

# ISO/TC 249 NEWSLETTER

# Congratulations on the publication of international standards of ISO/TC249 in 2015



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

This International Standard specifies determination methods of lead (Pb), arsenic (As), cadmium (Cd) and mercury (Hg) in herbal medicines used in Traditional Chinese Medicine (TCM). It is applicable to natural materials of TCM that are sold and used as food supplements, functional foods or natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from plants or animals. It is not applicable to mineral drugs used in TCM.

This International Standard is not intended to set maximum limits (ML) for individual nations; rather, it is intended to give a reference for standardized testing method and risk assessment.

ISO link to purchase at

http://www.iso.org/iso/home/store/catalogue\_tc/catalogue\_detail.htm?csnumber=63150&commid=598435

#### ISO 18665:2015

#### Traditional Chinese medicine -- Herbal decoction apparatus

This International Standard specifies the general requirements of herbal decoction apparatus with design pressures less than 0.1MPa. It includes both hermetic and non-hermetic decoction apparatus.

It is applicable to the herbal decoction apparatus for individual herbal formula prescriptions and for commercial use as well as private use. It also applies to the decocting part of the integrated apparatus of decoction and package.

ISO link to purchase at

http://www.iso.org/iso/home/store/catalogue\_tc/catalogue\_detail.htm?csn umber=63152&commid=598435





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

This International Standard 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 uses 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 International Standard does not apply to devices that imitate moxibustion, such as electromoxibustion 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

http://www.iso.org/iso/home/store/catalogue\_tc/catalogue\_detail.htm?csnumber=63153&commid=598435

#### ISO/TS 18790-1:2015

# Health informatics-Profiling framework and classification for Traditional Medicine informatics standards development-Part 1: Traditional Chinese Medicine

This Technical Specification establishes common concepts and a vocabulary for describing the complex domain of various Traditional Chinese Medicine (TCM) informatics standards initiatives and their supporting artefacts. It provides a useful profiling framework to align existing and developing TCM informatics standards and to reference health informatics standards. It promotes the reuse of TCM informatics knowledge and improves the identification of opportunities for TCM informatics standards alignment, collaboration, and coordination.

Topics considered outside the scope of this Technical Specification include:

— profiling framework and classification for informatics standards of Kampo, Korean medicine, and other Traditional Medicine systems.

Led by ISO/TC215, ISO/TS 18790-1:2015 is the first successful project under the Joint Working Group mechanism which has been set up between TC215 and TC249. At each stage of this standard, TC249 experts have participated and given constructive comments to finalize the document.



#### ISO link to purchase at

http://www.iso.org/iso/home/store/catalogue\_tc/catalogue\_detail.htm?csnumber=63381&commid=54960







## The sixth plenary meeting of ISO/TC 249

The sixth plenary meeting of ISO/TC249 was held on June 1-4 in Beijing hosted by the Standardization Administration of China (SAC). Twelve national member bodies participated with two hundreds and forty-three delegates that also included representatives from two organizations in liaison and one internal liaison. Dr. Mary Lou Pelaprat, the committee's Technical Program Manager from ISO Central Secretariat, attended this meeting and the committee was appreciative of her contribution to the meeting.

The chair and the secretary of ISO/TC249 welcomed all the participants, and then gave reports covering

the general issues arising from the business of committee during the last year.

The following issues were discussed by the committee at the meeting:

- 1. The permanent title of the committee
- 2. The scope of the committee
- 3. Liaison arrangements
- 4. Appointment of Working Group Convenors for another three years
- 5. Proposal regarding the guidelines on 'traditional use'
- 6. Priorities for Working Groups
- 7. Proposal that a working draft to be submitted with the Form 4

Each of the committee's six working groups including JWG1 met on 1st, 2nd or 3rd June and their work programs were subsequently discussed by the committee.

The committee expressed its appreciation to SAC, SATCM, the China mirror committee, the volunteers and the Jilin Zixin Pharmaceutical Industrial Co., Ltd for such a well-organized meeting in Beijing.

The resolutions of the 6th plenary meeting in Beijing (N334) can be found in ISO/TC249 e-committee at:

 $\frac{\text{http://isotc.iso.org/livelink/livelink?func=}ll\&objId=16910472\&objActio}{\text{n=browse\&viewType=}1}$ 

# TMB's official approval on the permanent title of ISO/TC249 and its scope

At the 6th plenary meeting of ISO/TC249, the committee agreed that the permanent title of the committee should be "Traditional Chinese Medicine", with the process assisted by Dr Pelaprat.

