



# ***ISO/TC 249 NEWSLETTER***

***— — Vol.15 — —***

*December 2023*





Dear colleagues and friends,

In 2023, we successfully held the 13th Plenary Meeting of ISO/TC 249 in Shanghai, China, where the ISO/TC 249 Secretariat is located. Since the establishment of ISO/TC 249, we have already published 101 ISO International standards, with 35 projects currently under development. We are delighted that there is renewed enthusiasm among all members of our committee as we move forward after the global pandemic.

Our work is progressing smoothly. In 2024, guided by ISO Strategy 2030, we will continue to ensure the high-quality development of ISO/TC 249 international standards based on the principles of voluntary, consensus-based, and market-relevant.

We would like to express our gratitude to all colleagues at ISO/TC 249 for their contributions in the year 2023.

Wishing you all a merry Christmas and a happy New Year!

Best regards,  
Shen Yuandong  
ISO/TC 249 Chair



The background features a light beige color with various winter-themed illustrations. On the left, there are green pine branches, a red cardinal perched on a brown branch, and a small blue snowflake. On the right, there is a red squirrel on a branch, a green Christmas ornament with yellow, purple, and red dots, a small blue snowflake, and a small green butterfly. A large, faint number '01' is visible behind the text box. The text is centered within a teal rectangular box with a white border and a dashed line inside.

# **Major Events** **of ISO/TC 249** **in 2023**

# The 13<sup>th</sup> Plenary Meeting of ISO/TC 249



The 13th plenary session of ISO/TC 249 convened at the Shanghai Academy of International Standardization for Traditional Chinese Medicine (SAIS-TCM) from June 4 to 9, 2023. The meeting brought together representatives from 16 national member bodies, including China, Japan, South Korea, Australia, Germany, the Netherlands, Hungary, Ghana, Saudi Arabia, Iran, Canada, Russia, Italy, Vietnam, Singapore, and Spain. Additionally, Ms. Monja Korter from ISO Central Secretariat, the secretariat of TC 249, representatives from 3 liaison organizations - World Federation of Acupuncture-Moxibustion Societies (WFAS), World Federation of Chinese Medicine Societies (WFCMS), and ISO/TC 314 - participated in the meeting. The event was attended by a hybrid way. Throughout the plenary, the Working Group held 8 meetings to discuss various topics related to their work.

During the five-day meeting, a total of 8 working group meetings were conducted, during which 16 new project proposals and 34 ongoing projects were thoroughly examined. The committee formed 49 resolutions on project development and significant matters. Consensus was reached regarding the expansion of CAG 1 membership, as well as the promotion of liaison organization work and overall terminology coordination efforts.

The awarding ceremony took place during the banquet, where 52 standards published in the past three years were recognized and their project leaders and teams were honored.





**WG1**



**WG2**



**WG3**



**WG4**



**WG5**



**JWGI**



**AHG**

# Summary of WG meetings in 2023

Committee	Start date	City	Attended participant
ISO/TC 249/WG 2	3-Nov	Shaoxing	45
ISO/TC 249/WG 1	2-Nov	Shaoxing	56
ISO/TC 249/WG 5	12-Oct	Shenyang	52
ISO/TC 249/WG 5	6-Jun	Shanghai	67
ISO/TC 249/WG 4	7-Jun	Shanghai	57
ISO/TC 249/WG 3	5-Jun	Shanghai	44
ISO/TC 249/WG 2	7-Jun	Shanghai	80
ISO/TC 249/WG 1	5-Jun 6-Jun	Shanghai	99
ISO/TC 249/JWG 1	7-Jun	Shanghai	48
ISO/TC 249/CAG 1&2	4-Jun	Shanghai	19
ISO/TC 249/AG	6-Jun	Shanghai	13
ISO/TC 249/CAG 1&2	22-Mar	Virtual	19
ISO/TC 249/WG 1	6-Mar	Virtual	59
ISO/TC 249/WG 2	23-Feb	Virtual	48
ISO/TC 249/JWG 1	31-Jan	Virtual	35



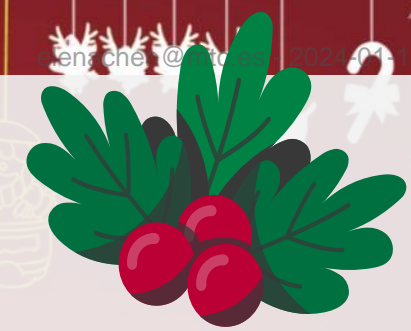
# **Project Development of ISO/TC 249 in 2023**

