



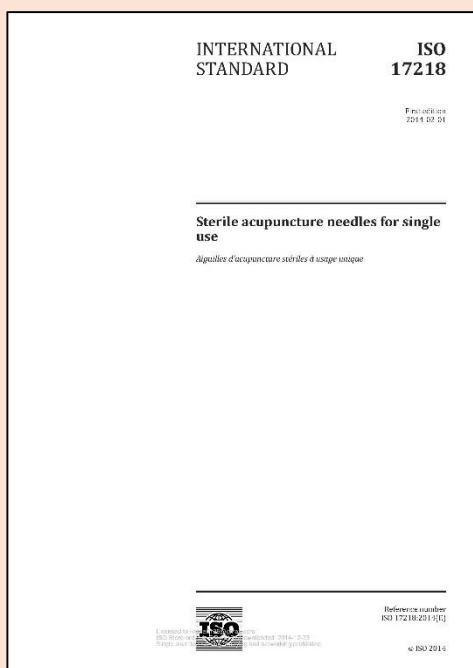
ISO/TC 249 Newsletter

—Vol. 6 (2014 Christmas Edition)

Congratulations to the publications of the first two international standards of ISO/TC249

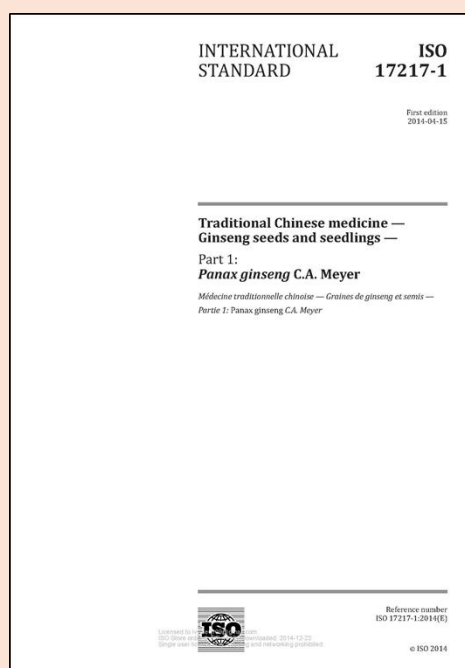
ISO 17218:2014

Sterile acupuncture needles for single use



ISO 17217-1:2014

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



ISO17218:2014 Sterile Acupuncture Needle for Single Use has been proposed by SAC since 2011 and published on 3rd Feb., 2014. This international standard which harmonizes and defines the acceptable specifications and the requirements for the sterile acupuncture needles for single use (specialized for filiform needles) not only assists trade and commerce but protect the reputation of acupuncture and the safety of the community.

Led by SAC in 2011 and published on 22nd Apr., 2014, **ISO 17217-1:2014 Traditional Chinese medicine -- Ginseng seeds and seedlings -- Part 1: Panax ginseng C.A. Meyer** specifies minimum requirements and test methods for ginseng seeds and seedlings, Panax ginseng C.A. Meyer. It is suitable for marketing of cultivated ginseng seeds and seedlings, P. ginseng C.A. Meyer. It is also suitable for quality assurance for ginseng cultivators.

Standards are essential to underpin and protect the use of Traditional Medicine systems that extend into international use. The work in developing ISO 17218:2014 and ISO 17217-1:2014 have demonstrated the benefits of the collaborative and cooperative approach of all the countries and organisations and the strength of the ISO processes. There are many more, important standards being developed within ISO/TC249 which will support the appropriate international use of Traditional Medical systems.

ISO link to purchase both standards at

ISO17218:http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=59443&commid=598435

ISO 17217-1:http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=63485&commid=598435

The fifth plenary meeting of ISO/TC 249



The fifth plenary meeting of ISO/TC249 was held on May 26-29 in Kyoto, hosted by the Japanese Industrial Standards Committee (JISC) and the Japanese Liaison of Oriental Medicine (JLOM). Two hundred and five delegates participated in this meeting representing twelve national member bodies, two organizations in liaison and one internal liaison. Dr. Mary Lou Pelapat from the ISO Central Secretariat also attended this meeting.

