



ISO/TC 249 NEWSLETTER

—— VOL.13 ——

DECEMBER 2021



Dear Colleagues,

The year of 2021 is coming to its end, and the New Year is around the corner. Despite the difficulties brought by the pandemic, ISO/TC 249 has made a steady progress with the joint efforts of all our members: holding the 11th plenary meeting virtually, publishing 13 international standards and 16 new projects in a total being launched since last year.

Thanks to the dedicated leadership and experts from the 6 ongoing Working Groups, 17 WG sessions have been successfully held in 2021. Moreover, we are thrilled to see a new Advisory Group established to support the consistency of terms and vocabularies.

Our achievements are not easy to come by. As many of our members are medical practitioners, when they were fighting against coronavirus, they managed to contribute to the work of international standardization. On behalf of the committee, I would like to extend my sincere appreciation to our colleagues and experts. We would continue to proceed the standardization work of TCM in light of the new *ISO Strategy 2030*.

At the moment of ringing out the old year and ringing in the new, I miss you all deeply. I hope such difficult situations will end soon so I can meet you in person. More than ever, wish you and your family a Merry Christmas and in good health!

Best wishes,

ISO/TC 249 Chair

SHEN. 



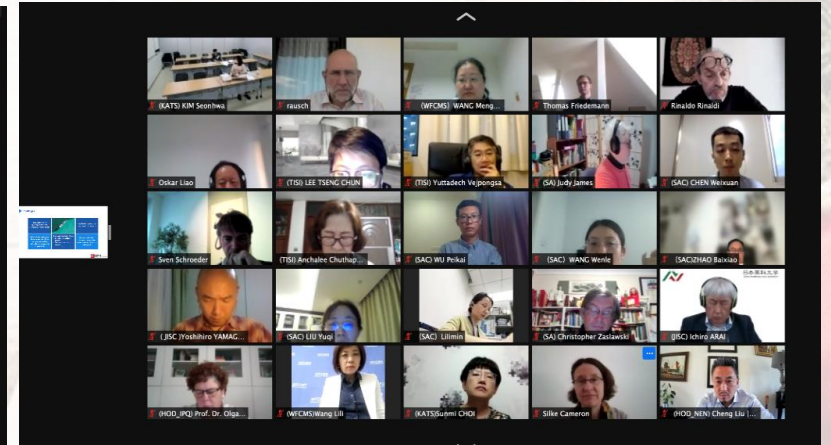
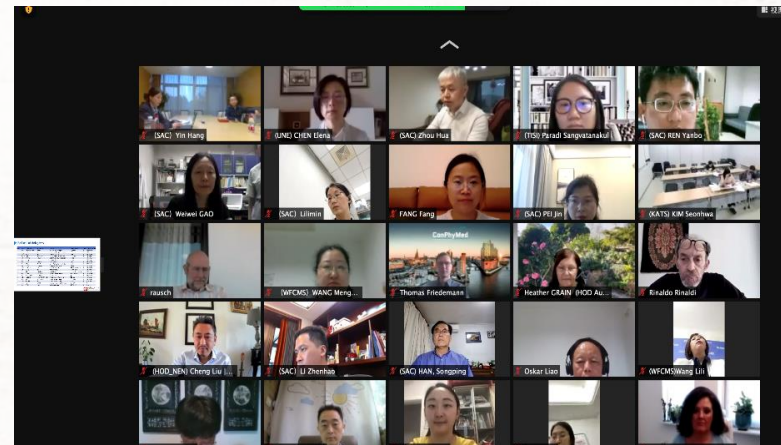
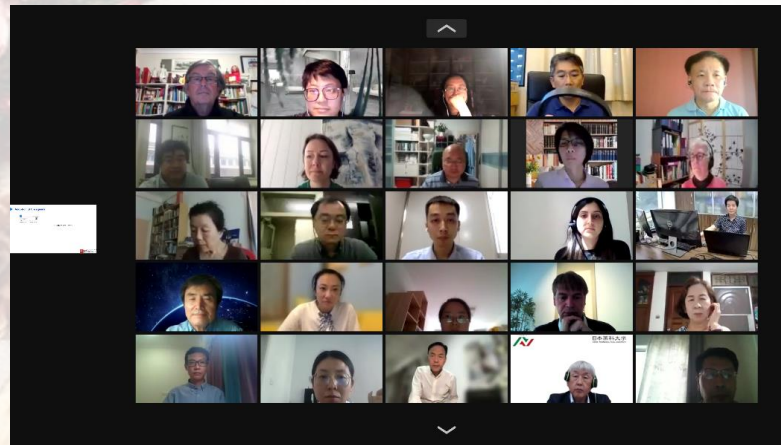
Major Events of TC249 in 2021

