

Dear ISO/TC249 members and all experts,

It's now been over a year since we were gathering together in Bangkok, Thailand at the last plenary meeting in June 2019. At this time filled with uncertainties, I would like to extend my sincere wishes to you and your family.

I appreciate your excellent efforts to progressing ISO/TC249 standards work all the time. Over the past ten years, the committee has made an essential contribution to the health and wellbeing by developing a total of 62 international standards and 33 projects are now under development. From the last plenary meeting, 17 international standards being newly published and there are more key and recent developments I would like to share with you in this Secretariat report which also include a summary of WG virtual meetings and an introduction of a new platform: ISO Documents to replace the previous e-committee platform.

Very importantly, in the midst of the global pandemic, the secretariat team would like to assist you in any way we could, therefore please feel free to reach out to us at any time.

We wish you all the best.

Kind regards Sang Zhen ISO/TC249 Committee manager



ISO/TC249 N 2020-10-12

The Secretariat Report of ISO/TC249,

Traditional Chinese medicine

October 12, 2020

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1. ISO/TC249 Scope

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 & medicine, but not into the clinical practice or application of those products.

2. ISO/TC249 Structure

- ISO/TC 249/CAG 1 Chair's Advisory Group for governance
- ISO/TC 249/CAG 2 Chair's Advisory Group for working group management
- ISO/TC 249/WG 1 Quality and safety of raw materials and traditional processing
- ISO/TC 249/WG 2 Quality and safety of manufactured TCM products
- ISO/TC 249/WG 3 Quality of acupuncture needles and safe use of acupuncture
- ISO/TC 249/WG 4 Quality and safety of medical devices other than acupuncture needles
- ISO/TC 249/WG 5 Terminology and Informatics
- ISO/TC 249/JWG 1 Joint ISO/TC 249 ISO/TC 215 WG: Informatics

Note: ISO/TC 249/JWG 6 (Joint ISO/TC 249 - IEC/SC 62D WG: Electromedical equipment) was disbanded in June 2020.

3. ISO/TC249 Participating and Observing member

Participating Members (23)	Observing Members (22)
Australia (SA)	Argentina (IRAM)
Canada (SCC)	Austria (ASI)
China (SAC)	<u>Burundi (BBN)</u>
Czech Republic (UNMZ)	Finland (SFS)
Germany (DIN)	France (AFNOR)
Ghana (GSA)	Hong Kong (ITCHKSAR)
Hungary (MSZT)	India (BIS)
Italy (UNI)	Iran, Islamic Republic of (ISIRI)
Japan (JISC)	Ireland (NSAI)
<u>Kenya (KEBS)</u>	Israel (SII)
Korea, Republic of (KATS)	Lithuania (LST)
Mongolia (MASM)	Macao (CPTTM)
Netherlands (NEN)	Nepal (NBSM)
Norway (SN)	New Zealand (NZSO)
Portugal (IPQ)	Poland (PKN)
Russian Federation (GOST R)	Romania (ASRO)
Saudi Arabia (SASO)	Seychelles (SBS)
Singapore (ESG)	Sweden (SIS)
South Africa (SABS)	<u>Togo (ATN)</u>
Spain (UNE)	<u>Tunisia (INNORPI)</u>
Switzerland (SNV)	United Kingdom (BSI)
Thailand (TISI)	Zimbabwe (SAZ)
Viet Nam (STAMEQ)	

*Note: New member body registered and changed from June 2019-Sept 2020.

4. ISO/TC249 internal and external liaisons

a. Internal liaisons				
IEC/SC 62D	Electromedical equipment			
ISO/TC 215	Health informatics			
ISO/TC 304	Healthcare organization management			
ISO/TC 314	Ageing societies			
b. External liaison organizations				
WFAS	World Federation of Acupuncture and			
	Moxibustion Societies			
WFCMS	World Federation of Chinese Medicine Societies			
WHO World Health Organization				

5. ISO/TC249 WG Convenors and Secretaries

Working Group	Convenor(s)	Secretaries	National body		
1	LIU Liang	ZHOU Hua	SAC		
2	Sven SCHRÖDER	Matthias KRITZLER-PICHT	DIN		
3	ZHAO Hong	WANG Li	SAC		
4	CHOI Sun-mi	LEE Yujung	KATS		
5	KOH Byung-hee	LEE Juyeon; (KATS) Song Meng (SAC)	KATS		
JWG1	LI Haiyan	CUI Meng	SAC		
*Note: WG secretaries have recently been nominated.					