The Chair and Secretary gave reports covering the general issues arising from the business of committee during the last year.

The following important issues have been discussed at the meeting:

1. Scope of the technical work of the committee
2. Introductory element for individual standard
3. The scope of ISO/TC249
4. Liaison arrangement
5. Establishment of CAG2
6. Progress on technical work which has been achieved in ISO/TC249 by 5th plenary meeting

The committee thanked Japan for its excellent hosting of the meeting. China has offered to host the next meeting in June 2015.

The resolutions of the 5th plenary meeting in Kyoto (N215) can be found in ISO/TC249 e-committee at:

[http://isotc.iso.org/livelink/livelink?func=ll&objId=16373286&objAction=br
owse&viewType=1](http://isotc.iso.org/livelink/livelink?func=ll&objId=16373286&objAction=browse&viewType=1)



WG1 meeting



WG2 meeting



WG3 meeting



The 5th meeting of ISO/TC249/WG4
Kyoto, Japan on May 28, 2014

WG4 meeting



4th WG5 & 2nd JWG1 Meeting, Kyoto Japan, May 26-27, 2014

WG5 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: 30.60

ISO/WD 18663 Traditional Chinese Medicine - - Electroacupuncture stimulator device for quality
Stage: 20.60

ISO/DIS 18664 Traditional Chinese Medicine - - Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine
Stage: 40.40

ISO/DIS 18665 Traditional Chinese Medicine - - Herbal decoction apparatus
Stage: 40.00

ISO/DIS 18666 Traditional Chinese medicine -- General requirements of moxibustion devices
Stage: 40.00

ISO/CD 18668-1 Traditional Chinese Medicine -- Coding System of Chinese Medicines -- Part 1: Coding Rules for Chinese Medicines
Stage: 30.99

ISO/AWI 18668-2 Traditional Chinese medicine -- Coding System of Chinese Medicines -- Part 2: Codes of Decoction Pieces
Stage: 20.00

ISO/CD 18746 Traditional Chinese Medicine -- Intradermal acupuncture needles
Stage: 30.60

ISO/CD 19465 Traditional Chinese Medicine (TCM) -- Categories of TCM
Stage: 30.99

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/AWI 19610 Traditional Chinese medicine -- Requirements for industrial manufacturing process of red ginseng
Stage: 20.00

ISO/AWI 19611 Traditional Chinese medicine -- Cupping apparatus for medical use except for the traditional cupping apparatuses
Stage: 20.00

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/AWI 19824 Traditional Chinese Medicine -- Schisandra Chinensis seeds and seedlings
Stage: 20.00

ISO/AWI 20333 Traditional Chinese Medicine -- Coding Rules for Chinese Medicines in Supply Chain Management
Stage: 20.00

ISO/AWI 20334 Traditional Chinese Medicine -- Coding System of Formulas
Stage: 20.00

