



ISO/TC 249 NEWSLETTER



The seventh plenary meeting of ISO/TC 249 in Rome, Italy

The 7th plenary meeting of ISO/TC249 was held on June 6-9, 2016, hosted by Fitochina Italia and Istituto Paracelso in Rome, Italy. Two hundred and five delegates participated in this meeting representing thirteen national member bodies and two organizations in liaison. Dr. Mary Lou Pelaprat from the ISO Central Secretariat attended this meeting and the committee was very appreciative of her contribution to the meeting.

As the work of TC249 increases in volume and complexity, it is ever more important to adjust its management structure. Through a twinning agreement between Standards Australia and Standardization Administration of China, Dr David Graham and Prof Shen Yuandong have been nominated as the chair and vice chair of the committee from 2016-2018.

The Chair and the vice Chair gave reports covering the general issues arising from the business of committee during the last year. The standing agenda items for liaison arrangements and the Strategic

Business Plan have been reviewed and the committee especially congratulated and gave awards to the project leaders of the 6 published international standards.

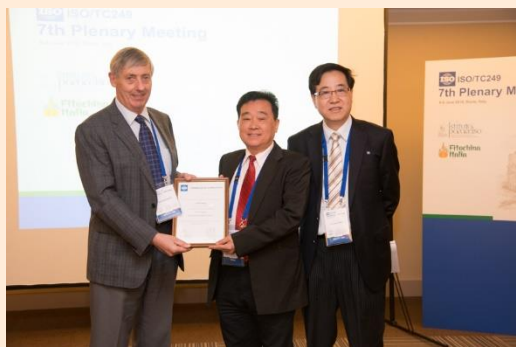
A joint meeting of the advisory committees, CAG1 and CAG2, which was held late on June 6, emphasized that a proposed decision tree and checklists were valuable contributions to assist improving the quality of new applications of projects.

Each of the on-going Working Groups (WGs) held its meeting in between the two plenary sessions and reported to the committee on the final day of the plenary meeting. Since the number of new proposals is increasing significantly, the Working Groups have been expected to set the priority of the technical areas within its scope and assess whether there are sufficient resources available for the project to meet the ISO timeframes taking account of the overall work plan of the Working Group.

The committee thanked Italy for its excellent hosting of the 7th plenary meeting. China has offered to host the next meeting in Hong Kong from June 5-8 2017.



ISO 17217-1:2014 Traditional Chinese medicine -- Ginseng seeds and seedlings -- Part 1: Panax ginseng C.A. Meyer



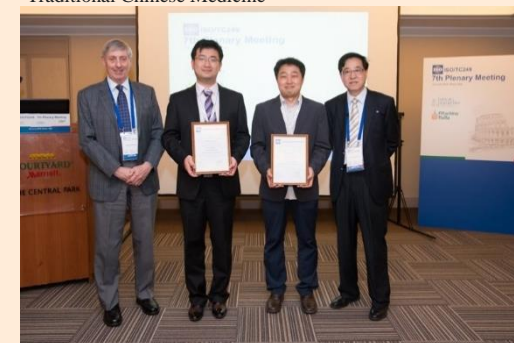
ISO 17218:2014 Sterile acupuncture needles for single use



ISO 18664:2015 Traditional Chinese Medicine -- Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine



ISO 18665:2015 Traditional Chinese medicine -- Herbal decoction apparatus



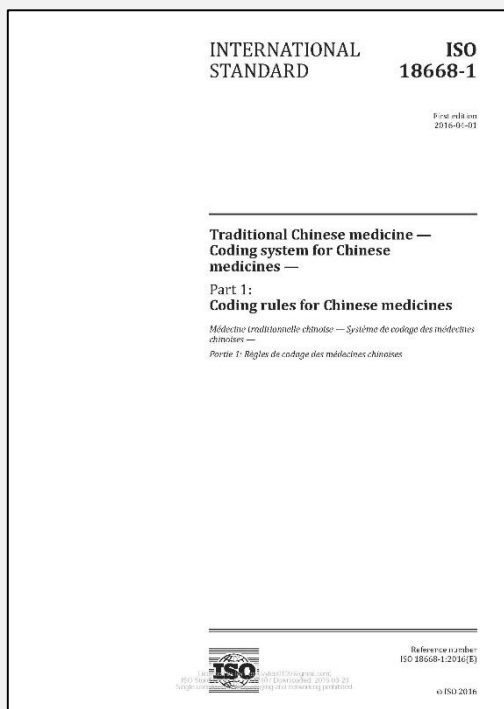
ISO 18666:2015 Traditional Chinese medicine -- General requirements of moxibustion devices