On June 19, 2015, ISO Technical Management Board officially approved "Traditional Chinese Medicine" as the permanent title of ISO/TC 249 and further approved the modified scope of ISO/TC 249 as follows:

"Standardization in the field of medical systems derived from ancient Chinese medicine which shall be able to share one common set of standards. Both traditional and modern aspects of these systems are covered. The committee focuses on quality and safety of raw materials, manufactured products and medical devices and of informatics, including service standards limited to involving the safe use and delivery of devices & medicines, but not into the clinical practice or application of those products."

# **Consultation on Strategic Business Plan of ISO/TC249**

Following the approval by ISO/TMB of the title and scope of ISO/TC249, the Chair and Secretariat drafted an update of the Strategic Business Plan which was circulated to the committee for comment on Sep 17, 2015...

The comments and input have been accepted and the revised document will be provided to members and then submitted to TMB for updating.

## **GROUP PHOTO**



WG1 meeting



WG2 meeting



WG3 meeting



WG4 meeting



WG5 meeting



JWG1 meeting

## **Progress on projects**

ISO/WD 18586 Traditional Chinese medicine --Requirements for basic safety for Electroacupuncture Stimulator

Stage: 20.60

ISO/WD 18615 Traditional Chinese medicine --General requirements of electric radial pulse tonometric devices

Stage: 20.20

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

Stage: 30.99

ISO/WD 18663 Traditional Chinese Medicine --Electroacupuncture stimulator device for quality

Stage: 20.60

ISO/FDIS 18668-1 Traditional Chinese medicine
-- Coding system of Chinese medicines -- Part 1:
Coding rules for Chinese medicines

Stage: 50.20

End of FDIS: 2016-02-07

ISO/CD 18668-2 Traditional Chinese medicine --Coding System of Chinese Medicines -- Part 2: Codes of Decoction Pieces

Stage: 30.99

ISO/CD 18668-3 Traditional Chinese medicine --Coding System of Chinese Medicines -- Part 3: Codes of Chinese Materia Medica

Stage: 30.99

ISO/CD 18668-4 Traditional Chinese medicine --Coding System of Chinese Medicines -- Part 4: Codes of granule forms of individual medicinals for prescriptions (GFIMP) Stage: 30.99

ISO/DIS 18746 Traditional Chinese Medicine -- Intradermal acupuncture needles

Stage: 40.99

ISO/DIS 19465 Traditional Chinese Medicine --Categories of TCM Clinical Terminological System

Stage: 40.20

End of DIS ballot: 2016-01-22

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

Stage: 20.00

ISO/CD 19610 Traditional Chinese medicine --Requirements for industrial manufacturing process of red ginseng

Stage: 30.99

ISO/CD 19611 Traditional Chinese medicine --Cupping apparatus for medical use except for the traditional cupping apparatuses

Stage: 30.20

End of CD ballot: 2016-02-14

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

Stage: 20.00

ISO/AWI 19617 Traditional Chinese Medicine --General requirements for manufacturing process of natural products used in and as Traditional Chinese Medicine

Stage: 20.00

ISO/CD 19824 Traditional Chinese Medicine --Schisandra Chinensis seeds and seedlings

Stage: 30.99

ISO/AWI 20308 Traditional Chinese Medicine --Gua Sha instruments

Stage: 20.00

ISO/NP 20311 Traditional Chinese Medicine --Salvia miltiorrhiza seeds and seedlings

Stage: 10.99

ISO/CD 20333 Traditional Chinese Medicine --Coding Rules for Chinese Medicines in Supply Chain Management

Stage: 30.99

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

Stage: 20.00

ISO/CD 20408 Traditional Chinese Medicine-Panax Notoginseng Seeds and Seedlings

Stage: 30.99

ISO/NP 20409 Traditional Chinese medicine-Panax Notoginseng Root and Rhizome

Stage: 10.99

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/NP 20498-2 Traditional Chinese medicine --Computerised tongue image analysis system --

Part 2: Light environment

Stage: 10.99

ISO/WD 20520 Infection control for acupuncture treatment

Stage: 20.20

ISO/NP 20758 Traditional Chinese medicine --Abdominal physiological parameter detector

Stage: 10.99

ISO/NP 20759-1 Traditional Chinese medicine --Artemisiae Argyi Folium -- Part 1: Artemisia argyi L évl. et Vant

Stage: 10.99

ISO/NP 21291 Traditional Chinese medicine-

**Therapeutic Fumigation Devices** 

End of NP ballot: 2016-03-09

ISO/NP 21292 Traditional Chinese medicine-

**Electric Heating Moxibustion Equipment** 

End of NP ballot: 2016-03-09

ISO/NP 21310 Microscopic examination on

medicinal herbs

End of NP ballot: 2016-03-10

ISO/NP 21311 Astragalus Root (Astragalus

membranaceus)

