

	<i>N0204 The liaison report by WFCMS to ISO TC249</i>
11:00-11:10	Discussion on the inclusion of Ayurveda <i>N0197 Agenda paper on relevance of Ayurveda to the work of ISO/TC 249</i>
11:10-11:15	The establishment of Work Coordination Group <i>N0198 Agenda paper on the establishment of work coordination group</i>
11:15-11:25	Report by ISO/TC249 TF "Guidelines for Manufacturing Safe and Regular Herb Preparations in Individual Clinics"
11:25-12:00	Discussion on the work priorities of ISO/TC249 <i>N0169 The suggestions for Adjustment of the ISO/TC249's Priority Areas</i> <i>N0199 Agenda paper on technical work priorities</i>
12:00-13:30	Lunch
14:00-16:00	Training session by ISO/CS TPM
18:30-20:30	Welcome banquet

26 May afternoon, 2014

WG5 & JWG1 meeting	
13:30-13:35	Opening of the meeting
13:35-13:45	Roll call of participants
13:45-13:55	Adoption of the agenda
13:55-14:05	Appointment of resolution drafting committee
14:05-14:15	Group photo
14:15-14:25	Review the scope and work plan of WG5
14:25-14:40	Development introduction of JWG1 projects
14:40-15:40	Discussion on projects: 1. ISO/WD 18662-1 TCM - Vocabulary-Part 1: CMM 30' 2. ISO/AWI 19465 TCM-Categories of TCM Clinical Terminological System 30' --N45 consultation result on ISO/AWI 19465 - Categories of TCM CTS
15:40-16:00	Coffee Break
16:00-17:30	3. Discussion on projects of Coding System of CMs: --N35 comments and observation on Coding System of Chinese Medicines Part 2 Codes of Decoction Pieces --N36 comments and observation on Coding System of CMs Part 3 Coding Rules for CMs in Supply Chain Management --N37 comments and observation on Coding System of CMs Part 4 Coding Rules for Formulas and Their Codes --N38 The suggestion on adjustments to the title and framework of Coding System of Chinese Medicines --N40 Drafts of Coding System of Chinese Medicines V.1 --N41 Drafts of Coding System of Chinese Medicines V.2 Note: The sequence of presentations will be in accordance to the result of discussion on the framework adjustments.
17:30-17:35	Closure of the meeting

27 May, 2014

WG1 meeting		WG3 meeting		WG5 &JWG1 meeting	
9:00-9:05	Opening of the meeting	9:00	Opening of the 5th meeting of WG3	08:30-9:00	Review and adoption of the resolutions on the first day meeting (Document to be prepared by the resolution drafting committee)
9:05-9:10	Roll call of participants	9:00-9:10	Roll call of delegates	9:00-10:00	Discussion on projects: 4. N43 ISO/NP TS 16843-2 Health Informatics — Categorical structures for representation of acupuncture Needling 30’ 5. N44 ISO/DTS 18790-1 Working draft profiling framework and classification for traditional medicine informatics standards development Part 1 Traditional Chinese Medicine 30’
9:10-9:15	Adoption of the draft agenda -N0043: WG1 5th meeting draft agenda	9:10-9:15	Adoption of agenda	10:00-10:20	Coffee Break (Preparation of the draft resolution by the resolution drafting committee)
9:15-9:20	Appointment of the resolution draft committee	9:15-9:25	Appointment of the Resolution Drafting Committee	10:20-10:35	Discussion on other business and future plan
9:20-9:40	Report by ISO/TC249/WG1 Prof. Liang Liu -1. Work progress after the 4th meeting at Durban, South Africa -2. Strategic report including work plan, new proposals and recommendations	9:25-9:40	Report by Prof. Zhao Baixiao	10:35-11:05	Review and adoption of the resolutions
9:40-10:10	Presentation and discussion on NWIP: N152 Seed and seedling quality of panax notoginseng - N0044: Application form - N0045: Annex A-Outline of Seed and seedling quality of panax notoginseng	9:40-10:00	Group Photo	11:05-12:05	Training Session led by ISO/CS TPM
10:10-10:30	Group Photo & Tea Break	10:00-10:15	Tea Break	12:05-12:10	Closure of the meeting