ISO 18668-1:2016 Traditional Chinese medicine -- Coding system for Chinese medicines -- Part 1: Coding rules for Chinese medicines

Published international standards of ISO/TC249 in 2016

ISO 18668-1:2016 *Traditional Chinese medicine -- Coding system for Chinese medicines -- Part 1: Coding rules for Chinese medicines*



ISO 18668-1:2016 specifies rules to encode Chinese medicines, including decoction pieces, Chinese Materia Medica (raw materials) and granule forms of individual medicinals for prescriptions (GFIMP), but not Chinese patent medicines (CPM).

Relevant coding standards for Kampo medicine, Korean medicine and other traditional medicines will be separately formulated as needed by experts in these areas.

ISO 18668-1:2016 is suitable for decoction pieces, Chinese Materia Medica (raw materials), and granule forms of individual medicinals for prescriptions (GFIMP) in the fields of clinical medication, scientific research and teaching, and statistics and management.

ISO link to purchase at

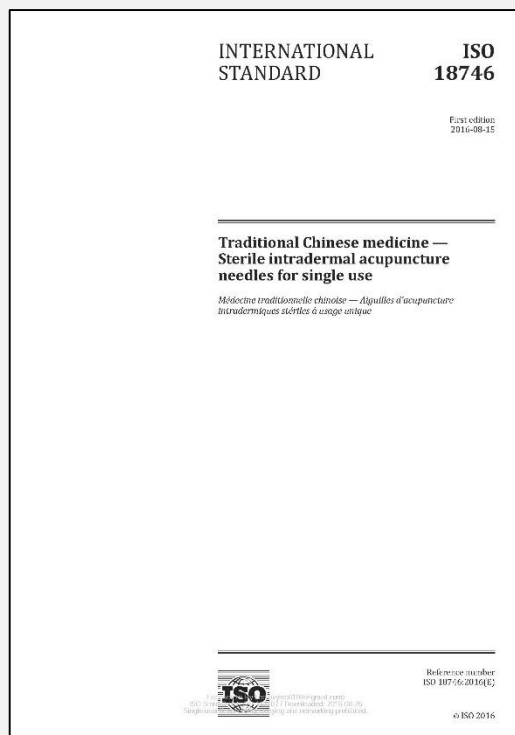
http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=63155

ISO 18746:2016 *Traditional Chinese medicine -- Sterile intradermal acupuncture needles for single use*

ISO 18746:2016 specifies the requirements of sterile intradermal acupuncture needle for single use as a medical device, including the following factors:

- a) size;
- b) material;
- c) quality;
- d) testing methods;
- e) packing;
- f) identification.

ISO link to purchase at



http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=63263

Progress on projects

ISO/FDIS 18662-1 Traditional Chinese medicine -- Vocabulary -- Part 1: Chinese Materia Medica

Stage: 50.00

ISO/AWI 18662-2 Traditional Chinese medicine -- Vocabulary -- Part 2: Processing of Chinese materia medica

Stage: 20.00

ISO/FDIS 18668-2 Traditional Chinese medicine -- Coding system for Chinese medicines -- Part 2: Codes for decoction pieces

Stage: 50.20

ISO/FDIS 18668-3 Traditional Chinese medicine -- Coding system for Chinese medicines -- Part 3: Codes for Chinese Materia Medica

Stage: 50.20

ISO/FDIS 18668-4 Traditional Chinese medicine -- Coding system for Chinese medicines -- Part 4: Codes for granule forms of individual medicinals for prescriptions

Stage: 50.20

ISO 19465 Traditional Chinese medicine -- Categories of traditional Chinese medicine (TCM) clinical terminological systems

Stage: 60.00

ISO/AWI 19609-1 Traditional Chinese medicine -- Quality and safety of natural materials and manufacturing products made with natural materials used in and as traditional Chinese medicine (TCM) -- Part 1: General

Stage: 20.00

ISO/AWI 19609-2 Traditional Chinese medicine -- Quality and safety of natural materials and manufacturing products made with natural materials used in and as traditional Chinese medicine (TCM) -- Part 2:

Identity testing

Stage: 20.00

ISO/FDIS 19610 Traditional Chinese medicine -- General requirements for industrial manufacturing process of red ginseng (Panax ginseng C.A. Meyer)

