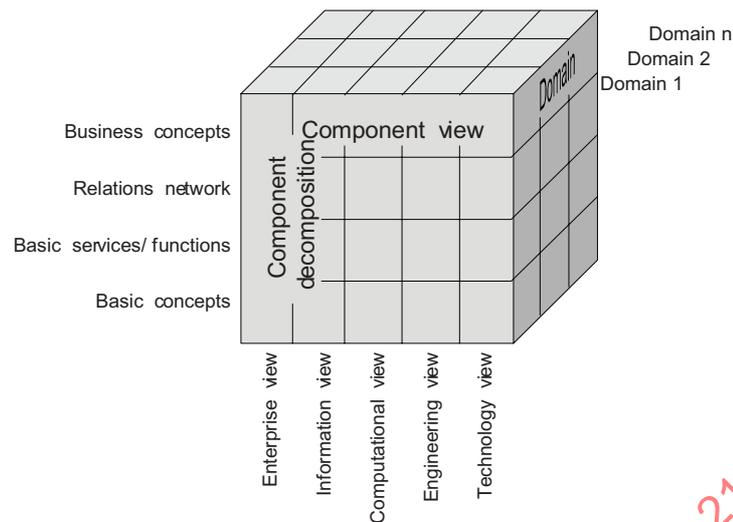
Figure 1 — Generic component model

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

5.2 Roles and policy aspects

Roles are components reflecting specific aspects of a system. They have to be managed according to all dimensions of the GCM. As policies are properties and functions in another system/component dimension, policies have to be embedded in the component specification through corresponding constraints. Interrelated classes and associations can be simplistically modelled by component attributes and operational constraints. This is done, for example, in some simplistic RBAC specifications, ignoring the policy-driven correct approach. Associating, for example, a functional role class with the related policy class defining context and other constraints to access target objects, the resulting component can summarise those constraints in a permission bound to this role and expressed as permission 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 a relationship to actors and therefore to actions. Functional and structural roles are associated with and defined by policies.

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.

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

— in a policy agreement as specified in ISO/TS 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).

A policy may be applied as a set of rules describing the design and operation of a system. Health information systems such as the Electronic Health Record (EHR), for instance, should have a patient policy, enterprise policy, policies defined by laws and regulations, and one policy per structural role as well as one policy per functional role. Further details regarding policy specification and the relationship to privilege management and access control are provided in ISO/TS 22600-1.

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 must 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).

The following are all 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 the discussion of structural and functional roles below. Further details regarding the expression of roles through digital certificates are provided in ISO 17090-2. Further details regarding the representation of roles as a directory entry are provided in ISO/TS 21091.

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

Health information systems such as the Electronic Health Record (EHR), for instance, should have a patient policy, an enterprise policy, policies defined by laws and regulations, and one policy per structural role as well as one policy per functional role. Further details regarding policy specification and the relationship to privilege management and access control are provided in ISO/TS 22600-1.

5.3   Roles in privilege management

Privileges can be assigned to an individual by a role assignment, or directly. A role can be expressed in public key certificates, attribute certificates or in a directory entry as described in ISO 17090-2 and ISO/TS 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 must have an understanding of the privileges specified for the role. The assignment of those privileges to the role may be done within the 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 Technical Specification. 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 must 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 to be followed. The delegation path for the role assignment certificate may involve different AAs and may be independent of the AA that issued the role specification certificate.

5.4   Structural roles

5.4.1   General

In general, two types of role 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 facilitate certain services within the generic structure-function relationship. Many structural roles may be assigned to a single entity reflecting the same entities 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, feasibilities or competences for actors to interact within their particular functional role. Concepts and functions bound to a structural role are dependent 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 (Figure 1).

5.4.2   Structural roles of healthcare professions from the ILO

In order to facilitate international interoperability, the following structural roles shall be used where there are more than one set of functional roles useful for authorization and access rights. The International Standard Classification of Occupations 2008 (ISCO-08) shall be used where more specific structural roles known to the communicating parties are unavailable. The vocabulary identification for this list of coded values shall be referenced by the following OID.

Vocabulary identification: ISO (1) standard (0) functional and structural roles (21298) structural role vocabulary (1).

This structural role is reflected in the CodedData of the hcRole attribute as described in ISO 17090-2. An example is provided in Annex B to further clarify this usage.

