# ISO/TC 249 Newsletter



Information related to ISO/TC 249, Traditional Chinese Medicine (provisional)

Vol. 2 (June 2011-October 2011)

## **NWIP PROGRESS**

 ISO/TC249 N13 NWIP Standardization on seed and seedling standards of ginseng

Vote started from 2011-02-24 to 2011-06-24

The result of voting is that there are 14 out of 18 P-members showing their agreements to the project and 8 members are committed to participate actively in the development of the project and have nominated their experts. The voting result with a simple majority approval and 5 or more P-members having committed to participate in the project has met the criteria of the approval of a NWIP in accordance with the ISO/IEC Directives.

(Please find more detailed information in N24 The report of voting on N13 Ginseng seeds and seedling.)

Current status: ISO/NP 17217 Stage: 10.99 being handled by ISO/TC 249/WG 1

• **ISO/TC249 N14 NWIP** *Acupuncture Needles* Vote started from 2011-02-24 to 2011-07-08

The result of voting is that there are 15 out of 18 P-members showing their agreements to the project and 13 members are committed to participate actively in the development of the project and have nominated their experts. The voting result with a simple majority approval and 5 or more P-members having committed to participate in the project has met the criteria of the approval of a NWIP in accordance with the ISO/IEC directives.

(Please find more detailed information in N23 The report of voting on N14 Acupuncture Needles.)

Current status: ISO/NP 17218 Stage: 10.99 being handled by ISO TC

249/ WG 3

## **ACTIVITIES WITHIN ISO/TC 249 AND ISO**

## • Nomination of Chair's Advisory Group (CAG)

After deliberation following the receipt of CAG nominations, the chair, Dr. Graham appointed seven experts as the ISO/TC249 CAG members:

Prof. Marilyn Allen (USA)

Dr. Ramon Calduch (Spain)

Prof. Chen Kaixian (China)

Prof. Seung Hoon Choi (Korea)

Dr. Michael Hammes (Germany)

Prof. Yoshiharu Motoo (Japan)

Prof. Chris Zaslawski (Australia)

Five members were agreed at the last plenary meeting and the two additional members were appointed in order of receipt of their nominations. One later nomination from the Netherlands is held in reserve for when there is a vacancy.

## • The first Chair's Advisory Group (CAG) meeting

On Aug. 9th, the first CAG teleconference has been convened with the participants of the chair, the secretary, and 7 CAG members.

Items discussed were:

- Progress of the Working Groups.
- Draft Committee procedures
- Official languages
- TC 249 Newsletter
- Draft Business Plan
- Next plenary meeting
- Next meeting of the CAG

#### • Activities of the Working Groups

The five working groups have been established and are:

- ISO TC 249/WG 1 Quality and safety of raw materials used in TCM, chaired by LIU Liang
- ISO TC 249/WG2 Quality and safety of manufactured TCM products, chaired by Hans RAUSCH
- ISO TC 249/WG 3 Quality and safety of acupuncture needles, chaired by HUANG Longxiang
- ISO TC 249/WG 4 Quality and safety of TCM medical devices other than acupuncture needles, chaired by KIM Yong-suk and CHOI Sun-mi
- ISO TC 249/WG 5 Informatics of TCM, chaired by WANG Kui and KANG Sungkeel (CHOI Seunghon is replaced by KANG Sungkeel)
- In addition, a Joint Working Group is being established ISO TC 215 for handling items of common interest in informatics.

## • The first meeting of ISO/TC 249/WG3



The first meeting of WG3 was held on Oct. 20-21 in Beijing, China. There were 22 delegates from 5 countries (Australia, China, Japan, Korea, South Africa), WFAS and Ms. Ivy LEE from TC 249 secretariat participated in this meeting.

The meeting was chaired by Prof. HUANG Longxiang, the convener of WG3. The main discussed issues were:

Generic terms-of-reference for WG

- Scope of WG3
- Work plan of WG3
- Project NP 17218 Acupuncture Needles
- Future activities of WG3

The scope and work plan are resolved as:

- 1. Scope: all kinds of invasive and potentially invasive single use needles that are commonly used in the acupuncture field.
- 2. Work plan:

The top three priorities for WG3 are:

- Single use filiform needle
- Single use intradermal needle
- Single use dermal needle

The following items are low priority:

- Single use thread embedding therapy needle
- Single use three-edged needle
- Single use needle-shaped knife
- Single use fire needle
- Single use floating needle

(Please find more detailed information in N3 Resolutions of the first meeting of working group 3 displayed in WG3 working area.)