Stage: 50.20

ISO/FDIS 19611 Traditional Chinese medicine -- Air extraction cupping device

Stage: 50.00

ISO/FDIS 19614 Traditional Chinese medicine -- Pulse graph force transducer

Stage: 50.00

ISO/CD 19617 Traditional Chinese medicine -- General requirements for the manufacturing process of natural products used in and as traditional Chinese medicine (TCM)

Stage: 30.20

ISO 19824 Traditional Chinese medicine -- Schisandra chinensis (Turcz.) Baill seeds and seedlings

Stage: 60.00

ISO/DIS 20308 Traditional Chinese medicine - - Gua Sha instruments

Stage: 40.60

ISO/FDIS 20311 Traditional Chinese medicine -- Salvia miltiorrhiza seeds and seedlings

Stage: 50.20

ISO/DIS 20333.2 Traditional Chinese medicine -- Coding rules for chinese medicines in supply chain management

Stage: 40.60

ISO/CD 20334 Traditional Chinese Medicine - - Coding System of Formulas

Stage:30.99

**ISO 20408 Traditional Chinese medicine --
Panax notoginseng seeds and seedlings**
Stage:60.00

**ISO/FDIS 20409 Traditional Chinese medicine
-- Panax notoginseng root and rhizome**
Stage:50.00

**ISO/AWI 20487 Traditional Chinese medicine
-- Test method for acupuncture needles for
single use on electrical stimulation**
Stage:20.00

**ISO/NP 20493 Traditional Chinese medicine --
Infrared moxibustion-like instruments**
Stage:10.99

**ISO/NP 20495 Traditional Chinese medicine --
Electrical resistance detector at acupuncture
points**
Stage:10.99

**ISO/NP 20498-1 Traditional Chinese medicine
-- Computerized tongue image analysis system
-- Part 1: General requirements**
Stage:10.99

**ISO/FDIS 20498-2 Traditional Chinese
medicine -- Computerised tongue image
analysis system -- Part 2: Light environment**
Stage:50.00

**ISO/NP 20498-3 Traditional Chinese medicine
-- Computerized tongue image analysis system
-- Part 3: Colour chart**
Stage:10.99

**ISO/NP 20498-4 Traditional Chinese medicine
-- Computerized tongue image analysis system
-- Part 4: Peripheral visual instruments**
Stage:10.99

**ISO/AWI 20498-5 Traditional Chinese
medicine -- Computerized tongue image
analysis system -- Part 5: Tongue color and
tongue coating color**
Stage:20.00

**ISO/CD 20520 Traditional Chinese medicine --
Infection control for acupuncture treatment**
Stage:30.99

**ISO/NP 20758 Traditional Chinese medicine --
Abdominal physiological parameter detector**
Stage:10.99

**ISO/CD 20759 Traditional Chinese medicine --
Artemisia argyi leaf**
Stage:30.60

**ISO/NP 21291 Traditional Chinese medicine --
Therapeutic fumigation devices**
Stage:10.99

**ISO/NP 21292 Traditional Chinese medicine --
Electric heating moxibustion equipment**
Stage:10.99

**ISO/NP 21300 Traditional Chinese medicine --
Specification and grades for Chinese material
medicine**
Stage:10.99

**ISO/NP 21310 Traditional Chinese medicine --
Microscopic examination on medicinal herbs**
Stage:10.99

**ISO/NP 21311 Traditional Chinese medicine --
Astragalus root (astragalus membranaceus)**
Stage:10.99

**ISO/NP 21312 Traditional Chinese medicine --
Safe use of acupuncture needles in the
acupoints requiring special caution**
Stage:10.99

**ISO/NP 21313 Traditional Chinese medicine --
Platycodon grandiflorum root**
Stage:10.99

**ISO/NP 21314 Traditional Chinese medicine --
Salvia miltiorrhiza root and rhizome**
Stage:10.99

**ISO/NP 21315 Traditional Chinese medicine --
Ganoderma lucidum fruiting body**
Stage:10.99

**ISO/AWI 21316 Traditional Chinese medicine
-- Isatis indigotica root**
Stage:20.00

**ISO/NP 21317 Traditional Chinese medicine --
Lonicera japonica flower**
Stage:10.99

**ISO/NP 21366 Traditional Chinese medicine --
General requirements for smokeless
moxibustion**
Stage:10.99

**ISO/NP 21370 Traditional Chinese medicine --
-Dendrobium officinale stem**
Stage:10.99

**ISO/CD 21371 Traditional Chinese medicine -
- Labelling requirements of products intended
for oral or topical use in and as traditional
Chinese medicine (TCM)**
Stage:30.20

