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Traditional Chinese medicine — Requirements for process traceability systems in Chinese materia medica and decoction pieces —

Part 1: Components

Médecine traditionnelle chinoise — Exigences relatives au système de traçabilité du processus pour la Materia Medica chinoise et les décoctions —

Partie 1: Composants

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

A list of all parts in the ISO 23963 series can be found on the ISO website.

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.html.

Introduction

Chinese medicine (medicinal plants, animals and minerals) originates from a wide variety of different sources of supply. The production documentation is handled differently by each company and important manufacturing steps are usually not fully documented. Several companies are usually involved in the manufacturing process of Chinese medicine and relevant information is often not passed on fully from one company to the other. This makes it very difficult for manufacturers and consumers to retrace the entire production process (e.g. cultivation, harvesting, processing, storage and logistics) and to assess the quality and safety of Chinese medicine. The lack of transparency in the manufacturing process slows down to a certain extent the further development and internationalization of traditional Chinese medicine. Therefore, a supply chain traceability system is needed which ensures that the documentation of all product-relevant information is standardized and available at all times. Such a system will enable companies to better evaluate their suppliers and to convince end users of the quality and safety of their products.

This document is consistent with ISO 18668-1, ISO 18668-2, ISO 18668-3 and ISO 20333. It includes the application of these documents and provides a solution to improve the management of all processes related to Chinese medicine, contributes to the establishment of the traditional Chinese medicine supply chain traceability system and quality-investigating mechanism, enhances product quality and competitiveness, protects consumers' rights and ensures safe and effective application in clinical use.

This document can promote the process of standardization, informatization and modernization for traditional Chinese medicine.

Traditional Chinese medicine — Requirements for process traceability systems in Chinese materia medica and decoction pieces —

Part 1:
Components

1 Scope

This document specifies the requirements for process traceability systems in Chinese materia medica and decoction pieces, including checkpoints of traceability information about the planting or breeding and circulation of Chinese materia medica, and the manufacturing, processing and use of entities of decoction pieces.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 22217, *Traditional Chinese medicine —Storage requirements for raw materials and decoction pieces*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

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

3.1
traceability
ability to track Chinese materia medica and decoction pieces forward through specified stages of planting or breeding, manufacturing, processing, circulation, transport, storage and usage

3.2
traceability system
manual or electronic system that provides the ability to access any or all information relating to the material or product under consideration throughout their life cycle, by means of accessing documented information

3.3
Chinese materia medica
medicinal parts of medicinal plants, animals and minerals after preliminary processing, which are used as raw materials in Chinese medicines

Note 1 to entry: This refers to the raw materials used to make decoction pieces.

[SOURCE: ISO 18668-1:2016, 3.2, modified — abbreviated term CMM removed.]

3.4
decoction piece
prescription medicinal processed from Chinese materia medica under the direction of traditional Chinese medicine and processing methods for Chinese medicines, which can be directly used in clinical practice or the production of prepared medicines

[SOURCE: ISO 18668-1:2016, 3.3, modified — definition revised and note to entry removed.]

3.5
basic traceability information
minimum information that enables an item or product to be traced and tracked inside or outside of the organization

EXAMPLE Places of production, manufacturing enterprises and lot numbers of products.

3.6
extended traceability information
information relating to product quality, safety and other commercial purposes

EXAMPLE Qualification certification, codes and area.

3.7
inspection report
quality control documents (certificate of analysis) provided by third-party organizations regarding the inspection of each batch of Chinese materia medica

3.8
warehouse-in
storage of incoming qualified Chinese materia medica in a warehouse

Note 1 to entry: Storage shall be in accordance with the requirements of ISO 22217.

3.9
warehouse-out
removal of the qualified Chinese materia medica from a warehouse

Note 1 to entry: Handling of outgoing goods shall be in accordance with the requirements of ISO 22217.

4 Traceability requirements

4.1 Basic requirements

4.1.1 Process traceability systems enable transmission of information from upstream suppliers to downstream users.

4.1.2 Recorded information of products is divided into basic traceability information, which shall be recorded, and extended traceability information, which is recorded as necessary.

