

Annual Report of an ANSI/OEOSC TAG to ISO TC172 Subcommittee Covering the Year 2019

TAG Subcommittee Number and Name: SC5 Microscopes and Endoscopes

TAG Subcommittee Leader: Stanley Schwartz 1/27/2020

ISO Meetings Held During 2019

Subcommittee meetings usually include break-out meetings of working groups and project groups. List the top-level meeting; do not list the break-out meetings.

Subcommittee, Working, or Project Group Meeting Name	Date(s)	Location
33rd Meeting of TC172 SC5 Microscopes and Endoscopes WG 3,6,9,10	November 11–13, 2019	Ningbo, China

ISO Meetings Scheduled for 2020

Subcommittee meetings usually include break-out meetings of working groups and project groups. List the top-level meeting; do not list the break-out meetings.

Subcommittee, Working, or Project Group Meeting Name	Date(s)	Location
34th Meeting of TC172 SC5 Microscopes and Endoscopes WG 3,6,9,10	November 9-13 2020 (tentative)	Clearwater, Florida details to be announced

Significant Accomplishments in 2019

At the Ningbo, China ISO Annual Subcommittee Meeting:

A total of 42 experts representing 5 P-member countries in attendance. Additionally there were 3 representatives of ISO

The following is a breakdown of delegates by country.

China: = 21

Germany: = 9

Japan: = 6

Switzerland: = 1

USA = 5

Chairman and Secretariat (Germany) = +3

The meetings were well attended by the usual highly productive members, there were no significant attendance issues. There was a very large delegation from China and similar attendance was noted from the previous year's attendees. Delegates from France, Sweden and the UK could not attend this year due to the venue and travel costs.

P-Members not represented at the meeting:

Belgium (NBN), France (AFNOR), India (BIS), Korea, Republic of (KATS), Nigeria (SON), Sweden (SIS), United Kingdom (BSI)

The 5 members from the US delegation included; Stanley Schwartz (WG 3, 9, 10), Stephen Ross (WG 3, 9, 10), Dennis Leiner (WG 6), David Shaffer (WG6), Maciej Dybiec (WG 6). This team is highly motivated, was well prepared and enjoys working together.

The strong US delegation of 4 members representing WG 6 Endoscopes; contributed significantly to the high work-load of WG 6 and demonstrated superb leadership and expert advice. This year the China delegation had the largest contingent of members, because of language translation and many new attendees, the WG 6 meeting progress was slow and at times confusing. All Microscope WG sessions were well run and moved along quickly with considerable consensus.



The outgoing Chairman, Mr. Carsten Hoyer opened the meeting and the new committee manager (Secretariat), Ms. Petra Bischoff demonstrated excellent leadership meeting skills. The new SC5 chairman Birger Lang was introduced.

Working Group Name and Convenors:

WG 3 "Terms and definitions" Mr. Robert Paulus (SNV) was named as the new convener taking over for interim convener Dr. Christian Schultz (DIN)
WG 6 "Endoscopes" Mr. Toshi Nakamura (JISC)
WG 9 "Optical performance of microscope components" Mr. Katsuyuki Abe (JISC)
WG 10 "Confocal Microscope" Dr. Hilmar Gugel (DIN)

Ms. Sabina Pintaske, has resigned from ISO and the new TC172 Secretariat Clara Engesser was appointed. The new TC172 Chairman Mr. Swen Klontke was introduced.

TC172/SC5 currently has 37 current published standards.

Overall, this meeting was very well run, the arrangements, venue and social events were quite extravagant. The meeting was productive and the hospitality of the hosts were exceptional. It is noted that SC5 work performance statistics are on time, and moving forward at a good pace. An exception is a few Endoscope standards led by the Chinese delegation that have stalled and are approaching deadlines in 2020.

The next meeting will be in the USA, tentatively announced for Clearwater, Florida November 9-13, 2020.

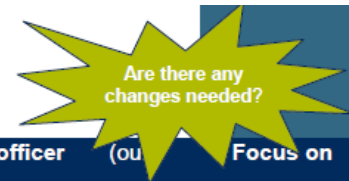
List any significant accomplishments for ANSI/OEOSC TAG/SC 5 this year (2019).

