标准制定和发布工作规范
Working Regulation for Formulation and Publication of Standard
Foreword

This Regulation describes the technical procedures for the formulation and publication for World Federation of Chinese Medicine Societies (WFCMS) standard.

The standard was proposed by and under the jurisdiction of WFCMS.

The standard was drafted by the Secretariat of the World Federation of Chinese Medicine Societies.

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Introduction

Standardization is a strategic choice for enhancing modernization of Chinese Medicine. It is WFCMS’ core commissions to study, formulate, promulgate and promote International Organizational Standards of Chinese Medicine, which is urgently needed in the international information communication, medical service, talent cultivation, scientific research, management regulation.

International standard, in broad sense, includes standards formulated by international standardization organizations like ISO, IEC, ITU, international organizational standards formulated by standardization-related international organizations, and standards formulated by regional standardization institutions. Whereas, in narrow sense, International standard indicates ISO, IEC, ITU standards and those of other international organizations which are recognized and promulgated on the standard list of ISO. WFCMS standard belongs to international organizational standard.

In order to standardize the work of formulation and publication of International Organizational Standards of Chinese Medicine, an International Standardization Conference of Chinese Medicine was held during the WFCMS Establishment Congress. The proposal of formulating Working Regulation for Formulation and Publication of Standard was raised by representatives from WFCMS member societies. Afterwards, with reference to Procedures for the Technical Work of ISO/IEC Directives, the secretariat drafted the regulation on the principle of high quality, scientificity, objectivity, fairness, impartiality. Simplification and revision was made to the Procedures for the technical work of ISO/IEC Directives so as to comply with the characteristic of international standardization of Chinese Medicine and that of our organization. Eventually, a tryout version took into form after a series of discussion on Chairpersons’ Meeting and Council Board Meeting, during which extensive solicitation of opinions was made. The tryout version was released on WFCMS website in 2006 and served as a ground for standardization work of WFCMS.

Under the guidance of the tryout regulation, the International Standard Chinese-English Basic Nomenclature of Chinese Medicine was formulated and promulgated, and several first working drafts, committee drafts, final draft standards were prepared. During the process of formulating international organizational standard of Chinese Medicine, WFCMS perfected the organization structure of standardization with its Standardization Construction Committee officially registered in state Administration of TCM and Civil Affair Ministry, PRC, and have its technical organizational structure and responsibilities defined. With the combination of Chinese Medicine characteristics and general rules of international standard formulation, the accumulation of precious experiences, and the command of working procedures of international standardization, WFCMS officially promulgates the regulation as a standard making amendments to the tryout version.
1 Scope

This Regulation describes the technical procedures for formulation and publication of International Organizational Standards of Chinese Medicine (IOSCM).

This Regulation is applicable to formulation and publication for WFCMS standard.

2 Structure and Responsibilities of Technical Organization

2.1 Department of International Standardization (DIS) of WFCMS

Being a functional department, the Department of International Standardization is in full charge of the international organizational standardization construction of Chinese Medicine under the leadership of WFCMS Secretariat. Its major responsibilities including: laying out the development plan, organizing the standard study, formulating and implementing standard, building the Technical Committee.

2.2 Standardization Construction Committee (SCC)

As the consultative and decision-making organ of WFCMS, the major responsibilities of Standardization Construction Committee lie in the following areas: conducting scientific research, carrying out academic exchange, reasoning and examining draft of administrative and programming standard on commission, drafting comprehensive standard, cultivating professionals on standardization construction, studying the promotion strategy for international standardization, and raising suggestion on formulation, revision, publication and promotion of international organizational standards. The working fruits are submitted to the Department of International Standardization in forms of suggestion, research report, examining report and final draft Standard.

2.3 Technical Committee (TC) and Professional Standard Inspecting Committee (PSIC)

Organized for formulating comprehensive administrative and programming standards, the Technical Committee is mainly responsible for preparing the draft document, namely committee draft. Considering the strong professionalism, Professional Standard Inspecting Committee is organized to formulating fundamental and technical standards. Professional Standard Inspecting Committee, consisting of authoritative experts normally from relevant specialty committees, is in charge of the study, examining, approval of standards of its own field, and submission of draft document, namely final draft standard. The constitutes of Technical Committee and Professional Standard Inspecting Committee should be approved by relevant Specialty Committee’s Chairpersons’ Meeting with the nomination of the Chairperson and authorized by the Department of International Standardization. In the absence of Specialty Committee, the above-mentioned organizations’ constitutes could be nominated by the Department of International Standardization and established with the examining and approval of WFCMS Secretaries’ Meeting.

2.4 Working Group (WG)

Depending on the work demand, the Standardization Construction Committee, Technical Committee and Professional Standard Inspecting Committee could establish working groups for a particular project. Each working group consists no less than 3 persons without setting up secretariat.