4.1.3 Organizations that establish a traceability system according to this document shall identify and confirm their role and position in the links of planting or breeding, circulation, processing and use of Chinese medicines in order to determine the traceability point.

4.1.4 Relevant traceability information regarding entities of the planting or breeding and circulation of Chinese materia medica and the processing and use of decoction pieces shall be recorded.

4.1.5 To successfully trace products through a supply chain, it is necessary to identify the following four key elements in a standardized way:

i) products;

ii) stakeholders;

iii) subsets of products based on manufacturing or production;

iv) locations.

This should start with the master data unambiguously identifying products, distinguishing between them by name, index ingredient, strength, pharmaceutical form, packaging and often their pre-established market destination. Medicines need to be identified at the saleable package level (sometimes referred to as the lowest level of packaging for sale to a pharmacy or patient).

The number of uniquely identified manufacturing or production units conversely determines the accuracy of possible tracking and tracing.

Locations and all parties involved shall be clearly identifiable so that product movements between owners and/or locations can be documented in the traceability system.

4.2 Requirements for traceability procedures and archives

4.2.1 Documents

4.2.1.1 The organization shall develop procedure documents to specify the requirements and implement procedures of the traceability system.

4.2.1.2 The organization shall establish procedural documents for the traceability system, including at least the following information:

a) organization structure, obligations and rights of the traceability system;

b) traceability procedures of key links in the process from source material to the delivery of final products;

c) review procedure.

4.2.2 Archives

4.2.2.1 The organization shall record the necessary data for all links of the traceability procedure by electronic or paper documents and identify the responsible person and keeper of these records.

4.2.2.2 The organization shall record all the important information in the process from incoming materials to the delivery of final products.

4.2.2.3 All records shall be kept for at least one year after the expiry date, usage or any other situation when Chinese materia medica arrives at the end of the traceability chain.

4.3 Requirements for traceability information

4.3.1 General

According to the traceability process condition of decoction pieces, the requirements for information records can be divided into several categories, including the planting or breeding and circulation of Chinese materia medica, the processing and use of entities of decoction pieces and the recording of wild medicinal materials' origins.

4.3.2 Traceability information regarding planting and breeding

For traceability information regarding planting and breeding, see Table 1.

Table 1 — Traceability information regarding planting and breeding

Traceability information	Information points	Information type	
		Basic traceability information	Extended traceability information
Planting bases	Planting or breeding enterprise name, legal representative, contact information, address or organization code, good agricultural practice (GAP) certificate, production licence and production address	•	
	Qualification certification, codes, area, plan and personnel situation of bases, qualification and training situation of key personnel and medicinal material varieties		•
Planting and breeding	Name and code of standards of Chinese materia medica, genera and species, and the origins and planting or breeding method of their seeds and seedlings	•	
	Person in charge of planting or breeding and his or her contact information, the time, techniques and surrounding environmental conditions of planting or breeding		•
Disinfectant medicament	Name, manufacturer, production licence number, usage amount and date of usage of disinfectant medicament		•
	Usage, user, qualification of user, ingredients, working concentration, product batch number and registration certificate number of disinfectant medicament		•
Pesticides and chemical fertilizers	Name, manufacturer, production licence number, usage amount and date of usage of pesticides and chemical fertilizers	•	
	Usage, users, qualifications of user and working concentration of pesticides and chemical fertilizer		•
Harvesting	Season and date of harvesting, maturity and harvested medicinal parts	•	
	Weather conditions, information on product certification (e.g. organic food, green food or pollution-free food), the amount, method and tools of harvesting, the sanitary condition of harvesting tools, coding and identification of products harvested		•
After-harvest processing	Processing methods and recording of grades of decoction pieces	•	
	Quantity, processing time, processing cycles, temperature, humidity, sanitary conditions, processing techniques and parameters		•
Transportation	Transportation start and end times and locations	•	
	Transportation company name and address, sanitary conditions of transportation tools, methods, channels, tools and personnel of transportation		•

NOTE Basic traceability information is an essential element and extended traceability information is an optional element.