6. Work programme of ISO/TC249

a. Published standa	a. Published standards (62)				
Ref.	Title	Stage	Action to be expected		
ISO 17218:2014	Sterile acupuncture needles for single use	90.20	SR from 2019-1-15 and end on 2019-6-4		
ISO 17217-1:2014	Traditional Chinese medicine Ginseng seeds and seedlings Part 1: Panax ginseng C.A. Meyer	90.20	SR from 2019-4-15 and end on 2019-9-2		
ISO 18664:2015	Traditional Chinese Medicine Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine	90.20	SR from 2020-07-15 and will end on 2020-12-02		
ISO 18665:2015	Traditional Chinese medicine Herbal decoction apparatus	60.60	Next SR: 2020-10-15		
ISO 18666:2015	Traditional Chinese medicine General requirements of moxibustion devices	60.60	Next SR: 2020-10-15		
ISO 18668-1:2016	Traditional Chinese medicine Coding system for Chinese medicines Part 1: Coding rules for Chinese medicines	60.60	Next SR will be in 2021		
ISO 18746:2016	Traditional Chinese medicine Sterile intradermal acupuncture needles for single use	60.60	Next SR will be in 2021		
ISO 20408:2017	Traditional Chinese medicine Panax notoginseng seeds and seedlings	60.60	Next SR will be in 2022		
ISO 19465:2017	Traditional Chinese medicine Categories of traditional Chinese medicine (TCM) clinical terminological systems	60.60	Next SR will be in 2022		
ISO 18668-2:2017	Traditional Chinese medicine Coding system for Chinese medicines Part 2: Codes for decoction pieces	60.60	Next SR will be in 2022		
ISO 18668-3:2017	Traditional Chinese medicine Coding system for Chinese medicines Part 3: Codes for Chinese Materia Medica	60.60	Next SR will be in 2022		

ISO 18668-4:2017	Traditional Chinese medicine	60.60	Next SR will be in 2022
	Coding system for Chinese	00.00	
	medicines Part 4: Codes for		
	granule forms of individual		
	medicinals for prescriptions		
ISO 19824:2017	Traditional Chinese medicine	60.60	Next SR will be in 2022
	Schisandra chinensis (Turcz.) Baill.		
	seeds and seedlings		
ISO 20311:2017	Traditional Chinese medicine	60.60	Next SR will be in 2022
	Salvia miltiorrhiza seeds and		
	seedlings		
ISO 19610:2017	Traditional Chinese medicine	60.60	Next SR will be in 2022
	General requirements for industrial		
	manufacturing process of red		
	ginseng (Panax ginseng C.A. Meyer)		
ISO 19611:2017	Traditional Chinese medicine Air	60.60	Next SR will be in 2022
	extraction cupping device		
ISO 19614:2017	Traditional Chinese medicine —	60.60	Next SR will be in 2022
	Pulse graph force transducer		
ISO 20308:2017	Traditional Chinese Medicine-Gua	60.60	Next SR will be in 2022
	Sha Instruments		
ISO 20498-2:2017	Traditional Chinese medicine —	60.60	Next SR will be in 2022
	Computerised tongue image		
	analysis system — Part 2: Light		
	environment		
ISO 20409:2017	Traditional Chinese medicine —	60.60	Next SR will be in 2022
	Panax notoginseng root and		
	rhizome		
ISO 18662-1:2017	Traditional Chinese Medicine -	60.60	Next SR will be in 2022
	Vocabulary - Part 1: Chinese		
	Materia Medica		
ISO 20333:2017	Traditional Chinese medicine —	60.60	Next SR will be in 2022
	Coding rules for Chinese medicines		
	in supply chain management		
ISO 20759:2017	Traditional Chinese medicine —	60.60	Next SR will be in 2022
	Artemisia argyi leaf		
ISO 21371:2018	Traditional Chinese medicine	60.60	Next SR will be in 2023
	Labelling requirements of products		
	intended for oral or topical use		
ISO 19617:2018	Traditional Chinese medicine	60.60	Next SR will be in 2023
	General requirements for		
	manufacturing process of natural		
	products		