# New publications of ISO/TC 249 in 2023

Reference	Document title	Current stage
ISO/TS 13126:2023	Traditional Chinese medicine — Determination of ochratoxin A in natural products by liquid chromatography coupled with fluorescence detector	60.60
ISO 4564:2023	Traditional Chinese medicine — <i>Scutellaria baicalensis</i> root	60.60
ISO 22587:2023	Traditional Chinese medicine — Acupoint magnetotherapy plasters for single use	60.60
ISO 7177:2023	Traditional Chinese medicine — <i>Coptis chinensis</i> and <i>Coptis japonica</i> rhizome	60.60
ISO 5228:2023	Traditional Chinese medicine — <i>Rheum palmatum</i> , <i>Rheum tanguticum</i> and <i>Rheum officinale</i> root and rhizome	60.60
ISO 7450:2023	Traditional Chinese medicine — <i>Pinellia ternata</i> tuber	60.60
ISO 4904:2023	Traditional Chinese medicine — Inner pack of decoction pieces	60.60
ISO 9306:2023	Traditional Chinese medicine — <i>Ephedra sinica</i> , <i>Ephedra intermedia</i> and <i>Ephedra equisetina</i> herbaceous stem	60.60



# Results of Systematic Review



Projects	Start Date	End Date	SR Result	Adopted or intended to be adopted as National Standard by Member Bodies
ISO 20498-2:2017	2022-04-15	2022-09-02	Confirm	China (SAC) Ghana (GSA) Kenya (KEBS) Korea, Republic of (KATS) Thailand (TISI) United Kingdom (BSI) Viet Nam (STAMEQ)
ISO/TS 22990:2019	2022-04-15	2022-09-02	Confirm	Ghana (GSA) Kenya (KEBS) Saudi Arabia (SASO) Viet Nam (STAMEQ)
ISO 20333:2017	2022-07-15	2022-12-02	Confirm	China (SAC) Netherlands (NEN) United Kingdom (BSI) Viet Nam (STAMEQ)
ISO 18662-1:2017	2022-07-15	2022-12-02	Revised	China (SAC) Kenya (KEBS) Netherlands (NEN) United Kingdom (BSI) Viet Nam (STAMEQ)



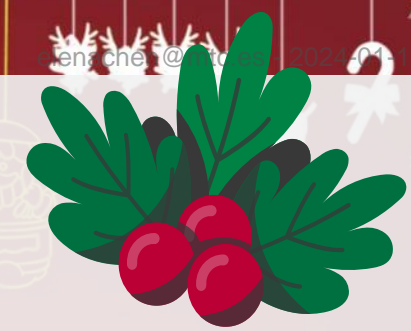
# Results of Systematic Review



Projects	Start Date	End Date	SR Result	Adopted or intended to be adopted as National Standard by Member Bodies
ISO 20759:2017	2022-10-15	2023-03-04	Confirm	China (SAC) Ghana (GSA) Kenya (KEBS)
ISO 21371:2018	2023-01-15	2023-06-04	Confirm	Ghana (GSA) Italy (UNI) Japan (JISC) Kenya (KEBS)
ISO/TS 20498-3:2020	2023-04-15	2023-09-02	Confirm	Ghana (GSA) Japan (JISC) Netherlands (NEN)
ISO 20495:2018	2023-04-15	2023-09-02	Confirm	China (SAC) Ghana (GSA) Netherlands (NEN) United Kingdom (BSI)



# Results of Systematic Review



Projects	Start Date	End Date	SR Result	Adopted or intended to be adopted as National Standard by Member Bodies
ISO 20334:2018	2023-04-15	2023-09-02	Confirm	China (SAC) Ghana (GSA) Kenya (KEBS) Netherlands (NEN) United Kingdom (BSI)
ISO 19617:2018	2023-04-15	2023-09-02	Confirm	Ghana (GSA) Japan (JISC) Kenya (KEBS) United Kingdom (BSI)
ISO/TS 21310:2020	2023-07-15	2023-12-02	Confirm	Ghana (GSA) Japan (JISC)
ISO 20493:2018	2023-07-15	2023-12-02	Confirm	China (SAC) Ghana (GSA) Switzerland (SNV)