Draft agenda for TC249 5th plenary meeting+WG meetings

10:30-11:00	<p>Presentation and discussion on NWIP: N153 Dao-di herbs --Cistanches Herba from Alxa league - N0046: Application form - N0047: Annex A-Outline of Dao-di herbs -- Cistanches Herba from Alxa league</p>	10:15-10:45	<p>Presentation and discussion on N150: Test method on acupuncture needles for single use on electrical stimulation (replace N60) by KATS</p>		
11:00-11:30	<p>Presentation and discussion on NWIP: N155 Geo-authentic Traditional Chinese Medicine--Artemisiae Argyi Folium in Qizhou - N0048: Application form - N0049: Annex A-Outline of Geo-authentic Traditional Chinese Medicine--Artemisiae Argyi Folium in Qizhou</p>	10:45-11:15	<p>Presentation and discussion on N162: Guidelines on acupuncture safety practice in dangerous areas(replace N66) by SAC</p>		
11:30-12:00	<p>Presentation and discussion on NWIP: N157 Quality of Radix Notoginseng - N0050: Application form - N0051: Annex A-Outline of Quality of Radix Notoginseng</p>	11:15-11:45	<p>Presentation and discussion on N149: Guidelines on safety control for acupuncture treatment by KATS</p>		
12:00-13:30	Lunch	11:45-13:30	Lunch		
13:30-14:00	<p>Presentation and discussion on NWIP: N158 Seed and seedlings of Salvia miltiorrhiza Bunge - N0052: Application form - N0053: Annex An Outline of Seed and seedlings of Salvia miltiorrhiza Bunge</p>	13:30-14:00	<p>Presentation and discussion on N148: Knife needles by KATS</p>		
14:00-14:30	<p>Presentation and discussion on NP: NP19824Traditional Chinese</p>	14:00-15:00	<p>Presentation and discussion on the future activity of WG3</p>		

	Medicine-Schisandra Chinensis seeds and seedlings - N0054: Application form - N0055: Annex An Outline of Traditional Chinese Medicine-Schisandra Chinensis seeds and seedlings		1.Standard and clinical practice by Prof. Chris Zaslowski 2. Future plan by Prof. Zhao Baixiao		
14:30-15:00	Presentation and discussion on NWIP: N165 Geo-herbs (replace N65) - N0056: Application form - N0060: Annex A-Outline of Geo-herbs - N0061: Annex B Outline of Geo-herbs Mao-cangzhu:Atractylodes lancea (Thunb) DC in Maorshan Mountain	15:00-15:15	Tea Break		
15:00-15:30	Presentation and discussion on the progress on standards of quality of seeds and seedlings of Panax quinquefolius	15:15-16:15	Preparation of resolutions		
15:30-16:00	Discussion on the future activities and next meeting of WG1	16:15-16:25	Adoption of resolutions		
16:00-17:00	Tea Break	16:25	Closure of the 5th meeting of WG3		
16:00-17:00	Preparation of resolutions				
17:00-17:50	Approval of resolutions				
17:50-18:00	Closure of the meeting				

28 May, 2014

WG2 meeting		WG4 meeting	
1	Opening of the meeting	09:00-09:05	Opening of the Meeting
2	Roll call of experts	09:05-09:15	Roll call of delegates
3	Adoption of the agenda	09:15-09:20	Adoption of the agenda
4	WG Secretary Report	09:20-09:30	Appointment of the recommendation draft committee
5	Development of standards and new proposals	09:30-09:40	Briefing on WG4 activities
5.1	ISO/AWI 19609 Quality and Safety of natural materials and manufacturing products made with natural materials used in and as traditional Chinese medicine (TCM) – Report and discussion on the current status of the work	09:40-09:55	Review and discussion of roadmap of ISO/TC249/WG4 -including Harmonization with IECISO
5.2	ISO/AWI 19617 General requirements for manufacturing process of natural products used in and as Traditional Chinese Medicine – Report and discussion on the current status of the work	09:55-10:10	Coffee Break
5.3	ISO/AWI 19610 Traditional Chinese medicine – Requirements for industrial manufacturing process of red ginseng – Report and discussion on the current status of the work –	10:10-10:40	Report for WD of AWI Projects (presentation 15min/
5.4	New Proposal on General requirements for labelling of finished natural products	10:40-11:10	discussison 15min)
6	New Proposal on Analytical method of single herb products for herbal decoction/preparation	11:10-11:40	Discussion of PWI
7	Organisation /Allocation of work	12:00-13:30	Lunch
8	Any other business	13:30-14:00	Introduction and
9	Dates and places of the next meeting/s of ISO/TC 249/WG 2	14:00-14:30	discussion of NPs (presentation 15min/
10	Closure of the meeting	14:30-15:00	discussion 15min)
		15:00-15:30	

Draft agenda for TC249 5th plenary meeting+WG meetings

		15:30-16:00		Coffee Break
		16:00-16:30		N163 Infrared moxibustion instruments (replace N67)
		16:30-17:00		N164 Meridians balanced treatment instrument (replace N71)
		17:00-17:30		N168 General Requirements of Abdominal Palpation Diagnosis Devices
		17:30-17:40	Discussion on future plan	
		17:40-18:00	Review and adoption of Recommendations	
		18:00	Closure of the meeting	

