

# Annual Report of an ANSI/OEOSC TAG to ISO TC172 Subcommittee Covering the Year 2018

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**TAG Subcommittee Number and Name:** SC5 Microscopes and Endoscopes

**TAG Subcommittee Leader:** Stanley Schwartz 1/11/2019

## ISO Meetings Held During 2018

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
<b>32<sup>nd</sup> Meeting of TC172 SC5 Microscopes and Endoscopes WG 3,6,9,10</b>	<b>November 7-9 2018</b>	<b>BSI Offices Chiswick London, Great Britain</b>

## ISO Meetings Scheduled for 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
<b>33<sup>st</sup> Meeting of TC172 SC5 Microscopes and Endoscopes WG 3,6,9,10</b>	<b>November 13-15 2019 (tentative)</b>	<b>Ningbo, China details to be announced</b>

## Significant Accomplishments in 2018

**At the Chiswick London ISO Annual Subcommittee Meeting:**

**A total of 35 experts representing 7 P-member countries were in attendance. Additionally there were 4 observers/participants from China and 2 from France making a total of 42 participants. The following is a breakdown of delegates by country.**

China: = 4 + 4 observers  
France: = 0 + 2 observers  
Germany: = 14  
Japan: = 7  
Sweden = 1  
Switzerland: = 1

UK = 3  
USA = 5  
Chairman and Secretariat (Germany) = +2

The meetings were well attended by the usual highly productive members, there were no significant attendance issues. 4 experts but not P-Members attended from China FDA and 2 experts but not P-Members from Argolight France were in attendance.

P-Members not represented at the meeting:

Belgium (NBN), France (AFNOR), India (BIS), Israel (SII), Republic of Korea (KATS)

Russian Federation (GOST R) has left ISO participation

Members from the US delegation included; Stanley Schwartz (WG 3, 9, 10), Dennis Leiner (WG 6), Quanzeng Wang (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 WG6 Endoscopes; contributed significantly to the high work-load of WG 6 and demonstrated superb leadership and expert advice. This year the German delegation sent the largest contingent of members, China had a reduced contingent and 2 experts from France joined the WG 10 session.

ISO TC 172/SC5 Chiswick London Meeting 2018



The Chairman, Mr. Carsten Hoyer opened the meeting and the Secretariat, Ms. Sabine Pintaske demonstrated excellent leadership meeting skills.

**Working Group Name and Convenors:**

- WG3 “Terms and definitions” Mr. Reto Zuest Leica, Switzerland resigned, Dr. Christian Schultz Leica, Germany will be interim convenor in 2019
- WG6 “Endoscopes” Mr. Toshi Nakamura Olympus, Japan
- WG9 “Optical performance of microscope components” Mr. Katsuyaki Abe Olympus, Japan
- WG10 “Confocal Microscope” Dr. Helge Eggert Leica, Germany has resigned, Dr. Hilmar Gugel Leica Germany is now the convenor.

Mrs. Sabina Pintaske, the current Secretariat is promoted within ISO and will hand over the secretariat position to Ms. Petra Bischoff in early 2019.

TC172/SC5 currently has 41 published standards.

Overall, this meeting was very well run, extremely productive, the BSI offices are well located with excellent meeting facilities. It is noted that SC5 work performance statistics are on time, at 95% in all areas and has an average standard development time of around 24 months. We are very proud of this work effort.

The BSI meeting staff and Secretariat Sabine Pintaske were excellent hosts and put together a wonderful agenda although no official social events were scheduled.

The next meeting will be in Ningbo, China - details to be announced tentative for November 13-15 2019.

**List any significant accomplishments for ANSI/OEOSC TAG/SC 5 this year (2018).**

**Significant Progress of Work**

Since the 2017 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 Sabine Pintaske (Sec.)	operation microscopes
ISO/TC 121/SC 2 (Res. 266/2014)	Airways and related equipment	David Feinstein	Sabine Pintaske (Sec.)	endoscopes
ISO/TC 210 (Res. 268/2014) (Res. 330/2017)	Quality management and corresponding general aspects for medical devices"		<b>Felix Bitroff</b> <b>Florian Wanner</b> Sabine Pintaske (Sec.)	endoscopes (ISO 80369 series)
ISO/TC 213 (Res. 341/2017)	Dimensional and geometrical product specifications and verification		<b>Helge Eggert</b> <b>Sabine Pintaske (Sec.)</b>	confocal microscopes
IEC/SC 62D (Res. 93/2004) (Res. 267/2014)	Electromedical equipment	Mike Schmidt (Sec.)	Sabine Pintaske (Sec.)	endoscopes (IEC 60601-2-18)
IEC/TC 47 (Res. 318/2016)	Semiconductor devices		Mr. Yoshihiro Okada Sabine Pintaske (Sec.)	endoscopes (ISO 8600-8)

