

**A.2.4.4****concept name**

canonical expression

**term** (B.3.4.3) which uniquely designates a **concept** (B.3.2.1) within a **concept system** (B.3.2.11)

EXAMPLE 1 Machine readable: <Inflammation that <hasCause Bacteria hasLocation Lung>> (with compositional characteristics sorted alphabetically after semantic link) instead of <pulmonaryInfection that hasCause Bacteria>

EXAMPLE 2 General language: Inflammation that has cause bacteria and has location lung (with compositional characteristics sorted alphabetically after semantic link) instead of pulmonary infection that has cause bacteria.

NOTE 1 It is preferred expression to represent a **concept** (B.3.2.1) in a given terminology system

NOTE 2 It is unique within the system unambiguous

**A.2.4.5****categorial structure**minimal set of **domain constraints** (A.2.3.2) for representing **concepts systems** (B.3.2.11) in a **subject field** (B.3.1.2).**A.2.4.6****precoordinated concept representation****compositional concept representation** (A.2.4.1) within a **formal system** (A.2.5.1), with an equivalent single unique identifier

EXAMPLE Problem=Fracture that hasLocation Femur. This is an example of how a precoordinated concept is represented

NOTE The identifier (code, term etc) may be within or outside the terminology system in question.

**A.2.4.7****post-coordinated concept representation****compositional concept representation** (A.2.4.1) using more than one **concept** (B.3.2.1) from one or many **formal systems** (A.2.5.1), combined using mechanisms within or outside the formal systems

EXAMPLE Problem.Main = Fracture, Problem.Location = Femur within a template for a problem description

NOTE Combining concepts from disparate terminologies can cause problems with overlapping and/or conflicting concepts. Typically, the mechanisms for making **compositional concept representations** (A.2.4.1) are specified in an information model (e.g. as templates for a certain type of concept).

**A.5 Terminology and information models, concept systems****A.2.5.1****formal [concept representation] system**set of machine processable definitions in a **subject field** (B.3.1.2)**A.2.5.2****compositional system**system that supports the creation of **compositional concept representations** (A.2.4.1)**A.2.5.3****formal category****generic concept** (B.2.1.4) represented by a **formal definition** (A.2.4.3)

NOTE This implies that the generic concept's **extension** (B.3.2.8) can be determined algorithmically and includes extensionally defined **concepts** (B.3.2.1) and formal **intensional definitions** (B.3.3.2).

## A.6 Specified concepts

### A.2.6.1 mapping

assigning an element in one set to an element in another set through **semantic correspondence** (A.2.6.2)

NOTE It is the relation with the best semantic correspondence between an element in one set and an element in another set

### A.2.6.2 semantic correspondence

measure of similarity between two concepts

NOTE The opposite semantic distance

### A.2.6.3 instance of a concept

member of the **extension** (B.3.2.8) of a **concept** (B.3.2.1)

### A.2.6.4 focus concept representation

specified representation of the **concept** (B.3.2.1) of interest within a **formal system** (A.2.5.1)

EXAMPLE "Moderately severe inflammation caused by pneumococci located in the upper lobe of the left lung, ascertained by plain film pulmonary X-ray and sputum culture" in the context of a diagnosis with confirmatory evidence.

NOTE It including context information, enabling independent use

### A.2.6.5 generic relation

subtype relation

relation between two **concepts** (B.3.2.1) where the **intension** (B.3.2.9) of one of the concepts includes that of the other concept and at least one additional **delimiting characteristic** (B.3.2.7)  
[ISO 1087-1:2000, A.3.2.21]

NOTE All individuals in the **extension** (B.3.2.8) of the second are included in the extension of the first.

EXAMPLE A generic relation exists between the concepts 'internal organ' and 'heart', 'surgical deed' and 'appendectomy', 'inflammatory disease' and 'pericarditis'.

## A.7 Terminological systems

### A.2.7.1 classification

exhaustive set of mutually exclusive **categories** (A.2.1.4) to aggregate data at a pre-prescribed **level of specialization** (A.2.1.3) for a specific purpose

EXAMPLE ICD 10

### A.2.7.2 coding scheme

collection of rules that maps the elements in one set, the "coded set" onto the elements in a second set "the code set"

[ISO 2382-4]

NOTE The two sets are not part of the coding scheme.

**A.2.7.3****coding system**

combination of a set of **concepts** (B.3.2.1) [coded concepts], a set of code values, and at least one **coding scheme** (A.2.7.2) mapping code values to coded concepts

NOTE Coded concepts are typically represented by **terms** (A3.4.3), but can have other representation. Code values are typically numeric or alphanumeric.

**A.2.7.4****reference terminology**

set of atomic level designations structured to support representations of both simple and compositional concepts independent of human language (within machine)

NOTE 1 Reference terminology is designed to uniquely represent **concepts** (A.3.2.1)

NOTE 2 The terminology lists the concepts and specifies their structure, relationships and, if present, their systematic and **formal definitions** (A.2.4.3).

**A.2.7.5****clinical terminology**

terminology required directly or indirectly to describe health conditions and healthcare activities

NOTE 1 Health conditions include symptoms, complaints, illness, diseases, disorders etc.

