



INFORMATION RELATED TO ISO/TC 249 TRADITIONAL CHINESE MEDICINE (PROVISIONAL)



ISO/TC249 Newsletter

VOL. 3 (NOVEMBER 2011-JUNE 2012)

The 3rd plenary meeting of ISO/TC249

The third plenary meeting of ISO/TC 249 was held in Daejeon, Republic of Korea from May 21 to 24, 2012, hosted by Korean Agency for Technology and Standards with support of Korea Institute of Oriental Medicine and The Association of Korean Oriental Medicine. There were 166 participants from 14 P-members and 2 liaison organizations attending this meeting.

Dr. David GRAHAM, the chair of ISO/TC249 and Prof. SHEN Yuandong, the secretary, gave reports covering the general issues arising from the business of committee during the last year. The main agenda items for

the meeting were:

- Establishing an Editing panel
- Official languages
- Business Plan
- TC249 committee procedures
- Progress on working groups (title, scope, new work item proposals, etc.). Each of the working groups held a meeting during the plenary.

The four days' meeting was considered to be a successful and fruitful one. The Business Plan has been approved by the plenary and will be submitted to TMB for approval. Two active projects within the TC249 work program, ISO/WD 17217 *Ginseng Seeds and Seedlings: Panax ginseng C.A. Meyer* and ISO/WD 17218 *Sterile acupuncture needles for single use*, were agreed to proceed to the next stage and the corresponding drafts will be submitted to the



TMB for CD registration via the Secretariat.

Eleven new proposals were approved by the plenary committee to proceed to ballot and the secretariat will circulate the revised Form 4 and relevant documents for balloting and approval as new work items.

The agreement for a Joint Working Group (Informatics of TCM) between TC249 and TC215 was approved and the central secretariat of ISO will be soon informed of this decision. Upon its formal establishment, the TC249 secretariat will deal with the issue of a co-convenor from TC249 for the Joint Working Group.

With the experience now gained from the work of 5 Working Groups and governance arrangements, the committee is striving for the development of high-quality international standards on traditional Chinese medicine.

The committee was very grateful to the Korean hosts for their excellent arrangements.

Progress on the working groups (WG)

WG1 Quality and safety of raw materials and traditional processing

Convenor: Prof. LIU Liang (SAC)

The scope of WG1 is to create standards related to raw materials at any stage up to and including harvest of a plant ingredient and collection of an animal or mineral ingredient, and the traditional processing of raw materials.

Active project:

ISO/WD 17217 Ginseng Seeds and Seedlings: Panax ginseng C.A. Meyer

Project leader: HUANG Luqi (SAC)

Proposals:

- *Limited value standard of heavy metal in Traditional Medicine materials* (proceed to ballot)
- *PWI Ginseng seeds and seedlings - Part 2: P. quinquefolius* (it will not be an active work item until enough resources and expertise are sought)
- *PWI Determination of arsenic, cadmium and lead in Ginseng and Ginseng products by inductively coupled plasma spectrometry*
- *PWI Microbiological quality control of ginseng and ginseng products*
- *PWI Ginseng and ginseng products -Determination for pesticide multi-residues - Method by GC/MS/MS and LC/MS/MS*



The first meeting of WG1



The second meeting of WG1

WG2 Quality and safety of manufactured TCM products

Convenor: Mr. Hans RAUSCH (DIN)

The scope of WG2 is to create standards for testing, processing (other than traditional processing) and manufacturing of TCM products, from starting materials to finished products, in a framework of quality and safety.

Proposals:

PWI 1 - Quality and Safety of natural materials and manufacturing products made with natural materials used in and as traditional Chinese medicine (TCM)

PWI 2 - Quality and Safety of natural materials and manufacturing products in Traditional Chinese Medicine (provisional): General requirements for manufacturing process of finished products



WG3 Quality and safety of acupuncture needles (tentative)

Convenor: Prof. HUANG Longxiang (SAC)

The scope of WG3 is standardization of all kinds of potentially invasive needles for single use that are commonly used in the acupuncture field.

Active project:

ISO/WD 17218 Sterile acupuncture needles for single use

Project leader: CAO Yang (SAC)

Proposals (proceed to ballot):

- *Intradermal needles*
- *Thumbtack needles*



WG4 Quality and safety of medical devices other than acupuncture needles

Convenor: Prof. Yong-Suk KIM, Prof. Sun Mi CHOI (KATS)

The scope of WG 4 is to develop standards for quality and safety of medical devices other than acupuncture needles.