29 May, 2014 Plenary meeting

9:00-9:15	Review of Resolutions from Day 1
9:15-12:30	WG 1, 2, 3, 4 convenors' report: - 1. Work progress during the past year - 2. outcomes from WG meeting including recommendations - 3. future work plan <i>N0201 Notes for convenors of working groups</i>
12:30-14:00	Lunch
14:00-15:30	WG 5, JWG1 convenors' report: - 1. Work progress during the past year - 2. outcomes from WG meeting including recommendations - 3. future work plan <i>N0201 Notes for convenors of working groups</i>
15:30-16:30	Tea Break (allows time for drafting resolutions)
16:30-17:30	Review of Resolutions from Day 2, Day 3 and Day 4
17:30-17:40	Details concerning the next meeting and possible venues
17:40	Closure of the meeting
18:30-20:30	Farewell banquet

Notice :

1. As part of ISO's ongoing continuous improvement process, the ISO Technical Management Board (TMB) has created a survey to gather feedback from attendees of all TC meetings. Please take the opportunity after the 5th plenary meeting to provide feedback and suggestions to assist future meetings and the work of TC 249. Anonymous feedback is provided to the Secretary and chair. ISO-CS will close the survey two weeks after the meeting. The link is: https://www.surveymonkey.com/s/template_generic (N0211)
2. Please kindly update your agenda for the 5th plenary meeting of ISO/TC249. To make the meeting effective, you are expected to bring all the relevant documents either as printed material or via laptop to the venue since the hard copies will NOT be provided before the meeting. The secretariat will post a detailed meeting document list in advance both onto the TC website and through the participants' email address if available.



ISO/TC249 N 215

2014-05-29

Resolutions of the 5th plenary meeting of ISO/TC249 held in Kyoto, Japan on May 26-29th, 2014

Resolution 83 (Kyoto 2014: 1): Adoption of agenda

ISO/TC249 resolves that the agenda be adopted.

Resolution 84 (Kyoto 2014: 2) : Appointment of Resolution Drafting Committee

ISO/TC249 resolves that the Resolution Drafting Committee consist of:

- Suzanne COCHRANE (Australia): Chair
- ZHAO Bai Xiao (China)
- Klaus HAMBRECHT (Germany)
- Satyabrata MAITI (India)
- Michiho ITO (Japan)
- LEE Soojin (Republic of Korea)
- Marilyn ALLEN (USA)
- Mary Lou PELAPRAT (ISO/CS)
- SANG Zhen (ISO/TC249 Secretariat)

Resolution 85 (Kyoto 2014: 3): Annual review of the Strategic Business Plan

ISO/TC 249 resolves that the Secretariat will update the draft Strategic Business Plan and this will be circulated to all members for comments in the near future.

Resolution 86 (Kyoto 2014: 4): Discussion on the inclusion of Ayurveda

ISO/TC 249 resolves to undertake a formal CIB Ballot to resolve the issue of the inclusion of Ayurveda within ISO/TC 249.

Resolution 87 (Kyoto 2014: 5):

ISO/TC 249 resolves that at the next plenary of TC249 that an agenda item be prepared for further discussion of which traditional medicines originating from ancient Chinese

medicine are within the scope of TC249.

Resolution 88 (Kyoto 2014:6): Establishment of Work Coordination Group

ISO/TC 249 resolves to form a Work Coordination Group (CAG2) as outlined in the meeting documents.

Resolution 89 (Kyoto 2014:7): Establishment of Work Coordination Group

ISO/TC 249 resolves to accept the draft guidelines of the Work Coordination Group (CAG2) as circulated with the inclusion of the secretaries of the working groups.

Resolution 90 (Kyoto 2014:8):

ISO/TC 249 resolves that ISO/TC 249 not extend its scope into educational services and standards at this time.

Resolution 91 (Kyoto 2014:9): Extension of working scope

ISO/TC 249 resolves to extend the TC249 scope to include service standards limited to involving the safe use and delivery of devices & medicines but not into the clinical practice or application of those products.

WORKING GROUP 1 :QUALITY AND SAFETY OF RAW MATERIALS AND TRADITIONAL PROCESSING

Resolution 92 (Kyoto 2014:10) [WG1-R1:N152 Panax notoginseng seeds and seedlings]

ISO/TC 249 resolves to accept the recommendation of WG1 that N152 *Seed and seedling quality of Panax notoginseng* [PL:CUI Xiuming] be revised and then proceed to balloting. The suggested revisions are:

- Collecting more data on correlation between seeds and quality of product;
- Clarifying the meaning of “solving the problem of miscellaneous cultivars” in the justification in Form 4;
- Changing title to “*Panax notoginseng seeds and seedlings*”.

Resolution 93 (Kyoto 2014:11)[WG1-R2: N165 Geo-herbs]

ISO/TC 249 resolves to accept the recommendation of WG1 that N165 *Geo-herbs* [PL: HUANG Luqi, GUO Lanping, GAO Wenyuan] does not proceed because Section 6.6.3 Part 2 of the ISO Directive does not allow for service name (geographical indicators).

Resolution 94 (Kyoto 2014:12)[WG1-R3: N153 Dao-di herbs - Cistanches Herba from Alxa league]

ISO/TC 249 resolves to accept the recommendation of WG1 that N153 *Dao-di herbs - Cistanches Herba from Alxa league* [PL: LI Minhui] remain within WG1 as a PWI for further development taking Section 6.6.3 Part 2 of the ISO Directives into consideration.