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

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

This vocabulary is freely available from the ILO and is therefore not replicated in this Technical Specification. Annex A is provided with an example of possible mappings for several national regulated healthcare professions.

Each jurisdiction or domain is responsible for mapping their local structural roles to the internationally recognised structured vocabulary identified. 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 must 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.

Vocabulary identification: ISO (1) standard (0) functional and structural roles (21298) healthcare person regulatory status (2).

Reg_status_id	Reg_status_name	description
01	regulated health professionals	person who is authorized by a nationally recognised body to be qualified to perform certain health services EXAMPLES Physicians, registered nurses and pharmacists. NOTE 1 The types of registering or accrediting bodies differ in different countries and for different professions. Nationally recognised bodies include local or regional governmental agencies, independent professional associations and other formally and nationally recognised organizations. They may be exclusive or non-exclusive in their territory. NOTE 2 A nationally recognised body in this definition does not imply one nationally controlled system of professional registration but, in order to facilitate international communication, it would be preferable for one nationwide directory of recognised health professional registration bodies to exist.
02	non-regulated health professionals	person employed by a healthcare organization but who is not a health professional EXAMPLES Receptionist or secretary who organizes appointments, or a business manager who is responsible for validating patient health insurance. NOTE The fact that the employee is not authorized by a body independent of the employer in his professional capacity does not, of course, imply that the employee is not professional in conducting his services.
03	sponsored healthcare providers NOTE This category is used to reflect health care 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 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 employees	person employed by a supporting organization EXAMPLES Medical records transcriptionists, healthcare insurance claims adjudicators and pharmaceutical order entry clerks.

5.4.3 Medical specialties

Structural roles describing medical professions may be further classified by medical specialty. Medical specialties are typically associated with medical doctors, but may also be used to qualify the structural roles associated with nursing, and other healthcare professions or supporting roles.

The following medical specialties, adopted from the World Health Organization World Alliance for Patient Safety, shall be used for such sub-classification to enable international interoperability.

Vocabulary identification: ISO (1) standard (0) functional and structural roles (21298) medical specialty vocabulary (3).

role_identifier	role_name	description
01	Anaesthesia	The medical specialty concerned with the pharmacological, physiological, and clinical basis of anaesthesia (pharmacologic depression of nerve function or from neurologic dysfunction) and related fields, including resuscitation, intensive respiratory care, and acute and chronic pain.
02	Administrative services	The organizational services pertaining to, or designed to deal with, the conduct or management of organizational affairs.
03	Allied health	The health profession comprised of qualified health professionals trained to assist, facilitate or complement the work of physicians, dentists, podiatrists, nurses, pharmacists and other specialists in the health care system.
04	Dietetics	The health profession concerned with the practical application of diet in the prophylaxis and treatment of disease.
05	Breast surgery	The surgical specialty concerned with the treatment of breast and associated tissue disease, injury and deformity by physical operation or manipulation.
06	Cardiothoracic surgery	The branch of medicine concerned with treatment of heart and thorax disease, injury and deformity by physical operation or manipulation.
07	Cardiology	The medical specialty concerned with the diagnosis and treatment of heart disease.
08	Care of the elderly (also referred to as geriatrics)	The branch of medicine concerned with prevention, treatment of medical problems, and care of the aged (usually 65 y of age or older).
09	Clinical immunology and allergy	The specialty concerned with the structure and function of the immune system, various phenomena of immunity, induced sensitivity and allergy.
10	Dental medicine and surgery	The specialty related to the function and diseases of the teeth, mouth and gums.
11	Dermatology	The branch of medicine concerned with the study of the skin, nails and hair, diseases of the skin, nails and hair, and the relationship of coaetaneous lesions to systemic disease.
12	Diagnostic services	The services related to the determination of the nature of a disease or injury.