Proposals (proceed to ballot):

- *Electro-acupuncture stimulator device for quality*
- *Electro-acupuncture stimulator device for safety*
- *Herbal Decoction Apparatus*
- *Moxibustion devices*
- *General requirements for electric pulse tomography device**

*note: restricted to safety and accuracy of the tomography trace and does not include differential diagnosis and interpretation of the diagnostic data obtained from the use of the device

- *Computerized tongue imaging device **

*note: restricted to safety and accuracy of the computerized tongue imaging device and does not include differential diagnosis and interpretation of the diagnostic data obtained from the use of the device



The first meeting of WG5



The second meeting of WG5

- *Traditional Chinese Medicine- Categories of SNOTCM-CT* (be referred to the Joint Working Group for harmonized coordination)

Joint Working Group with TC 215 : Informatics of TCM

Convenor: Co-convenors, one from TC 249 and one from TC 215 (under nomination)

Upon JWG's establishment, the scope will be decided at its meeting and the operating procedures will be drafted by the group in accordance with *Agreement on setting up Joint Working Groups between ISO/TC215 and ISO/TC249 in the field of informatics on Traditional Chinese Medicine.*

WG5 Informatics of TCM

Convenor: Prof. Byunghee KOH (KATS), Prof. WANG Kui (SAC)

The scope of WG 5 shall be the standardization of TCM nomenclature, terminology, classification, and ontology. Health informatics technology shall be standardized by a joint working group between TC 249 and TC 215.

Proposals:

- *Basic Terms of Chinese Materia Medica* (proceed to ballot)
- *Coding System of Chinese Materia Medica* (proceed to ballot, after consulting the Joint Working Group)
- *Basic Nomenclature of Traditional Chinese Medicine* (proceed to further development)

Chairman Advisory Group

(CAG)

The Chairman Advisory Group of TC249 consists of the following seven experts since its establishment of May, 2011:

- Prof. Marilyn ALLEN (USA)
- Dr. Ramón CALDUCH (Spain)
- Prof. CHEN Kaixian (China)
- Prof. CHOI Seung-Hoon (Republic of Korea)
- Dr. Michael HAMMES (Germany)
- Prof. MOTOO Yoshiharu (Japan)
- Prof. Christopher ZASLAWSKI (Australia)

Four CAG meetings have been held since its establishment. The fourth meeting of CAG was held on May 21 in Daejeon, Korea during the third plenary of ISO/TC 249. The chair, secretary, CAG members and the secretariat attended this meeting.

Editing Panel

The editing panel of TC249 is established since the 3rd plenary meeting, currently with two experts-Dr. James Flowers from Australia and Dr. Eric Brand from USA who can be called on for assistance if needed.

When requested by the convenor or the project leader, the Panel member can assist in preparing draft documents used in the preparation of an ISO standard, in accordance with drafting requirements of the ISO Directives. However the Panel member's role is not to alter the technical content.

Follow-ups after the 3rd plenary meeting

- The Resolutions of the third plenary meeting of TC249 (N27) have been posted to the TC website on May 29th, 2012.
- The Report of the third plenary meeting of TC249 (N28) has been submitted to TMB on June 12th, 2012.
- The procedures of TC249 (N30-36) have been circulated on the TC249 homepage on June 20th, 2012.
- The Business Plan has been formally submitted to the TMB for review and final approval on June 12th, 2012.
- The committee drafts of *Ginseng Seeds and Seedlings: Panax ginseng C.A. Meyer* and *Sterile acupuncture needles for single use* have been sent to the editing panel with a one month turnaround. After that, the secretariat will circulate the revisions to all members and proceed to a three-month ballot on CDs.

Education and training in international standardization

ISO Central Secretariat (ISO/CS) organizes structured training activities for ISO members and professionals carrying out specific standards development activities.

The training activities focus on the transfer of knowledge and refinement of skills needed to meet the requirements associated with the development, production and dissemination of international standards.

ISO organizes both classroom and distance learning courses on the tools and services supporting the standards development process, as well as courses which are designed to assist ISO member bodies with managing their involvement in international standardization.

All these courses are designed for a specific audience.

Some of the courses are aimed at providing key professionals with the opportunity of acquiring or refreshing the knowledge needed to manage ISO committee work. These include both experienced or newly appointed secretaries and Chairs of ISO committees, working group (WG) convenors, as well as committee members.

Other courses are designed specifically for the staff of ISO members in order to help them to carry out their roles i.e. communication or marketing staff, staff from departments for international relations, or technical directors.