NOTE 2 It is used in, for example, medical records, clinical communication, and medical science.

## Annex B (normative)

### Selected definitions from ISO 1087-1:2000

The following terms and definitions are selected from ISO 1087-1:2000. They are included here as background to the key terms and definitions in Clause 3 of this Technical Specification. The numbering in this Annex reflects the numbering in ISO 1087-1:2000, for consistency.

#### B.1 Language and reality

##### B.3.1.1

##### **object**

anything perceivable or conceivable

NOTE Objects may be material (e.g. an engine, a sheet of paper, a diamond), immaterial (e.g. conversion ratio, a project plan) or imagined (e.g. a unicorn).

##### B.3.1.2

##### **subject field**

domain

field of special knowledge

NOTE The borderlines of a subject field are defined from a purpose-related point of view.

#### B.2 Concept

##### B.3.2.1

##### **concept**

unit of knowledge created by a unique combination of **characteristics** (B.3.2.4)

NOTE Concepts are not necessarily bound to particular languages. They are, however, influenced by the social or cultural background which often leads to different categorizations.

##### B.3.2.2

##### **individual concept**

**concept** (B.3.2.1) which corresponds to only one **object** (B.3.1.1)

NOTE 1 Examples of individual concepts are 'Saturn', 'the Eiffel Tower'.

NOTE 2 Individual concepts are usually represented by **appellations** (B.3.4.2).

##### B.3.2.3

##### **general concept**

**concept** (B.3.2.1) which corresponds to two or more **objects** (B.3.1.1) which form a group by reason of common properties

NOTE Examples of general concepts are 'planet', 'tower'.

##### B.3.2.4

##### **characteristic**

abstraction of a property of an **object** (B.3.1.1) or of a set of objects

NOTE Characteristics are used for describing **concepts** (B.3.2.1).

**B.3.2.5****type of characteristics**

category of **characteristics** (B.3.2.4) which serves as the criterion of subdivision when establishing **concept systems** (B.3.2.11)

NOTE The type of characteristics colour embraces **characteristics** (B.3.2.4) being red, blue, green, etc. The type of characteristics material embraces characteristics made of wood, metal, etc.

**B.3.2.6****essential characteristic**

**characteristic** (B.3.2.4) which is indispensable to understanding a **concept** (B.3.2.1)

**B.3.2.7****delimiting characteristic**

**essential characteristic** (B.3.2.6) used for distinguishing a **concept** (B.3.2.1) from related concepts

NOTE The delimiting characteristic support for the back may be used for distinguishing the **concepts** (B.3.2.1) 'stool' and 'chair'.

**B.3.2.8****extension**

totality of **objects** (B.3.1.1) to which a **concept** (B.3.2.1) corresponds

**B.3.2.9****intension**

set of **characteristics** (B.3.2.4) which makes up the **concept** (B.3.2.1)

**B.3.2.10****concept field**

unstructured set of thematically related **concepts** (B.3.2.1)

NOTE Concept fields may be used as a starting point for establishing **concept systems** (B.3.2.11).

**B.3.2.11****concept system**

system of concepts

set of **concepts** (B.3.2.1) structured according to the relations among them

**B.3.2.12****concept diagram**

graphic representation of a **concept system** (B.3.2.11)

**B.3.2.13****superordinate concept**

broader concept

**concept** (B.3.2.1) which is either a **generic concept** (B.3.2.15) or a **comprehensive concept** (B.3.2.17)

**B.3.2.14****subordinate concept**

narrower concept

**concept** (B.3.2.1) which is either a **specific concept** (B.3.2.16) or a **partitive concept** (B.3.2.18)

**B.3.2.15****generic concept**

**concept** (B.3.2.1) in a **generic relation** (B.3.2.21) having the narrower **intension** (B.3.2.9)

**B.3.2.16****specific concept**

**concept** (B.3.2.1) in a **generic relation** (B.3.2.21) having the broader **intension** (B.3.2.9)

**B.3.2.17**

**comprehensive concept**

**concept** (B.3.2.1) in a **partitive relation** (B.3.2.22) viewed as the whole

**B.3.2.18**

**partitive concept**

**concept** (B.3.2.1) in a **partitive relation** (B.3.2.22) viewed as one of the parts making up the whole

**B.3.2.19**

**coordinate concept**

**subordinate concept** (B.3.2.14) having the same nearest **superordinate concept** (B.3.2.13) and same criterion of subdivision as some other **concept** (B.3.2.1) in a given **concept system** (B.3.2.11)

**B.3.2.20**

**hierarchical relation**

relation between two **concepts** (B.3.2.1) which may be either a **generic relation** (B.3.2.21) or a **partitive relation** (B.3.2.22)

**B.3.2.21**

**generic relation**

genus-species relation

relation between two **concepts** (B.3.2.1) where the **intension** (B.3.2.9) of one of the concepts includes that of the other concept and at least one additional **delimiting characteristic** (B.3.2.7)

NOTE A generic relation exists between the **concepts** (B.3.2.1) 'word' and 'pronoun', 'vehicle' and 'car', 'person' and 'child'.