**ISO/NP 21373 Traditional Chinese medicine --
Minimum requirements for herbal
preparations services**
Stage:10.99

**ISO/NP 21374 Traditional Chinese medicine --
Herbal medicine decoction service**
Stage:10.99

**ISO/NP 80601-2-81 Medical electrical
equipment -- Part 2-81: Particular
requirements of electric radial pulse
tonometric devices**
Stage:10.99

**ISO/NP 22212 Traditional Chinese Medicine --
Gastrodia tuber**
End of NP ballot: 2017-03-09

**ISO/NP 22213 Traditional Chinese Medicine --
Traditional glass cupping device**
End of NP ballot: 2017-03-09

**ISO/NP 22217 Traditional Chinese Medicine --
Storage requirements for Chinese materia
medica and decoction pieces**
End of NP ballot: 2017-03-09

**ISO/NP 22236 Traditional Chinese Medicine -
Thread Embedding Acupuncture Needle for
single use**
End of NP ballot: 2017-03-12

Events within the committee

THE OPEN WEEK OF ISO/TC 249 SECRETARIAT

The secretariat has proposed an annual event of “The Open week of TC 249 Secretariat” in early March. Global professionals are invited to visit the Secretariat mainly,

- to join with the secretariat to discuss the projects as well as NWIPs to provide advices to the committee;
- to be an opportunity for any training of convenors etc if thought necessary.

On 21-25 March, 2016, Dr. Michiho ITO from Japan was invited to discuss the projects in the field of herbal medicine with ISO/TC 249 secretariat. Many thanks to Dr. ITO for providing many constructive suggestions.



International workshop on TCM medical devices in Shanghai



On 24 March, 2016, the secretariat of ISO/TC 249 held an international workshop of standardization on TCM medical devices in Shanghai. This workshop was aiming at promoting the cooperation between different international organizations in the field of TCM medical devices. About thirty experts from Australia, China, Japan, Korea, Thailand,

USA and some experts from IEC and ISO/TC 249 secretariat participated in this meeting. Participants introduced the current situation on TCM medical devices in their own country and IEC expert made an explanation on drafting rules for IEC standards. All participants emphasized the necessity on developing international standards on TCM medical devices which can be beneficial to promoting the international trade and safe use of TCM medical devices and agreed with strengthening the cooperation with ISO/TC 249 and IEC/SC 62D.

Celebration on World Standards Day



Each year on 14 October, the members of the IEC, ISO and ITU celebrate World Standards Day, which is a means of paying tribute to the collaborative efforts of the thousands of experts worldwide who develop the voluntary technical agreements that are published as international standards.

ISO/TC 249 held a press conference on 18 October to celebrate World Standards Day in Shanghai. Over 20 press media were invited to attend the conference, including ICS (INTERNATIONAL CHANNEL SHANGHAI) and Shanghai Daily.

Vice chair of ISO/TC 249 Prof. Shen Yuandong introduced the working scope of ISO/TC 249 and its current development situation. Chair of ISO/TC 249 Dr. David GRAHAM explained the significance of developing international standards. He said, the standardization of traditional medicines is challenging, particularly because they are usually made from natural

substances and these substances vary in purity and potency from batch to batch. But this is also why the standards work in this area is so important and urgent, to ensure that consumers receive consistent and appropriate treatments.

The press media showed great interest in the benefits of ISO standards and gave a wide publicity to World Standards Day. They are hoping that ISO standards may bring new life to TCM, an ancient Chinese wisdom, and enable it to contribute to the health of people all over the world.

International workshop of standardization on Traditional Chinese Medicine in Chengdu

ISO/TC 249 held an international workshop of standardization on Traditional Chinese Medicine during the 5th International Conference on the Modernization of Traditional Chinese Medicine on 24 October, 2016 in Chengdu, Sichuan province. The main topics are:

1. The feasibility to develop international standards of Chinese medicine granules;
2. The status of “traditional use” in contributing to the evidence body of Chinese herbal medicine’s safety and effectiveness.

After two-hour discussion, the experts reached following consensus.

For Chinese medicine granules, giving full consideration of the international market, the experts thought that there is of urgent need to develop international standards on granules and it may be starting with some aspects that are simple and easy to reach consensus.

For traditional use, the experts indicated that traditional use can be one of the evidence body, however clear definition should be made precisely. The issue is a very complex work, therefore relevant researches should be done to support the project.