Significant Progress of Work

Since the 2018 annual meeting of SC 5, the following status or progress was made:

Liaisons

ISO/TC 172/SC 5 Liaisons



Liaison committee	Title	Liaison officer (their)	Liaison officer (our)	Focus on
ISO/TC 172/SC 7 (Res. 265/2014)	Ophthalmic optics and instruments	Elisabeth Beck (Sec.)	Christian Thomas Petra Bischoff (Comm. Manager)	operation microscopes
ISO/TC 121/SC 2 (Res. 266/2014)	Airways and related equipment	David Feinstein	Petra Bischoff (Comm. Manager)	endoscopes
ISO/TC 210 (Res. 268/2014) (Res. 330/2017)	Quality management and corresponding general aspects for medical devices"		Florian Wanner Petra Bischoff (Comm. Manager)	endoscopes (ISO 80369 series)
ISO/TC 213 (Res. 341/2017)	Dimensional and geometrical product specifications and verification		Hilmar Gugel Petra Bischoff (Comm. Manager)	confocal microscopes
IEC/SC 62D (Res. 93/2004) (Res. 267/2014)	Electromedical equipment	Mike Schmidt (Sec.)	Petra Bischoff (Comm. Manager)	endoscopes (IEC 60601-2-18)
IEC/TC 47 (Res. 318/2016)	Semiconductor devices		Mr. Yoshihiro Okada Petra Bischoff (Comm. Manager)	endoscopes (ISO 8600-8)

WG-10 requested a bilateral liaison with ISO/TC 201 WG 5 regarding confocal microscopes as per resolution 379/2019

Activity

21 Total items were worked on in 2019

- 3 Newly published standards in 2019
- 1 Standard to be published in early 2020
- 9 Active work items (3 in DIS, 1 in CD, 5 working)
- 1 New Preliminary Work Items
- 7 Systematic Reviews for 2019

3 Newly published standards

ISO 8600-3 Dennis Leiner (US) WG 6	Endoscopes - Medical endoscopes and endotherapy devices - Part 3: Determination of field of view and direction of view of endoscopes with optics	Publication 2019-07-29
ISO 9345 Lei Mao (China) WG 3	Microscopes - Interfacing dimensions for imaging components	Publication: 2019-03-22
ISO 19056-2 Katsuyuki Abe (Japan) WG 9	Microscopes - Definition and measurement of illumination properties - Part 2: Illumination properties related to the colour in bright field light microscopy	Publication: 2019-11-04
ISO/FDIS 21073 Hilmar Gugel (Germany) WG 10	Microscope - Confocal microscopes - Optical data of fluorescence confocal microscopes for biological imaging	In Preparation for Publication in January

1 Preliminary work items

ISO/PWI 19645 Xiao Hang Jia (China) WG 6 CRITICAL	Endoscopes - Determination of the luminous energy transfer efficiency	00.00 Project back staged and to be re-registered by March 2020
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9 Active work items

ISO/CD 8600-5 Dennis Leiner (US) WG 6 CRITICAL → proceed to DIS	Endoscopes - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics	48 months' time frame Limit date DIS: 2019-09-14 Revised DIS draft prepared
ISO/DIS 8600-6 Ryohei Sugihara (Japan) WG 6	Endoscopes - Medical endoscopes and endotherapy devices - Part 6: Vocabulary	DIS ballot ongoing 2019-10-07 until 2019-12-30 Awaiting vote results
ISO/NP 8600-8 Yoshihiro Okada (Japan) WG 6	Endoscopes - Medical endoscopes and endotherapy devices - Part 8: Particular requirements for capsule endoscopes	10.99 Limit date DIS: 2020-08-13 CD draft by Jan 2020
ISO/AWI 19644 Yan Qinglai (China) WG 6	Endoscopes - Determination of the color difference distinction ability and the color reducing properties	20.00 Limit date DIS: 2019-03-10 Project in HOLD status
ISO/AWI 19646 Yan Qinglai (China) WG 6	Endoscopes - Determination of the relative effect of edge photometry	20.00 Limit date DIS: 2019-03-10 Project in HOLD Status
ISO/DIS 10934 Christian Schulz (Germany) WG 3	Optics and photonics - Vocabulary for microscopy - Light microscopy	DIS ballot ongoing 2019-10-09 until 2020-01-01 Waiting for DIS vote results/comms

ISO/DIS 18340 Xiao Hang Jia (China) WG 6	Endoscopes — Trocar pins, trocar sleeves and endotherapy devices for use with trocar sleeves	40.60 Since 2019-06-05 ?????
ISO/CD 19056-3 Christian Schultz WG 9	Microscopes — Definition and measurement of illumination properties — Part 3: Incident light fluorescence microscopy with incoherent light sources	30.00 Since 2019-11-14 CD draft registered
ISO/PWI 19012-4 Atsushi Takeuchi WG 9	Microscopes – Designation of microscope objectives — Part 4: Polarization characteristics	00.00 Since 2019-11-14 Registered as PWI