Resolution 95 (Kyoto 2014:13)[WG1-R4: N155 Traditional Chinese Medicine-- Artemisiae Argyi Folium in Qizhou]

ISO/TC 249 resolves to accept the recommendation of WG1 that N155 *Geo-authentic Traditional Chinese Medicine--Artemisiae Argyi Folium in Qizhou* [PL: WAN Dingrong] be revised and then proceed to balloting. The suggested revisions are:

- Changing title; removing reference to “Geo-authentic” and consulting with WG4 regarding project for moxa-related devices.
- Ensuring compatibility with Section 6.6.3 Part 2 of the ISO Directives.

Resolution 96 (Kyoto 2014:14)[WG1-R5: N157 Radix Notoginseng]

ISO/TC 249 resolves to accept the recommendation of WG1 that N157 *Quality of Radix Notoginseng* [PL:CUI Xiuming] be revised and then proceed to balloting. The suggested revisions are:

- Removing the term of “Quality” in the title;
- Explaining the quality data related to the sources.

Resolution 97 (Kyoto 2014:15)[WG1-R6: N158 Salvia miltiorrhiza seeds and seedlings]

ISO/TC 249 resolves to accept the recommendation of WG1 that N158 *Seed and seedlings of Salvia miltiorrhiza Bunge* [PL: SONG Yan] be revised and then proceed to balloting. The suggested revisions are: changing title to “*Salvia miltiorrhiza seeds and seedlings*” and some minor revisions on the native geographical areas.

Resolution 98 (Kyoto 2014:16)[WG1-R7: PWI 17217-2 Traditional Chinese Medicine – Ginseng seeds and seedlings-Part 2: Panax quinquefolius ginseng]

ISO/TC 249 resolves to accept the recommendation of WG1 that PWI 17217-2 *Traditional Chinese Medicine – Ginseng seeds and seedlings-Part 2: Panax quinquefolius ginseng* [PL: Edmund LUI] remains within WG1 as a PWI for further development. WG1 suggests the PL to prepare Form 4 for the next meeting.

Resolution 99 (Kyoto 2014:17):

ISO/TC 249 resolves that the work plan of WG1 is achievable and appropriate.

WORKING GROUP 2: QUALITY AND SAFETY OF MANUFACTURED TCM PRODUCTS

Resolution 100 (Kyoto 2014:18)[WG2-R28: AWI 19609 Quality and safety of natural materials and manufacturing products made with natural materials used in and as traditional Chinese medicine (TCM)]

ISO/TC 249 resolves to accept the recommendation of WG2 that the AWI 19609 *Quality and safety of natural materials and manufacturing products made with natural materials used in and as traditional Chinese medicine (TCM)* [PL: Hans Rausch] check if a Management System Standard like ISO 22000 is necessary for this project.

Resolution 101 (Kyoto 2014:19)[WG2-R29: N167 General requirements for labelling of finished manufacturing products used in and as Traditional Chinese Medicine]

ISO/TC 249 resolves to accept the recommendation of WG2 that N167 *General requirements for labelling of finished manufacturing products used in and as Traditional*

Chinese Medicine (provisional) [PL: Ichiro ARAI]

- Deleting the word 'provisional' after approval;
- Forming close cooperation with WG5 regarding the coding system;
- Taking European, American, Australian and other countries labelling requirements into consideration;
- Accepting the recommendation that the project remains within WG2 as a PWI for further development.

Resolution 102 (Kyoto 2014:20)[WG2-R30: N 57 Analytical method of single herb products for herbal decoction/preparation]

ISO/TC 249

- Notes that the title of N 57 *Analytical method of single herb products for herbal decoction/preparation* [PL: CHOI Hyugyong] was changed before the meeting to "Standard of Single Herb Extract for Herbal Decoction/ preparation-LICORICE EXTRACT"];
- Resolves to accept the recommendation this PWI does not proceed because it has not an appropriate priority.

Resolution 103 (Kyoto 2014:21)[WG2-R31: N 170 Labelling for packaged medicinal herbs]

ISO/TC 249 resolves to accept the recommendation of WG2 that N 170 *Labelling for packaged medicinal herbs* [PL: CHOI Goya]

- Forming close cooperation with WG 5 regarding the coding system
- Taking European, American, Australian and other countries labelling requirements into consideration
- The project remains within WG 2 as a PWI for further development.

Resolution 104 (Kyoto 2014:22):

ISO/TC 249 resolves that the work plan of WG2 is achievable and appropriate.

Resolution 105 (Kyoto 2014:23):

ISO/TC 249 resolves to direct the Work Coordination Group to explore management system standards with ISO/CS, MSS/SG secretary and CASCO.