# Projects under development


Reference	Document title	Current stage
ISO 9109	Traditional Chinese medicine — <i>Rehmannia glutinosa</i> root	60.00
ISO/DTR 18986	Traditional Chinese medicine — Report on the global industry and standardization development of <i>Panax ginseng</i>	50.20
ISO/FDIS 9319	Traditional Chinese medicine — <i>Poria cocos</i> sclerotium	50.20
ISO/FDIS 8071	Traditional Chinese Medicine — <i>Ligusticum chuanxiong</i> rhizome	50.00
ISO/FDIS 6904	Traditional Chinese Medicine — General requirements for the ultrafine powder of herbs	50.00
ISO/DIS 13619	Traditional Chinese medicine — <i>Gardenia jasminoides</i> fruit	40.99
ISO/DIS 8959	Traditional Chinese Medicine — <i>Eucommia ulmoides</i> stem bark	40.99
ISO/DIS 6559	Traditional Chinese medicine — Sterile three-edge needle for single use	40.60
ISO/DIS 13615	Traditional Chinese Medicine — <i>Atractylodes macrocephala</i> rhizome	40.60
ISO/DIS 9299	Traditional Chinese Medicine — <i>Curcuma Longa</i> rhizome	40.60



Reference	Document title	Current stage
ISO/DIS 8284	Traditional Chinese medicine — Simplified accelerated stress simulation methods	40.20
ISO/DIS 5076	Traditional Chinese Medicine — <i>Angelica dahurica</i> root	40.20
ISO/DIS 19025	Traditional Chinese Medicine — <i>Glycyrrhiza uralensis</i> , <i>Glycyrrhiza inflata</i> , and <i>Glycyrrhiza glabra</i> roots and rhizome	40.00
ISO/CD TS 23961-3	Traditional Chinese Medicine — Vocabulary for Diagnostics — Part 3: Abdomen	30.99
ISO/CD 5106	Traditional Chinese Medicine — <i>Polygala tenuifolia</i> and <i>Polygala sibirica</i> root	30.99
ISO/AWI 19617	Traditional Chinese medicine — General requirements for the manufacturing process of natural products	30.99
ISO/CD TS 6818	Traditional Chinese medicine — Test method for moxa floss quality — concentration of waste particles	30.60
ISO/CD 19851	Traditional Chinese Medicine — <i>Cinnamomum cassia</i> branch	30.60
ISO/CD 19842	Traditional Chinese Medicine — <i>Dioscorea opposita</i> rhizome	30.60
ISO/CD 19836	Traditional Chinese Medicine — <i>Platycodon grandiflorus</i> root	30.60
ISO/CD 19015	Traditional Chinese Medicine — <i>Glycyrrhiza uralensis</i> and <i>Glycyrrhiza glabra</i> seeds and seedlings	30.60



Reference	Document title	Current stage
ISO/CD 5471	Traditional Chinese Medicine — <i>Carthamus tinctorius</i> flower	30.60
ISO/CD 18662-3	Traditional Chinese medicine — Vocabulary — Part 3: Efficacy of Chinese Materia Medica	30.20
ISO/CD 19047	Traditional Chinese Medicine — <i>Polygonum multiflorum</i> root	30.00
ISO/CD 18977	Traditional Chinese medicine — Minimum requirements for herbal dispensing services	30.00
ISO/CD 18662-1	Traditional Chinese medicine — Vocabulary — Part 1: Chinese Materia Medica	30.00
ISO/AWITR 23975	Traditional Chinese medicine — Priority list of single herbal medicines for developing standards	20.00
ISO/AWITS 21758	Traditional Chinese Medicine — General requirements of stick-type package for viscous extracts	20.00
ISO/AWITS 21756	Traditional Chinese Medicine — General requirements of manufacturing procedures and quality for <i>Salvia miltiorrhiza</i> formula granules	20.00
ISO/AWI 21590	Traditional Chinese Medicine — <i>Crocus sativus</i> stigma	20.00
ISO/AWI 24066	Traditional Chinese medicine-- <i>Euodia</i> (syn. <i>Evodia</i> or <i>Tetradium</i> ) fruit	20.00
ISO/AWI 24063	Traditional Chinese medicine — <i>Ziziphus jujuba</i> fruit	20.00
ISO/AWI 24049	Traditional Chinese medicine — <i>Aconitum carmichaelii</i> parent root tuber	20.00
ISO/AWI 19611	Traditional Chinese medicine — Air extraction cupping device	10.99
ISO/AWI 18615	Traditional Chinese medicine — General requirements of electric radial pulse tonometric devices	10.99