role_identifier	role_name	description
13	Emergency medicine	The branch of medicine related to the diagnosis and treatment of conditions arising suddenly and unexpectedly, calling for prompt action and requiring immediate treatment.
14	Endocrinology	The science and medical specialty concerned with the internal or hormonal secretions and their physiologic and pathologic relations.
15	Gastroenterology	The medical specialty concerned with the function and disorders of the gastrointestinal tract, including stomach, intestines and associated organs.
16	General medicine	The branch of medicine involving the study and treatment of general diseases or those affecting the internal parts of the body, especially those not usually requiring surgical intervention.
17	General nursing	The branch of healthcare concerned with caring for the sick or injured in any environment.
18	General surgery	The branch of medicine concerned with treatment of disease, injury or deformity by the performance of invasive procedures, physical operation or manipulation.
19	Genetics	The branch of medicine concerned with applying the science of the means and consequences of transmission and generation of components of biologic inheritance and the genetic features and constitution of a single or set of organisms to diagnosis, prognosis, management and prevention of genetic diseases.
20	Gynaecology	The medical specialty concerned with the diseases of the female genital tract, as well as endocrinology and reproductive physiology of the female.
21	Haematology	The medical specialty concerned with the anatomy, physiology, pathology, symptomology and therapeutics related to the blood and blood-forming tissue.
22	Infectious diseases	The medical specialty concerned with the prevention and treatment of diseases caused by micro-organisms capable of being transmitted from person to person, with or without actual contact.
23	Intensive care	The specialty related to advanced and highly specialized care provided to medical or surgical subjects whose conditions are life-threatening and require comprehensive care and constant monitoring.
24	Maxillo-facial surgery	The surgical specialty concerned with the treatment of diseases of the mouth, jaw and face by the performance of physical operation or manipulation.
25	Neonatology	The paediatric specialty concerned with the systematic evaluation and treatment of the newborn (relating to the period immediately succeeding birth and continuing through the first 28 d of extra-uterine life), including premature newborns.
26	Nephrology/renal	The branch of medical science concerned with medical diseases of the kidneys.

role_identifier	role_name	description
27	Neurology	The branch of medical science concerned with the various nervous systems (central, peripheral and autonomic), plus the neuromuscular junctions and muscles, and their disorders.
28	Neurosurgery	The surgical specialty concerned with the treatment of diseases of the brain, spinal cord, spinal column, and peripheral nerves through the performance of physical operation or manipulation.
29	Obstetrics	The medical specialty concerned with the care of women during pregnancy, parturition and the puerperium.
30	Oncology	The medical and/or surgical specialty concerned with the study or science dealing with the physical, chemical and biologic properties and features of malignant neoplasms, including causation, pathogenesis and treatment.
31	Ophthalmology	The medical specialty concerned with the eye, its diseases, and refractive errors.
32	Orthopaedics	The surgical specialty concerned with the treatment of acute and chronic disorders of the musculoskeletal system, including injuries, diseases, dysfunction, and deformities (original deformities in children) in the extremities and spine.
33	Otolaryngology	The specialty concerned with diseases of the ear and larynx, including the upper respiratory tract and diseases of the head and neck, tracheobronchial tree and oesophagus.
34	Pain services	The specialty concerned with the control and regulation of pain, especially through the use of medication.
35	Palliative medicine	The specialty concerned with providing treatment to reduce the severity of and/or alleviate symptoms without curing the underlying disease.
36	Paediatrics	The medical specialty concerned with the study and treatment of children in health and disease during development from birth through adolescence.
37	Pharmacy	The branch of medical science that deals with drugs and their uses.
38	Physiotherapy (also referred to as physical therapy)	The health profession concerned with promotion of health, with prevention of physical disabilities, with evaluation and rehabilitation of persons disabled by pain, disease or injury, and with treatment by physical therapeutic measures as opposed to medical, surgical or radiologic measures.
39	Plastic surgery	The surgical specialty concerned with the restoration, construction, or reconstruction of the shape and appearance of body structures that are missing, defective, damaged or misshapen.
40	Podiatry	The health profession concerned with the diagnosis and/or medical, surgical, mechanical, physical and adjunctive treatment of the diseases, injuries, and defects of the human foot.

