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Health informatics —— Information model ~~of representation~~ for quality control of traditional Chinese medicinal products

~~DTS – stage~~

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Foreword

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.htmlThe committee responsible for this document is ISO/TC 215.

Introduction

Chinese materia medica, especially traditional Chinese medicinal products are widely utilized as a part of complementary and alternative medicine throughout East Asia and western countries. In order to guarantee ~~the~~ quality and therapeutic ~~effect~~effects, quality control of traditional Chinese medicinal products is very significant and valuable.

Quality control of traditional Chinese medicinal products is very difficult. This ~~arises for~~is due to five main reasons~~ as follows~~: firstly, a wide variety of dosage ~~form~~forms and the manufacturing ~~process~~processes are difficult to accurately ~~classified ;~~ classify; secondly, the influencing factors in the manufacturing process are very complicated, which are difficult to be accurately described and controlled; thirdly, ~~the~~an information model of the preparation of Chinese materia medica has not been described and published; fourthly, the therapeutic effect of Chinese medicine is the comprehensive result of multi-component material ~~basis in~~based on biological metabolism engineering, and the quality control technology of Chinese medicine is often unable to meet the practical needs due to its complex mechanism; fifthly, the requirements for quality control of traditional Chinese medicinal products and relevant regulations vary greatly from country to country, resulting in various and inconsistent standards ~~of~~ for traditional Chinese medicinal products and the inability to achieve drug circulation and resource sharing.

The wide range of disciplines and the ~~individualities of~~specific national usages have led to different meanings being attributed to particular terms and different terms being used to describe the same concept. To avoid the consequent misunderstandings and to facilitate the exchange of information, it is essential to clarify the concepts, to establish the correct terms for use, and to establish their definitions.

~~This document defines the~~

Health informatics — **Information model ~~of representation~~ for quality control of traditional Chinese medicinal products~~.~~**

~~Health Informatics — Information model of representation for quality control of traditional Chinese medicinal products~~

1 ~~1~~ Scope

This document specifies an information model ~~of representation for~~representing the quality control of the manufacturing process of traditional Chinese medicinal products by defining a set of domain constraints of sanctioned characteristics, each composed of a relationship~~ and an applicable information model in order to represent the quality control of manufacturing process of Chinese materia medica.~~ .

It is applicable to the quality supervision and management of manufacturing process of Chinese materia medica.

Japanese KAMPO medicine is ~~out of~~outside the scope~~.~~

of this document.

2 ~~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 17115, Health informatics — Vocabulary for terminological systems*~~

~~*ISO 18668-1:2016(en)Traditional Chinese medicine -- Coding system for Chinese medicines — Part 1: Coding rules for Chinese medicines*~~

~~*ISO 18668-2:2017 Traditional Chinese medicine -- Coding system for Chinese medicines -- Part 2: Codes for decoction pieces.*~~

~~3~~ There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain ~~*terminological*~~terminology databases for use in standardization at the following addresses~~.~~ :

~~*IEC Electropedia: available at*~~ — ISO Online browsing platform: available at https://www.iso.org/obp

~~3.1~~ — IEC Electropedia: available at https://www.electropedia.org/

3.1 General

3.1.1
concept
unit of knowledge created by a unique combination of characteristics

Note 1 to entry: A concept can have one or more names. It can be represented using one or more terms, pictures, icons or sounds.

3.1.2
category
division of sets of entities regarded as having particular shared characteristics

EXAMPLE~~:~~ Freeze drying, spray drying and all other drying share characteristics particular to the category drying.

Note 1 to entry: Categories ~~may~~can be more or less general. Where one category is subsumed by another,~~ there is~~ a relation is asserted to obtain a hierarchy between the more specific or subsumed category and the more general or subsuming category. For example, "parenteral route" is more general than "intravenous route~~.~~".

3.1.3
information model
graphical and textual representation of entities and the relationships between them

Note 1 to entry: Can also be known as a data model, a conceptual data model, a logical data model, an entity relationship model, an object class diagram, or a database definition.

[SOURCE: ISO/IEC 19763-12: 2015, 4.2.24]

3.1.4
characteristic
abstraction of a property of an object or of a set of objects

EXAMPLE ~~:~~ Fever is a characteristic symptom of the flu.

Note 1 to entry: Characteristics are used for describing *concepts* (3.1.1) and for differentiating *categories* (3.1.2).

3.1.5
semantic link
formal representation of a directed associative relation or partitive relation between two concepts

Example: Is cause of (with inverse has cause); has Location (with inverse is Location Of).

Note 1 to entry: This includes all relations except the generic relation.

Note 2 to entry: A semantic link always has an inverse, i.e. another semantic link with the opposite direction.

[SOURCE: ISO 17115:2020, 3.2.5, modified~~, example~~ — Example has been changed~~]~~.]

3.1.6
Chinese medicine
substance or combination of substances used under the guidance of traditional Chinese medicine (TCM) theory for medical care and the prevention and treatment of disease

Note 1 to entry: This includes Chinese materia medica, decoction pieces, granule forms of individual medicinals for prescriptions (GFIMP~~),~~) and Chinese patent medicines (CPM).

[SOURCE: ISO 18668-1:2016, 3.1]

3.2 ~~3.2~~ Characterizing categories

3.2.1
chemical analysis
qualitative and quantitative analysis based on the chemical reactions of substances

EXAMPLE ~~:~~ HPLC, MS, NMR, IR, UV, GC, CE and other combined techniques were used for the quantitative determination of active ingredients or index components

3.2.2
bioanalysis
analysis of the biological activity (including efficacy and toxicity) of drugs using organisms including whole animals, in vitro tissues, organs, cells and microorganisms

3.2.3
character analysis
~~a~~ simple physical and chemical test method ~~is~~ used to distinguish the true and the false by the apparent characters of the objects

3.2.4
impurity
~~a~~ substance that has no therapeutic effect ~~and~~or damages to the body

3.2.5
effective constituent
chemical constituents of Chinese materia medica, intermediates and Chinese patent medicine that ~~have the efficacy~~are efficacious

3.2.6
endogenous toxic component
~~a~~ substance in medicine that causes adverse effects and damage to the body

3.2.7
exogenous harmful substance
harmful ingredients in medicine including pesticide residue, heavy metals ~~and so on~~, etc.

3.2.8
heavy ~~metals~~metal
metal usually of relatively high density, atomic weight, or atomic number

Note 1 to entry: In metallurgy, for example, a heavy metal ~~may~~can be defined on the basis of density, whereas in physics, the distinguishing criterion ~~might~~can be the atomic number, while a chemist would likely be more concerned with chemical behaviour. More specific definitions have been published, but none of these have been widely accepted. A density of more than 5 g/cm3 is sometimes quoted as a commonly used criterion.

EXAMPLE~~:~~ Pb, Hg, Bi, As, Ti, Sn, Cd, Ag, Cu and Mo.

3.2.9
pesticide residue
chemical agent that remains in organisms, harvests, soil, water, pesticide progenitor in the atmosphere, toxic metabolites, degradation products and impurities

3.2.10
microbiological detection
process of active data-gathering with appropriate analysis and interpretation of biosphere data that ~~might~~can relate to disease activity and threats to human or animal health – whether infectious, toxic, metabolic, or otherwise, and regardless of intentional or natural origin – in order to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity

3.2.11