The 11th Plenary Meeting of ISO/TC 249



Due to the COVID-19 pandemic, the 11th ISO/TC 249 plenary meeting had to be postponed to this year and held virtually from June 1-29, 2021.

20 national member bodies (Argentina, Australia, Bahrain, Canada, China, Germany, Ghana, Hungary, Italy, Japan, Kenya, Norway, Republic of Korea, Netherlands, Russian Federation, Saudi Arabia, Spain, Portugal, Thailand, Vietnam) participated with 206 delegates that also included the ISO/TC 249 secretariat, Chair, Mr. Charles-Pierre Bazin de Caix from ISO Central Secretariat and representatives from two Category-A liaison organizations WFAS, WFCMS and a representative from ISO/TC 215.



Summary of WG virtual meetings in 2021

The following 17 virtual sessions of Working Groups were held from June to December 2021.

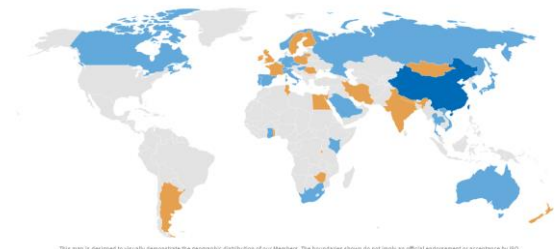
WG	Meetings held	Number of participants
WG1	March 15	52
	April 12	56
	May 10	56
	June 2	75
	October 25	56
WG2	March 11	45
	June 8	73
WG3	January 26	37
	June 22	47
WG4	June 10	57
	June 17	61
	November 4	48
	December 9	38
WG5	June 9	66
	June 16	63
JWG1	June 11	42
	December 1	48

Welcome New Member Bodies to ISO/TC 249 Family

There are 2 new member bodies joining the ISO/TC 249 in 2021.

- Egypt (EOS)
- Bahrain (BSMD)

ISO/TC 249 now has 22 Participating Members and 24 Observing Members



This map is designed to visually demonstrate the geographic distribution of our Members. The boundaries shown do not imply an official endorsement or acceptance by ISO.



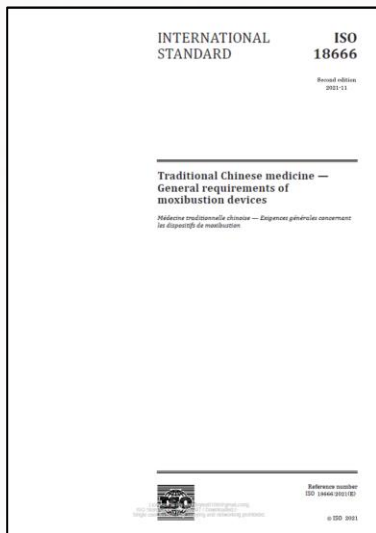
Project Development of TC249 in 2021

Results of Systematic Review

Projects	Start Date	End Datie	SR Result	Adopted as National Standard by Member Bodies
ISO 17218:2014 Sterile acupuncture needles for single use	2019-01-15	2019-06-04	Confirm	Adopted (identical) : SA、NEN、TISI Adopted (modified) : SAC、UNI、JISC、KATS、SASO
ISO 17217-1:2014 Traditional Chinese medicine -- Ginseng seeds and seedlings -- Part 1: Panax ginseng C.A. Meyer	2019-04-15	2019-09-02	Confirm	Adopted (identical) : SA、SAC、NEN、BSI Adopted (modified) : JISC
ISO 18664:2015 Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine	2020-07-15	2020-12-02	Confirm	Adopted (identical) : SAC、KEBS、NEN、GOST R、BSI Adopted (modified) : JISC