ISO 20495:2018	Traditional Chinese medicine Skin electrical resistance measurement devices	60.60	Next SR will be in 2023
ISO/TR 20520:2018	Traditional Chinese medicine Infection control for acupuncture treatment	60.60	Not limited
ISO/TR 23022:2018	Traditional Chinese medicine Controlled vocabulary on Japanese Kampo formulas and the indication codes for the products	60.60	Not limited
ISO 20334:2018	Traditional Chinese medicine Controlled vocabulary on Japanese Kampo formulas and the indication codes for the products	60.60	Next SR will be in 2023
ISO 20493:2018	Traditional Chinese medicine — Infrared moxibustion-like instruments	60.60	Next SR will be in 2023
ISO/TR 23021:2018	Traditional Chinese medicine Controlled vocabulary on Japanese Kampo crude drugs	60.60	Not limited
ISO 21315:2018	Traditional Chinese Medicine- Ganoderma lucidum fruiting body	60.60	Next SR will be in 2023
ISO/TR 20498-5:2019	Traditional Chinese medicine — Computerized tongue image analysis system — Part 5: Tongue color and tongue coating color	60.60	Not limited
ISO 21316:2019	Traditional Chinese Medicine-Isatis indigotica root	60.60	Next SR will be in 2024
ISO 21370:2019	Traditional Chinese Medicine- Dendrobium Officinale stem	60.60	Next SR will be in 2024
ISO 20498-1:2019	Traditional Chinese medicine Computerized tongue image analysis system Part 1: General requirements	60.60	Next SR will be in 2024
ISO/TS 20758:2019	Traditional Chinese medicine Abdominal physiological parameter detector	60.60	Next SR will be in 2022
ISO 21300:2019	Traditional Chinese medicine Guidelines for Chinese materia medica specification	60.60	Next SR will be in 2024
ISO 21314:2019	Traditional Chinese medicine-Salvia miltiorrhiza Root and Rhizome	60.60	Next SR will be in 2024
ISO 21317:2019	Traditional Chinese medicine	60.60	Next SR will be in 2024

	Lonicera japonica flower		
ISO 22212:2019	Traditional Chinese Medicine —	60.60	Next SR will be in 2024
	Gastrodia tuber		
ISO 21366:2019	Traditional Chinese medicine	60.60	Next SR will be in 2024
	General requirements for		
	smokeless moxibustion devices		
ISO 20487:2019	Traditional Chinese medicine Test	60.60	Next SR will be in 2024
	method of single-use acupuncture		
	needles for electrical stimulation		
ISO/TS 22990:2019	Traditional Chinese medicine	60.60	Next SR will be in 2022
	Categories of clinical terminological		
	system to support the integration		
	of clinical terms from traditional		
	Chinese medicine and Western		
	medicine		
ISO 21291:2019	Traditional Chinese medicine —	60.60	Next SR will be in 2024
	Therapeutic fumigation devices		
ISO 22584:2019	Traditional Chinese medicine —	60.60	Next SR will be in 2024
	Angelica sinensis root		
ISO/TR 23975:2019	Traditional Chinese medicine —	60.60	Not limited
	Priority list of single herbal		
	medicines for developing standards		
ISO 18615:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	General requirements of electric		
	radial pulse tonometric devices		
ISO 18662-2:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Vocabulary — Part 2: Processing of		
	Chinese Materia Medica		
ISO/TS 20498-3:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2023
	Computerized tongue image		
	analysis system — Part 3: Colour		
	chart		
ISO 21292:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Electric heating moxibustion		
	equipment		
ISO/TS 21310:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2023
	Microscopic examination of		
	medicinal herbs		
ISO 22213:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Glass cupping device		
ISO 22217:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Storage requirements for raw		
	materials and decoction pieces		

ISO 22236:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Thread-embedding acupuncture		
	needle for single use		
ISO 22256:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Detection of irradiated natural		
	products by photostimulated		
	luminescence		
ISO 22258:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Determination of pesticide		
	residues in natural products by gas		
	chromatography		
ISO 22283:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Determination of aflatoxins in		
	natural products by LC-FLD		
ISO 22894:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Pulse waveform format		
ISO 22988:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Astragalus mongholicus root		
ISO 23191:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Determination of selected		
	Aconitum alkaloids by high-		
	performance liquid		
	chromatography (HPLC)		
ISO 23193:2020	Traditional Chinese medicine —	60.60	Next SR will be in 2025
	Lycium barbarum and Lycium		
	chinense fruit		

b. Standards under development (33)

WG	Ref.	Title	Stage	Action to be expected
1	ISO/DIS 23723	Traditional Chinese Medicine	40.20	DIS ballot from 2020-08-13 to
		General requirements for		2020-11-05.
		herbal raw material and		
		materia medica		
1	ISO/DIS 23959	Traditional Chinese Medicine-	40.60	DIS ballot passed and to be
		Glehnia littoralis root		discussed at the next WG1
				meeting.
1	ISO/DIS 23962	Traditional Chinese Medicine	40.20	DIS ballot from 2020-08-07 to
		Processed Aconitum		2020-10-30.
		carmichaelii lateral root		
1	ISO/AWI 23965	Traditional Chinese Medicine-	20.00	WD need further discussion to
		-Bupleurum chinense and		reach consensus within WG1.
		Bupleurum scorzonrifolium		