## Activity

19 Total items were worked on in 2018

0 Newly published standards in 2018 (delayed until early 2019)

11 Active work items (2 in DIS, 2 in CD, 3 working, 2 submitted as FDIS and 2 Canceled)

Active work items		
ISO/ 8600-5 Dennis Leiner (US) WG 6	Endoscopes - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics	20.00 Extended time frame Limit date DIS: 2019-09-14 <b>Rev. WD and Cir CD by 2/19</b>
ISO/DIS 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	40.20 DIS ballot until 2019-01-08 <b>DIS ballot approved by 1/19</b>
ISO/CD 8600-6 Ryohei Sugihara (Japan) WG 6	Endoscopes - Medical endoscopes and endotherapy devices - Part 6: Vocabulary	30.00 approved CD Extended time frame Limit date DIS: 2019-06-23 <b>Cir. Rev. CD by 5/19</b>
ISO/NP 8600-8 Yoshihiro Okada (Japan) WG 6	Endoscopes - Medical endoscopes and endotherapy devices - Part 8: Particular requirements for capsule endoscopes	10.09 Limit date DIS: 2020-08-13 <b>Working on</b>
ISO/AWI 19644 Xiao Hang Jia (China) WG 6	Endoscopes - Determination of the color difference distinction ability and the color reducing properties	20.00 Limit date DIS: 2019-03-10 <b>Extend time, working on WD by 4/19</b>
ISO/AWI 19646 Xiao Hang Jia (China) WG 6	Endoscopes - Determination of the relative effect of edge photometry	20.00 Limit date DIS: 2019-03-10 <b>Extend time, working on WD by 6/19</b>
ISO/DIS 21073 Hilmar Gugel (Germany) WG 10	Microscope - <u>Confocal</u> microscopes - Optical data of fluorescence confocal microscopes for biological imaging	40.60 approved DIS Publication: 2020-03-07 <b>Revised DIS review and send as FDIS by 5/19</b>
ISO/CD 10934-1 Christian Schulz (Germany) WG 3	Optics and photonics - Vocabulary for microscopy - Part 1: Light microscopy	30.00 approved CD Limit date DIS: 2019-11-20 <b>Canceled to be replaced by merged parts 1&amp;2</b>
ISO/CD 10934-2 Christian Schulz (Germany) WG 3	Microscopes - Vocabulary for microscopy - Part 2: Advanced techniques in light microscopy	30.00 approved CD Limit date DIS: 2019-10-28 <b>Canceled to be replaced by merged parts 1&amp;2</b>
ISO/DIS 9345 Lei Mao (China) WG 3	Microscopes - Interfacing dimensions for imaging components	40.99 approved DIS Limit date Publication: 2019-05-09 <b>Submitted FDIS for Pub by 1/19</b>
ISO/DIS 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	40.60 approved DIS Limit date Publication: 2019-03-11 <b>Revised DIS to be sent for direct pub by 4/19</b>

### 3 New Preliminary Work Items

Preliminary work items		
ISO/PWI 19645 Xiao Hang Jia (China) WG 6	Endoscopes - Determination of the luminous energy transfer efficiency	00.00 Rev PWI draft by 6/19 Project back staged
ISO/PWI 10934 Christian Schulz (Germany) WG 3	Microscopes - <u>Vocabulary for microscopy</u>	Not yet registered - Aim to merge Part 1 and 2 NWIP to be Cir as CD by merged parts 1&2 by 1/19
ISO/PWI 19056-3 Christian Schultz (Germany) WG-9	" <i>Microscopes - Definition and measurement of illumination properties - Part 3: Incident light fluorescence microscopy with incoherent light sources</i> "	PWI to be NWIP to be Cir by 1/19