role_identifier	role_name	description
41	Primary care	The medical specialty concerned with providing and managing basic routine health care.
42	Psychiatry	The medical specialty concerned with the diagnosis and treatment of mental disorders.
43	Public health	The health profession concerned with protecting, promoting, restoring and improving the health of a community through disease prevention, health education, control of communicable diseases, application of sanitary measures and monitoring environmental hazards.
44	Rehabilitation	The medical specialty concerned with the diagnosis and treatment of patients with impairments or disabilities, focusing primarily on maximal restoration of physical, psychological, social and vocational functions and the alleviation of pain.
45	Radiation oncology	The medical specialty concerned with the use of ionizing radiation in the treatment of neoplasms.
46	Rheumatology	The medical specialty concerned with the study, diagnosis and treatment of various conditions with pain or other symptoms of articular origin or related to other elements of the musculoskeletal system.
47	Speech and language therapy	The health profession concerned with functional and organic speech, language, oral and pharyngeal sensorimotor, cognitive or communicative defects and disorders.
48	Thoracic/respiratory medicine	The medical specialty concerned with the diagnosis and treatment of conditions affecting the upper part of the trunk between the neck and the abdomen containing the chief organs of the circulatory and respiratory systems.
49	Vascular surgery	The surgical specialty concerned with the diagnosis and treatment of diseases related to the circulatory system (the blood vessels in the cardiovascular and lymphatic systems collectively).
50	Urology	The medical specialty concerned with the diagnosis, and treatment of diseases of the adrenal gland and reproductive and urinary systems and adjoining structures.
51	Other specialty not elsewhere classified	

Each jurisdiction or domain is responsible for mapping their medical specialties to the internationally recognised structured vocabulary identified. 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 shall be reconciled through policy agreement (see ISO/TS 22600-1 as an example of a policy model).

5.5 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 authorization 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 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 of engineering processes and related policies can be found in ISO/TS 22600-1.

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:

Functional roles coded values vocabulary identification: ISO (1) standard (0) functional and structural roles (21298) functional role vocabulary (4).

role_identifier	role_name	description
01	Subject of care	principal data subject of the electronic health record
02	Subject of care agent	e.g. parent, guardian, carer or other legal representative
03	Personal healthcare professional	healthcare professional or professionals with the closest relationship to the patient, often the patient's GP
04	Privileged 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 over-ride)
05	Healthcare professional	party involved in providing direct care to the patient
06	Health-related professional	party indirectly involved in patient care, teaching, research, etc.
07	Administrator	any other parties supporting service provision to the patient

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;

— authorizer;

— subject of information;

— information provider.

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, therefore established as association classes. For harmonization with HL7's modelling 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 as the ISO/HL7 21731 RIM Role_Relationship_Class.

As developed in the mid-nineties (e.g. References [1], [2], [3]) and introduced in ISO/TS 22600-1, a future-proof health information system architecture has been defined using the generic component model (Reference [4]). The 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 2). Starting with this computation-independent model of real systems, the different views of open distributed systems are considered according to ISO 10746-2[8]. Further details of the modelling approach and policy driven role based access control can be found in ISO/TS 22600-1.

6.2 Developing the role model

6.2.1 Relationships and transformation

Expressing this in UML, the many-to-many relationships between entities and acts can be transformed according to Figure 2.
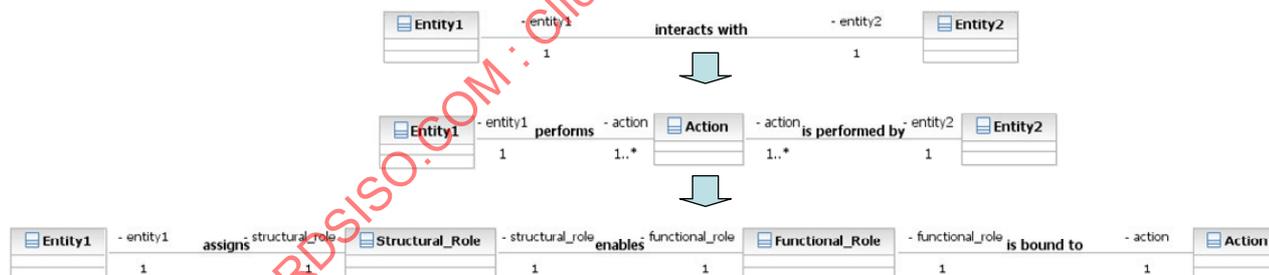