**B.3.2.22**

**partitive relation**

part-whole relation

relation between two **concepts** (B.3.2.1) where one of the concepts constitutes the whole and the other concept a part of that whole

NOTE A partitive relation exists between the **concepts** (B.3.2.1) 'week' and 'day', 'molecule' and 'atom'.

**B.3.2.23**

**associative relation**

pragmatic relation

relation between two **concepts** (B.3.2.1) having a nonhierarchical thematic connection by virtue of experience

NOTE An associative relation exists between the **concepts** (B.3.2.1) 'education' and 'teaching', 'baking' and 'oven'.

**B.3.2.24**

**sequential relation**

**associative relation** (B.3.2.23) based on spatial or temporal proximity

NOTE A sequential relation exists between the **concepts** (B.3.2.1) 'production' and 'consumption', etc.

**B.3.2.25**

**temporal relation**

**sequential relation** (B.3.2.24) involving events in time

NOTE A temporal relation exists between the **concepts** (B.3.2.1) 'spring' and 'summer', 'autumn' and 'winter'.

**B.3.2.26**

**causal relation**

**associative relation** (B.3.2.23) involving cause and its effect

NOTE A causal relation exists between the **concepts** (B.3.2.1) 'action' and 'reaction', 'nuclear explosion' and 'fall-out'.

## B.3 Definitions

### B.3.3.1

#### definition

representation of a **concept** (B.3.2.1) by a descriptive statement which serves to differentiate it from related concepts

### B.3.3.2

#### intensional definition

**definition** (B.3.3.1) which describes the **intension** (B.3.2.9) of a **concept** (B.3.2.1) by stating the **superordinate concept** (B.3.2.13) and the **delimiting characteristics** (B.3.2.7)

NOTE The following is an example of an intensional definition for the **concept** (B.3.2.1) 'incandescent lamp':

#### **incandescent lamp**

electric lamp in which a filament is heated by an electric current in such a way that it emits light.

### B.3.3.3

#### extensional definition

description of a **concept** (B.3.2.1) by enumerating all of its **subordinate concepts** (B.3.2.14) under one criterion of subdivision

#### EXAMPLES

#### **Family 18 in the Periodic Table**

helium, neon, argon, krypton, xenon and radon

#### **noble gas**

helium, neon, argon, krypton, xenon, or radon.

statement which provides further information on any part of a **terminological entry** (B.3.8.2)

## B.4 Designations

### B.3.4.1

#### designation

#### designator

representation of a **concept** (B.3.2.1) by a sign which denotes it

NOTE In **terminology work** (B.3.6.1) three types of designations are distinguished: symbols, **appellations** (B.3.4.2) and **terms** (B.3.4.3).

### B.3.4.2

#### appellation

#### name

verbal **designation** (3.4.1) of an **individual concept** (3.2.2)

### B.3.4.3

#### term

verbal **designation** (B.3.4.1) of a **general concept** (B.3.2.3) in a specific **subject field** (B.3.1.2)

NOTE A term may contain symbols and can have variants, e.g. different forms of spelling.

### B.3.4.14

#### term acceptability rating

rating established from a predetermined scale and used to evaluate a **term** (3.4.3)

NOTE The following ratings are common: preferred, admitted, deprecated.

**B.3.4.15**

**preferred term**

**term** (B.3.4.3) rated according to the scale of the term **acceptability rating** (B.3.4.14) as the primary term for a given **concept** (B.3.2.1)

**B.3.4.19**

**synonymy**

relation between or among **terms** (B.3.4.3) in a given language representing the same **concept** (B.3.2.1)

NOTE 1 The relation of synonymy exists, for example, between deuterium and heavy hydrogen.

NOTE 2 **Terms** (B.3.4.3) which are interchangeable in all **contexts** (B.3.6.10) are called synonyms; if they are interchangeable only in some contexts, they are called *quasisynonyms*.

**B.3.4.20**

**antonymy**

relation between two **terms** (B.3.4.3) in a given language representing opposite **concepts** (B.3.2.1)

NOTE 1 The relation of antonymy exists, for example, between encoding and decoding, positive and negative.

NOTE 2 The **terms** (B.3.4.3) in the relation of antonymy are called *antonyms*.

**B.3.4.21**

**equivalence**

relation between **designations** (B.3.4.1) in different languages representing the same **concept** (B.3.2.1)

**B.3.4.22**

**mononymy**

relation between **designations** (B.3.4.1) and **concepts** (B.3.2.1) in a given language in which one concept has only one designation

NOTE The **designations** (B.3.4.1) in the relation of mononymy are called mononyms.

**B.3.4.23**

**monosemy**

relation between **designations** (B.3.4.1) and **concepts** (B.3.2.1) in a given language in which one designation only relates to one concept

NOTE The **designations** (B.3.4.1) in the relation of monosemy are called *monosemes*.