End of NP ballot: 2016-03-10

ISO/NP 21313 Platycodon grandiflorum Root

End of NP ballot: 2016-03-10

N381 General requirements for smokeless

moxibustion

End of NP ballot: 2016-03-10

ISO/NP 21312 Safe use of acupuncture needles

in the acupoints

End of NP ballot: 2016-03-10

N383 Traditional Chinese medicine -

Vocabulary-Part 2

End of NP ballot: 2016-03-10

ISO/NP 21300 Traditional Chinese medicine-

**Specification and Grades for Chinese Material** 

Medicine

End of NP ballot: 2016-03-10

ISO/NP 21314 Traditional Chinese medicine-

Salvia miltiorrhiza Root and Rhizome

End of NP ballot: 2016-03-10

ISO/NP 21315 Traditional Chinese medicine-

Ganoderma lucidum fruiting body

End of NP ballot: 2016-03-10

ISO/NP 21316 Traditional Chinese medicine-

Isatis indigotica root

End of NP ballot: 2016-03-10

ISO/NP 21317 Traditional Chinese medicine-

Lonicera japonica Flower

End of NP ballot: 2016-03-10

N392 Traditional Chinese Medicine-

**Dendrobium Officinale Stem** 

End of NP ballot: 2016-03-18

N393 Traditional Chinese Medicine - Labelling

requirements of products intended for oral or

topical use in and as Traditional Chinese

Medicine

End of NP ballot: 2016-03-17

## **Confirmation of the appointment of Working Group Convenors**

Upon the resolutions taken at the 6th plenary meeting, the Secretariat submitted the list of convenors to ISO/CS for appointment for another three years:

- WG 1 LIU Liang
- WG 2 Sven SCHRÖDER
- WG 3 HUANG Longxiang
- WG 4 CHOI Sun-Mi
- WG 5 WANG Kui; KOH Byung-hee
- JWG 1 Michael HAMMES

Mr. ZHANG Haiming from China has been elected to be the convenor of JWG6 (a joint working group with IEC/62D) by a CIB which closed on 12 October, 2015.

At the end of this year, DIN and SAC requested respectively to change the convenor of JWG1 and co-convenor of WG5. The secretariat will start two one-month CIBs on both turnovers.

## **Communication & Cooperation**





# **International Chinese Medicine Summit Forum (Toronto, Canada)**

In order to celebrate the 20 year anniversary of the Canada-China Medicine cultural exchange agreement, Dr. SANG Zhen, the assistant secretary of ISO/TC 249 and Ms. XU Xiaoting (Shirley) were invited as the representatives of ISO/TC 249 to attend International Chinese Medicine Summit Forum and Exhibition on Traditional Chinese medical history which were organized by Canadian Association of Acupuncture & Traditional Chinese Medicine from Sept. 19-22 in Toronto, Canada.

Dr. SANG gave an introduction to international standardization on TCM and accepted a gold medal of the Foundation of Development in Traditional Chinese Medicine of Canada on behalf of Prof. SHEN Yuandong. This medal is awarded to Prof. SHEN for his commitment and passion in supporting Traditional Chinese Medicine development worldwide.

## 12th World Congress of Chinese Medicine (2015 Barcelona, Spain)

The 12th World Congress of Chinese Medicine was successfully held by World Federation of Chinese Medicine Societies (WFCMS) in Barcelona, Spain, on Sep. 25, 2015. More than 1000 experts from 35 countries or regions, including China, China Hong Kong, China Macao, China Taiwan, South Korea, Japan, Singapore, United States, Brazil, Argentina, Peru, Chile, Costa Rica, Columbia, United Kingdom, France, Spain, Italy, Hungary, Holland, Belgium, Switzerland, Gabon, South Africa, New Zealand, and Australia etc. attended the congress. With the theme of "Traditional Medicine Systems Derived from Ancient Chinese Medicine in Modern Health Care", the participants shared latest information of theoretical research, clinical experience, scientific achievements and new inventions & creations about Chinese medicine.

The Chair of ISO/TC249, Dr. David Graham was invited to attend the Congress and gave a keynote speech titled "The importance of standardization for the future health of TCM". It was emphasized that ISO and its international standards (or similar products such as guidelines) provide fundamental and harmonised resources to assist countries to be able to ensure the quality control of products and services for TCM and related medical systems.