		root		
1	ISO/CD 23972	Traditional Chinese Medicine	30.99	CD ballot passed and wait for
		Zingiber officinale rhizome		PL's submission for DIS.
1	ISO/WD 4154	Traditional Chinese Medicine	20.00	NP ballot passed and to be
		— Sinomenium acutum stem		discussed at the next WG1
				meeting.
1	ISO/WD 4564	Traditional Chinese Medicine	20.00	NP ballot passed and to be
		— Scutellaria baicalensis		discussed at the next WG1
		Georgi root		meeting.
1	ISO/AWI 22585	Traditional Chinese Medicine	20.00	WD needs further discussion
		— Codonopisis pilosula root		to reach consensus within
				WG1.
1	ISO/CD 22586	Traditional Chinese Medicine-	30.60	CD ballot passed and to be
		Paeonia lactiflora root—		discussed at the next WG1
		White peony root		meeting.
1	ISO/WD 23964	Traditional Chinese Medicine	20.00	NP ballot passed and to be
		— Saposhnikovia divaricata		discussed at the next WG1
		root and rhizome		meeting.
2	ISO/ FDIS 19609-1	Traditional Chinese medicine	50.00	FDIS ballot from 2020-10-01 to
		Quality and safety of		2020-11-26.
		natural materials and		
		manufacturing products		
		made with natural materials -		
		- Part 1: General requirement		
2	ISO/FDIS 19609-2	Traditional Chinese medicine	50.00	FDIS ballot from 2020-10-02 to
		Quality and safety of		2020-11-27.
		natural materials and		
		manufacturing products		
		made with natural materials -		
		- Part 2: Identity testing		
2	ISO/DIS 22467	Traditional Chinese medicine	40.60	DIS ballot passed and to be
		Determination of		discussed at the next WG2
		microorganism in natural		meeting.
_		products		
2	ISO 22590	Traditional Chinese medicine	60.00	To be published.
		Determination of Sulfur		
		Dioxide in natural products		
		by titration		
2	ISO/CD 23956	Traditional Chinese medicine	30.60	CD ballot passed and to be
		Determination of		discussed at the next WG2
		benzopyrene in processed		meeting.
		natural products	10.00	
2	ISO/DIS 23190	Traditional Chinese medicine	40.60	DIS ballot passed and to be

4	ISO/DIS 22466	Traditional Chinese medicine- Laser acupoint radiation device	40.20	DIS ballot from 2020-08-20 to 2020-11-12.
4	ISO/TS 20498-4	Traditional Chinese medicine Computerized tongue image analysis system Part 4: Peripheral visual instruments	60.00	To be published.
3	ISO/AWI 23958-2	TCM- Dermal Needle for single use Part 2: Roller Type	20.00	Ready for starting CD ballot.
3	ISO/AWI 23958-1	TCM- Dermal Needle for single use Part 1: Tapping type	20.00	Ready for starting CD ballot.
2	ISO/WD 4904	Traditional Chinese Medicine — inner pack of decoction pieces	20.99	Ready for starting CD ballot after the WD consultation within WG2.
2	ISO/WD 4754	Traditional Chinese Medicine — Fermented Cordyceps Powder	20.99	Ready for starting CD ballot after the WD consultation within WG2.
		 Quality and safety of natural materials and manufacturing products made with natural materials Part 4: Part 4: Testing of Preservatives and non wanted compounds 		
2	ISO/AWI 19609-4	 Quality and safety of natural materials and manufacturing products made with natural materials Part 3: Part 3: Testing of the absence of contaminants Traditional Chinese medicine 	20.00	Ready for starting CD ballot.
2	ISO/CD 23419 ISO/AWI 19609-3	Traditional Chinese medicine General requirement of manufacturing procedure and its quality control for granules Traditional Chinese medicine	20.00	CD ballot passed and to be discussed at the next WG2 meeting. Ready for starting CD ballot.
		Determination of aristolochic acids in natural products by HPLC		discussed at the next WG2 meeting.