**B.3.4.24**

**polysemy**

relation between **designations** (B.3.4.1) and **concepts** (B.3.2.1) in a given language in which one designation represents two or more concepts sharing certain **characteristics** (B.3.2.4)

NOTE 1 An example of polysemy is:

bridge

1 'structure to carry traffic over a gap'

2 'part of a string instrument'

3 'dental plate'

NOTE 2 The **designations** (B.3.4.1) in the relation of polysemy are called *polysemes*.

**B.3.4.25**

**homonymy**

relation between **designations** (B.3.4.1) and **concepts** (B.3.2.1) in a given language in which one designation represents two or more unrelated concepts

NOTE 1 An example of homonymy is:

bark



- 1 'sound made by a dog'
- 2 'outside covering of the stem of woody plants'
- 3 'sailing vessel'

NOTE 2 The **designations** (B.3.4.1) in the relation of homonymy are called *homonyms*.

## B.5 Terminology

### 3.5.1

#### **terminology 1**

set of **designations** (B.3.4.1) belonging to one **special language** (B.3.1.3)

### 3.5.2

#### **terminology 2**

terminology science

science studying the structure, formation, development, usage and management of **terminologies** (B.3.5.1) in various **subject fields** (B.3.1.2)

### 3.5.3

#### **nomenclature**

**terminology** (B.3.5.1) structured systematically according to pre-established naming rules

NOTE Nomenclatures have been elaborated in various fields, such as biology, medicine, physics and chemistry.

## B.6 Aspects of terminology work

### B.3.6.7

#### **term excerption**

part of **terminology work** (B.3.6.1) which involves extracting **terminological data** (B.3.8.1) by searching through a **corpus** (B.3.6.9)

NOTE Term excerption involves identifying **concepts** (B.3.2.1) and their **designations** (B.3.4.1) and noting any relevant information about a concept such as **definitions** (B.3.3.1), **contexts** (B.3.6.10) and usage labels.

### B.3.6.8

#### **term identification**

part of **term excerption** (B.3.6.7) involving recognition and selection of **designations** (B.3.4.1)

### B.3.6.9

#### **corpus**

collection of language data brought together for analysis

### B.3.6.10

#### **context**

text which illustrates a **concept** (B.3.2.1) or the use of a **designation** (B.3.4.1)

### B.3.6.11

#### **base list**

list of **designations** (B.3.4.1) resulting from **term identification** (B.3.6.8)

NOTE A base list is usually subject to further **terminology work** (B.3.6.1).

## B.7 Terminological data

### B.3.8.1

#### **terminological data**

data related to **concepts** (B.3.2.1) or their **designations** (B.3.4.1)

NOTE The more common terminological data include **entry term** (B.3.8.4), **definition** (B.3.3.1), **note** (B.3.8.5), **grammatical label** (B.3.8.6), **subject label** (B.3.8.7), **language identifier** (B.3.8.8), **country identifier** (B.3.8.9) and **source identifier** (B.3.8.10).

#### **B.3.8.2**

##### **terminological entry**

part of a terminological data collection (ISO 1087-2:2000, 2.21) which contains the **terminological data** (B.3.8.1) related to one **concept** (B.3.2.1)

NOTE Adapted from ISO 1087-2:2000.

#### **B.3.8.4**

##### **entry term**

**term** (B.3.4.3) which heads a **terminological entry** (B.3.8.2)

NOTE The entry term usually corresponds to the **preferred term** (B.3.4.15)

#### **B.3.8.7**

##### **subject label**

information in a **terminological entry** (B.3.8.2) which indicates the **subject field** (B.3.1.2)

#### **B.3.8.8**

##### **language identifier**

information in a **terminological entry** (B.3.8.2) which indicates the name of a language

#### **B.3.8.9**

##### **country identifier**

information in a **terminological entry** (B.3.8.2) which indicates the name of a geographical region where the **designation** (B.3.4.1) is used

#### **B.3.8.10**

##### **source identifier**

information in a **terminological entry** (B.3.8.2) which indicates the source documenting the **terminological data** (B.3.8.1)

## Annex C (normative)

### Selected definitions from EN 12264:2005

The following terms and definitions are selected from EN 12264:2005. They are included here as background to the key terms and definitions in Clause 3 of this Technical Specification. The numbering in this Annex reflects the numbering in EN 12264:2005, for consistency.

#### C.3.5

##### **formal representation**

system of symbols which stand for **concepts** (C.3.1) and/or the relations between them and which is governed by explicit rules

#### C.3.6

##### **concept representation**

**formal representation** (C.3.5) of a **concept** (C.3.1)

**NOTE** Informally, we often talk of 'concepts' when we mean 'concept representations'. However, this leads to confusion when precise meanings are required. Concepts arise out of human individual and social conceptualisation of the world around them. Concept representations are artefacts constructed of symbols and often manifest in computer programs. Because they are artefacts, we can be precise about the functioning and capabilities of concept representations. It is more difficult to be clear about the yet poorly understood function of human conceptualisation.

#### C.3.7

##### **concept system representation**

**formal representation** (C.3.5) of a **system of concepts** (C.3.4)

**NOTE** Informally, we often talk of 'concept systems' when we mean 'concept system representations'. However, this leads to confusion when precise meanings are required. Concepts arise out of human individual and social conceptualisation of the world around them. Concept system representations are artefacts constructed of symbols and often manifest in computer programs. Because they are artefacts, we can be precise about the functioning and capabilities of concept systems representation. It is more difficult to be clear about the yet poorly understood function of human conceptualisation.

