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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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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.

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

Part 1:
Traditional Chinese Medicine

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*.
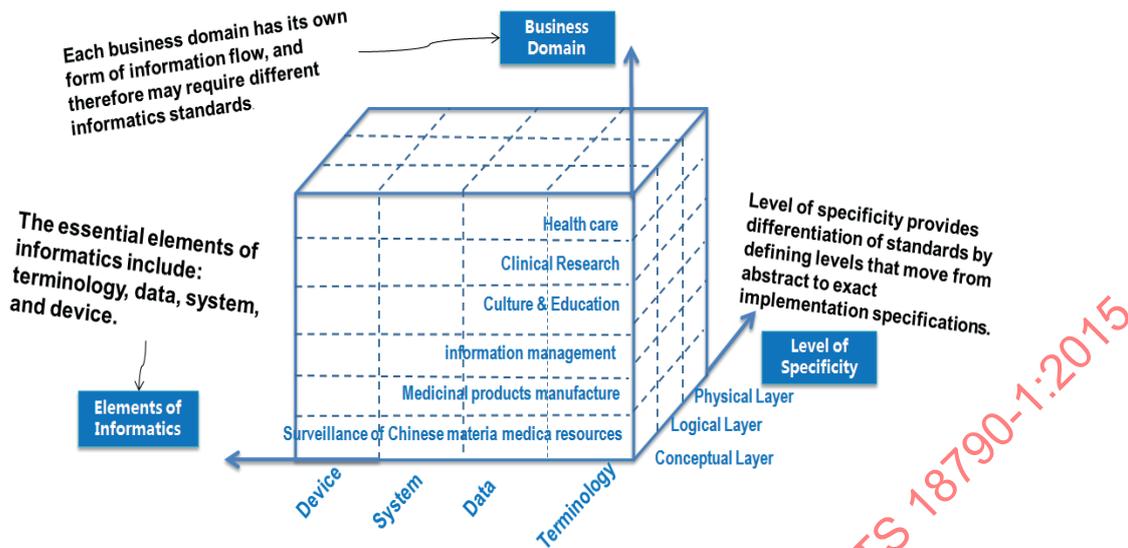
Figure 1 — The Elements of Informatics, Level of Specificity, and Business Domains involving TCM

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*;

— ISO/TS 29585:2010, *Health informatics — Deployment of a clinical data warehouse*;

— ISO 11615:2012, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*;

— ISO 11239:2012, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*;

— ISO 13119:2012, *Health informatics — Clinical knowledge resources — Metadata*;

— ISO 21549-1:2013, *Health informatics — Patient healthcard data — Part 1: General structure*.

4.3.3 Information system

Information systems also can be defined as a collection of hardware, software, data, people, and procedures that work together to produce quality information. The four components *hardware, software, database, and network* make up what is known as the information technology platform. Information technology workers use these components to create information systems that monitor safety measures, risk and the management of data. TCM *Information system* category includes standards for TCM information technology platform and their development, management, and maintenance.

Characteristic standards of TCM information system underdeveloped within this category include the following:

— goals, strategies, guidelines, and plans for the development of TCM information systems;

— general and context-dependent processes for developing TCM information systems;

— classification of TCM information systems;

— workflow models of TCM information systems;

— state transition models of TCM information systems;

— management policies for TCM information systems;

— use case models of TCM information systems;

— architectures and architectural models of information systems;

— logical and physical security models and security policies of TCM information systems;

— functional models;

— physical designs of information systems;

— user manuals of information systems.

Related health informatics standards developed/underdeveloped include the following:

— ISO 27799:2008, *Health informatics — Information security management in health using ISO/IEC 27002*;

— ISO/TR 16056-2:2004, *Health informatics — Interoperability of telehealth systems and networks — Part 2: Real-time systems ISO Architecture for information system*;

— ISO 10781:2009, *Electronic Health Record-System Functional Model*;

— ISO/TS 16058:2004, *Health informatics — Interoperability of telelearning system*;

— ISO 18812:2003, *Health informatics — Clinical analyser interfaces to laboratory information systems — Use profiles*.

4.3.4 Device

TCM device is an instrument, apparatus, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body. Medical devices act by other means like physical, mechanical, or thermal means. Normally, computer assists in the conduct of TCM body check and treatment.

The *device* perspective includes information communication standards for various TCM electric or computer-based devices.

Characteristic standards within this category include the following:

— vocabularies of devices communication;

— management policies of information systems for TCM device;

— logical and physical designs of TCM devices;

— communication protocols of devices;

— security policies of devices communication.

Related health informatics standards developed include the following:

— ISO/IEEE 11073-10404:2010, *Health informatics — Personal health device communication — Part 10404: Device specialization — Pulse oximeter*;

— ISO/TR 11633-1:2009, *Health informatics — Information security management for remote maintenance of medical devices and medical information systems — Part 1: Requirements and risk analysis*;

— ISO/TS 11073-92001:2007, *Health informatics — Medical waveform format — Part 92001: Encoding rules*;

— ISO/IEEE 11073-10472:2012, *Health informatics — Personal health device communication — Part 10472: Device specialization — Medication monitor*.