WORKING GROUP 3: QUALITY AND SAFETY OF ACUPUNCTURE NEEDLES

Resolution 106 (Kyoto 2014:24)[WG3-R1: Scope of WG3]

ISO/TC 249 resolves to accept the recommendation of WG3 that the scope of the WG3 be amended to the 'Standardization in the field of quality of acupuncture needles and safe practice' but not include the clinical treatment or efficacy.

Resolution 107 (Kyoto 2014:25)[WG3-R2: N150 Test Method on Acupuncture needles for single use on electrical stimulation]

ISO/TC 249 resolves to accept the recommendation of WG3 that N150 *Test Method on Acupuncture needles for single use on electrical stimulation* [PL: LEE Sanghun, Ryoichi

NAKANO] proceed to NP balloting.

Resolution 108 (Kyoto 2014:26)[WG3-R3: N162 Guidelines on acupuncture safety practice in dangerous acupoints]

ISO/TC 249 resolves to refer N162 *Guidelines on acupuncture safety practice in dangerous acupoints* [PL: GUO Yi] back to WG3 for further clarification due to the concerns expressed by plenary.

Resolution 109 (Kyoto 2014:27)[WG3-R4: N149 Infection control for acupuncture treatment]

ISO/TC 249 resolves to accept the recommendation of WG3 that N149 *Guidelines on safety control for acupuncture treatment* [PL: NAM Dongwoo] be amended and renamed as “Standard for infection control for acupuncture treatment” and proceed to balloting to include decision on whether this is more appropriate as an International Standard or Technical Report.

Resolution 110 (Kyoto 2014:28)[WG3-R5: Joint project leader of N 162 and N 149]

ISO/TC 249 resolves to accept the recommendation of WG3 that JISC will be a joint project leader (subject to agreement by KATS and SAC) for the amended projects N162 *Guidelines on acupuncture safety practice in dangerous acupoints* and N149 *Guidelines on safety control for acupuncture treatment*.

Resolution 111 (Kyoto 2014:29)[WG3-R6: N148 Knife Needle]

ISO/TC 249 resolves to accept the recommendation of WG3 that N148 *Knife Needle* [PL: LEE Jeong-beom] remain within WG 3 as a PWI for further development.

Resolution 112 (Kyoto 2014:30)[WG3-R7: ISO/AWI 18746 Sterile intradermal acupuncture needle for single use]

ISO/TC 249 resolves to accept the recommendation of WG3 that ISO/AWI 18746 *Sterile intradermal acupuncture needle for single use* [PL: RYU Yeonhee, Ryoichi NAKANO] be amended by incorporating the merged three related parts (general, granule and thumbtack intradermal needle) and be circulated to all experts within one month prior to submission to ISO/TC 249 as a final WD.

*[Plenary discussed removing ‘acupuncture’ from the project title]

Resolution 113 (Kyoto 2014:31)[WG3-R8: Road map of WG3]

ISO/TC 249 resolves to accept the recommendation of WG3 that a road map incorporating future project priorities be developed for discussion at the next WG3 meeting.

Resolution 114 (Kyoto 2014:32):

ISO/TC 249 resolves that the work plan of WG3 is achievable and appropriate.

WORKING GROUP 4: QUALITY AND SAFETY OF MEDICAL DEVICES OTHER THAN

ACUPUNCTURE NEEDLES**Resolution 115 (Kyoto 2014:33)[WG4-R1: Liaison arrangements of WG4]**

ISO/TC 249 resolves to accept the recommendation of WG4 that a liaison relationship be established with IEC/TC 62 and ISO/TC 210, agreeing that this may include the other Committees requesting a joint working group arrangement.

Resolution 116 (Kyoto 2014:34)[WG4-R2: ISO/PWI 18585 Computerised tongue image analysis system- Part 1: General requirements]

ISO/TC 249 resolves to accept the recommendation of WG4 that ISO/PWI 18585 *Computerized tongue diagnosis system* change the title to *Computerised tongue image analysis system- Part 1: General requirements* [PL: KIM Keun Ho] and proceed to NP ballot.

Resolution 117 (Kyoto 2014:35)[WG4-R3: N 156 Computerised tongue image analysis system-Part 2: Light environment]

ISO/TC 249 resolves to accept the recommendation of WG4 that N 156 *Light environment in tongue image analysis instrument* change the title to *Computerised tongue image analysis system-Part 2: Light environment* [PL: ZHOU Huilin] and proceed to NP ballot.

Resolution 118 (Kyoto 2014:36)[WG4-R4: N 154 Gua Sha instruments]

ISO/TC 249 resolves to accept the recommendation of WG4 that N 154 *Scraping devices* be renamed to *Gua Sha instruments* [PL: WANG Yingying] and proceed to NP ballot.

Resolution 119 (Kyoto 2014:37)[WG4-R5: N 159 Facial imaging device – face information acquisition instrument]

ISO/TC 249 resolves to accept the recommendation of WG4 that N 159 *Facial diagnosis device-Part 1: face information acquisition instrument* be renamed *Facial imaging device –face information acquisition instrument* [PL: LI Fufeng] and proceed to NP ballot.