#### C.3.8

##### **concept name**

**term** (C.3.36) which uniquely designates a **concept** (C.3.1) within a **concept system** (C.3.4)

#### C.3.9

##### **concept representation name**

**term** (C.3.36) which uniquely designates a **concept representation** (C.3.7)

#### C.3.12

##### **individuation relation**

relation between a **concept** (C.3.1) and the members of its **extension** (C.3.27)

**NOTE** It is a relation between **concept** (C.3.1) and **object** (C.3.3)

#### C.3.21

##### **relation type**

category of relations between the members of the **extension** (C.3.27) of one or more **concepts** (C.3.1)

### C.3.22

#### representation of relation type

#### semantic link

**formal representation** (C.3.5) of a directed **associative relation** (C.3.14) or **partitive relation** (C.3.13) between two  $y$  (C.3.1)

EXAMPLE has Location (with inverse is Location Of); is Cause Of (with inverse has Cause)

NOTE 1 This includes all relations except the **generic relation** (3.11).

NOTE 2 A semantic link always has an inverse, i.e. another semantic link with the opposite direction.

### C.3.28

#### instance of a concept

member of the **extension** (C.3.27) of a **concept** (C.3.1)

### C.3.32

#### sanctioned characteristic

#### representation of type of characteristic

**formal representation** (C.3.5) of a **type of characteristics** (C.3.23) whose **domain** (C.3.40) is the **concept representation** (C.3.6) in question

NOTE A representation of a type of characteristic could be made up of a combination of a **semantic link** (C.3.22) and a **characterising category** (C.3.33), and intended to be used in **domain constraints** (C.3.42).

EXAMPLE Cause of inflammation: the set of bacteria, virus, parasite, autoimmune, chemical, physical, unknown, formally expressed e.g. "CauseOfInflammation canBe (semantic link) set {bacteria, virus, parasite, autoimmune, chemical,physical, unknown}" (Characterising category)

### C.3.33

#### characterising category

#### range

#### value domain

set of **concepts** (C.3.1) which are allowed by a **domain constraint** (C.3.42) to specialise a concept in a particular **domain** (C.3.40)

NOTE The characterising category is usually described by a superordinate **concept** (3.15).

EXAMPLE Cause of inflammation: the set of bacteria, virus, parasite, autoimmune, chemical, physical, unknown, formally expressed e.g. "Cause Of Inflammation can Be (semantic link) set {bacteria, virus, parasite, autoimmune, chemical, physical, unknown}" (characterising category)

### C.3.42

#### domain constraint

#### range constraint

#### sanction

rule prescribing the set of representations of **type of characteristics** (C.3.32) that are valid to specialise a **concept** (C.3.1) in a certain domain

NOTE The rule describes the set of representations of **type of characteristics** (C.3.32) by combining the **semantic link** (C.3.22) and the **characterising categories** (C.3.33) it links to, possibly based on a full enumeration of **concepts** (C.3.1).

EXAMPLE The domain constraint "Fracture possibly has Location Skeletal Structure" describes that the concept "Fracture" can be specialised according to location (through semantic link "has Location") where the link points to a member of the characterising category "Skeletal Structure" in this precise domain.

### C.3.43

#### domain concept model

set of **domain constraints** (C.3.42) for representing **concepts systems** (C.3.4) in a precise **domain** (C.3.40)

**C.3.44****category structure****reference terminology model**

minimal set of **domain constraints** (C.3.42) for representing **concepts systems** (C.3.4) in a precise **domain** (C.3.40) to achieve a precise goal

EXAMPLE A precise goal can be controlled vocabularies, classifications, nomenclatures, terminologies and thesauri, with or without coding schemes.

## Annex D (informative)

### Complicated designation among names and objects

#### D.1 Neutrality of this Technical Specification

The International Standards and Technical Specifications shall be neutral with respect to any given official nomenclatures. In the present Technical Specification, there is no intention to force various countries to unify terms in different languages into one unique term in a specific language. This Technical Specification specifies only a conceptual framework for the conformance among terminological systems, better handling of terms.

#### D.2 Reality of relations among names and objects

Some pharmacopoeia define “**official name** (5.2.1) in Latin” besides “**official name** (5.2.1) in country official language”, but those “Latin names” are not **scientific names** (5.2.3). Therefore, official Latin names vary among pharmacopoeias. In addition, some pharmacopoeias often define “**official names** (5.2.1) in country language” at different levels on **hierarchical relations** (B.3.2.20) among a group and the name of top node represents other **subordinate concepts** (B.3.2.14). However, there is no “**official name** (5.2.1) in Latin” equivalent for those subordinate names. Such situation may cause the risks of confusion in the base if the top word and the subordinate words are morphologically similar, similarity of form of word [50-52,54] (cf. 3.4).

Although in rare cases, officially regulated **term** (B.3.4.3) designates different herbal medicament (3.2) **objects** (B.3.1.1) in a same country: As an example, medicinal product domain vs. medical education domain [49,51,52].