4	ISO/CD 24571	Traditional Chinese medicine	30.60	CD ballot passed and wait for
		- General requirements for		PL's submission for DIS.
		the basic safety and essential		
		performance of electro-		
		acupuncture stimulator		
4	ISO/WD 22587	Traditional Chinese Medicine-	20.00	NP ballot passed and to be
		Acupoint Magnetotherapy		discussed at the next WG4
		Plaster		meeting.
4	ISO/WD 5227	Traditional Chinese Medicine	20.00	NP ballot passed and to be
		 — Safety controls of cupping 		discussed at the next WG4
		device		meeting.
5	ISO/CD 23961-1	Traditional Chinese Medicine-	30.99	CD ballot passed and moved to
		Vocabulary for Diagnostics		DIS stage.
		Part 1: Tongue		
5	ISO/CD 23961-2	Traditional Chinese Medicine-	30.99	CD ballot passed and moved to
		Vocabulary for Diagnostics		DIS stage.
		Part 2: Pulse		
JWG1	ISO/ PRF TS 23030	Traditional Chinese medicine	50.00	Paralleled DTS ballot passed
		Clinical Document		and moved to publication
		specification for prescription		stage.
		of TCM decoction pieces		
JWG1	ISO/CD 23963-1	Traditional Chinese Medicine	30.99	CD ballot passed and wait on
		requirements for process		PL's submission for DIS ballot.
		traceability system of Chinese		
		materia medica and		
		decoction pieces Part 1:		
		components		
JWG1	ISO/CD 23963-2	Traditional Chinese Medicine	30.99	CD ballot passed and wait on
		requirements for process		PL's submission for DIS ballot.
		traceability system of Chinese		
		materia medica and		
		decoction pieces Part 2:		
		electronic labelling		

7. Progress report on the resolutions taken at the TC249 10th plenary

meeting in Bangkok 2019

Ref.	Content	Action
2019-2	 ISO/TC 249 resolves to set up the internal liaison arrangement with ISO/TC314 Ageing Societies. ISO/TC249 resolves to note the liaison reports of WFCMS, WFAS, ISO/TC 215, ISO/TC304 and their contributions to the work of ISO/TC 249. 	Complete. TC249 secretariat representatives attended the meetings of ISO/TC314.
2019-3	ISO/TC 249 resolves to send the updated Strategic Business Plan of TC249 to an 8-week Committee Internal Ballot to seek comments and input from the National Member Bodies no later than August 15th, 2019.	Complete. The CIB started from Aug 15 to Oct 12, 2019 and after incorporating comments from members, the secretariat submitted the revised BP to ISO CS in Feb 2020.
2019-5	ISO/TC 249 resolves to accept the recommendation of WG1 that WD 21310 Traditional Chinese medicineMicroscopic examination on medicinal herbs [PL: CHOI Goya] proceed to DTR ballot.	According to suggestions from ISO/CS, this project is more suitable to be TS rather than TR. After CIB in TC 249, the committee agreed to change this project from TR to TS. ISO/TS 21310 was published on 2020-07-15.
2019-6	 ISO/TC 249 resolves to accept the recommendation of WG1 that WD 21311 Traditional Chinese MedicineAstragalus root (astragalus membranaceus) [PLs: HAN Sinhee, HUR Mok, KANG Youngmin] be revised to change the title to "Traditional Chinese Medicine Astragalus membranaceus root" and then extend timeline for 9 months for further project development due to difficulty in reaching consensus. 	The request for timeline extension has been refused by ISO/CS and this project has been cancelled.
2019-7	ISO/TC 249 resolves to accept the recommendation of WG1 that WD 21313 Traditional Chinese MedicinePlatycodon grandiflorum root [PLs: HAN Sinhee, KIM Yongil, KANG Youngmin] timeline be extended by 9 months for project development due to difficulty in reaching consensus.	The request for timeline extension has been refused by ISO/CS and this project has been cancelled.
2019-8	ISO/TC 249 resolves to accept the recommendation of WG1 that WD 23723 Traditional Chinese MedicineGeneral requirements for herbal raw material and materia medica [PLs: Heidi HEUBERGER, ZHOU Hua] proceed to CD ballot.	Complete. The CD ballot result is positive.
2019-9	ISO/TC 249 resolves to accept the recommendation of WG1 that N1018	Complete. The NP ballot