7 Systematic Reviews for 2019

ISO 11884-1: 2006	Optics and photonics - Minimum requirements for stereomicroscopes - Part 1: Stereomicroscopes for general use	2019-07-15 Confirmed
ISO 11884-2: 2007	Optics and photonics - Minimum requirements for stereomicroscopes - Part 2: High performance microscopes	2019-07-15 Confirmed
ISO 10935: 2009	Microscopes - Interfacing connection type C	2019-07-15 Confirmed
ISO 8037-2: 1997	Optics and optical instruments - Microscopes - Slides - Part 2: Quality of material, standards of finish and mode of packaging	2019-04-15 Confirmed
ISO 8039: 2014	Microscopes - Values, tolerances and symbols for magnification	2019-10-15 Confirmed
ISO 15362: 2014	Stereomicroscopes - Information provided to the user	2019-07-15 Confirmed
ISO 8600-4: 2014	Endoscopes - Medical endoscopes and endotherapy devices - Part 4: Determination of maximum width of insertion portion	2019-01-15 Not Confirmed. Project timeline of 24 months for review and update

Significant Problems Encountered in 2019

ISO Subcommittee

No problems encountered. Some new national delegates added by Germany due to attrition of older members or corporate reassignments. China introduced a few new members and changes of assignments.

US TAG Subcommittee

No real problems but some significant new opportunities. US SC 5 has 10 current members. WG 6 Endoscopes is represented by 8 dedicated members and represents the US TAG very well. Within WG 3, 9 and 10 for Microscopes, there are 3 dedicated members. At the 2019 annual meeting there were now 2 US delegation member

representing microscopes. Additional experts are trying to be recruited from other companies that may have a stake in standards other than the big 4 microscope manufacturers. Companies such as Thermo-Fisher, GE Healthcare, Bruker, Thor-Labs are appropriate. I have worked with Allen Krisiloff to provide principal names and contacts to network at these companies for recruitment follow up. We have solicited them at Photonics West meetings and other biological meetings to no avail. In addition academic experts are trying to be recruited with little success. This is due partly to perceived conflict of interest with active academics, time commitment and lack of budget, but a few are willing to help advice on a case by case basis. Now that new work items involving fluorescence, confocal and LED illumination standards are almost finished it is even more critical to obtain additional US experts in microscopes. Our next effort will be to establish a Liaison relationship with the US Bioluminescence of North America initiative BINA which will give us access to leading microscopy experts. See <https://www.bioimagingna.org/> . The previously mentioned Trump administration trade policies have now hit home and several US microscope manufactures have now indicated interest in the ISO process and US based national standards participation.

Projections for 2020

ISO Subcommittee

A new format for TC172 meetings and SC interaction was introduced by the outgoing Chairman Carsten Hoyer. He gave direction on **Future challenges and topics** such as:

- New applications like “Super Resolution“ need to be defined
- Whole systems will gain importance over single components
- More standards in automation expected
- More end-user experts desirable

All members were excited to see the collectively agreed upon new directions and topics to address in the future.

For Endoscopes the China delegation will have to speed up their process and understand the ISO procedures so as not to hold up forward progress. They were reminded of this by the WG 6 convener and ISO committee manager and SC5 incoming Chairman.

There are 7 standards up for Systematic Review in 2020

DUE BY DATE:			
2020-05-12	ISO 19012-3: 2015	Microscopes — Designation of microscope objectives — Part 3: Spectral transmittance	ISO/TC 172/SC 5/ WG 9
2020-05-12	ISO 8600-2:2015	Endoscopes - Medical endoscopes and	ISO/TC 172/SC 5/ WG 6

		endotherapy devices — Part 2: Particular requirements for rigid bronchoscopes	
2020-05-12	ISO 8600-2:2015	Endoscopes - Medical endoscopes and endotherapy devices — Part 2: Particular requirements for rigid bronchoscopes	ISO/TC 172/SC 5/ WG 6
2020-05-12	ISO 8036:2015	Microscopes — Immersion liquids for light microscopy	ISO/TC 172/SC 5
2020-05-12	ISO 12853:2015	Microscopes — Information provided to the user	ISO/TC 172/SC 5/ WG 3
2020-05-12	ISO 19056-1: 2015	Microscopes — Definition and measurement of illumination properties — Part 1: Image brightness and uniformity in bright field microscopy	ISO/TC 172/SC 5/ WG 9
2020-05-12	ISO 19055:2015	Microscopes — Minimum requirements for binocular tubes	ISO/TC 172/SC 5/ WG 9
2020-05-12	ISO 8600-1:2015	Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements	ISO/TC 172/SC 5/ WG 6

The TAG SC5 Subcommittee

Hopefully new members of US microscope manufacturers or activity by academic experts will be supporting the US SC5 TAG. An ongoing initiative is planned. Last years proposed NWI by the US on Focus Maintaining Systems, will now be addressed as additions to WG 3 terms and definitions Vocabulary standard. Additionally, the US delegation was asked to investigate a possible new work item on “Automation and Microscopic Systems” (Slide Scanning Systems) to see if any experts exist in the US and wish to participate in this or other advanced Applications and Techniques as per the overall SC5 future challenges and topics SC5 café poster.

We will also begin to solicit prominent microscope and endoscope companies to help support this year’s annual meeting, which will require more than a modest budget.