**Vernacular name** (5.2.2) is not official term, however, it is often like **official name** (5.2.1) and is commonly used in international trading. In addition, some of **vernacular name** (5.2.2) hold **polysemy** (B.3.4.24). As a result, the extents of **polysemy** (B.3.4.24) refer not only to HB-SNM (4.3) but also **origin** (5.2.4) and **source** (5.2.7). Consequently, **vernacular names** (5.2.2), **official names** (5.2.1), name of **origin** (5.2.4) and name of **source** (5.2.7) may be lead to confusion in identification of herbal medicament (3.2) and related **objects** (B.3.1.1).

Occurrence of **synonymy** (B.3.4.19), **polysemes** (B.3.4.24), and **homonyms** (B.3.4.25) can be classified onto three types: (i) **official name** (5.2.1) and other **official names** (5.2.1), a certain **scientific name** (5.2.3) and other **scientific names** (5.2.3), (ii) a certain **vernacular name** (5.2.2) and other **vernacular names** (5.2.2), (iii) a certain **vernacular name** (5.2.2) and **official names** (5.2.1) or **scientific names** (5.2.3). It should be paid attention to that **polysemes** (B.3.4.24) also occur in **designation** (B.3.4.1) of **origin** (5.2.4), the **source** (5.2.7) from it, and consequently **official name** (5.2.1) of HB-SNM (4.3), one because **polysemy** (B.3.4.24) of **vernacular names** (5.2.2) induce, and another because variation of histories and areas or the difference of domain policies [24,56,57].

**Scientific name** (5.2.3) is usually unique in its **domain** (B.3.1.2) due to the design of a **terminology 1** (B.3.5.1) and the maintenance policy about those. However, in rare cases, **designation** (B.3.4.1) with **binomial system** (3.7) with suffixed cannot identify what this living thing is, **homonyms** (B.3.4.25). In such case, other **designator** (B.3.4.1) and/or **botanical feature** (5.2.5) **characterizing category** (A.2.3.3) may be utilized in order to identify **origin** (5.2.4).

People in general who harvest **natural materials** (3.1) do not necessarily use **scientific names** (5.2.3) in **binomial system** (3.7) but **vernacular names** (5.2.2) and **botanical features** (5.2.5). And people who trade

**source** (5.2.7) or the herbal medicament (3.2) also do not necessarily use **scientific names** (5.2.3) or **official names** (5.2.1), but **vernacular names** (5.2.2) and **basic characteristics** (5.2.9). Besides, **scientific names** (5.2.3) are also defined majorly from morphological features.

