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Traditional Chinese medicine — Requirements for herbal dispensing services

Médecine traditionnelle chinoise — Exigences relatives aux services de délivrance de plantes médicinales

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Foreword

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This document was prepared by Technical Committee ISO/TC 249, *Traditional medicine*, Subcommittee SC 1, *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.html.

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Traditional Chinese medicine — Requirements for herbal dispensing services

1 Scope

This document specifies the safety and quality requirements for herbal dispensing services. It is applicable to facilities related to large-scale herbal dispensaries, in-house hospital dispensaries and medium to large commercial dispensaries.

It does not apply to dispensing services in medical clinics where herbal preparations are dispensed to patients by or under the supervision of the prescribing practitioners. The specifications regarding tools and equipment used in these services are excluded.

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*

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

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
herbal medicine dispensary
place where *medicinal herbs* (3.3) are either traditionally processed or prepared into decoctions or other dosage forms, or both, in accordance with prescriptions or in-pharmacy formulation guidelines, and subsequently dispensed

Note 1 to entry: This term does not include dispensing services provided within medical clinics where herbal preparations are dispensed directly to patients by, or under the supervision of, the prescribing practitioners.

3.2
dispensing
process by which *medicinal herbs* (3.3) are traditionally prepared through cleaning, cutting, roasting, steaming, or other processing techniques, and subsequently extracted, decocted, or formulated into specific dosage forms according to an individualized prescription or standardized in-pharmacy formulation

3.3
medicinal herb
material collected from plants, minerals or animals, processed or to be processed for use as raw material for *finished herbal preparations* (3.6)

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3.4
subsidiary material
material used for packaging, storing and labelling of *finished herbal preparations* (3.6)

3.5
herbal preparation
dosage form made with *medicinal herbs* (3.3) to be used for the purposes of treatment or prevention of a certain disease for a specific individual according to the prescription or guidelines for in-pharmacy formulation

3.6
finished herbal preparation
dosage form that has been dispensed and is ready to be administered to patients

Note 1 to entry: This applies to traditionally processed herbal formulations that have been processed into decoction or dosage forms ready for administration.

3.7
standard operating procedure
SOP
documented sets of instructions or guidelines that describe the steps and specifications for carrying out a particular task or process

Note 1 to entry: SOPs aim to standardize operations, ensure consistency, and promote efficiency within organizations.

4 Facilities and environment

4.1 Facility requirements

4.1.1 General

The herbal medicine dispensary is equipped with the necessary and qualified equipment for preparation and decoction, such as a dispensing room, medicinal herbs storage facility, and workroom. Regular records and inspections shall be conducted to ensure proper operation and eliminate errors in the process.

General safety includes as following:

a) As part of the operational procedure, the ID code of critical equipment used for preparation should be documented.

b) Equipment that are broken, malfunctioning, or otherwise unusable should be removed or marked as unavailable.

c) Lubricating oil or refrigerant shall be managed to avoid affecting the quality of finished herbal preparations.

4.1.2 Dispensing room

The dispensing room shall be furnished with a clean cabinet to store and preserve opened in-use medicinal herbs and granules, table and also machine and devices to dispense herbal preparations. The dispensing room should be maintained with well controlled sanitation. The weighing devices shall be provided after verifying their accuracy.

4.1.3 Medicinal herbs storage cabinet

a) The storage cabinet for medicinal herbs , partially prepared and finished herbal preparations shall operate under controlled temperature and humidity conditions as specified in ISO 22217.

b) The cabinet shall be well-ventilated and kept out of direct light.

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