# **ISO/TC 249 and Liaison's Activities in 2023**

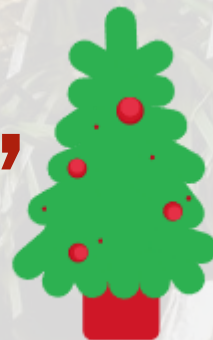
# The 10<sup>th</sup> and 11<sup>th</sup> joint meeting of CAG1 & CAG2

The 10th joint CAG1 and CAG2 teleconference was held on 22 March 2023. 2 month later, the 11th joint CAG1 and CAG2 teleconference was held during the 13th plenary meeting at the Shanghai Academy of International Standardization for Traditional Chinese Medicine (SAIS-TCM). The following agenda items have been discussed,

- Updating on SBP document
- Liaison arrangements (USP&IEC)
- Expansion of CAG 1 membership
- Discussion about the meeting arrangements and agenda items of TC249 13th plenary meeting.
- Discussion on the new projects submitted to the 13th plenary meeting and intended allocation of projects to each Working Group.
- WG leaders' reports on the progress of Working Group.



# Visit of ISO Vice-President, Javier Garcia



On November 5th, **Javier Garcia**, the Technical Management Vice President of ISO, together with Li Yubin, the Deputy Director of the Standard Innovation Department of SAC visited ISO/TC 249 Secretariat.

Prof. Shen Yuandong introduced the development history and innovative work achievements of ISO/TC 249, and demonstrated successful cases of ISO international standards promoting industrial development.

Javier Garcia highly praised the significant achievements and excellent management skill of ISO/TC 249 in the field of international standardization of traditional Chinese medicine. He expected ISO/TC 249 would further implement the United Nations Sustainable Development Goals, actively respond to climate change, promote the implementation of "ISO Strategy 2030" and "ISO London Declaration", and develop relevant international standards.

# ISO/TC 215 Plenary Meetings in 2023

ISO/TC 215 *Health Informatics* held its 40th plenary meeting from Nov. 8-16, 2023 in Arlington, USA and the next plenary meetings are scheduled in April 2024 by virtual mode and in November 2024 in New Delhi, India.

As the representative of ISO/TC249 Secretariat and the secretary for WG 10, *Traditional Medicine*, Ms. Li Jing (Ivy) joined the JWG 1 and WG 10 meetings and a couple of subsequent joint sessions with WG 6 *Pharmacy and medicines business* and WG 11 *Personalized digital health*. Up to date, the JWG 1 groups (of TC249 and TC215) have made significant progress in the domain of TCM informatics standards, including 31 published standards and 6 projects under development.



There are 6 previous standards going through the systematic review process in 2023. Two recent publications led by JWG 1 are listed as follows,

- ISO/TS 5044:2023 *Health informatics — Information model for quality control of traditional Chinese medicinal products*
- ISO/TS 5569:2023 *Health informatics — Conceptual data model for Chinese medicinal herbs*



## ISO/TC 314 Plenary Meeting in 2023

ISO/TC 314 had its yearly plenary meeting in Helsinki in October 2023. As the representative of ISO/TC 249, Mr Huang Yiran took part in 11th plenary meetings of ISO/TC 314 and submit liaison report. Throughout the plenary week's discussions, it became clear that ISO/TC 314 still holds a unique and important scope. Given this is a significant moment in time where older persons outnumber young children and improvements in healthcare enable a longer longevity.

### TC 314 has 3 published standards:

- Ageing Societies -- Framework for Dementia-inclusive communities
- Ageing Societies -- Guidelines for an age inclusive work force
- Ageing societies -- Carer-inclusive and accommodating organizations

### 5 active work items:

- ISO 25553 - Smart Multigenerational Neighbourhoods- Guidance and Requirements
- ISO 25554 - Ageing Societies-- Guidelines for Promoting Wellbeing in Local Communities and Organizations
- ISO TS 25555 - Aging society — Accessibility and usability considerations for home-based healthcare products, related services and environments
- ISO 25556 - Ageing societies — General requirements and guidelines for ageing-inclusive digital economy
- ISO/WD 25557.2 - Ageing societies — Care for older persons at home and in residential care facilities