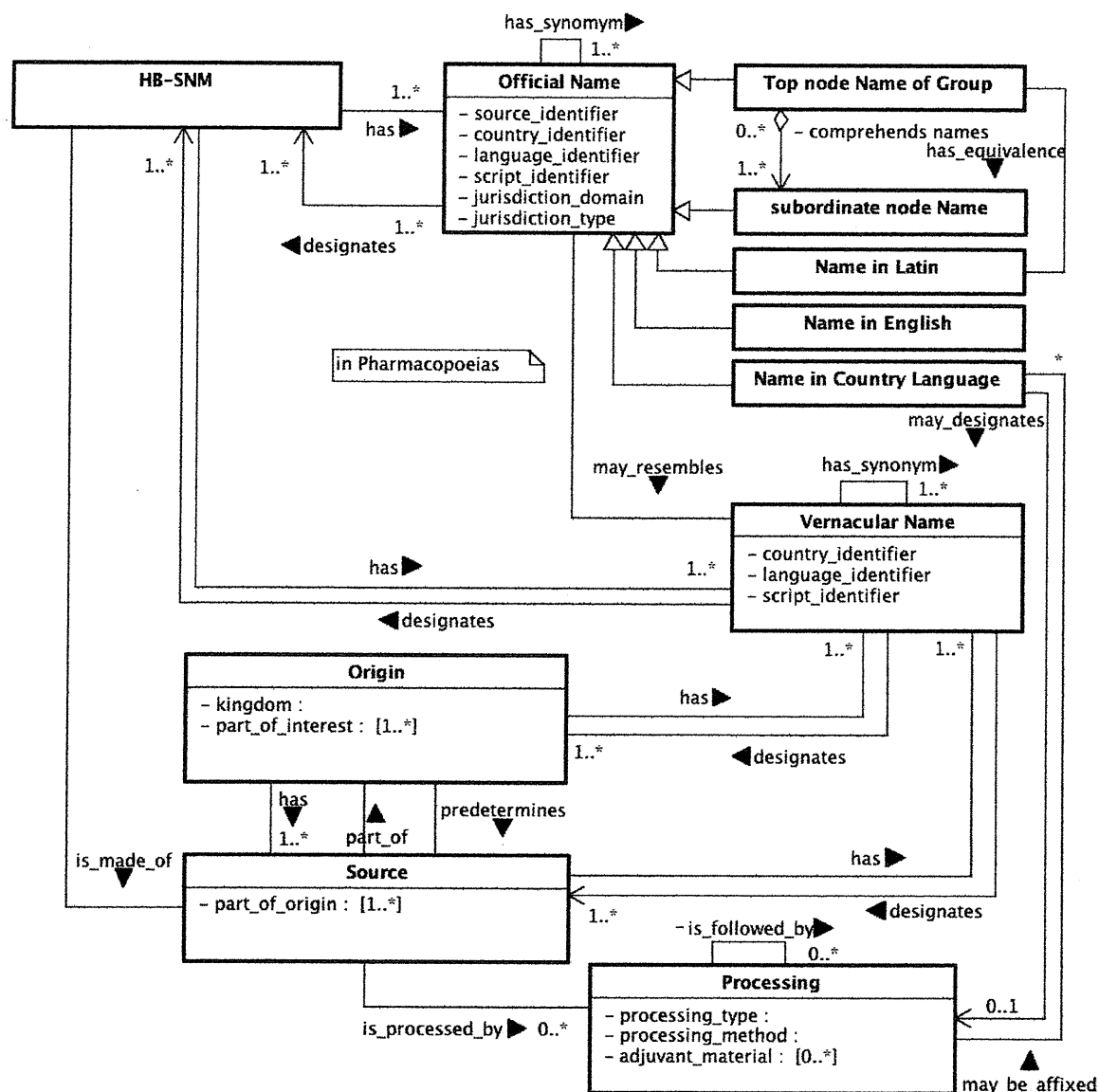


Figure 3 — Relations among designations for HB-SNM related characterizing categories

Thus, at one side, there are complicated designation among herbal medicaments (3.2) and materials in social activities, and at the other side, **origin** (5.2.4) genetically predetermines **characteristics** (B.3.2.4) of **source** (5.2.7) especially biomedical active **substances** (3.16) that **source** (5.2.7) contains. Besides, there also issues on scientific papers for evidences, use and monitoring, agriculture, collection, and quality control [40-44].

There is no magical solution. One of tactics is the identification of individual products, and this has been performed in IMDPs by ISO/TC215/WG6, it has originated in ICH/M5 and has been supported by HL7. Another of tactics may also contribute to the better handling of **terms** (B.3.4.3) and **concepts** (B.3.2.1) in **terminology 2** (B.3.5.2) for **reference terminology** (A.2.7.4) or **reference terminology model** (C.3.44). Therefore, the proposer and project leader of this project submit this New Work Item in order to provide some clue to the better handling of this situation.

## Annex E (informative)

### Sample values for Biomedical Effect

#### E.1 Perspective and Aspect

##### E.1.1 Perspective

Medicine is based on a scientific philosophy, in other words, epistemology and ontology. Epistemology and ontology (and logics) form the basic way of thinking in any **domain** or **subject field** (B.3.1.2). Such kind of meta-framework can be called *Perspective*.

Any types of medicine have also been developed on and surround *Perspective*. East and West have their own epistemology and ontology; so, their scientific philosophies are also different from each other. Herbal medicaments have been used in all over the world from ancient days, and in some areas, they are still utilized as main interventions in clinical settings. The differences of scientific philosophies reflect 'Biomedical Effect' of medicaments.

Consequently, **concepts** (B.3.2.1) and their **terms** (B.3.4.3) of 'Biomedical Effect' in Orient often differ from those in Occident. Furthermore, there are no absolutely persuasive reasons forcing one side to adapt to the other side's *Perspective*. Therefore, { medical domain type } is prepared in 'Biomedical Effect' **characterizing category** (A.2.3.3).

##### E.1.2 Aspect

Even in the same { medical domain type }, *Aspect* or view point in a certain **context** (B.3.6.10), varies diversely. Single pharmacological fact can be explained or notified in various *Aspect*, in other words, { effect type } in this Technical Specification.

Of course, explanations and notifications should be practically informed in an adequate or preferable expression, but *Aspect* may be beyond the issue whether preferable or not. In fact, some physical and/or chemical **characteristics** (B.3.2.4) remain merely **characteristics** (B.3.2.4) of a certain substance, for laboratory researchers; however, for clinicians, they may be adverse to usual people but they may have excellent efficacies to the patients suffered from a certain type of diseases.

From the very beginning, toxicity is one of *Aspects* in pharmacology, and also, precautions and efficacies. Anyway, one matter appears different way for angle, as like a coin has head and tail. Therefore, { effect type } is prepared in 'Biomedical Effect' **characterizing category** (A.2.3.3).

#### E.2 Sample values

Usually, { effect type } may be classified five types ::= [ Clinical Efficacy | Indication | Pharmaceutical Precaution | Contraindication | Adverse Effect ]. And { effect } of Pharmaceutical Precaution may concerned with the followings ::= [ lethal dose | chronic toxicity | carcinogenicity | immunogenicity | genotoxicity | mutagenicity | dependency | irritative | corrosiveness | drug interaction | risk of age | risk of condition ].

Rather simplified pattern may be preferred in certain situations. { effect type } can hold one of four ::= [ Function | Indication | Precaution | Contraindication ]. Indication is subcategorized into two ::= [ Syndrome Differentiation/Pattern | Therapeutic Principle ], from the point of view in a type of traditional medicine [29].