Results of Systematic Review

Projects	Start Date	End Date	SR Result	Adopted as National Standard by Member Bodies
ISO 18665:2015 Traditional Chinese medicine — Herbal decoction apparatus	2020-10-15	2021-03-04	Revise / Amend, Underdevelopment	Adopted (identical) : GSA、JISC、 KATS、NEN、BSI、STAMEQ Adopted (modified) : TISI
ISO 18666:2015 Traditional Chinese medicine — General requirements of moxibustion devices	2020-10-15	2021-03-04	Revise / Amend, Republished as ISO 18666:2021	Adopted (identical) : GSA、 NEN、BSI、STAMEQ Adopted (modified) : KATS、 TISI



ISO 18666:2021 (Revision of ISO 18666:2015)

Traditional Chinese medicine — General requirements of moxibustion devices

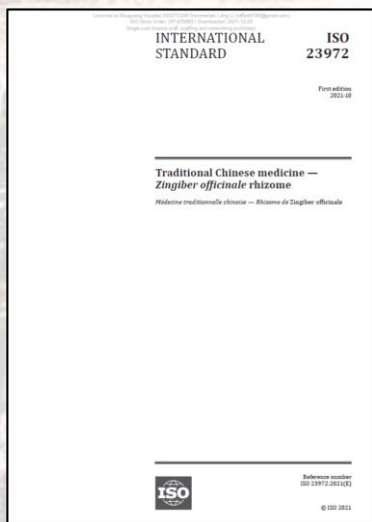
This document specifies the general requirements for configuration, materials, performance and safety requirements of moxibustion devices. It also specifies the minimum requirements for moxibustion materials used in moxibustion devices.

It is applicable across a wide range of moxibustion devices that use moxa floss as the main combustion material and can remain on or over the body throughout the moxibustion process. It is applicable to moxibustion devices for both single and repeated usage.

This document does not apply to devices that imitate moxibustion, such as electro-moxibustion and infrared moxibustion devices that do not involve the use of moxa floss. It also does not apply to moxa floss used in direct moxibustion.

ISO link to purchase at <https://www.iso.org/standard/83343.html?browse=tc>

New publications of ISO/TC 249 in 2021

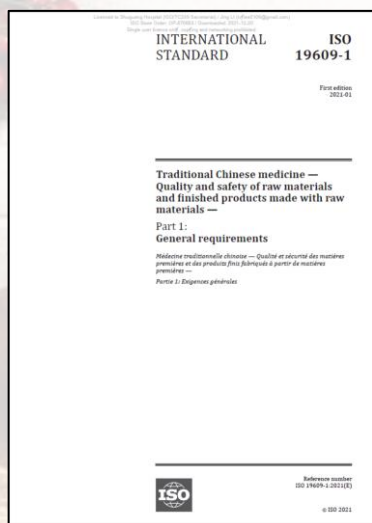


ISO 23972:2021 Traditional Chinese medicine — *Zingiber officinale* rhizome

This document specifies the quality and safety requirements of *Zingiber officinale* rhizome derived from the plant *Zingiber officinale* Roscoe, including the minimum requirements and test methods.

This document applies to *Zingiber officinale* rhizome that is sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from this plant. It is not applicable to *Zingiber officinale* rhizome sold and used as food or spices.

ISO link to purchase at <https://www.iso.org/standard/77470.html?browse=tc>

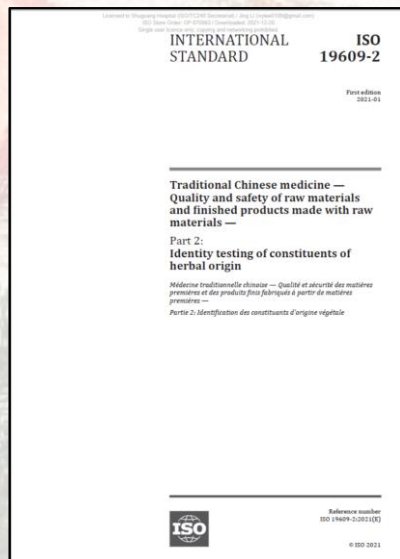


ISO 19609-1:2021

Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials — Part 1: General requirements

This document specifies general requirements within a quality control framework for raw materials and finished products used in and as traditional Chinese medicine (TCM) and derivative forms, and the comparison between the starting materials and the finished products, if necessary.