## IEC/TC 62 and its subcommittees' Plenary Meetings in 2023



IEC/TC 62, IEC/SC 62B and IEC/SC 62D are liaison committees of ISO/TC 249. The plenary meetings of ISO/TC 62 and its subcommittees were held in Seoul, South Korea on September 11-22, 2023. As the representatives of ISO/TC 249, Ms. XU Xiaoting from ISO/TC 249 secretariat and Ms. LEE Yujung, the secretary of WG4 attended their meetings and made communications with IEC experts in the field of electrical TCM medical devices and the potential possibilities of AI application. In the plenary meeting of IEC/SC 62B, Ms. LEE made a report about the work of TCM medical devices in ISO/TC 249.

Now IEC/SC 62B has established PT 63524 to develop a standard focusing on **“Artificial intelligence-enabled medical devices — Computer-assisted analysis software for pulmonary images — Algorithm performance”**. ISO/TC 249 is also very concerned about the standardization of artificial intelligence in TCM medical devices and we will keep to monitor the progress of the related projects in IEC.

# WHO TCI Department

On April 25th, Dr. Rudolf Richard Eggers, Director of Integrated Health Services at WHO, accompanied by Kim Sungchol, Head of the Traditional, Complementary, and Integrative Medicine Unit within the Integrated Health Services at WHO, visited SAIS-TCM.

Prof. Shen Yuandong provided an overview of the development of ISO/TC 249. He underscored that WHO holds an A-level liaison with ISO/TC 249, expressing the aspiration for enhanced communication and collaboration between ISO/TC 249 and relevant WHO departments in the realm of traditional medicine. Discussions encompassed various subjects, including collaboration between ISO traditional Chinese medicine standards and the WHO International Pharmacopoeia of Herbal Medicines, international intervention classification research in traditional medicine, and joint initiatives in international standardization research on traditional medicine.



Dr. Rudolf Richard Eggers acknowledged the substantial contributions of ISO/TC 249 and underscored the pivotal role of standardization in the advancement of traditional medicine. He affirmed his commitment to fostering collaboration between WHO departments and ISO/TC 249 in the field of traditional medicine standardization. Dr. Eggers also expressed a readiness to explore innovative modes of collaboration to contribute to the global advancement of health.

## The 7th Summer Summit of the World Congress of Chinese Medicine convened in Guiyang, Guizhou Province, China

The 7th Summer Summit of the World Congress of Chinese Medicine opened on June 25, 2023, in Guiyang, Guizhou Province, China. Prof. SHEN Yuandong, Chair of ISO/TC 249, was invited to attend the Congress and delivered a welcome speech on the opening ceremony.



## The 20th World Congress of Chinese Medicine was convened in Manila, Philippines on November 15, 2023

The 20th World Congress of Chinese Medicine was convened in Manila, Philippines, and in visual meeting at the same time, on November 15, 2023. It was also held for celebrating the 20th anniversary of World Federation of Chinese medicine societies (WFCMS).



## WFCMS Secretary's Visit to the Secretariat of ISO/TC 249

On Nov 30th, the Secretary of WFCMS, Li Yu, and his delegation visited the Secretariat of ISO/TC 249. The purpose of this visit is to explore new mechanisms for international standardization cooperation in traditional Chinese medicine. Both parties expressed their intention to strengthen cooperation and further promote domestic and international standard synergy and connectivity in the field of key types of Chinese materia medica, novel dosage forms of Chinese materia medica, new modes of health systems, etc.



## WFAS President's Visit to the Secretariat of ISO/TC 249

On May 17th, the President of the World Federation of Acupuncture Societies (WFAS), **Liu Baoyan**, and **his delegation** visited the Secretariat of ISO/TC 249.

During this meeting, both parties fully exchanged ideas on how to deepen inter-organizational cooperation, promote the implementation and application of acupuncture international standardization. Both parties expressed their intention to strengthen cooperation and further promote domestic and international standard synergy and connectivity.



## Progress of new international standards

In June 2023, the Standardization Working Committee of WFAS completed change of term. The third session of Committee consists of a total of 28 members from 11 countries/regions. In 2023 the Standardization Working Committee of WFAS organized the release of 21 international standards for acupuncture-moxibustion of the WFAS.