Liaisons' activities

The meeting of IEC/TC 62 and its Subcommittees, *Electrical Equipment in Medical Practice*

The meeting of IEC/TC 62 and its Subcommittees, Electrical Equipment in Medical Practice was held on 03-19 October 2016 in Frankfurt am Main, Germany. JWG6 convenor Mr. Zhang Haiming attended the meeting as the representative of ISO/TC249.

Mr. Zhang made a report on the progress of ISO/TC249/JWG6 (in IEC is IEC/SC62D/JWG37). The secretary of IEC/SC 62D Mr. Jeffrey L. Eggleston and assistant secretary Ms. Hae Choe thought this report would help the experts from IEC/SC62D to understand projects in IEC/SC62D/JWG37 which are circulating on the IEC website. After the meeting, experts from some member bodies of IEC/SC62D showed their interests to participate in the work of IEC/SC62D/JWG37.

IEC/SC62D has started NP balloting on seven projects led by ISO/TC 249 from 16 September to 9 December 2016. The results will be circulated as soon as the secretariat of ISO/TC 249 receives them from IEC/SC 62D. The list of these projects are:

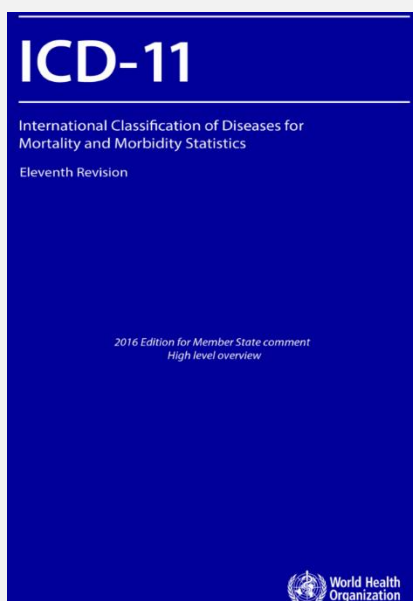
- ISO/NP 80601-2-81 Medical electrical equipment -- Part 2-81: Particular requirements of electric radial pulse tonometric devices
- ISO/NP 20493 Traditional Chinese medicine-Infrared Moxibustion-like Instruments
- ISO/NP 20498-1 Traditional Chinese medicine -- Computerized tongue image analysis system -- Part 1: General requirements
- ISO/NP 20495 Skin electrical resistance detector at acupuncture points
- ISO/NP 20758 Abdominal Physiological Parameter Detectors
- ISO/NP 21291 Traditional Chinese medicine --Therapeutic Fumigation Devices
- ISO/NP 21292 Electric Heating Moxibustion Equipment

The meetings of ISO/TC215 Health Informatics

On May 2-6 and November 13-17, 2016, ISO/TC215 plenary meetings have been held in Amsterdam and Lillehammer. ISO/TC249 experts attended the sessions of TM/TF, JWG1 and WG3 and further communicated on the arising problems and new opportunities with ISO/CS TPM, Ms. Mary Lou, TC215 secretary, Ms. Lisa Spellman, JWG1 convenor, Dr Ken Toyoda and the relevant experts.

It was agreed that this innovative mechanism of a joint working group has achieved great progress in the field of informatics which supported the appropriate international use of Traditional Medical systems. It was also noted that ISO/TC215 resolved at the Lillehammer meeting to disband the WG3 Traditional Medicine Task Force and establish a new Traditional Medicines Task Force (TMstF) under ISO/TC215. ISO/TC249 secretariat will keep communicating with TC215 on the common interests in the field of informatics.

WHO ICD-11 Traditional Medicine Chapter-Module I



In 2010, WHO started the international classification of traditional medicine (ICTM) project. A major output developed for inclusion within ICD has been the classification of the diagnostic categories used in the traditional medicine that originated in ancient Chinese Medicine and are commonly used in China, Japan, Korea, and elsewhere around the world. This classification represents a unified set of harmonized traditional medicine conditions (disorders and patterns) of the Chinese, Japanese, and Korean classifications. The use of the ICD-11 TM Chapter is optional for those who would like to record epidemiological data about traditional medicine practice.

A disorder in traditional medicine, disorder(TM), refers to a set of dysfunctions in any of the body systems which presents with associated manifestations, i.e. a single or a group of specified signs, symptoms, or findings. Each disorder(TM) may be defined by its symptomology, etiology, course and outcome, or treatment response. A pattern in traditional medicine, pattern(TM), refers to the complete clinical presentation of the patient at a given moment in time including all findings. Findings may include symptomology or patient constitution, among other things.