ISO link to purchase at <https://www.iso.org/standard/70976.html?browse=tc>

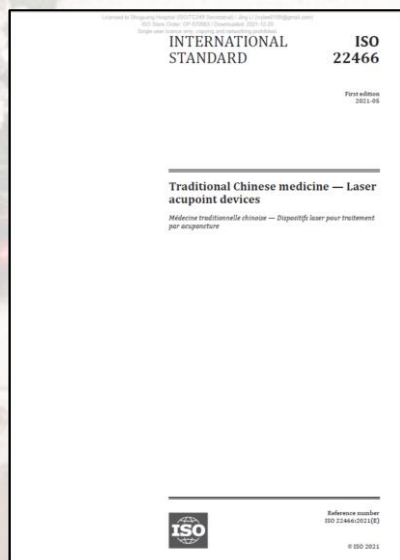


ISO 19609-2:2021

Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials — Part 2: Identity testing of constituents of herbal origin

This document specifies requirements for identity testing within a quality control framework for raw materials and finished products used in and as traditional Chinese medicine (TCM) and derivative forms. It is applicable to natural products used in TCM, including starting materials and finished products of herbal origin.

ISO link to purchase at <https://www.iso.org/standard/71152.html?browse=tc>



ISO 22466:2021

Traditional Chinese medicine — Laser acupoint devices

This document specifies requirements and test methods for laser acupoint devices. This document is not applicable to carbon-dioxide-type lasers. In the case of combined devices, it is applicable only to the laser features.

ISO link to purchase at <https://www.iso.org/standard/73287.html?browse=tc>

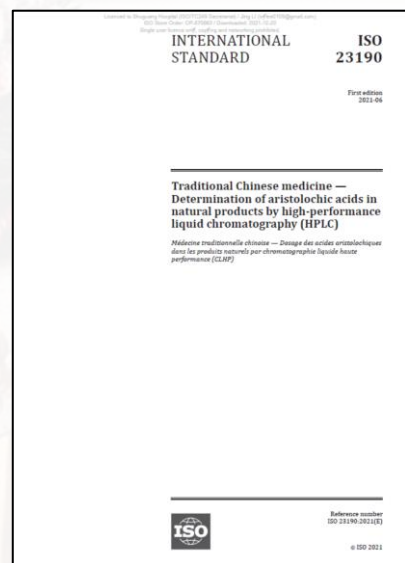


ISO 22467:2021

Traditional Chinese medicine — Determination of microorganisms in natural products

This document specifies test methods to determine microorganisms in natural products. It is applicable only to natural products used in traditional Chinese medicine, including raw materials, herbal pieces and preparations.

ISO link to purchase at <https://www.iso.org/standard/73288.html?browse=tc>



ISO 23190:2021

Traditional Chinese medicine — Determination of aristolochic acids in natural products by high-performance liquid chromatography (HPLC)

This document specifies a method for using high-performance liquid chromatography (HPLC) to determine the presence of aristolochic acid I in natural products.

ISO link to purchase at <https://www.iso.org/standard/74848.html?browse=tc>



ISO 23419:2021

Traditional Chinese medicine — General requirements for manufacturing procedures and quality assurance of granules

This document specifies general requirements for manufacturing procedures and quality and safety assurance of granules and compactates made from traditional Chinese medicine extracts or powder for oral use. This document excludes granules or compactates made from pure compounds (chemically defined) even if they are isolated as naturally occurring constituents of decoction pieces or crude herbal and mineral drugs.