### 5 Systematic Reviews for 2018

Systematic review 2018		
ISO 19012-1: 2013 (WG 9)	Microscopes - <u>Designation of microscope objectives - Part 1: Flatness of field/Plan</u>	90.60 Review replies/ comments, conclusion at the SC 5 meeting Confirmed
ISO 19012-2: 2013 (WG 9)	Microscopes - <u>Designation of microscope objectives - Part 2: Chromatic correction</u>	90.60 Review replies/ comments, conclusion at the SC 5 meeting Confirmed
ISO 8255-2: 2013	Microscopes - <u>Cover glasses - Part 2: Quality of materials, standards of finish and mode of packaging</u>	90.93 confirmed Confirmed
ISO/TS 18339: 2015 (WG 6)	Endotherapy devices - <u>Eyepiece cap and light guide connector</u>	90.60 Review replies/ comments, conclusion at the SC 5 meeting Confirmed
ISO/TS 18340: 2015 (WG 6)	Endoscopes - <u>Trocar pins, trocar sleeves and endotherapy devices for use with trocar sleeves</u>	90.60 Review replies/ comments, conclusion at the SC 5 meeting Cir. Rev. DIS by 1/19

## Summary of Projects for 2018

### General project overview

WG	Project	Titel	stage	PL	Nov 17	Dec 17	Jan 18	Feb 18	Mrz 18	Apr 18	May 18	Jun 18	Jul 18	Aug 18	Sep 18	Oct 18	Nov 18
3	9345	imaging distances	DIS	Lei Mao					DIS - 2018-05-15								
9	19056-2	illumination properties	DIS	Katsuyuki Abe										DIS - 2018-09-20			
10	21073	confocal	DIS	Hilmar Gugel				CD - 2018-03-28						DIS - 2018-10-19			
3	10934-1	Vocabulary - light microscopy	CD	Christian Schulz				CD - 2018-04-17									
3	10934-2	Vocabulary - advanced techniques	CD	Christian Schulz				CD - 2018-04-17								DIS	
3	10934	Vocabulary	PwI	Christian Schulz				Vote to combine both doc.						rev. WD 2018-10-19			
6	8600-6	Vocabulary	CD	Pyohei Sugihara				CD-2018-05-12									
6	8600-3	Determination of field of view and dire	DIS	Denis Leiner				CD - 2018-04-06							DIS	DIS	
6	8600-5	Determination of optical resolution of	WD	Denis Leiner	Berlin 06-08			rev. WD						rev. WD			
6	8600-8	capsule endoscopes	PwI	Yoshihiro Okada						NwIP - 2018-08-03							
6	19644	Determination of the color difference	AWI	Xiao Hang Jia				WD									
6	19645	Determination of the luminous energy	PwI	Xiao Hang Jia				WD									
6	19646	Determination of the relative effect of	AWI	Xiao Hang Jia													
	19012-1:201	Designation of microscope objectives - f	SR						SR					decision at the meeting			
	19012-2:201	Designation of microscope objectives - f	SR						SR					decision at the meeting			
	8255-2:201	Cover glasses - Part 2. Quality of materia	SR						SR					confirmed			
6	18339:2018	Eyepiece cap and light guide connector	SR						SR					decision at the meeting			
6	18340:2018	Trocar pins, trocar sleeves and endother	SR						SR					decision at the meeting			
Secretariat																	
Project leader																	
ballot or commenting period																	
meeting																	
limit date																	

## Significant Problems Encountered in 2018

### ISO Subcommittee

No problems encountered

### US TAG Subcommittee

SC 5 has 10 current members. WG 6 Endoscopes is represented by 6 dedicated members and represents the US TAG very well. Within WG 3, 9 for Microscopes, there are 3 active members; WG 10 Confocal has 1 active member. At the 2018 annual meeting there was only 1 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 an established academic standards group, named ABRF. Additionally, the Trump

administration, has indicated “Buy America” will become an issue, enacting trade agreements and tariffs making non US manufactured goods more expensive in the US. All of this will become more of an issue in 2019 for ISO and US National. Standards.

## Summary

- The US delegation attended a well-run and productive annual meeting at the BSI Offices in London, Great Britain Nov 7-9, 2018.
- 0 standards were published in 2018, several being deferred to 2019
- 11 active work items continue
- 3 preliminary work items are being voted on
- 5 Standards were under systematic review with 4 confirmed and 1 under revision
- Discussions on new future standards were held in WG 9 and WG 10. Good ideas were presented. A few were unanimously agreed upon to discuss further in 2019 and bring NWI proposals to the annual meeting in November.
  - PNWI on Polarization qualities and labeling of Objectives ISO 19012-x (Japan)
  - PNWI on incident fluorescence ISO 19056-3 (Germany)
  - PNWI on Focus Maintaining Systems (US)
  - PNWI on Defining Signal to Noise measurement in Total Systems (France)
- The next meeting is in Ningbo, China Nov 13-15, 2019 details to be determined.