	Traditional Chinese MedicineSinomenii stem [PL: LIU Liang] be revised and	result is positive and the
	then proceed to NP ballot.	allocated ISO number is 4154.
2019-10	ISO/TC 249 resolves to accept the recommendation of WG1 that N1029 Traditional Chinese MedicineDetermination of ginseng growth year (replace N807) [PL: ZHOU Hua] be changed the type of deliverable from IS to TR and then proceed to DTR ballot.	This project is more suitable to be TS rather than TR and it will be discussed in WG1 meeting when documents are prepared.
2019-11	ISO/TC 249 resolves to accept the recommendation of WG1 that N1041 Traditional Chinese MedicineScutellaria baicalensis Georgi root [PL: YIN Hang] be revised and then proceed to NP ballot.	Complete. The NP ballot result is positive and the allocated ISO number is 4564.
2019-12	ISO/TC 249 resolves to accept the recommendation of WG1 that WD 23959 Traditional Chinese MedicineGlehnia littoralis root [PLs: KUANG Pengqun, CHOI Hoyoung] proceed to CD ballot after WG consultation.	Complete. It has passed DIS ballot and wait for submission for FDIS.
2019-13	ISO/TC 249 resolves to accept the recommendation of WG1 that WD 23962 Traditional Chinese MedicineProcessed Aconitum carmichaelii lateral root [PLs: XIE Ying, HUANG Yufeng] proceed to CD ballot after WG consultation.	Complete. DIS ballot will be ended on 2020-10-30.
2019-14	ISO/TC 249 resolves to accept the recommendation of WG1 that WD 23965 Traditional Chinese MedicineBupleurum chinense and Bupleurum scorzonrifolium root [PL: YANG Meihua] proceed to CD ballot after WG consultation.	WD needs further discussion to reach consensus within WG1 before CD balloting.
2019-15	ISO/TC 249 resolves to accept the recommendation of WG1 that WD 23972 Traditional Chinese MedicineZingiber officinale rhizome [PL: GAO Weiwei] proceed to CD ballot after WG consultation.	Complete. The CD ballot result is positive.
2019-16	 ISO/TC 249 resolves to accept the recommendation of WG1 that the work priority of the Working Group be revised as follows: 1) Projects for raw materials used in or as traditional Chinese medicine with high priority identified by WG1 based on a priority list of top 100 single herbs in ISO/TR 23975; 2) Projects for detection methods related to the safety of herbs, including detection method of toxins; and unwanted substances, etc. 3) Projects for improving the quality of herbs, including general requirements for herbal raw material and materia medica; and general requirements for primary processing of raw materials, etc. 	Complete.
2019-18	ISO/TC 249 resolves to accept the recommendation of WG2 that ISO/CD 19609-1 Traditional Chinese MedicineQuality and Safety of natural materials and manufacturing products made with natural materialsPart 1: General requirements [PL: Hans RAUSCH] to change the title to "Traditional Chinese MedicineQuality and Safety of raw materials and manufacturing products made with raw materialsPart 1: General requirements" and proceed to DIS ballot.	Complete. The project right now is under FDIS stage.

2019-19 2019-20	ISO/TC 249 resolves to accept the recommendation of WG2 that ISO/CD 19609-2 Traditional Chinese MedicineQuality and Safety of natural materials and manufacturing products made with natural materialsPart 2: Identity testing [PL: Hans RAUSCH] to change the title to "Traditional Chinese MedicineQuality and Safety of raw materials and manufacturing products with raw materialsPart 2: Identity testing of constituents of herbal origin" and proceed to DIS ballot. ISO/TC 249 resolves to accept the recommendation of WG2 that ISO/AWI 23419 Traditional Chinese medicineGeneral requirement of manufacturing procedure and its quality control for granules [PLs: QIAN Zhongzhi, HAKAMATSUKA Takashi, CHO Hyunjoo] to change the title to "General requirement of manufacturing procedure and its quality approximation of the title to "General requirement of manufacturing procedure and its quality approximation of the title to "General requirement of manufacturing procedure and its quality approximation of the title to "General requirement of manufacturing procedure and its quality approximation of the title to "General requirement of manufacturing procedure and its quality assurance for granules".	Complete. The project right now is under FDIS stage. Complete. The CD ballot result is positive.
2019-21	ISO/TC 249 resolves to accept the recommendation of WG2 that N796 Traditional Chinese MedicineFermented Cordyceps Powder [PL: LI Bangliang] proceed to NP ballot after the revision of the Form 4 and the working draft.	Complete. The NP ballot result is positive.
2019-22	ISO/TC 249 resolves to accept the recommendation of WG2 that N1017 Traditional Chinese MedicineInner pack of decoction pieces [PLs: Thomas FRIEDEMANN, WU Peikai] proceed to NP ballot.	Complete. The NP ballot result is positive.
2019-23	ISO/TC 249 resolves to accept the recommendation of WG2 that N1032 Traditional Chinese MedicineChemical profiling of herbal medicines [PL: KIM Jung Hoon] proceed to DTR ballot after the WG consultation and the revision of the document.	ISO CS instructed that this document is not suitable for a Technical Report. The PL is preparing the new documents targeting IS or TS.
2019-25	ISO/TC 249 resolves to accept the recommendation of WG3 that ISO/CD 22236 Traditional Chinese MedicineThread embedding acupuncture needle for single use [PLs: WANG Shoudong, KAWG Dong Ryel] be revised according to the experts' suggestions and submit it to TC 249 secretariat for DIS ballot no later than 2nd July 2019.	Complete. 22236 was published in June 2020.
2019-26	ISO/TC 249 resolves to accept the recommendation of WG3 that N1039 Traditional Chinese medicine Sterile knife needle for single use [PLs: KAWG Dong Ryel, WANG Shoudong] be revised and then submitted to TC 249 secretariat no later than 15th July 2019 for NP ballot.	Complete. The NP ballot result is negative and the project remains as PWI 24655.
2019-28	ISO/TC 249 resolves to accept the recommendation of WG4 that ISO/AWI 24571 Traditional Chinese MedicineGeneral requirements for the basic safety and essential performance of electro-acupuncture stimulator [PLs: HAN Songping, LEE Sanghun, YUAN Xiaoning (James), KIMURA Tomoaki] proceed to CD ballot.	Complete. The CD ballot result is positive.
2019-29	ISO/TC 249 resolves to accept the recommendation of WG4 that the time track of ISO/NP 22466 Traditional Chinese medicineLaser acupoint radiation device [PL: QI Lijing] be changed from track 2 (36 months) to track	Complete. DIS ballot will be ended on 2020-11-12.