ISO link to purchase at <https://www.iso.org/standard/75513.html?browse=tc>



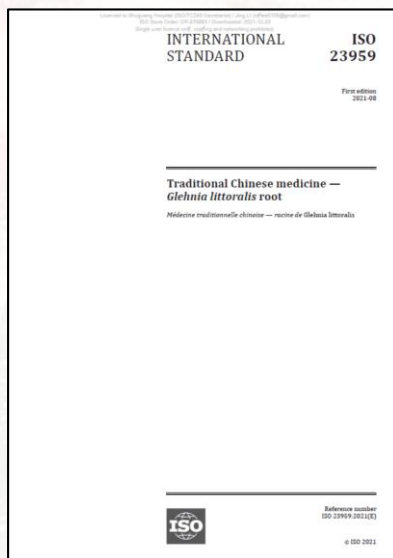
ISO 23723:2021

Traditional Chinese medicine — General requirements for herbal raw material and materia medica

This document specifies the general requirements and test methods for herbal raw material and materia medica.

This document provides minimum requirements for those herbal materials that are not covered by individual standards.

ISO link to purchase at <https://www.iso.org/standard/76765.html?browse=tc>



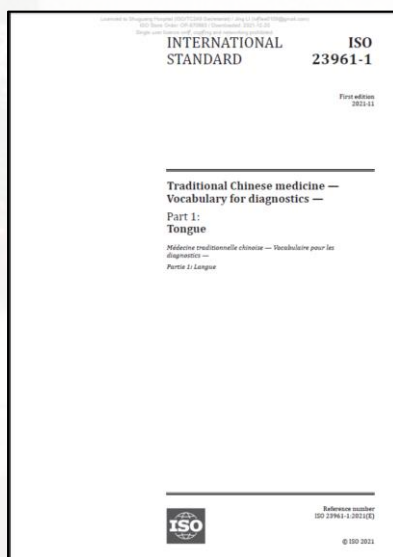
ISO 23959:2021

Traditional Chinese medicine — *Glehnia littoralis* root

This document specifies the quality and safety requirements of *Glehnia littoralis* root, which is derived from the plant *Glehnia littoralis* Fr Schmidt ex Miq.

This document applies to *Glehnia littoralis* root that is sold and used as natural medicine in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from this plant.

ISO link to purchase at <https://www.iso.org/standard/77466.html?browse=tc>



ISO 23961-1:2021

Traditional Chinese medicine — Vocabulary for diagnostics — Part 1: Tongue

This document specifies the basic terminology and classification of tongue diagnostic methods. Each term of tongue diagnosis includes the English name, the classical Chinese characters and its definition. The classification structure of tongue diagnosis terms is shown in Figure 1.

ISO link to purchase at <https://www.iso.org/standard/77468.html?browse=tc>

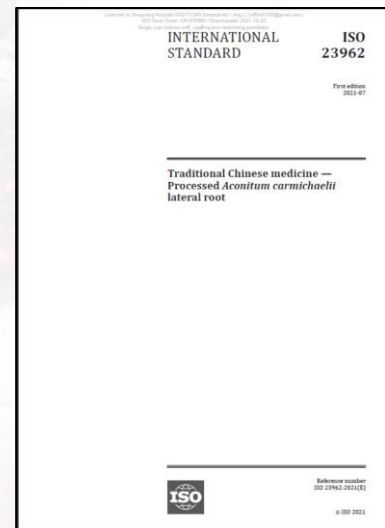


ISO 23961-2:2021

Traditional Chinese medicine — Vocabulary for diagnostics — Part 2: Pulse

This document specifies the basic terminology of pulse diagnostic methods, the key elements of pulse and pulse condition. Each term of pulse diagnosis includes the English name, the classical Chinese characters and its definition.

ISO link to purchase at <https://www.iso.org/standard/77470.html?browse=tc>



ISO 23962:2021

Traditional Chinese medicine — Processed *Aconitum carmichaelii* lateral root

This document specifies minimum requirements and test methods for processed *Aconitum carmichaelii* lateral root (lateral root of *Aconitum carmichaelii* Debx.).

This document applies to processed *Aconitum carmichaelii* lateral root that is sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from this plant. Processing methods of *Aconitum carmichaelii* lateral root are excluded.