Some monographs have many { effect type } and kinds of { effect }. For example, ESCOP [37-38] has at least fifteen { effect type } and twenty-seven kinds of { effect }, WHO monographs [32-35] has twenty-two and forty-nine respectively. These numbers may not be accurate because failing to notice. However, in this context, precise number is not important at all, but it is worthy noticing that aspects cause to alter kinds and numbers of both { effect type } and { effect }.

This Technical Specification only intended to specify the conceptual framework for representation of herbal medicaments in terminological systems, and the definition of **values** (3.19) used in implementation is out of scope. Therefore it will be sufficient to list the third sample in addition to two samples described above.

{ medical domain type } ::= modern ;

{ effect type } and { effect } ::=

effect type	effect
Therapeutic indications	Internal use
	External use
Posology and method of administration	Dosage
	Method of administration
	Duration of administration
Contraindications	should not be used in patients with intestinal obstruction or stenosis
Special warnings and special precautions for use	Chronic use may cause pigmentation of the colon ( <i>Pseudomelanosis Coli</i> )
Interaction with other medicaments and other forms	Hypokalaemia (resulting from long term laxative abuse) potentiates the action of cardiac glycosides
Pregnancy and lactation	has/no report for laxative effect in breast-fed babies
Effects on ability to drive and use machines	
Undesirable effects	abdominal spasms and pain which is not clinically significant
Overdose	gripping and severe diarrhea
Pharmacological properties : Pharmacodynamics	In vitro experiments
	In vivo experiments
	Pharmacological studies in humans
	Pharmacological properties : Increase in cardiac contractility
	Increase in cardiac contractility (positive inotropic action)
	Increase in coronary blood flow and myocardial circulation
	Negative bathmotropic action
	Protection from ischemia-reperfusion induced damage
	Vasorelaxation, decrease of peripheral vascular resistance
Pharmacological properties : Pharmacokinetic	Gastrointestinal absorption
	Percutaneous absorption
	Metabolism and excretion
Pharmacological properties : Preclinical safety data	Acute toxicity
	Subchronic and chronic toxicity
	Mutagenicity and carcinogenicity
	Sensitizing potential
Pharmacological properties : Mechanisms of action	
Pharmacological properties : Clinical studies	

; extracted from ESCOP [37-38]

## Annex F (informative)

### Sample values for Laboratory Test Profile

#### F.1 Neutrality of this Technical Specification

The International Standards and Technical Specifications shall be neutral with respect to any given official nomenclatures. In this Technical Specification, there is no intention of determination to specify some of laboratory test profiles for market control. The present Technical Specification specifies only a conceptual framework as generic model for the conformance of information models in terminological systems.

#### F.2 Sample values

This Technical Specification only intended to specify the conceptual framework for representation of **herbal medicaments** (3.2) in terminological systems, and the definition of **values** (3.19) used in implementation is out of scope. Therefore it will be sufficient to list part of values for sample.

{ test purpose } ::= [ identity test | purity test ] ;

{ system adequacy } ::= [ pharmacopoeia | WHO guideline ] ;

{ test type } and { test method } ::=

test type	test method
microscopic morphology	
physical identification	refractive index
	specific gravity
chemical identification	fluorescence test
	micro-sublimation
	high-performance liquid chromatographic methods
	gas-liquid chromatographic methods
	thin-layer chromatography
	microchemical analyses
	spectrophotometry
incubate and microscopic examination	
dissolution	acid-soluble extracts
	alcohol-soluble extracts under ultraviolet light
radioactive contamination	<i>laboratory techniques are available from IAEA</i>

; extracted from some references listed in bibliography [32-35,41,47]

## Annex G (informative)

### Sample values for Botanical Feature and Processing

This Technical Specification only intended to specify the conceptual framework for representation of **herbal medicaments** (3.2) in terminological systems, and the definition of **values** (3.19) used in implementation is out of scope. Therefore it will be sufficient to list part of values for sample.

#### G.1 Botanical Feature

{ morphology }, { size } and { color } ::=

stem	stem height
	stem length
	stem thickness
	sharp
	color
	pilosity
blade	whole
	tip
	leaf base
	leaf margin
	delamination
	pilosity
	size
	color
flower	ovary
	size
	sharp
	color
	perianth
	inflorescence
	sexual
fruit	organ
	number of flower and ovary
	pericarp
	sharp
root	rhizome
	tubercle
	root hair
	accessory root
	subterranean

; extracted from some references listed in bibliography [32-35]

## G.2 Processing

{ processing type } and { processing method } ::=

processing type	processing method
filtering	sorting
	screening
	selection in wind
	selection in water
washing	washing and rinsing
	moistening
	inmersion
	rinsing moistening
	showering moistening
cutting	soaking moistening
	cutting
	slicing
	sectioning
heating	chopping
	sliver
	stir-frying
	stir-bake to yellow
	stir-bake to brown
	simple stir-frying
	plain stir-bake
	fried with adjuvant material
stir-frying with bran	

; extracted from some references listed in bibliography [23,39]