4.4 Business Domain

Business Domain provides differentiation of TCM informatics standards by defining the application domains of TCM informatics standards. As shown in Table 1 below, each business domain has its own form of information flow, and therefore can require different informatics standards. The main categories are *TCM Healthcare, TCM clinical research, TCM Culture and Education, TCM information management, TCM medicinal products manufacture and marketing, Surveillance of Chinese materia medica resources.*

4.4.1 TCM Healthcare

TCM Healthcare is the diagnosis, treatment, and prevention of disease, disorders, TCM patterns, injury, and other physical and mental impairments in humans. Healthcare is delivered by practitioners in traditional Chinese medicine, TCM nursing, pharmacy, and other care providers.

4.4.2 TCM Clinical Research

TCM Clinical Research is a branch of TCM healthcare science that determines the safety and effectiveness of medications, devices, diagnostic products, and treatment regimens intended for human use. These can be used for prevention, treatment, diagnosis, or for relieving symptoms of a disease or disorder. TCM Clinical Research is different from clinical practice. In clinical practice, one uses established treatments, while in clinical research, evidence is collected to establish a treatment.

4.4.3   TCM Information Management (IM)

TCM Information management (IM) is the collection and management of TCM information from one or more sources and the distribution of that information to one or more audiences. This sometimes involves those who have a stake in, or a right to that information. Management means the organization of and control over the planning, structure and organization, controlling, processing, evaluating, and reporting of information activities in order to meet client objectives and to enable corporate functions in the delivery of information.

4.4.4   TCM Culture and Education

TCM Culture and Education is the safeguarding of TCM cultural heritage, management, and spread of TCM culture and knowledge with audiovisual system and connecting this with educational information systems, both in the college education systems and in lifelong-learning programmes, such as TCM museums and libraries.

4.4.5   TCM medicinal products manufacture and marketing

TCM medicinal product is any medicinal product containing as active ingredients one or more traditional Chinese herbal substances or one or more traditional Chinese herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations. Herbal medicines must be manufactured under Good Manufacturing Practice (GMP) to ensure the quality of the finished product and also demonstrate safety. The category includes the information standards for manufacturing, marketing and supply of TCM medicinal products.

4.4.6   Surveillance of Chinese materia medica resources

Surveillance of Chinese materia medica resources is the investigation, planting, cultivation, processing, authentification, purchase, quality control, and comprehensive development of Chinese Medicinal Materials.

Table 1 below describes the major activities, major actors and participators and information produced in each business domain.

Table 1 — Major activities, actors and information produced in each business domain

Business Domain	Major Activities	Actors and participators	Information Produced
TCM Healthcare	TCM Clinical Practice	TCM Hospitals: TCM Health-care providers and patients	TCM EHRs TCM device interoperability
Clinical research	Clinical Trials	TCM Clinical Research Institutions	TCM clinical research records
Information management	TCM database, information platform management, including planning, security, et,al.	TCM information/data centre	collection and management of TCM information
Culture and Education	TCM learning, Ancient books protection...	TCM college/library/museum	TCM Knowledge resources E-library TCM telelearning
TCM medicinal products manufacture & marketing	TCM medicinal products manufacture and marketing	Pharmaceutical company	TCM GMP records
Surveillance of Chinese materia medica	investigation, cultivation, and quality control of Chinese material medica	TCM resources centre	Surveillance records of Chinese materia medica resources

4.5   How to use the TCM informatics profiling framework (TCMIPF)

The TCMIPF provides a structure to make the standards artefacts systematically organized and indexed. It provides benefit for planning, developing, researching, and extending TCM informatics standards. The TCMIPF partitions the domain of TCM informatics into 72 separate sub-domains and provides classification guidelines so that a model or other standards artefact can be placed in one or more of the cells defined in the framework. The classification helps avoid unnecessary problems and confusion as the cell placement indicates which artefacts are unlikely or likely candidates for comparison or integration by clearly illustrating where they are related and how.

The identity of a "cell" is specified by a vector, in which the first element comes from Levels of Specificity the second element comes from Business Domain, and the third element comes from Elements of Informatics. For example, the 'cell' identified by the (Logical, Culture, Data) vector corresponds to the TCM informatics standards that can be classified as Logical in the dimension of "Levels of Specificity", as Culture in the dimension of "Business Domain", as Data in the domain of "Elements of Informatics".