Figure 2 — Development of the role model

6.2.2 Assignment of structural roles

A relationship between two 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 describes the assignment process and the deployment process of structural roles.
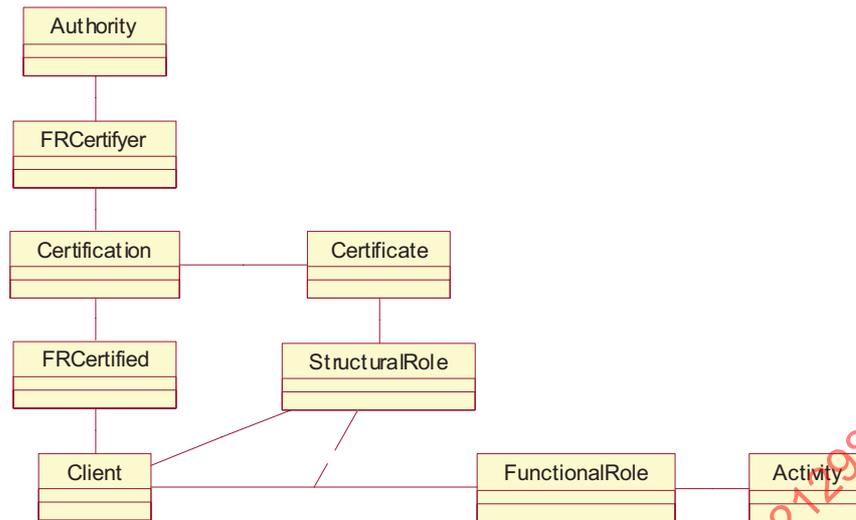
Figure 3 — Establishment of a structural role within an act according to specific functional roles

Considering both structural roles and functional roles in the same context, structural roles provide the prerequisites/competences for entities to perform interactions (an act) within their specific functional roles. Qualifications, skills, etc., influence 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 describes a role using XML.

```
<role>
        <role_name/>
        <role_ID/>
        <role_authority/>
        <authority_ID/>
        <role_description>
                …
        </role_description>
</role>
```

Figure 4 — Role specification

Table 1 — RoleClass 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 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. Therefore, the medical domain of, e.g., creating, storing, processing, retrieving and communicating Electronic Health Records (EHR) have 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' behaviour. ISO/TS 22600-1 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 the aforementioned ISO/TS 22600 specification.
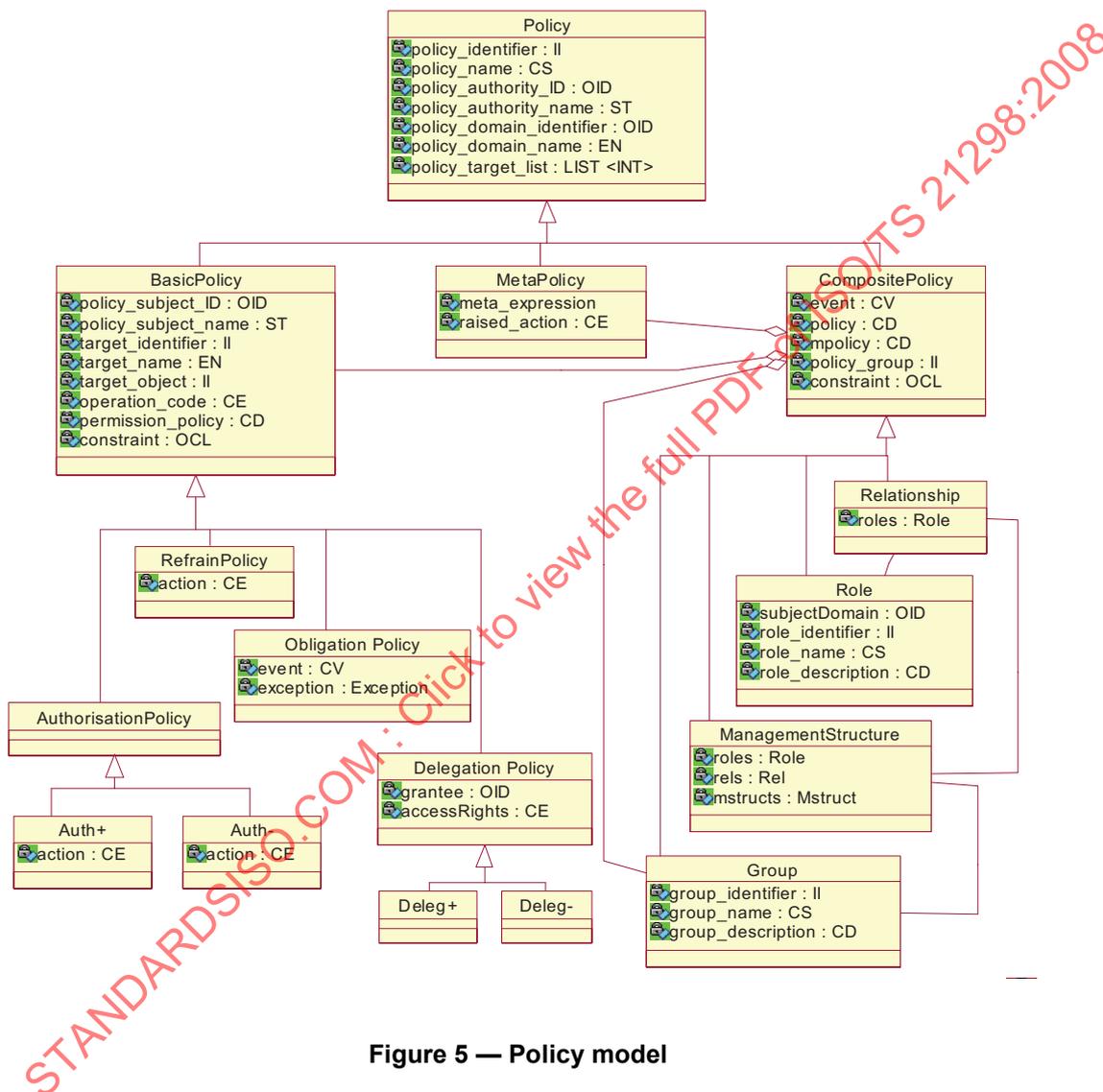