ICD-11 TM Chapter Beta Edition is released and online. The ICD-11 Browser is a web site that allows users to browse the classification and see the content of the ICD-11. A category or grouping can be accessed using the search engine, or browsing the tree. The TM Chapter is located at the last of the classification hierarchy. For more information about ICD-11 Traditional Medicine Chapter, please refer to <http://apps.who.int/classifications/icd11/browse/l-m/en>

Action items

- Finalise TM Chapter
 - Structure
 - Content: Codes, including code structure, code length
 - Finalise residuals
- Finalise TM Coding Guidelines
- Use results of peer review to inform changes
- Incorporate results from field trials
- Ensure consistency of structure and code length between TM Chapter and other chapters of ICD-11
- Develop education and training material
- Final version release in early 2018

The 13th World Congress of Chinese Medicine was convened in Auckland on Nov 12th, 2016



The 13th World Congress of Chinese Medicine, which was held by WFCMS and the New Zealand College of Chinese Medicine, was convened in Auckland, New Zealand on Nov 12th, 2016. The theme of the Congress was “Embrace the past and step into the future –Chinese Medicine as a sustainable health system for the 21st Century”. The congress attracted over 800 representatives from the world covering approximately 30 countries and regions, including Argentina, Australia, Austria, Brazil, Kampuchea, Canada, Chinese China, Hongkong, Egypt, France, Philippines, Germany, Hungary, Ireland, Italy, Japan, Malaysia, Holland, New Zealand, Pakistan, Russia, Singapore, South Africa, Spain, Thailand, Britain and the United States.

Research on TCM international standardization was one of the key heated topics on the congress. Prof. LI Zhenji, the founder Vice-chairperson and secretary-general of WFCMS delivered a speech named Plans and Tasks for International Standardization of Traditional Chinese Medicine in New Era and Dr. Joan Campbell, Chairman of New Zealand New Zealand Acupuncture Standard Authority Inc attended the congress and delivered his speech.

The 13th World Conference of Chinese Medicine was accompanied with the 10th exhibition of TCM trade in service and organized 12 workshops, including special sessions on TCM intangible cultural heritage, diagnosis and treatment technology of traditional Chinese medicine, etc., in order to provide an academic platform for exchanges in clinical experience and promotion of research fruits.

During the congress, it was agreed that the 14th World Conference of Chinese Medicine will be held in Bangkok, Thailand in October next year.

International Conference of WFAS Tokyo/Tsukuba 2016 was successfully hosted in Japan



From Nov 5th to 6th, 2016, the WFAS International Acupuncture Academic Symposium was held in Tsukuba International Congress Center, Japan. This conference was co-hosted by the World Federation of Acupuncture-Moxibustion Societies (WFAS) and the China Academy of Chinese Medical Sciences (CACMS) and supported by the Japan Society of Acupuncture and Moxibustion (JSAM) and the Japan Traditional Acupuncture and Moxibustion Society (JTAMS).

The theme of the conference was “The Art of Acupuncture and Moxibustion-For Sustainable Health Care and Health Promotion”. More than 2000 representatives from over 30 countries and regions have participated in this symposium. Over 330 articles have been received during the conferences. During the conference, technical sessions, a medical instrument exhibition and 212 posters have been presented as well.

Before the academic symposium, the 4th Session of the 8th Executive Committee (EC) of WFAS was also held in Tsukuba, Japan on Nov 4th and over 50 executives abroad have participated. This EC meeting was significant since it is the preparation meeting for the 9th General Assembly and multiple proposals and work reports have been passed here.

After nearly 30 years of development, WFAS now has 194 member societies in over 53 countries and regions. It has already become an influential international medical academic organization. WFAS shall continue its efforts in the development of acupuncture worldwide under the leadership of the next board of executives so as to make greater contributions to the transmission and further development of world acupuncture.



The eighth plenary meeting of ISO/TC 249

According to Resolution 265, the next plenary meeting of ISO/TC 249 will be held in Hong Kong from 5th-8th June, 2017. The exact details of the venue will be available soon.

Deadlines of posting committee documents for the 8th plenary meeting in 2017

The cutoff dates for posting papers for preparation of the 8th plenary meeting in Hong Kong, 2017 are:

- **4 February** 2017 for major documents including NWIPs to be discussed during the meeting
- **23 April** 2017 for other papers
- **30 May** 2017 for the final agenda and minor papers

Since the 2017 Spring Festival holiday in China is from Jan 27-Feb 2, 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 **20 January, 2017** to allow processing time for the **4 February** cutoff date.



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