A TCM informatics standard is mapped into one or more cells in the TCMIPF by applying the classification to its characteristics. Those that are placed in or mapped to the same cell have at least the characteristics of that cell to provide a basis for comparison or collaboration. For example, the ISO/TS 17938, *Health informatics: Semantic network framework of traditional Chinese medicine language system* can be mapped into the (Logical, Culture and education, Terminology) cell. The ISO/AWI 19465, *Traditional Chinese medicine — Categories of TCM Clinical Terminological System* can be mapped into the (Conceptual, Healthcare, Terminology) cell. The ISO/DTS 17948, *Health informatics — Traditional Chinese medicine literature metadata* can be mapped into the (Logical, Culture, Data) cell. These mappings are illustrated in Figure 2 below.
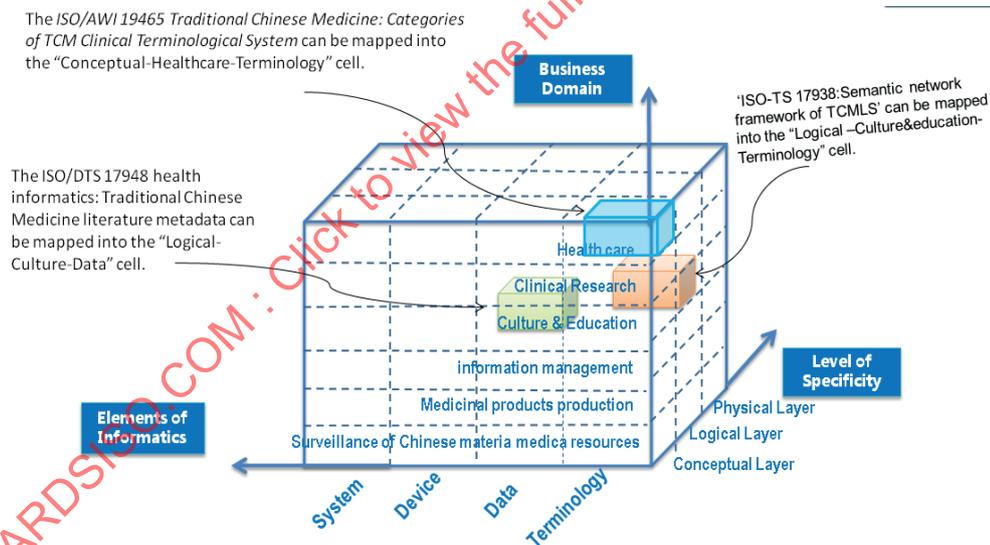

Figure 2 — Example for a TCM informatics standard mapping into TCMIPF

4.5.1   The "Specificity-Informatics" Matrix

A simple dimensional matrix can be used initially in order to understand the framework. As shown in Table 2 below, the "Specificity-Informatics" Matrix including the two dimensions: *Levels of specificity* (contains three rows) and *Elements of Informatics* (contains four columns). This matrix provides a means of identifying and classifying the content of an informatics standard.

There are 12 cells, each of which lies at the intersection of an **element of informatics** and a **level of specificity**. This classification matrix provides a classification system for standards with a focus on characteristics of informatics.

Table 2 — "Specificity-Informatics" Matrix

Informatics/ Specifity	Terminology	Data	Information system	Device
Conceptual level	— classification — conceptual framework — coding scheme — coding system — reference terminology	— data model — data element — metadata	— business requirement — risk analysis — information privacy — quality criteria	— requirements — application profile
Logical level	— categorial structure — content model — semantic type — semantic relation	— E-R Model — data structure — reference information model	— architecture — functional model — interoperability	— communication protocol
Physical level	— XML representation	— data type	— Interface specification — network — software	— device Interface — digital imaging

4.5.2 The "Domain-Informatics" Matrix

As shown in Table 3 below, the "Domain-Informatics" Matrix includes two dimensions: *Business Domain* (contains six rows) and *Elements of Informatics* (contains four columns). This matrix provides a means of identifying and classifying the content of an informatics standard.

Table 3 — "Domain-Informatics" Matrix

Informatics/ Domain	Terminology	Data	Information System	Device
TCM Health-care	— ICTM/-SNO-TCM — Categories of TCM clinical terminology system	— data elements of EMR — TCM CDA — data type	— clinical decision supporting system — requirement of EMR — functional model	— tongue diagnosis device interoperability — pulse diagnosis device interoperability
Clinical research	— terminology for TCM clinical trials — vocabulary for TCM herbal drugs	— Statistical Data — data model — TCM Clinical Data Interchange Standards (TCM-CDISC)	— clinical trial records system	— device interoperability
Information management	— dictionary	— classification of data sets	— security of system — architecture of TCM System	— system communication for TCM device
Culture and Education	— TCM language system — TCM subject heading	— metadata for TCM literature	— telelearning system — E-Library/ E-Museum	— device communication
TCM medicinal products production	— coding rules for decoction pieces — coding rules of formula	— data model — data type	— GMP information System	— device communication and interoperability
Surveillance of Chinese material medica	— coding rules for Chinese materia medica	— data elements	— functional model for surveillance system	— device communication