Figure 5 — Policy model

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 an 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 Technical Specification 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, e.g., separation of duties, other administrative, organizational, or time constraints, etc. For example, authorization restrictions may be applied by policy that requires constraints related to:

— cardinality;

— time of day;

— static and dynamic separation of duties.

See 5.1 for an overview of the relationship between roles and policies. See ISO/TS 22600-1 for details regarding policy and privilege management.

6.3   Relationships between structural and functional roles

In general, two types of role can be distinguished: structural roles and functional roles. Structural roles reflect the structural aspects of relationships between entities. Structural roles describe prerequisites, feasibilities or competences 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/competences for entities to perform interactions (an act) within their specific functional roles.

In the generic component model described in ISO/TS 22600-1, 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 physician's chambers' 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 (Reference [5]).

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 rights 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 must conform such as legislation, regulations, etc. This structural role is typically related to certain formal or informal qualifications such as 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 the 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) writes a prescription as part of his/her structural role obligations dedicated to a specific patient 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 recognised transactions may be agreed upon through the policy agreement process to enable interoperable prescription signing functions at a more detailed functional role level. Course-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, such as a health-related professional (06). If interoperability is to be achieved, the rights and obligations of each different healthcare professional shall be examined, and a common consensus shall be achieved through policy agreement between these two jurisdictions.

Annex A
(informative)

ISCO-08 Sample mapping

Sample mapping of multiple national regulated professionals to ISCO-08:

ISCO-08	Japan	France	Finland	Ontario	The Netherlands	Australia
2211 Generalist medical practitioners, 2212 Specialist medical practitioners	Medical doctor	GPs and specialists	Physician	Physicians and surgeons	Physicians	Medical practitioners
2241 Dentists	Dentist	Dental surgeons, interns	Dentist	Dental surgeons	Dentists	Dental practitioners
2242 Pharmacists	Pharmacist	Pharmacists	Head dispenser, pharmacist	Pharmacists	Pharmacists	Miscellaneous professionals/ pharmacists
3142 Medical laboratory technicians	Medical technologist		Medical laboratory technologist	Medical laboratory technologist		
3236 Medical equipment technicians	Radiological technologist	Radiation technologist, Manipulateur d'electroradiologie medicale	Radiographe	Medical radiation technologists		Nuclear medicine technologist, medical diagnostic radiographer, radiation therapist, Sonographer
2221 Nursing professionals	General nurse	Nurses	Nurse	Nurses	Nurses	Nursing professionals
2221 Nursing professionals	Public health nurse		Public health nurse			
2222 Midwifery professionals	Midwife	Midwives	Midwife	Midwives	Midwives	Nursing professionals, registered midwife
2244 Physio-therapists	Physical therapist	Physiotherapists	Physio-therapist	Physio-therapists	Physio-therapists	Physiotherapy
2249 Health professionals not elsewhere classified	Occupational therapist	Occupational therapist	Occupational therapist	Occupational therapists		Occupational therapy
3234 Optometrists and opticians	Orthoptist	Orthoptists				Orthoptist
2246 Audiologists and speech therapists	Speech therapist	Speech and language pathologist	Speech therapist	Audiologists and speech-language pathologists	Speech pathology, audiologist	