**N151 Coding System of Chinese Medicines -
Part 3: Codes of Chinese Materia Medica**

End of NP ballot: 2014-12-28

**ISO/NP 20493 Infrared moxibustion-like
instrument**

End of NP ballot: 2015-02-26

ISO/NP 20308 Gua Sha instruments

End of NP ballot: 2014-12-29

**N 251 Electrical resistance detector at
Acupuncture Points**

End of NP ballot: 2015-02-27

**N214 Coding System of Chinese Medicines -
Part 4: Codes of Granule Forms of
Individual Medicinals for Prescriptions**

End of NP ballot: 2014-12-28

**ISO/NP 20497 Facial imaging device – face
information acquisition instrument**

End of NP ballot: 2015-02-27

**ISO/NP 20311 Salvia miltiorrhiza seeds and
seedlings**

End of NP ballot: 2014-12-29

**ISO/NP 20498-2 Computerised tongue image
analysis system-Part 2: Light environment**

End of NP ballot: 2015-02-27

**ISO/NP 20408 Panax notoginseng seeds and
seedlings**

End of NP ballot: 2015-01-29

**ISO/NP 20498-1 Computerised tongue image
analysis system- Part 1: General requirements**

End of NP ballot: 2015-02-28

**ISO/NP 20409 Panax notoginseng root and
rhizome**

End of NP ballot: 2015-01-29

**ISO/NP 20520 Infection control for
acupuncture treatment**

End of NP ballot: 2015-03-03

**ISO/NP 20487 Test Method on Acupuncture
needles for single use on electrical stimulation**

End of NP ballot: 2015-02-25

Ballot on the inclusion of Ayurveda within ISO/TC249

At the 4th and 5th plenary meetings of ISO/TC249, the committee explored the request from India to include Ayurveda into the scope of committee in great detail, it was then resolved at Kyoto meeting [Resolution 86 (Kyoto 2014:4)] to carry out a formal CIB following the meeting to finalise the matter.

The secretariat launched a formal ballot on this issue on Aug 27, 2014. The CIB has been closed on Sep 27 and the outcome is a consensus by members that Ayurveda should not be included within the scope of ISO/TC 249. The ISO Central Secretariat has been advised of this outcome. The discussions by the committee demonstrated a high

respect for the importance of Ayurveda but the primary difficulties were the high workload of ISO/TC 249 in the area of TCM and related TM's and the different range of stakeholders involved with Ayurveda.

It was also recognised that many general aspects of standards developed by ISO/TC 249 in areas such as quality and safety could be relevant to the standards development for Ayurveda. The committee greatly appreciates the active contribution of the Indian delegation to the work of ISO/TC 249 and encourage their future participation.

Ballot on the form of modification of the TC249 scope

In accordance with the past committee resolutions and the outcome of CIB balloting on Ayurveda, TC249 secretariat has drafted the Form "MODIFICATION OF THE TITLE AND SCOPE OF AN ISO TECHNICAL COMMITTEE" for submission to the TMB. Before the formal approval of ISO/TMB, the committee was requested to pass a resolution accepting the exact wording of the new Scope, thus the secretariat launches a one-month ballot within TC249 on Nov 15, 2014. The voting which ended on Dec 15 and its result indicates a consensus by TC249 members that the committee focuses on standardization in the field of medical systems derived from ancient Chinese medicine which shall be able to share one common set of standards. The secretariat will submit the scope form and the results of voting to TMB for approval.

The Strategic Business Plan (SBP) will state the technical work areas that the committee has prioritised and which are consistent with and are carried out under the committee's scope. These are quality and safety of natural raw materials and manufactured products and of medical devices and informatics, including service standards limited to involving the safe use and delivery of devices and medicines but not into the clinical practice or application of those products. The draft of the updated SBP will be circulated for input as soon as the TMB decision is made.

Activities within ISO/TC 249 and ISO/IEC

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

The eighth TC249/CAG meeting has been held via WebEx meeting tool on May 7th, 2014.

The ninth TC249/CAG meeting has been held via WebEx meeting tool on Dec 3rd, 2014.

The fourth meeting of ISO/TC 249/WG3&WG4

The fourth meetings of ISO/TC249/WG3 & WG4 were held on February 13-14th in Sydney, Australia. Thirty-six attendees from 4 countries participated in the meetings, including the representatives from Standards Australia and TC249 Secretariat.

On Feb 13th, WG3 had the discussion on expanding the scope of WG3 and participants agreed that the WG3 recommends to the ISO/TC249 that the scope of the WG be amended to the 'Standardisation in the field of safety and quality of acupuncture'. A couple of projects have been discussed as well in the meeting.

On Feb 14th, WG4 convener presented a roadmap for the harmonization of projects within the scope WG4 regarding IEC requirements and discussed several working drafts of active projects in the meeting. The revised final WDs will be sent to the secretariat for the next steps.