ISO link to purchase at <https://www.iso.org/standard/77469.html?browse=tc>

Projects under development

Reference	Document title	Current stage
ISO/AWI TS 23961-3	Traditional Chinese Medicine — Vocabulary for Diagnostics — Part 3: Abdomen	20.00
ISO/AWI 6559	Traditional Chinese Medicine — Sterile Three-Edge Needle for Single Use	20.00
ISO/AWI 8071	Traditional Chinese Medicine — <i>Ligusticum chuanxiong</i> rhizome	20.00
ISO/AWI 7450	Traditional Chinese Medicine — <i>Pinellia ternata</i> tuber	20.00
ISO/AWI TS 6818	Traditional Chinese medicine — Test method for moxa floss quality — concentration of waste particles	20.00
ISO/AWI 9306	Traditional Chinese Medicine — <i>Ephedra sinica</i> , <i>Ephedra intermedia</i> , and <i>Ephedra equisetina herbaceous</i> stem	20.00
ISO/AWI 9299	Traditional Chinese Medicine — <i>Curcuma Longa</i> rhizome	20.00
ISO/AWI 9109	Traditional Chinese medicine — <i>Rehmannia glutinosa</i> root	20.00
ISO/AWI 8959	Traditional Chinese Medicine — <i>Eucommia ulmoides</i> stem bark	20.00
ISO/AWI 8284	Traditional Chinese Medicine — Simplified accelerated stress simulation methods	20.00
ISO/WD 6904	Traditional Chinese Medicine — General requirements for the ultrafine powder of herbs	20.20
ISO/WD 9319	Traditional Chinese medicine — <i>Poria cocos</i> sclerotium	20.20

Reference	Document title	Current stage
ISO/CD 22587	Traditional Chinese Medicine — Acupoint magnetotherapy plaster for single-use	30.20
ISO/CD 7177	Traditional Chinese Medicine — <i>Coptis chinensis</i> and <i>Coptis japonica</i> rhizome	30.20
ISO/CD 5228	Traditional Chinese Medicine — <i>Rheum palmatum</i> , <i>Rheum tanguticum</i> , and <i>Rheum officinale</i> root and rhizome	30.20
ISO/CD 4904	Traditional Chinese Medicine — inner pack of decoction pieces	30.60
ISO/DTS 6304	Traditional Chinese medicine — Categorical structure for disorder	30.60
ISO/CD 4564	Traditional Chinese Medicine — <i>Scutellaria baicalensis</i> root	30.99
ISO/DIS 19609-4	Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials — Part 4: Testing for preservatives and unwanted compounds	40.00
ISO/DIS 5227	Traditional Chinese Medicine — Safety controls of cupping device	40.00
ISO/DIS 23964	Traditional Chinese medicine — <i>Saposhnikovia divaricata</i> root and rhizome	40.20
ISO/DIS 19609-3	Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials — Part 3: Testing for contaminants	40.20
ISO/DIS 4754	Traditional Chinese Medicine — Fermented <i>Cordyceps</i> Powder	40.20
ISO/DIS 24571	Traditional Chinese medicine — General requirements for the basic safety and essential performance of electro-acupuncture stimulator	40.60

Reference	Document title	Current stage
ISO/DIS 23963-1	Traditional Chinese Medicine — Requirements for process traceability system of Chinese materia medica and decoction pieces — Part 1: Components	40.99
ISO/DIS 23963-2	Traditional Chinese Medicine — Requirements for process traceability system of Chinese materia medica and decoction pieces — Part 2: Electronic labelling	40.99
ISO/FDIS 23965	Traditional Chinese medicine — <i>Bupleurum chinense</i> , <i>Bupleurum scorzonerifolium</i> and <i>Bupleurum falcatum</i> root	50.00
ISO/FDIS 23958-1	Traditional Chinese Medicine — Dermal needle for single use — Part 1: Tapping type	50.00
ISO/FDIS 23958-2	Traditional Chinese Medicine — Dermal needle for single use — Part 2: Roller Type	50.00
ISO/FDIS 22586	Traditional Chinese medicine — <i>Paeonia lactiflora</i> root — White peony root	50.00
ISO/FDIS 22585	Traditional Chinese medicine — <i>Codonopsis pilosula</i> root	50.00
ISO/FDIS 4154	Traditional Chinese Medicine — <i>Sinomenium acutum</i> stem	50.00
ISO/FDIS 23956	Traditional Chinese medicine — Determination of benzopyrene in processed natural products	50.20
ISO 18665	Traditional Chinese medicine — Herbal decoction apparatus	60.00