## Projections for 2019

### ISO Subcommittee

Based on the above 11 active work items, 3 preliminary work, 4 potential NWI's and 6 systematic reviews items for 2019, SC 5 will be very busy. Several of the active work items will move to publish status by mid-year.

Endoscopes will have 6 or 7 work items progressing, including 2 lead by US project leader Dennis Leiner.

### There are 7 standards up for Systematic Review in 2019

Systematic review 2019		
ISO 11884-1: 2006	Optics and photonics - Minimum requirements for stereomicroscopes - Part 1: Stereomicroscopes for general use	2019-07-15
ISO 11884-2: 2007	Optics and photonics - Minimum requirements for stereomicroscopes - Part 2: High performance microscopes	2019-07-15
ISO 10935: 2009	Microscopes - Interfacing connection type C	2019-07-15
ISO 8037: 1997	Optics and optical instruments - Microscopes - Slides - Part 2: Quality of material, standards of finish and mode of packaging	2019-04-15
ISO 8039: 2014	Microscopes - Values, tolerances and symbols for magnification	2019-10-15
ISO 15362: 2014	Stereomicroscopes - Information provided to the user	2019-07-15
ISO 8600-4: 2014	Endoscopes - Medical endoscopes and endotherapy devices - Part 4: Determination of maximum width of insertion portion	2019-01-15

## The TAG SC5 Subcommittee

New or additional projects or requirements for 2019 are a US proposal for a NWI regarding Microscopes: Focus Maintaining Systems, The US delegation will research and prepare a preliminary proposal to be presented for discussion to SC5 by July 2019. We will attempt to Liaison with the ABRF group to get participation from core microscopy laboratory managers on current and new topics for standards. We will start planning the 2020 annual meeting to be held in Silver Springs, MD at the FDA offices, We will need to secure a modest budget to provide a proper meeting. We will focus on our work items and continue recruiting efforts for microscope experts / members.

ISO/TC 172/SC 5 N 835: Report meeting London/UK, 2018-11-07+09

WG	Project	Title	stage	PL	Nov 18	Dec 18	Jan 19	Feb 19	Mar 19	Apr 19	May 19	Jun 19	Jul 19	Aug 19	Sep 19	Okt 19	Nov 19	Dec 19	Jan 20
3	9345	imaging distances	DIS	Lei Mao		Submission to publication					Publ								
9	19056-2	illumination properties	DIS	Katsuyuki Abe			final review within WG 9			Submission to publication									
9	19056-3	illumination properties - light fluore	PWI	Christian Schulz			NWIP												
10	21073	confocal	DIS	Hilmar Gugel			final review within						FDIS						
3	10934-1	Vocabulary - light microscopy	cancel	Christian Schulz			project cancelled												
3	10934-2	Vocabulary - advanced techniques	cancel	Christian Schulz			project cancelled												
3	10934	Vocabulary	AWI	Robert Paulus				CD											
6	8600-6	Vocabulary	CD	Ryohei Sugihara	London 07-09			rev. CD in WG 6			DIS		DIS						
6	8600-3	Determination of field of view and d	DIS	Denis Leiner		2019-01-08													
6	8600-5	Determination of optical resolution	CD	Denis Leiner				CD						DIS					
6	8600-8	capsule endoscopes	AWI	Yoshihiro Okada					WD										
6	19644	Determination of the color differenc	freeze	Xiao Hang Jia				DIS		rev. WD and round-robin tests									Ningbo
6	19645	Determination of the luminous ene	PWI	Xiao Hang Jia			round-robin	rev. PWI document		round-robin									
6	19646	Determination of the relative effect	freeze	Xiao Hang Jia			round-robin	DIS		round-robin		rev. WD							
6	18340	Trocar pins, trocar sleeves and end	DIS	Felix Bittrolf						DIS									
	11884-1	Stereomicroscopes	SR							SR vote									
	11884-2	Stereomicroscopes	SR							SR vote									
	10935	Interfacing connection C-Type	SR							SR vote									
	8037	Slides	SR							SR vote									
	8039	Values tolerances symbols and ma	SR							SR vote									
	15362	Stereomicroscopes	SR							SR vote									
	8600-4	Determination of maximum width o	SR							SR vote									

Secretariat	
Project leader	
ballot or commenting period	
meeting	
final vote	
status	
planned	