Resolution 120 (Kyoto 2014:38)[WG4-R6: N 160 Electrical resistance detector at Acupuncture Points]

ISO/TC 249 resolves to accept the recommendation of WG4 that N 160 *Meridian detector* be renamed to *Electrical resistance detector at Acupuncture Points* [PL: ZHOU Huilin] and proceed to NP ballot.

Resolution 121(Kyoto 2014:39)[WG4-R7: N 163 Infrared moxibustion-like instrument]

ISO/TC 249 resolves to accept the recommendation of WG4 that N 163 *Infrared moxibustion instrument* be renamed to *Infrared moxibustion-like instrument* [PL: YANG Huayuan] and proceed to NP ballot.

Resolution 122(Kyoto 2014:40)[WG4-R8: N 164 Meridians balanced treatment instrument]

ISO/TC 249 resolves to accept the recommendation of WG4 that N 164 *Meridians balanced treatment instrument* [PL: YANG Huayuan] remain within WG 4 as a PWI for further development.

Resolution 123(Kyoto 2014:41)[WG4-R9: N 168 Abdominal physiological parameter detector]

ISO/TC 249 resolves to accept the recommendation of WG4 that N 168 *General requirements of abdominal palpation diagnosis devices* be renamed to *Abdominal physiological parameter detector* [PL: Hiroshi Odaguchiand, Xiaoyu MI] proceed to NP ballot.

Resolution 124(Kyoto 2014:42)[WG4-R10: Joint project leader of ISO/AWI 19614]

ISO/TC 249 resolves to accept the recommendation of WG4 that JISC will be a joint project leader (following approval by SAC) for the project ISO/AWI 19614 *Pulse graph force transducer*.

Resolution 125(Kyoto 2014:43):

ISO/TC 249 resolves that the work plan of WG4 is achievable and appropriate.

WORKING GROUP 5: TERMINOLOGY AND INFORMATICS

Resolution 126 (Kyoto 2014:44)[WG5-R1: Scope of WG5]

ISO/TC 249 resolves to accept the recommendation of WG5 & JWG1

- Revising the statement of scope adopted in 4th plenary to: “The scope of WG5 shall be the standardisation of TCM nomenclatures, terminology, classification and ontology. Health informatics technology as it relates to TCM shall be addressed within the scope of JWG1.”
- According to resolution 77 of 4th Plenary note that ‘TCM’ in this WG refers to traditional and modern aspects of medical systems derived from ancient Chinese medicine.

Resolution 127 (Kyoto 2014:45)[WG5-R2: ISO/WD 18662-1 TCM - Vocabulary-Part 1: Chinese Materia Medica]

ISO/TC 249 resolves to accept the recommendation of WG5 that ISO/WD 18662-1 *TCM - Vocabulary-Part 1: Chinese Materia Medica* [PL: WANG Kui] proceeds to CD ballot following incorporation of the following (in addition the WG5 resolution 6 confirmed at 4th plenary):

- The project leader be asked to implement resolution 6 in relation to the order of names, that is, Latin name as defining term;
- Botanical/pharmaceutical name that will allow precise identification of product used [subspecies if appropriate];
- Han character include both simplified and traditional characters;
- Japanese & Korean names might be included in an original vocabulary rather than incorporated in this Chinese materia medica irrespective of WG5 resolution 6 of 4th plenary part (iv).

Resolution 128 (Kyoto 2014:46)[WG5-R3: ISO/AWI 19465 TCM – Categories of TCM Clinical Terminological System]

ISO/TC 249 resolves to accept the recommendation of WG5 that ISO/AWI 19465 *TCM – Categories of TCM Clinical Terminological System* [PL: CUI Meng] continues to be refined incorporating comments including a clear description of the aspects that are out-of-scope within 1 month before being progressed to CD balloting.

Resolution 129 (Kyoto 2014:47)[WG5-R4: Coding System]

ISO/TC 249 resolves to accept the recommendation of WG5 that in relation to coding systems [PL: LIAO Liping]:

- (1) Varying WG5 resolution 9 from 4th plenary to retain separation of Part 1 & Part 2
- (2) Implementing WG5 resolution 11 in relation to Coding System of Formulas from 4th plenary in the coding system; and project leader implement resolution 11 with the cooperation of Korean & Japanese colleagues before 1 October 2014.
- (3) ISO/TC 249 to adopt new framework for WG5/N0038:
 - ISO/CD 18668-1 *Coding System of Chinese Medicines - Part 1: Coding Rules for Chinese Medicines*
 - ISO/AWI 18668-2 *Coding System of Chinese Medicines - Part 2: Codes of Decoction Pieces*
 - ISO/AWI 18668-4 *Coding System of Formulas* [this name has been changed from *Coding Rules for Formulas & their Codes*]
 - ISO AWI 18668-3 *Coding Rules for Chinese Medicines in Supply Chain Management*
- (4) That the following be included as NWIPs and proceed to NP voting
 - a. N151 *Coding System of Chinese Medicines - Part 3: Codes of Chinese Materia Medica*
 - b. N214 *Coding System of Chinese Medicines - Part 4: Codes of Granule Forms of Individual Medicinals for Prescriptions*

Approved subject to the inclusion of clarifying information and reformatting by the Secretariat and WG5 Secretary.