TC249 and Liaison's Activities in 2021

2021 Open Week of ISO/TC 249 Secretariat

Each year around March, the TC 249 Secretariat will arrange an annual event called '*Open week of ISO/TC 249 secretariat*' focusing on one specific topic/area and aiming at providing advice to the committee. For the year of 2021, on March 16, an online meeting was held with the purpose to support the terminology work with a question '*Should we establish an ad-hoc group to coordinate ISO/TC 249 terminology work (WG5)?*'. The attendees including leaders of each working group and several invited experts in the domains shared their input and suggestions to this topic.





The 8th joint CAG1 and CAG2 teleconference of ISO/TC 249

- The 8th joint CAG1 and CAG2 teleconference of ISO/TC 249 CAG2 was held on 24 March 2021. The following agenda items have been discussed,
 - Discussion about the arrangements and two main agenda items (external liaison arrangement with USP and Projects related to service standards) of TC 249 11th plenary meeting.
 - Discussion on the new projects submitted to the 11th plenary meeting and intended allocation of projects to each Working Group.
 - Report on the progress of WG.
 - Outcome of “The 2021 Open Week of ISO/TC 249 Secretariat”.

ISO/TC 215 Plenary Meetings in 2021

ISO/TC 215 *Health Informatics* held its 36th plenary meeting in June 2021 and the next meeting is scheduled on Jan 13, 2022.

As the representative of ISO/TC249, Ms. Li Jing (Ivy) joined the plenary meeting and the subsequent two joint sessions of JWG1. Up to date, the groups (of TC249 and TC215) have made great progress in the domain of TCM informatics, including 23 published standards and 9 projects under development.

There are 4 items ready for publication in early 2022,

- ISO/DTS 6304 Traditional Chinese medicine — Categorical structure for Disorder (TC249 led)
- ISO/DTS 16843-6 Health informatics — Categorical structures for representation of acupuncture - Part 6: Acupuncture effect (TC215 led)
- ISO/DTS 5346 Health Informatics — Categorical structure for representation of Traditional Chinese Medicine clinical decision support system (TC215 led)
- ISO/DTS 5118 Health informatics — Categorical Structure of Representation for evaluation of clinical practice guidelines of Traditional Chinese Medicine (TC215 led)

ISO/TC 314 Plenary Meetings in 2021



ISO/TC 314 held 2 plenary meetings this year. As the representatives of ISO/TC 249, Prof. SHEN Yuandong and HUANG Yiran took part in 7th and 8th plenary meetings of ISO/TC 314 and submit liaison reports. These two meetings took place virtually on July 8 and December 2.

TC 314 commenced development on two new work items:

- ISO 25554 — Ageing Societies — Guidelines for Promoting Wellbeing in Local Communities and Organizations
- ISO/AWI TR 25555 - Ageing society — Accessibility and usability considerations for home-based healthcare products, related services and environments

Since TR 25555 is related with several standards of medical devices developed by TC 249, like Air extraction cupping device, Gua Sha instruments, and Acupoint Magnetotherapy Plaster. On behalf of Prof SHEN, HUANG Yiran presented on developments of such documents within ISO/TC 249. These products can be used at home and are commonly used by older persons. Therefore, there is a request that ISO/TC 314/WG 5 takes these documents into account while developing ISO TR 25555.

TC 314 also approved the establishment of a liaison relationship with ISO/TC 249 Traditional Chinese Medicine and approved HAO Qiang to act as the liaison representative.

