TECHNICAL SPECIFICATION

ISO/TS 18790-1

Health informatics — Profiling framework and classification for Traditional Medicine informatics standards development —

Part 1:
Traditional Chinese Medicine

Informatique de santé — Cadre de profilage et classification pour le développement de normes informatiques relatives à la médecine chinoise —

Partie 1: Médecine chinoise traditionnelle

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Foreword

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary Information

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

Introduction

This Technical Specification provides a common framework for describing the artefacts of informatics standards for Traditional Chinese Medicine (TCM), which is intended for use by TCM informatics standard developers, reviewers, and users.

This Technical Specification brings order to the description of diverse TCM informatics standards artefacts by representing the complexity of TCM informatics as a matrix of understandable components. A common means of description is necessary to facilitate the coordination, communication, and comparability of TCM informatics standards across and between disciplines and Standards Development Organizations (SDOs), and this is provided by this Technical Specification for TCM informatics standards published by ISO/TC 215, ISO/TC 249, WHO, and other SDOs.

The framework addresses different needs of TCM informatics and provides a way to compare various health informatics standards. It specifies a capability to comprehensively define and classify TCM informatics standards artefacts, facilitate the coordination, communication, and comparability of TCM informatics standards through a common understanding of intended users and content, helps identify and coordinate TCM informatics standards development, promotes TCM informatics standards integration and alignment within and between standards from different SDOs, and provides a framework to assist with the coordination of ISO/TC 215 work items both within the technical committee and with related TCs, including ISO/TC 249 and ISO/TC 46.

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1 Scope

1.1 General

Traditional Chinese Medicine (TCM) is a form of traditional medicine that originated in China, and is characterized by holism and treatment based on pattern identification/syndrome differentiation. The Technical Specification establishes common concepts and a vocabulary for describing the complex domain of various Traditional Chinese Medicine (TCM) informatics standards initiatives and their supporting artefacts. It provides a useful profiling framework to align existing and developing TCM informatics standards and to reference health informatics standards. It promotes the reuse of TCM informatics knowledge and improves the identification of opportunities for TCM informatics standards alignment, collaboration, and coordination.

Topics considered outside the scope of this Technical Specification include:

— profiling framework and classification for informatics standards of Kampo, Korean medicine, and other traditional medicine.

1.2 Main purpose

The framework has been developed to address different needs of TCM informatics and compare with health informatics standards. The specific needs addressed in this Technical Specification are the following:

— provide the capability to comprehensively define and classify TCM informatics standards artefacts;

— facilitate the coordination, communication, and comparability of TCM informatics standards through a common understanding of intended users and content;

— help identify and coordinate TCM informatics standards development;

— promote TCM informatics standards integration and alignment within and between standards from different Standards Development Organizations (SDOs); and

— provide a framework to assist with the coordination of ISO/TC 215 work items both within the technical committee and with related TCs, including ISO/TC 249 and ISO/TC 46.

1.3 Benefits

The potential benefits of the Technical Specification include the following:

— introduction of classification concepts and terminology for TCM informatics standard artefacts;

— enhancement of TCM informatics standards development coordination through the identification of potential duplication between standards initiatives;

— enhancement of global understanding of TCM informatics standards in support of their knowledge management.

1.4   Target groups

The target groups include the following:

— managers and reviewers of TCM informatics standards;

— developers of TCM informatics standards;

— users of TCM informatics standards.

2   Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TR 17119:2005, *Health informatics - Health informatics profiling framework*

3   Terms and definitions

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

**3.1
artefact**
any model, document, or work product

**3.2
concept**
unit of knowledge created by a unique combination of characteristics

[SOURCE: ISO 1087-1:2000, 3.2.1]

**3.3
entity**
any concrete or abstract thing of interest

[SOURCE: ISO/IEC 10746-2, 6.1]

**3.4
category**
type of *entity* (3.3) shared by all the individual instances in existence in the present, past, and future

**3.5
categorial structure**
minimal set of *categories* (3.4) and the valid relationships between them for representing *concepts* (3.2) in *terminological systems* (3.7) for a specified subject field

[SOURCE: ISO 18104:2014, 4.2]

**3.6
characteristic**
abstraction of a property of an object or of a set of objects

[SOURCE: ISO 1087-1:2000, A.3.2.4]

3.7
terminological system
structured human and machine-readable representation of *concepts* (3.1) required directly or indirectly to describe certain domain and allow their subsequent retrieval or analysis

Note 1 to entry: Also the relationship of the terminology to the specifications for organizing, communicating, and interpreting such a set of concepts.

[SOURCE: ISO 18104:2014, 4.9]

3.8
data
"raw" alphanumeric text, objects, and symbols defined without any context in such a way that by itself one cannot tell its correct meaning

[SOURCE: ISO/TR 17119:2005, 2.5]

3.9
framework
structure for supporting or enclosing something else, often acting to partition something complex into simple components

[SOURCE: ISO/TR 17119:2005, 2.6]

4 TCM Informatics Profiling Framework (TCMIPF)

4.1 Overview

This Technical Specification defines a profiling framework for the standardization in the area of Traditional Chinese medicine informatics (TCM informatics), which provides a means to classify and compare TCM informatics standards. The scope of "TCM informatics standards" refers to the standardization of TCM information area, which includes TCM healthcare informatics, TCM management information, TCM scientific research information, TCM culture and education information, TCM resources information, TCM products manufacture and marketing information. The objective is to reach the standardization of management for TCM terminology, data, information system, and knowledge to promote the interoperability between TCM information system and other health information systems.