	3 (48 months) since the consensus on technical issues has not been resolved. The PL will be changed from QI Lijing to ZHOU Huilin.	
2019-30	ISO/TC 249 resolves to accept the recommendation of WG4 that N411 Traditional Chinese MedicineAcupoint Magnetotherapy Plaster [PL: ZHOU Huilin] be revised and then proceed to NP ballot and that KAWAKAMI Minoru [Japan] be added as a project co-leader. Document to be forwarded to the secretariat by August 2nd, 2019.	Complete. The NP ballot result is positive and the allocated ISO number is 22587.
2019-31	ISO/TC 249 resolves to accept the recommendation of WG4 that N1038 Traditional Chinese MedicineSample preparation and result of smoke density test [PL: KWON Osang] proceed to DTR ballot after WG consultation.	According to suggestions from ISO/CS, this project is more suitable to be TS rather than TR. The committee approved this change and made the resolution to proceed it to NP ballot (resolution 425).
2019-32	 ISO/TC 249 resolves to accept the recommendation of WG4 that ISO/NP TS 20498-3 Traditional Chinese medicineComputerized tongue image analysis systemPart 3: Colour chart [PLs: MIYAKE Yoichi, KIM Jihye, ZHANG Haiming, ZHOU Huilin] be revised and then proceed to DTS ballot. 	Complete. ISO/TS 20498-3 was published on 2020-04- 17.
2019-33	ISO/TC 249 resolves to accept the recommendation of WG4 that ISO/NP TR 20498-4 Traditional Chinese medicineComputerized tongue image analysis systemPart 4: Peripheral visual instruments [PLs: MIYAKE Yoichi, GAO Shan, KIM Jihye, YUAN Xiaoning (James), ZHOU Huilin] be revised and then proceed to DTR ballot.	According to suggestions from ISO/CS, this project is more suitable to be TS rather than TR. After CIB in TC 249, the committee agreed to change this project from TR to TS. This project is under proof checking for publication.
2019-35	 ISO/TC 249 resolves to accept the recommendation of WG 5 that ISO/NP 23961-1 Traditional Chinese MedicineVocabulary for DiagnosticsPart 1: Tongue [PLs: WANG Yiqin, Ted KLEIN] be revised and circulate the document to WG5 and the project leaders submit the revised draft along with comment disposition to TC249 secretariat by 2nd September 2019 for 8-week CD ballot. 	Complete. The CD ballot result is positive.
2019-36	 ISO/TC 249 resolves to accept the recommendation of WG 5 that ISO/NP 23961-2 Traditional Chinese MedicineVocabulary for DiagnosticsPart 2: Pulse [PLs: WANG Yiqin, Ted KLEIN, KANG Heejung] be revised and circulate the document to WG5 and the project leaders submit the revised draft along with comment disposition to TC249 secretariat by 2nd September 2019 for 8-week CD ballot. 	Complete. The CD ballot result is positive.
2019-38	ISO/TC 249 resolves to accept the recommendation of JWG 1 that ISO/AWI 23963-1 Requirement for process traceability system of Chinese materia medica and decoction pieces	Complete. The CD ballot result is positive.