The joint meeting of ISO/TC215 *Health Informatics* and CEN/TC251 *Health Informatics Working Group*

The joint meeting of ISO/TC215 *Health Informatics* and CEN/TC251 *Health Informatics Working Group* has been held in Berlin from Oct 6-10, 2014. Dr SANG Zhen and Ms. LI Jing (Ivy), the representatives from the TC249 secretariat attended the meeting including the TM/TF, JWG1 and WG3 sessions. Further communication with TC215 secretary, Lisa Spellman and the relevant leaders from TM/TF and JWG1 have been explored.



Since this innovative mechanism of JWG1 being set up in 2012, there are totally 4 joint projects under development, of which three are from TC249 (ISO/DIS18668-1, ISO/WD18668-2 and ISO/WD20333) and the other one from TC215 (ISO/DTS18790-1). Although two more projects from TC215, respectively, ISO/NP16843-1 and ISO/DTS16843-2 were not fallen into JWG1 items for both of them were reinstated projects and well advanced, the experts saw much interest of TC249 and recommended to have a consultation process within TC249. Both projects currently are under one-month consultation within TC249/WG5 from Dec 20, 2014-Jan 20, 2015. The secretariat of TC249 will then collate comments and submit them to TC215 secretary.

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 17-26 November 2014 in New Orleans, Louisiana USA. According to the resolutions made in the fifth plenary meeting of ISO/TC 249 in Kyoto this May, Dr. SANG Zhen and Ms. XU Xiaoting (Shirley) attended the plenary meeting of IEC/SC62D ELECTROMEDICAL EQUIPMENT as the representatives from ISO/TC 249 to explore the liaison relationship with IEC/SC 62D.

Ms. XU made a brief introduction to the work of ISO/TC 249 at that meeting. SC 62D approved the resolution to establish the liaison with ISO/TC 249 and the secretary of SC 62D will circulate the list of

projects currently underway or planned in TC 249 and 62D will be asked to either participate or comment on the documents.

International Forum on Standardization of Traditional Chinese Medicine

“International Forum on Standardization of Traditional Chinese Medicine” was organized by the secretariat of ISO/TC 249 and held on 14 December, 2014 in Shanghai, China. Thirty-eight experts including senior representatives of various pharmacopoeia organizations explored the opportunities and approaches for a coordinated approach to developing TCM standards.

The secretary of ISO/TC 249, Prof Shen Yuandong welcomed all the participants and noted that it’s an ideal opportunity for exchanging information and establishing cooperation for the international development of TCM.

Pharmacopoeias are a source of standards for a country or a region and are often mandated in law. Those represented at the meeting were the European Pharmacopoeia, the United States Pharmacopoeia,



the Chinese Pharmacopoeia and the Thai Pharmacopoeia. Also participants provided information on the Japanese Pharmacopoeia. Presentations were also made on the work of the Good Practice in Traditional Chinese Medicine Research Association (GP-TCM Research Association).

The participants then focused on specific advice to ISO/TC 249 in planning its work priorities in the herbal area for the development of international standards. The meeting also discussed the benefits of ongoing communication and coordination and planned how this might be done.

All the participants thought that the meeting had been valuable and the secretary indicated that a similar meeting might be arranged in the medical device area.

The meeting concluded with the participants being warmly thanked for their thoughtful contributions and an exchange of season greetings.

The outcomes will be circulated to TC249 members after receiving input from all participants.

The eighth meeting of ISO /WG2

The eighth meeting of ISO/WG2 will be held in Berlin, Germany on Feb. 12-13, 2015.

The sixth plenary meeting of ISO/TC 249

The cutoff dates for submitting papers for preparation of the 6th plenary meeting in Beijing, China on June 1-4, 2015 are:

- 31 January for major documents including NWIPs to be discussed during the meeting
- 15 April for other papers
- 23 May for the final agenda and minor papers

▼ *New Year's Wish* ▼



TC249 secretariat would like to extend our deep gratitude and warm greetings to all the experts who invested in and supported our standard work over the past 5 years.

Wishing you peace, joy and happiness through Christmas and the upcoming new year of 2015!

ISO/TC249 Secretary

A handwritten signature in black ink that reads "Shen Yuandong".

Shen Yuandong
Dec 24, 2014



Merry Christmas

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