Resolution 130 (Kyoto 2014:48) :

ISO/TC 249 resolves that the work plan of WG5 is achievable and appropriate.

JOINT WORKING GROUP 1: INFORMATICS

Resolution 131 (Kyoto 2014:49) [JWG1-R1: ISO/AWI/DTS 18790-1 Health informatics -- Profiling Framework and Classification for Traditional Medicine informatics standards development -- Part 1: Traditional Chinese Medicine]

ISO/TC 249 resolves to acknowledge and accept TC 215 resolution 35 [JWG1-R01] ISO/AWI/DTS 18790-1 for DTS ballot no later than 12 June 2014. It is noted that TC 215 has the lead for the joint project and TC 249 accepts to launch a parallel ad-hoc 2-month DTS ballot on ISO/AWI/DTS 18790-1 *Health informatics -- Profiling Framework and Classification for Traditional Medicine informatics standards development -- Part 1:*

Traditional Chinese Medicine.

As a consequence TC 249 instructs its secretariat to request the text of the ISO/DTS 18790-1 from TC 215 no later than 9 June 2014. Accept in principle with further editorial clarification of resolution needed.

[*TC 215 resolution 35 [JWG1-R01] ISO/AWI/DTS 18790-1 for DTS ballot
For ISO/AWI/DTS 18790-1, *Health informatics--Profiling Framework and Classification for Traditional Medicine informatics standards development--part1: Traditional Chinese Medicine*, ISO/TC215 approves the recommendation of JWG 1 to issue a DTS ballot; instructs the project lead to provide the text of ISO/DTS 18790 to the TC215 Secretary no later than 9 June 2014; instructs the TC215 Secretary to launch a two month DTS ballot no later than 12 June 2014(to be available for the Berlin meeting Oct 5 -10, 2014) and request that TC249 launch a parallel ad-hoc 2-month DTS ballot.]

Resolution 132 (Kyoto 2014:50)[JWG1-R2: ISO/AWI TS 16843-1 Categorical structure for representation of acupuncture—Part 1: Acupuncture points and ISO/AWI TS 16843-2 Categorical structures for representation of acupuncture - Part 2: Needling]

ISO/TC 249 resolves to accept the recommendation of JWG1 that ISO/AWI TS 16843-1 *Categorical structure for representation of acupuncture—Part 1: Acupuncture points* and ISO/AWI TS 16843-2 *Categorical structures for representation of acupuncture -Part 2: Needling* will not be put into JWG1 since these two projects are reinstatement projects from TC215 and as these projects are well advanced, they remain in TC215. Noting that comments from TC249 are still very welcome.

Resolution 133 (Kyoto 2014: 51)

ISO/TC 249 resolves that the secretariat with Work Coordination Group (CAG2) will prepare a paper for the 6th plenary meeting proposing a Technical Report on levels of evidence.

Resolution 134 (Kyoto 2014: 52)

ISO/TC 249 resolves that the introduction of relevant standards will include a statement that "the standard is applicable to TM systems derived from ancient Chinese medicine".

Resolution 135 (Kyoto 2014: 53)

ISO/TC 249 resolves to express its deep appreciation to Japan for hosting the 5th plenary meeting in Kyoto.

Resolution 136 (Kyoto 2014:54)

China has offered to host the next plenary in a city to be decided in first week of June 2015.

Safety of acupuncture and moxibustion

Hitoshi Yamashita

1. Definition and classification of adverse events

In this article, the clinical safety of acupuncture/moxibustion (as with drugs, etc.) is discussed in terms of adverse events which is defined as “any undesirable medical event that occurs during or after treatment, regardless of whether there is a causal relationship^{1,2)}” just as in clinical trials of pharmaceutical products. That is, in this chapter, the term “adverse event” tentatively includes symptoms and diseases that may be caused by other treatments or natural events/conditions when there is no physical evidence to indicate that acupuncture/moxibustion treatment is the cause (e.g., a needle fragment). This definition should be used because a causal relationship between medical events and therapeutic intervention is often difficult to establish. If practitioners of acupuncture/moxibustion or patients receiving acupuncture/moxibustion do not receive feedback until a causal relationship is established by medico-legal autopsy, epidemiologic study, judicial procedure, etc., the patients may be disadvantaged for a long time.