Courses are provided by staff from both the ISO/CS and from the ISO members themselves. Many of the courses provided are designed and operated by the same persons responsible for operating related activities and services at ISO/CS.

ISO/CS training services for ISO members include:

- a) a set of regular courses covering the most requested topics, and
- b) customized and on-site training to support specific requirements and particular needs of ISO members.

Regular Sessions 2012

Tenth ISO Secretaries' Week	
20 February	Procedures for ISO secretaries
21-22 February	Drafting standards in accordance with the ISO/IEC Directives Part 2, using the ISO STD Template
23-24 February	eServices for ISO secretaries
Eleventh ISO Secretaries' Week	
25 June	Procedures for ISO secretaries
26-27 June	Drafting Standards in accordance with the ISO/IEC Directives Part 2, using the ISO STD template
28-29 June	eServices for ISO secretaries (Course Full)
Twelfth ISO Secretaries' Week	
5 November	Procedures for ISO secretaries
6-7 November	Drafting Standards in accordance with the ISO/IEC Directives Part 2, using the ISO STD template
8-9 November	eServices for ISO secretaries
Other courses in 2012	
8-10 May	Pilot training workshop for ISO chairs and convenors (Course Full)
27-29 November	eServices for MBUAs

More information at

http://www.iso.org/iso/about/education_and_training/training_at_iso.htm

http://www.iso.org/iso/about/education_and_training/training_at_iso/dates_of_regular_training_sessions.htm

ISO/IEC Directives and ISO Supplement

The 2012 version of the ISO/IEC Directives Part 1 is now available online at www.iso.org/directives. Please note that the Consolidated ISO Supplement, which integrates all ISO specific clauses directly into the ISO/IEC Directives, Part 1, replaces the previous ISO Supplement. Both documents are applicable as of 1 May 2012.

As has been done in the past, the

principal changes since the previous editions are summarized in the first pages of the documents. In addition, two versions of both the ISO/IEC Directives, Part 1 and the Consolidated ISO Supplement are now available: one with track changes and one without. This is intended to help you to easily identify the changes that have been made since the last editions.

We would draw your attention to the fact that the changes to clauses 2.6.1 and 2.6.4 (in both the ISO/IEC Directives, Part 1 and the Consolidated ISO Supplement) are applicable as from 1 July 2012. Please check the new version of the ISO/IEC Directives and note the major changes that will affect your work.

Latest information on TCM in the world

Canada

Having recognized the unique nature of Traditional Chinese Medicines (TCM) in Canada, the Minister of Health, Leona Aglukkaq announced the creation of a national advisory committee on Traditional Chinese Medicines (TCMs) on Jan 12, 2012.

The mandate of the new Committee is to provide Health Canada's Natural Health Products Program Directorates with views, feedback, and advice on current and emerging issues related to Traditional Chinese Medicines (TCMs), including:

- the importation, sale, and use of TCMs in Canada;
- the practice of TCM in Canada, recognizing this is subject to provincial jurisdiction; and
- novel TCMs.

The structure and mandate of the Committee are intended to support advice that is based on broad input. Consideration will be given to common objectives, shared responsibility and accountability for assuring that Canadians have ready access to natural health products that safe, effective and of high quality.

Potential members have been identified from a cross-representation of key stakeholder groups including, industry, consumer, patient, health care professional, academic and government organizations, as appropriate.

(<http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2012/2012-03bk-eng.php>)

International Symposium on Theory & Evidence for Acupuncture 21-22 August 2012

Date: 21 & 22 August 2012
 Time: 9am to 6pm
 Venue: Nanyang Executive Centre, NTU
 60 Nanyang View #02-18
 Singapore 639



This symposium focuses on theory of acupuncture and the clinical evidence for its efficacy.

Traditional Chinese Medicine explains acupuncture in terms of the flow of qi along channels and collaterals and the effects of stimulating acupuncture points on the functions of organs. Western explanations vary from the effect of acupuncture on pain sensations travelling along the neurological network as well as the release of the body's own secretions that

deal with pain. The symposium invites papers that critically examine such theories from a modern scientific perspective and/or offer alternative explanations.

The efficacy of acupuncture is a subject of controversy. The symposium welcomes papers that offer meta-analyses of clinical trials on acupuncture therapies and on the placebo effects of acupuncture treatments. Of particular interest are papers that

deal with methodological issues in clinical trials.

For more information, please refer to website:

<http://www.ntu.edu.sg/ias/ACU>

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