Dr. David GRAHAM, chair of ISO/TC 249 made keynote speech at 12<sup>th</sup> world congress of Chinese Medicine



#### THE MEETINGS OF ISO/TC215 HEALTH INFORMATICS





On April 20-24 and November 2-5, 2015, the representative of ISO/TC249 secretariat, Li Jing (Ivy) attended the ISO/TC215 San Francisco plenary meeting and ISO/TC215 Berne plenary meeting. After taking part in the sessions of TM/TF, JWG1 and WG3, Ivy further communicated with ISO/CS TPM, Ms. Mary Lou, TC215 secretary, Ms. Lisa Spellman, JWG1 convenor, Dr Ken Toyoda and the relevant experts to explore the arising problems and new opportunities in pushing forwards the JWG1 standards work.

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. There are 10 joint items under development or in an early process, of which five are led by TC249 (ISO/FDIS18668-1, ISO/CD18668-2, -3, -4 and ISO/CD20333). The JWG1 work is elaborating a close cooperation within ISO internal committees.

# International Workshop on Cooperation between ISO/TC249 and US Pharmacopeia



The "International Workshop on Cooperation between ISO/TC249 and US Pharmacopeia" was organized by the secretariat of ISO/TC 249 and held on 23 October 2015, in Shanghai, China. Fifteen attendees including professionals from ISO/TC249 and senior representatives of Natural Herbal Compendium of the United States Pharmacopoeia (USP) explored the opportunities in harmonizing TCM standards.

The secretary of ISO/TC 249, Prof Shen Yuandong opened the meeting and welcomed all the participants. Prof Guo De-an, Shanghai Institute of Materia Medica, Chinese Academy of Sciences indicated that this workshop offered a good opportunity with each other to share information on the standards work of TCM.

Prof Shen noted that it's a second round discussion between two organizations for establishing cooperation since the last international forum in Shanghai and he then gave a general overview of work of ISO/TC249.

Both ISO/TC249 and the USP shared common interests such as aiming at improvement of global health, and market-driven/market-relevant policies. It was recognized that the processes of ISO and the

USP and their different approaches in positioning herbs and herbal products.

The participants discussed the recent established monographs on TCM by the Natural Herbal Compendium-of the USP which may integrate with the international standards activities being undertaken by ISO/TC 249. The meeting-explored a feasible list to harmonize between ISO/TC249 and US Pharmacopeia in the future.

The participants thought that the meeting had been valuable and that it would be beneficial to keep other relevant organizations such as the World Health Organization (WHO) and the European Pharmacopeia (EP) informed of the work of ISO/TC 249.



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

On Nov 11-17, the secretary Prof Shen Yuandong and Ms. XU Xiaoting (Shirley) participated in the plenary meeting of IEC/TC 62 and SC 62D as the liaison organization in Kobe, Japan.

ISO/TC 249 and IEC/SC 62D have agreed to established the joint working groups (ISO/TC 249/JWG6 and IEC/SC62D/JWG37) to develop the international standards in the field of TCM electromedical equipment.

ISO/TC 249 has submitted several proposals under development to IEC/SC 62D for further comment. The followings have been assessed as joint working projects:

- ➤ ISO/WD 18586 Traditional Chinese medicine -- Requirements for basic safety for Electroacupuncture Stimulator
- ISO/WD 18615 Traditional Chinese medicine -General requirements of electric radial pulse tonometric devices
- ➤ ISO/WD 18663 Traditional Chinese Medicine -- Electroacupuncture stimulator device for quality
- ISO/AWI 19614 Traditional Chinese medicine -Pulse graph force transducer

In Kobe meeting, the secretariat of ISO/TC 249 and IEC/SC 62D discussed the working procedures on the newly-built JWGs. JWG6 convenor Mr. Zhang Haiming and project team of ISO 19614 were also invited to discuss the technical issues on 19614 and clarify its assignment.



Prof. SHEN Yuandong, ISO/TC 249 secretary (2<sup>nd</sup> left)
 Prof. Mike W. Schmidt, IEC/SC 62D secretary (2<sup>nd</sup> right)
 Mr. ZHANG Haiming, ISO/TC 249/JWG6 convenor (1<sup>st</sup> right)

# The meetings of the Chair's Advisory Groups of ISO/TC 249

The first TC249/CAG2 meeting has been held via WebEx meeting tool on Mar 25th, 2015.

The tenth TC249/CAG1 meeting has been held via WebEx meeting tool on Dec 2nd, 2015.



"With the global spreading of TCM, all countries, industry experts and governments around the world start to cast great concentration to the issue of 'how to use TCM more scientifically, safely and effectively'." Prof. SHEN Yuandong said.