ISCO-08	Japan	France	Finland	Ontario	The Netherlands	Australia
7314 Medical and dental prosthetic and related technicians	Dental technician	Prothésiste dentaire/ technicien dentaire	Dental technician	Dental technologists		Dental technician, denturists
2245 Dieticians and nutritionists	National registered dietitian	Dieticians	Dietitian	Dieticians		Dietician
2636 Social work and counselling professionals	Certified social worker	Assistant en service social				Social worker
5133 Health care assistants, 5134 Home-based personal care workers	Certified care worker					Aged or disabled person carer, personal care assistant
2231 Paramedical practitioners, 2232 Emergency paramedic	Emergency medical technician		Protected occupational title: hospital and ambulance attendant		Ambulance officers and paramedics, intensive care ambulance paramedic	
2635 Psychologists	Psychiatric social worker	Psychologue	Psychologist	Psychologists	Healthcare psychologists, psycho-therapists	Psychologist, clinical psychologists
7314 Medical and dental prosthetic and related technicians	Clinical engineer					
3235 Physiotherapy technicians and assistants	Masseur		Protected occupational title: trained masseur	Massage therapists		Physiotherapist, massage therapist
3231 Dental assistants and therapists	Dental hygienist		Dental hygienist	Dental hygienists		Dental hygienist
7314 Medical and dental prosthetic and related technicians	Prosthetics and orthotic	Prosthetist, orthotist				Prosthetist, orthotist
7314 Medical and dental prosthetic and related technicians	Artificial limb fitter					
3142 Medical laboratory technicians	Clinical laboratory technician			Medical laboratory technologist		Pathology lab technicians

ISCO-08	Japan	France	Finland	Ontario	The Netherlands	Australia
1342 Health service managers, 1343 Aged care service managers, 1344 Social welfare managers	Care manager					
3213 Pharmaceutical technicians and assistants		Pharmaceutical assisstant				
2249 Health professionals not elsewhere classified		Podiatrist	Protected occupational title: podiatrist, protected occupational title: chiropodist	Chiropodists		Podiatrists
2244 Physio-therapists		Psychomotrician				
3234 Optometrists and opticians		Optician	Optician	Opticians		
7314 Medical and dental prosthetic and related technicians		Audioprothesist				
3234 Optometrists and opticians				Optometrists		Optometry
3239 Health associate professionals not elsewhere classified			Protected occupational title: trained chiropractor, protected occupational title: trained osteopath	Chiropractors		Chiropractor, osteopath
3238 Traditional and complementary medicine practitioners						Acupuncturist
3231 Dental assistants and therapists						Dental therapist
5133 Health care assistants, 3221 Nursing associate professionals, 3222 Midwifery associate professionals		Aide soignant	Protected occupational title: Assistant nurse		Nursing Assistant	

ISCO-08	Japan	France	Finland	Ontario	The Netherlands	Australia
3237 Environmental and occupational health inspectors and associates						Environmental health officer
3237 Environmental and occupational health inspectors and associates						Occupational health and safety officer
3238 Traditional and complementary medicine practitioners			Protected occupational title: trained naprapath			
3235 Physiotherapy technicians and assistants			Protected occupational title: physiotherapy assistant			
2111 Physicists and astronomers (includes medical physicist)			Protected occupational title: hospital physicist			
2352 Special needs teachers						
3212 Medical and pathology laboratory technicians, 2132 Pharma-cologists, pathologists and related professionals						Pathologies
3143 Veterinary assistants, 3214 Veterinary technicians and assistants						
3344 Medical secretaries						
3236 Medical equipment technicians						
3238 Traditional and complementary medicine practitioners						Homeopaths, traditional medicine (e.g. Chinese, Maori), naturopath, natural therapy professionals