	Part 1: Components [PLs: LIAO Liping, Thomas FRIEDEMANN] proceed to	
	8-week CD ballot targeting IS and instruct TC 215 secretariat to launch the	
	parallel CD ballot. The project leader shall submit revised document and	
	updated comment disposition to the TC 249 secretariat by Jan 15th, 2020.	
2019-39	ISO/TC 249 resolves to accept the recommendation of JWG 1 that ISO/AWI	Complete. The CD ballot
	23963-2 Traditional Chinese medicineRequirement for process traceability	result is positive.
	system of Chinese materia medica and decoction piecesPart 2: Electronic	
	labelling [PLs: WU Peikai, Thomas FRIEDEMANN] proceed to 8-week CD	
	ballot targeting IS and instruct TC 215 secretariat to launch the parallel CD	
	ballot. The project leader shall submit revised document and updated	
	comment disposition to the TC 249 secretariat by Jan 15th, 2020.	
2019-41	ISO/TC 249 resolves to accept the recommendation of JWG6 that PWI 22465	Complete. The NP ballot
	Traditional Chinese Medicine Electrical Cupping Device [PL: SHIN	result is negative, and it has
	Sanghoon] be revised and then proceed to NP ballot.	been allocated to WG4 as
		PWI due to the disbanding
		of JWG6.

8. Summary of WG virtual meetings from June to Sept 2020

The following 10 virtual sessions of Working Groups were held from June to September 2020,

WG	Meetings held	Number of participants
WG1	June 1, 2020	78
WG2	June 3, 2020	42
WG3	June 9, 2020	38
	August 18, 2020	35
WG4	June 3, 2020	50
	June 10, 2020	47
WG5	June 2, 2020	53
	June 8, 2020	44
JWG1	July 15, 2020	36
	September 29, 2020	29

The active participation reflects the importance and need that members place on the work of ISO/TC 249. After validating each recommendation out of WG online meetings,

the TC249 secretariat has circulated two sets of draft resolutions to the committee for approval and is now progressing the technical work of each WG in accordance with the approved resolutions. WG1 planned to hold virtual meetings to discuss the new NWIPs starting from December 2020.

9. ISO Documents – New platform to replace ISO e-Committees

In April 2019, the Information Technology Strategic Advisory Group (ITSAG) endorsed the recommendation from ISO/CS to replace ISO eCommittees with a new platform: ISO Documents. Since then, the project team worked with an early adopter groups representing the ISO Community to launch a pilot of the new tool in January 2020.

From January to June 2020, the pilot successfully on-boarded over 14,000 officers/ experts and their 280'000 documents thereby confirming the new platform with respect to its capacity to host ISO documents, ensure the integrity and traceability of the existing content and offer a streamlined and seamless experience to users. Thanks to the close collaboration between AFNOR, DIN and the project team, all ISO committee documents will now be managed centrally on the ISO Documents platform.

As mentioned previously on <u>ISO Connect</u>, the project team is now ready to launch the general on-boarding to this innovative and intuitive path to familiar content in the following 3 waves:

- 29th September 2020
- end-October 2020
- end-November 2020

To facilitate the on-boarding process, <u>full committee structures</u> will be on-boarded in each wave. **Our structure will be onboarded on November 3rd, 2020.** All working documents will be found on the new ISO Documents platform with continued access to folders and documents throughout migration.

Detailed information on the project, upcoming training dates and next steps can be found on the <u>ISO Document Webpage</u>.

10.ISO intellectual property and technical policies

ISO had published a number of brochures and materials to ensure an ISO expert understand and accept ISO's copyright and data protection policy. It is very important to comply with ISO policies when participating in the ISO standards development process. The TC249 secretariat summarized the following policies developed by ISO and a guidance on publishing publicly available information about ISO/TC 249 drafted by the secretariat in 2018,

- <u>ISO copyright</u> and <u>trademark</u> issues such as the copyrighted material including ISO standards and pages with ISO logos (<u>https://www.iso.org/declaration-for-participants-in-iso-activities.html</u>)
- <u>data protection policies</u> (<u>https://www.iso.org/iso-member-data-protection-policy.html</u>) such as the names of participants without express permission, and
- policies for participants in ISO work such as committee documents with detailed quoted comments, voting results, etc.(<u>https://www.iso.org/publication/PUB100382.html</u>)
- N 1093 Guidance on publishing publicly available information about ISO/TC 249

11. Standards quality evaluation work by TC249 secretariat

The numbers of on-going projects and new proposals are increasing steadily. Throughout the last couple of years, emphasis was being placed on strictly assessing the need and demand for a new standard and the available resources within the committee to undertake the development work in a timely and expert manner.

Besides measurements adopted to assist with the new proposals, the secretariat is

now exploring approaches to evaluate the quality of the published standards. We appreciate input from our experts as well as relevant organizations so that the quality of TC249 publications can be progressively improved.

12. The 11th plenary meeting of ISO/TC249

As the global impact of COVID-19 became apparent, the Chair, Prof Shen Yuandong and the secretariat will provide any guidance and support and work together with our experts on virtual development of the committee. We will continue evaluating the situations of holding the next face-to-face plenary meeting with the confirmed venue in Arnhem, the Netherlands and communicate with TC members on a regular basis.