## **Interview by CHINA STANDARDIZATION**

Prof. SHEN Yuandong, the secretary of ISO/TC 249 was interviewed by China Standardization, which is the best magazine focusing on standardization in China (*Volume 73, July/August 2015 China Standardization*). In his interview, Prof. SHEN reviewed the remarkable progress made by ISO/TC 249 and emphasized the importance and urgency of international standardization for TCM.

This volume introduced the development of TCM standardization in China and interviewed many notable officers and experts in the field of TCM such as Mr. WANG Guoqiang, vice-minister of NHFPC& Commissioner of SATCM.

For more information, please refer to the website:

http://www.cspress.cn/

#### **Latest Information on TCM in the world**

#### Attention paid to TCM as China's Tu Youyou receives 2015 Nobel Prize in Stockholm

China's pharmacologist Tu Youyou was awarded the 2015 Nobel Prize in Physiology or Medicine, highlighting the opportunities in research into traditional Chinese medicine (TCM).

Tu, 84, received the Nobel medal, Nobel diploma and a document confirming the Nobel Prize amount from King XVI Gustaf of Sweden at the Stockholm Concert Hall.

A big applause from the standing audience engulfed Tu, the first Chinese scientist to win a Nobel Prize in science for work done in China, and the first Chinese woman to win the prize.

With the right methods, and help of "a 1700-year-old book" on TCM, Tu found an active component, artemisinin, effective to cure malaria.

"The discovery of Artemisinin has led to the development of a new drug that has saved the lives of millions of people, halving the mortality rate of malaria during the past 15 years," said Professor Hans Forssberg, member of the Nobel Committee for Physiology or Medicine.

Tu said "Chinese medicine and pharmacology are a great treasure-house," which "should be explored and raised to a higher level."

For more information, please refer to website:

http://news.xinhuanet.com/english/2015-12/12/c\_134910357.htm





# WFAS 2015 First International Baikal Symposium on Traditional Medicine Held in Irkutsk, Russia

The WFAS 2015 First International Baikal Symposium on Traditional Medicine was held successfully from 24 to 25 May 2015 in Irkutsk, Russia. Themed as "topical issues of acupuncture and traditional medicine in the field of prevention, treatment and medical rehabilitation of patients with different diseases", the symposium was attended by approximately 200 delegates consisting of experts, scholars, and business representatives from Russia, Canada, Kazakhstan and Ukraine, with the majority of delegates being local doctors.

This symposium is the first academic conference held by WFAS in Russia in the past 28 years since its inception. The delegates exchanged views at the 2-day event through heated discussion about acupuncture and moxibustion in perspectives of mechanism study, education standard, clinical application and research, future trend and strategy in clinical practices, standardization, policy and safety, and education and training



#### WFAS 2015 Conference Held in Toronto, Canada

WFAS International Acupuncture Conference was held from 25 to 27 September 2015 in Toronto, Ontario, Canada. More than 300 delegates from 26 countries in 6 continents attended this conference and 50 delegates were acupuncture experts from China. Besides the distinguished guests addressed the opening ceremony, the conference received congratulatory letters from the Rt. Hon. Stephen Harper, Canadian Prime Minister, Luo Zhaohui, Chinese Ambassador to Canada, Kathleen Wynne, Premier of Ontario, John Tory, Mayor of Toronto and Xue Bing, Consul-General of China in Toronto.



The theme of this conference was "Connect, Collaborate and Innovate--Throughout the past and present, the tree of acupuncture is flourishing; throughout the west and east, the flower of TCM is blooming". There were 129 academic papers presented in 6 keynotes, 75 orals and 14 workshops in 3 parallel sessions.

After 30 years of development, WFAS as a liaison organization of ISO/TC249 and a cooperative partner of WHO with 178 member societies from 53 countries and regions has grown to be an NGO of international influence.

## 7<sup>th</sup> Plenary meeting of ISO/TC 249

We are very pleased to announce that the next plenary meeting for ISO/TC 249 will be held in Rome, Italy from 6-9 June 2016 and we thank our Italian colleagues for their invitation.

The exact details of the venue will be available soon.

# Deadlines of posting committee documents for the 7th plenary meeting in 2016

The cutoff dates for posting papers for preparation of the 7th plenary meeting in Rome, Italy 2016 are:

- 5 February 2016 for major documents including NWIPs to be discussed during the meeting
- 22 April 2016 for other papers
- 27 May 2016 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 25 January, 2016 to allow processing time for the 5 February cutoff date.

In line with the resolution from the  $6^{th}$  plenary meeting, you are encouraged to include a working draft or an outline of the working draft with an NWIP.

### Seasons best wishes

Our best wishes for the Christmas & New Year and thank you to all who have contributed to the work of ISO/TC 249 in 2015.

#### **CONTACTS**

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