A drug-related adverse event assumes the adverse reactions (or side effect) are caused by drug, whereas an acupuncture/moxibustion-related adverse events in this chapter include errors made by practitioners and other accidents as well as adverse reactions to acupuncture/moxibustion because the patients are physically stimulated by practitioners. Therefore, adverse events associated with acupuncture/moxibustion can be classified as follows:

- (1) Adverse effect (adverse reaction): An undesirable biological reaction that occurs unintentionally
- (2) Error: Event that occurs due to negligence, ignorance, intentional act, etc.

Additionally, (3) any inevitable accident (e.g., natural disaster) and (4) event that is not causally related to acupuncture/moxibustion treatment or behavior of the practitioner (e.g., symptom that occurs coincidentally) may also be included in the classification. The incidence of adverse effects of treatment that are basically unavoidable may be reduced by adjusting the degree of stimulation, etc. Errors (theoretically avoidable by improving training and preventive measures) will never be eliminated in reality.

2. Circumstances and incidence of adverse events

The databases of the Ichushi-Web (Japana Centra Revuo Medicina) and PubMed were searched, and

relevant articles were selected. We found published reports of a wide variety of acupuncture/moxibustion-related adverse events that occurred in Japan and were reported by physicians etc. in medical journals, as shown in **Tables 1** and **2**³⁻⁶). Again, it has not been confirmed that all of these events are attributable to acupuncture/moxibustion treatment; in particular, some infection events are unlikely to be causally connected to the treatment. Although scars of direct moxibustion have been reported to become cancerous, most of the cases of canceration caused by permeating heat moxibustion result from long-term self-administered moxibustion (over many decades) with multiple moxa cones that are much larger than those commonly used in modern moxibustion treatment. Therefore, handling such events as adverse events associated with common moxibustion treatments is inappropriate.

Figure 1 shows the adverse event claims handled by an insurer liable for damages due to acupuncture/moxibustion/massage⁷). The adverse events reported include pneumothorax, needle breakage, pyogenic infection, aggravation of symptoms, and nerve injury/paralysis, although a causal relationship is not necessarily proven in all cases.

There is no doubt that acupuncture and moxibustion pose a risk, as do more conventional treatment options such as medication and surgery. However, “safety evaluation based on literature reviews of case reports,” which are considered to be evidence of risk, may be problematic. First, many of the reports in medical journals describe serious adverse events such as bilateral pneumothorax and spinal cord injury, and not mild adverse events (which are frequently encountered by acupuncture/moxibustion practitioners in everyday practice). Conversely, reports on serious adverse events such as pneumothorax have been reported too many times in medical journals and therefore may be rejected due to a lack of originality. Second, adverse events are not planned in advance, therefore case reports are written after the adverse events have occurred and based on records and post-event recall of the details. As such, there is often a lack of information required to assess causality and problems (e.g., acupuncture point, size of a needle, depth of penetration). Third, the incidence (i.e., number of acupuncture/moxibustion sessions per event) is unknown because the total number of acupuncture/moxibustion sessions (denominator) is unknown.

Table 1. Domestic cases of acupuncture-related adverse events reported in medical journals (The number of cases is indicated in parenthesis.)

Classification	Late 1980s to 2002 ^{3, 4)}	2003 to 2006 ⁵⁾	2007 to 2009 ⁶⁾
Organ injury or foreign body	Organ injury Pneumothorax (26), arterial injury (3), cardiac tamponade (3, including 1 case complicated by hemothorax), renal injury (2), pseudoaneurysm of the aorta (1)	Organ injury Pneumothorax (6)	Organ injury Pneumothorax (5, including 2 bilateral cases), iliopsoas hematoma (1), popliteal pseudoaneurysm (1)
	Foreign body Urinary tract (3), retroperitoneum (2), right ventricle (1), lungs and diaphragm (1), liver (1), upper jaw (1), cervical interspinous ligament (1), hip joint (1), spine and surrounding tissue and paravertebral muscle (2), abdominal aortic aneurysm (1), nuchal region (1)	Foreign body Needle retained in the right ventricle (1)	Foreign body Spleen (1), neck (1), paravertebral muscle (1), right buttock (1), bladder stone (1)
Infection	Bacterial infection Abscess (11, including 2 cases overlapped with sepsis), sepsis (6), spinal cord infection (4, including 1 case overlapped with sepsis), erysipelas (3), fulminant group A streptococcal infection (2, including 1 death), pyohemothorax (2, including 1 death), skull tuberculosis (1), infected left atrial myxoma (1), localized redness (1)	Bacterial infection Abscess (3, including 1 case overlapped with sepsis), sepsis (1), arthritis (2: intervertebral and shoulder joints), meningitis (1), suppuration at the site of needle insertion (1)	Bacterial infection Abscess (3, including 1 case overlapped with paraplegia), purulent polyarthritis (1)
	Viral infection Acute hepatitis B (12)		
Neurological damage	CNS Spinal cord injury (21), subarachnoid hemorrhage (5), subdural hematoma (2), epidural hematoma (1),	CNS Needle retained in the medulla oblongata (1)	CNS Paraplegia (1, overlapped with abscess), dissociated sensory loss (1), traumatic subarachnoid