## • The first meeting of ISO/TC 249/WG4



The first meeting of WG4 was held on Sep. 19-20 in Daejeon, Republic of Korea. There were 20 delegates from 5 countries (Australia, Canada, China, Japan, and Korea) and Dr. SANG Zhen and Ms. Shirley XU from TC 249 secretariat participated in this meeting.

The meeting was chaired by Prof. KIM Yong-Suk and Prof. CHOI Sun Mi, the conveners of WG4. The main discussed issues were:

- Generic terms-of-reference for WG
- Scope of WG4
- Work plan of WG4
- WG4 meeting schedule

The scope and work plan are resolved as:

- 1. Scope: WG4 resolves that the scope of the working group include both therapeutic and diagnostic devices.
- 2. Work plan( priorities):
  - Moxibustion
  - Electro acupuncture stimulator
  - Herbal decoction apparatus (tentative)
  - Cupping
  - Other therapeutic equipment

#### - Other Diagnostic equipment

WG4 thinks the herbal decoction apparatus is ambiguous as a medical device and it seems to be more closely related with WG2 Quality and safety of manufactured TCM products, so it resolves that the decision to include herbal decoction apparatus within the scope be delayed until confirmation from the TC secretariat following consultation with WG2. The secretariat has emailed to the convener of WG2 for coordination this issue and we are waiting for their response.

Nowadays WG4 is seeking for expressions of interest from all WG4 members to lead the priority projects on moxibustion and electro acupuncture stimulator.

(Please find more detailed information in N2 Resolutions of the first meeting of working group 4 displayed in WG4 working area.)

## • The Fifth ISO Chairs' Conference 2011, 16-17 June 2011 Geneva



Dr. David GRAHAM, Prof. SHEN Yuandong and Dr. SANG Zhen attended the fifth ISO Chairs' conference held in Geneva on 16-17 June. The conference is hosted by the ISO executive and attended by chairs and secretaries of ISO TCs. This interactive conference addressed how to make ISO simpler, faster and better and was an excellent opportunity to exchange information with other TCs and to get up to date with ISO developments and directions.

## THE LATEST PROGRESS

#### • Business Plan (BP)

After several rounds of requesting input, the draft Business Plan has incorporated with NMBs' information and comments and finally sent to TMB for internal review in this

August. After one month review, TMB suggested the secretariat to further revise the draft with respect to TMB members' comments: DIN (Germany), JISC (Japan) and KATS (Korea) commented that this version has not been formally agreed by the committee due to the insufficient discussion in the 2<sup>nd</sup> plenary meeting.

In this case, the secretariat will continue the modification on BP and set it as one of agenda items in the 3rd plenary meeting.

#### • Joint Working Group (JWG) on Informatics with ISO 215

The JWG agreement has been drafted and submitted to the secretariats of TC 215 and TC 249, TPMs and TMB for consultation. It was discussed within TC 215/WG3 TM-TF in TC 215 Chicago Joint working group meeting this Oct. 17-21. The experts of TM-TF agreed on basic principles of JWG draft agreement. The draft agreement is under modification in accordance with the comments from TMB.

## RECENT MEETING SCHEDULE

The 2nd CAG teleconference Dec. 13, 2011

The first meeting of WG1 Dec. 1213, 2011 Beijing

The first meeting of WG5 Dec. 2011

The third plenary meeting May 21-23, 2012, Daejeon

# Third Plenary meeting of ISO TC 249

The cutoff dates for submitting papers for preparation of the 3rd plenary meeting in Daejeon on May 21-23, 2012 are:

- 21 January for major documents including NWIPs to be discussed during the meeting
- 9 April for other papers
- 14 May for the final agenda and minor papers

## LATEST INFORMATION OF TCM IN THE WORLD

#### Australia

#### 1. Chinese Medicine National Registration & Accreditation Scheme 2012

The Australian Health Ministers Advisory Council announced on the 18th July 2011 the appointment of the national Chinese Medicine Board for the registration of practitioners and accreditation of courses in Chinese Medicine in Australia is to begin on 1st July 2012.

### 2. Proposed Registration Standards for practitioners in Australia

The Chinese Medicine Board of Australia recently released a consultation paper on proposed FIVE MANDATORY registration standards for:

- 1. Continuing professional development
- 2. Criminal history
- 3. English language skills
- 4. Professional indemnity insurance (PII)
- 5. Recency of practice

News from all members would be appreciated so that it can be shared through this newsletter.

# CONTACTS

ISO/TC 249 Secretariat

Address: 3-IKL, 780 Cailun Road, Pudong New Area, Shanghai 201203,

P.R.China

Email: mscsh2009@gmail.com Tel: 0086-(0)21-51320018 Fax: 0086-(0)21-51320138