## WFAS 2023 International Symposium on Acupuncture-Moxibustion

WFAS 2023 International Symposium on Acupuncture-Moxibustion was held 18-19 November 2023 in Bangkok, Thailand. This Symposium is sponsored by WFAS and China Academy of Chinese Medical Sciences, and organized by TCM Doctor Association Thailand.



## US Pharmacopeia (USP)

organizational structure, progress, and future plans related to the development of dietary supplement standards. Prof. Shen offered insights into the historical development of ISO/TC 249 and presented the latest achievements of ISO international standards, highlighting successful cases where ISO standards have played a pivotal role in advancing industrial development.

Throughout the discussion, experts from both sides expressed keen interest in each other's work, engaging in conversations about the overall goals, key technologies, and indicator requirements associated with ISO and USP standards. Both parties shared the belief that robust collaboration between these institutions would significantly contribute to the more scientific and safe application of traditional medicine.



On November 17th, Dr. Nanadakumaran Sarma, Director of Dietary Supplement Standards at the United States Pharmacopeia (USP), and his team paid a visit to the Secretariat of ISO/TC 249.

Prof. Shen Yuandong extended a warm welcome to the USP experts visiting the Secretariat of ISO/TC 249. Dr. Nanadakumaran Sarma provided an overview of the USP's overarching goals,

# New Changes on ISO Directives 2023

2023 edition of the ISO/IEC Directives Part 1 & Consolidated ISO Supplement have been released. All the relevant files as well as a helpful PowerPoint presentation summarizing the changes are accessible here:

<https://isotc.iso.org/livelink/livelink?func=ll&objId=4230452&objAction=browse&sort=subtype>

**There are several key changes relevant to working procedures of committees and WGs in ISO/IEC Directives Part 1:**

- Participation in the work of committees: *Clause 1.7.4*  
Revised participation criteria.
- Working groups may establish subgroups: *Clause 1.12.1*
- Guests at WG and other groups meetings: *Clause 1.12.2*
- Change of project leader during a project: *Clause 2.1.8*  
Clarifications introduced on the process to nominate a new project leader when the current project leader resigns.

**There are several key changes in ISO Supplement:**

- Commenting at the CD stage: *Foreword*
- Proposal stage - PAS: *Clause 2.3.1* NP is no longer required for a new PAS – neither for its revision. The procedure to develop a PAS is now specified in clause 3.2.
- Review of documents: *Clause 2.9.2*

# The 14th Plenary Meeting of ISO/TC 249

The 14th plenary meeting of ISO/TC 249 including CAGs meeting will be held in **Sydney, Australia from June 2-7 2024**. Please finish the online meeting registration **before May 19, 2024** via

<https://sd.iso.org/meetings/138097>



## **Deadlines of posting committee documents for the 14th plenary meeting in 2024**

The cutoff dates for posting papers for preparation of the 14th plenary meeting in 2024 are:

- 2 February 2024 for major documents including NWIPs to be discussed during the meeting
- 17 April 2024 for other papers
- 24 May 2024 for the final agenda and minor papers

**Please note that** for those major documents including NWIPs (new work item proposals) to be discussed during the meeting, members are requested to submit them to the Secretariat at [mscsh2009@gmail.com](mailto:mscsh2009@gmail.com) by 18 January 2024 to allow processing time for the 2nd February 2024 cutoff date.



# Shanghai Academy of International Standardization for Traditional Chinese Medicine



Shanghai Academy of International Standardization for Traditional Chinese Medicine was **established in September 2022** and **officially inaugurated in June 2023**.

The academy includes **Secretariat of ISO/TC 249 Traditional Chinese Medicine, Center for International Classification Research on Traditional Chinese Medicine Clinical Conditions and Service Evaluation (WHO ICTM), Secretariat of Committee of Standardization Construction of World Federation of Chinese Medicine Societies (WFCMS-CSC), etc.**



World Health Organization  
(WHO)

世界卫生组织《国际疾病分类  
第十一次修订本(ICD-11)》



International Organization for  
Standardization (ISO)

国际标准化组织中医药技术委  
员会 (ISO/TC 249)



World Federation of Chinese  
Medicine Societies (WFCMS)

世界中医药学会联合会标准化  
建设委员会

The academy will be open to all ISO/TC 249 experts from around the world, providing a platform for promoting international standards, fostering collaboration, and advancing research among experts from diverse countries and regions.