As shown in Figure 1, the classification framework is represented as a three-dimensional structure (i.e. cube) whose axes are the *Level of Specificity*, the *Elements of Informatics*, and the *Business Domain*.
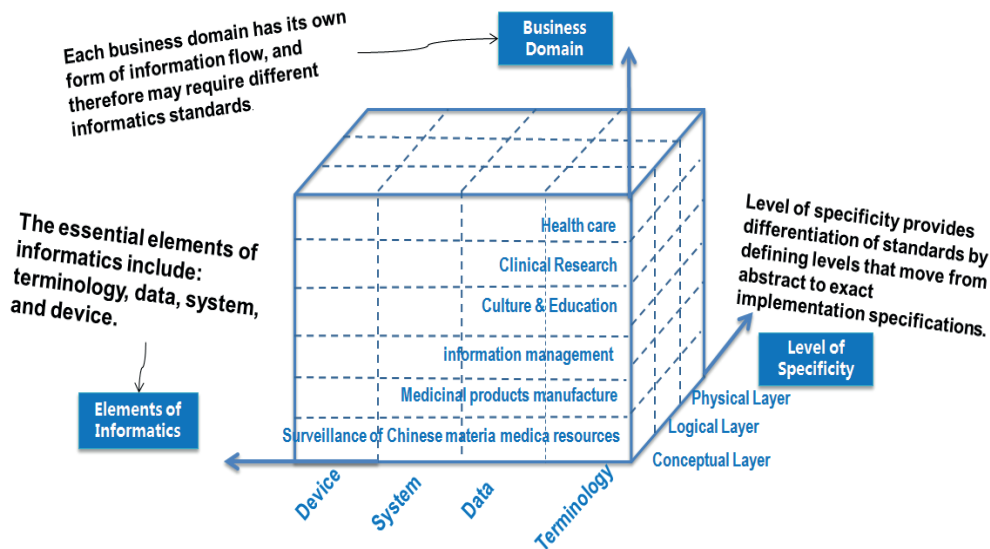
Figure 1 — The Elements of Informatics, Level of Specificity, and Business Domains involving TCM

The three dimensions are briefly described as follows:

— *Level of Specificity* provides differentiation of TCM informatics standards by defining levels that move from abstract to exact implementation specifications. The main categories are C*onceptual, Logical, and Physical Design*;

— *Elements of Informatics* provides differentiation of TCM informatics standards by defining the essential elements of standards from the perspective of informatics. The main categories are *Terminology, Data, Information System,* and *Device*;

— *Business Domain* provides differentiation of TCM informatics standards by defining the application domains of TCM informatics standards. The main categories are *TCM Healthcare, TCM clinical research, TCM Culture and Education, TCM information management, TCM medicinal products manufacture and marketing, and Surveillance of Chinese materia medica.*

4.2   Levels of specificity

Levels of specificity provides differentiation of TCM informatics standards artefacts by defining levels that move from abstract to exact implementation specifications. The main categories are conceptual, logical, and physical design.

— *Conceptual layer*: This specificity level contains classes of things of interest within TCM informatics. This level has no specifics, but contains shared fundamental meanings.

— *Logical layer*: This specificity level contains generalized models or informatics standards. It deals with specifics that provide coherence, without concern for technological constraints.

— *Physical design layer*: The specificity level contains informatics standards with concern for technological constrains.

4.3   Elements of Informatics

Elements of Informatics is a classification dimension for differentiating TCM informatics standards based on their essential elements in terms of informatics. The main categories are terminology, data, information system, and device. Each category has characteristic standards, and the values can be extended as needed. The characteristic standards and currently specified values are listed as below.

4.3.1 Terminology

Terminology category includes standards for TCM terminological systems, including classification, coding scheme, coding system, and reference terminology for TCM. For example, TCM subject headings, classification of TCM, semantic network, and encoding schemes for TCM language system.

Characteristic standards developed/underdeveloped within TCM terminology category include the following:

— definitions of vocabularies and terminologies, e.g. International standard terminology (IST) developed by WHO/WPRO;

— categorical structure of acupuncture, clinical finding, cupping, moxibustion, electro-acupuncture procedure, herbal drugs;

— content model of TCM clinical terminological system;

— semantic network of TCM language system, e.g. ISO/TS 17938, *Health informatics — Semantic network framework of traditional Chinese medicine language system*;

— TCM subject headings.

Related health informatics standards developed include the following:

— categorial structure of nursing, surgical procedure and anatomy, et,al., e.g. ISO 1828:2012, *Health informatics — Categorial structure for terminological systems of surgical procedures*;

— hierarchical categories and semantic link, e.g. Semantic types and semantic relation of UMLS developed by National library of Medicine (NLM) in United States;

— conceptual model, e.g. ISO/TS 22789:2010, *Health informatics — Conceptual framework for patient findings and problems in terminologies*;

— coding schema, e.g. ISO/TR 25257:2009, *Health informatics — Business requirements for an international coding system for medicinal products*;

— reference terminology, e.g. Medical subject headings (MeSH).

4.3.2 Data

Data category includes standards that define the format, structure, and meaning of various data sets, used for the collection, construction, management, and sharing of TCM data resources.

Characteristic standards developed/underdeveloped within TCM data category include the following:

— classification of TCM data sets;

— logical and physical data models for TCM data sets;

— entity relationship diagrams (include attribute, defined relationships and data type)of TCM data sets;

— TCM data elements for EHRs;

— TCM literature metadata, e.g. ISO/DTS 17948, *Health informatics — Traditional Chinese Medicine literature metadata*;

— Data Type Definitions (DTDs) for TCM ;

Related health informatics standards include the following:

— ISO/HL7 21731:2006, *Health informatics — HL7 version 3 — Reference information model — Release*;