2.5 Member

The core working team members of Standardization Construction Committee, Technical Committee and Professional Standard Inspecting Committee could be classified into two categories, positive (P) member and observatory (O) member. P members of Standardization Construction Committee should be approved by its Chairpersons’ Meeting with the nomination of its Chairperson, and recorded in the De-
partment of International Standardization. The number of P Members should be more than 15 persons. The distribution of Committees should take Internationalism and representativeness of the region into account. P members of newly established Technical Committee or Professional Standard Inspecting Committee should be approved by its Directors' Meeting with the nomination of its Director, and recorded in the Department of International Standardization. O members can register voluntarily, verified by the Chairperson or Director of relevant committee, and also be invited particularly by the Chairperson or Director according to the work requirements. The core working team members of Technical Committee and Professional Standard Inspecting Committee consists of P members, not fewer than 21 persons in number, being international and representative in regional distribution, Secretary Group could be established with its members nominated by Director of relevant Technical Committee and Professional Standard Inspecting Committee, and approved by its Directors’ Meeting. P members required to participate activities of the committee and take corresponding work, own their rights to vote and their obligations to fulfill. O members are allowed to attend conferences without being granted the voting rights, take part in activities and take some corresponding work, air their opinions and suggestions and get relevant documents.

3 Formulation and Publication Procedures

3.1 Formulating Development Plan

On the ground of the needs and conditions of international development of Chinese Medicine, the development plan of International Organizational Standardization is drafted by the Department of International Standardization through investigation. The draft should be verified by Standardization Construction Committee with a simple majority vote after consultation and reasoning, and approved by the Secretariat afterwards.

3.2 New Proposal (NP)

In accordance with the objectives and missions of development plan, new proposal could be raised by Member Societies, Specialty Committees, Technical Committees, Professional Standard Inspecting Committees, Committee for Senior Advisors, Advisory Committee for Working, Supervision Committee, and Executive Council Members. An NP might be a new standard, adding new content or making amendment on the present standard with several items, including synopsis (scope, main technical content, principle and basis, necessity, feasibility, and working outline). NP will be referred to the Department of International Standardization in the form of project proposal.

3.3 Project Acceptance

After a form examination by the Department of International Standardization, an NP will be handed over to Standardization Construction Committee for consultation and reasoning. After gathering opinions from O members, the NP could be accepted by a simple majority vote of P members. P members can participate voting via meetings or correspondences. This period will last no more than 3 months. To meet urgent needs, some projects can be accepted directly through discussion and approval of WFCMS Secretaries' Meeting after soliciting opinions from all parties involved by the Department of International Standardization.

3.4 Launching Preparation

Launching Preparation includes record, publication, solicitation and task implementation.

3.4.1 Accepted NP will be sent to WFCMS executive council members by email and publicized on the website of WFCMS by the Department of International Standardization.
3.4.2 Opinions and proposals will be collected extensively from WFCMS field and the public by The Department of International Standardization, followed by gathering and sorting out. The opinions and proposals should be handed over to relevant Technical Committee and Professional Standard Inspecting Committee for reference.

3.4.3 According to the working function, the drafting work of accepted NP will be resigned to relevant Technical Committee and Professional Standard Inspecting Committee. If necessary, a new Technical Committee or sub-Technical Committee can be founded.

3.5 Preparation of Draft Document

Preparation of draft document including drafting, reasoning and draft document confirming.

According to the maturity level, a standard could be classified into four periodic forms in the process of drafting, namely first working draft, committee draft, final draft, Standard and publication Standard. Time limits for preparing the four periodic forms are 10 months, 5 months, 5 months and 8 months respectively.

Technical Committee and Professional Standard Inspecting Committee, taking the accepted NP should designate a person or a working group to take charge of drafting. In an attempt to incorporate the latest research findings and practical working experience from various countries, reasoning conferences, seminars and discussions (via correspondence or internet) can be held to synthesize correct opinions from different sources.

Technical Committee’s first working draft, verified firstly by a simple majority vote of relevant committee, will be submitted to the Department of International Standardization as committee draft, which will form final draft Standard after being examined by Standardization Construction Committee or revised by soliciting opinions extensively on internet.

Professional Standard Inspecting Committee’s first working draft, verified by two-thirds majority vote of P members of relevant committee, will be referred to the Department of International Standardization as final draft Standard.

Committee draft or final draft standard, formulated by Technical Committee and Professional Standard Inspecting Committee, should be prepared bilingually according to a prescriptive form.

3.6 Procedure of Approval

Final draft standard is subject to vote for approval by WFCMS Council Board before an authorized standard comes into being.

After listening to the drafting introduction delivered by Technical Committee or Professional Standard Inspecting Committee, the final draft standard will be examined by the Council Board in respect of the working procedure and essential principal problems. After discussion and deliberation, the final draft standard could be approved with a simple majority vote.

3.7 Publication

Approved standard will be publicized in the name of WFCMS and in the form of Announcement with Chairperson Issue. The content of a standard could be a publication. Signatures of Drafters and verifiers can be attached with the standard to enhance its authority and have their contributions well recognized. Some fundamental or common standards can be publicized together with other relevant international organizations.

3.8 Revision

In order to adopt the new developments, maintain the advanced nature of standards and embody the era characteristics, the International Organizational Standards of Chinese Medicine is going to be revised around every five years.