WFCMS

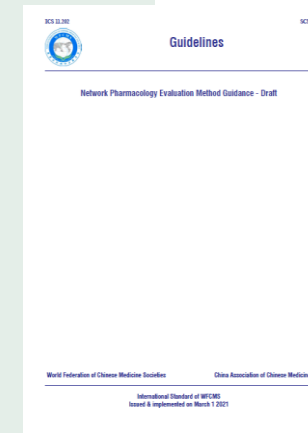
The 18th World Congress of Chinese Medicine was convened in Hong Kong, China on December 4th, 2021

The 18th World Congress of Chinese Medicine was convened in Hong Kong, China, and in visual meeting at the same time, on December 4th, 2021. The Congress attracted over 2, 000 representatives from more than 60 countries and regions all over the world. The theme of this year is *TCM Benefits Human Health-Opportunities and Challenges of Global TCM*. It was agreed by the Council of WFCMS that the 19th World Conference of Chinese Medicine will be held in Brazil next year.

World Federation of Chinese Medicine Societies 24 standards issued by in 2021

12 international standards and 12 committee standards were issued by WFCMS during the year of 2021. 25 international standards and 5 committee standards were initiated by WFCMS in 2021.

It is mentioned in the *Framework for Five-year Development Plan of World Federation of Chinese Medicine Societies (2021—2025)* that by the end of 2025, WFCMS will issue 150 standards, including 100 international standards of WFCMS.



WFAS

WFAS promotes acupuncture standardization in 2021

WFAS held a “Traditional Chinese Medicine Going Global” workshop in July 2021, offering lectures on current status and expert outlooks regarding Chinese medicine in the world, targeted to heads of international affairs of TCM organizations. ISO/TC249 Committee Manager Dr. Sang Zhen was invited for a lecture on *Current Situation and Prospect of International Standardization of TCM*.

WFAS 2021 International Symposium on Acupuncture-Moxibustion was held on 14 December 2021. With the theme of “TCM Acupuncture-Moxibustion Contributes to Building a Global Community of Health for All”. More than 400,000 people participated online and onsite. During the parallel session focusing on methodology for developing international acupuncture standards, progress of 14 WFAS standards under development were reported and work plan for the next stage was discussed. It is expected that the 14 standards including the *Norms for Formulation and Evaluation of the Guidelines on Clinical Practice of Acupuncture and Moxibustion* will complete development by October 2022.



Key changes in ISO/IEC Directives 2021

2021 edition of the ISO/IEC Directives Part 1 and its ISO supplement has been released from May. 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:

- **Active participation:** Clause 1.7.4 provides details on how to measure active participation and encourage inactive P-members to be active.
- **Enquiry stage, ballot results -Option to publish as TS or PAS:** Options added to clause 2.6.4 that when the approval criteria are not met, the publication can be cancelled or published as a TS or PAS.
- **Approval of TS and TR:** Approval ballot for TS and TR is managed by the CM. No technical change is allowed between the approved ballot and publication (Clauses 3.1.1 and 3.3.1)



Key Changes in ISO Supplement

- **Justification supporting a negative vote:** At DIS and FDIS, if a NSB has voted negatively but comments are not clearly technical, CM to ask the NSB within 2 weeks. If no agreement, the matter is escalated to TMB. (ISO Supplement, Clauses 2.6.2 and 2.7.2).
- **Systematic review:** Before the SR opens, a committee may approve a recommendation for members when they reply, to confirm, withdraw, revise or amend the standard. This will be visible to ISO members on the balloting application. (ISO Supplement, Clause 2.9.2)
- **Minor revision:** Minor revision: revision that does not impact on the technical content of the standard. Short approval path: committee resolution + FDIS. New: text to be submitted to ISO/CS within 16 weeks (ISO Supplement, Clause 2.9.1)



The 12th Plenary Meeting of ISO/TC 249

The next plenary meeting of ISO/TC 249 will be held virtually starting from 1 June 2022. The closing session will be held on 29 June. Please finish the online meeting registration before **May 24, 2022** via <https://sd.iso.org/meetings/105045>.

Deadlines of posting committee documents for the 12th plenary meeting in 2022

The cutoff dates for posting papers for preparation of the 12th plenary meeting in 2022 are:

- **1 February 2022** for major documents including NWIPs to be discussed during the meeting
- **16 April 2022** for other papers
- **24 May 2022** 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 by **16 January 2022** to allow processing time for the 1st February 2022 cutoff date.

Date	Meeting Schedule
1 June, 2022	Opening of plenary meeting
29 June, 2022	Closing of plenary meeting

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