

# Annual Report of an ANSI/OEOSC TAG to ISO TC172 Subcommittee Covering the Year 2016

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

**TAG Subcommittee Leader:** Stanley Schwartz 1/25/2017

## ISO Meetings Held During 2016

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>30<sup>th</sup> Meeting of TC172 SC5 Microscopes and Endoscopes WG 3,6,9,10</b>	<b>October 26-28, 2016</b>	<b>Tokyo, Japan</b>

## ISO Meetings Scheduled for 2017

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>31<sup>st</sup> Meeting of TC172 SC5 Microscopes and Endoscopes WG 3,6,9,10</b>	<b>November 6-8 2017</b>	<b>DIN Offices Berlin, Germany</b>

## Significant Accomplishments in 2016

### At the Tokyo Meeting:

A total of 39 experts representing 5 P-Member countries were in attendance. The following is a breakdown of delegates by country.

China: = 15

Germany: = 8

Japan: = 9

Switzerland: = 1

USA: = 6

Chairman and Secretariat (Germany) = +2

Members from the US delegation included; Stanley Schwartz (WG3,9,10), Dennis Leiner (WG6), Quanzeng Wang (WG6), Azadeh Khaniechah (WG6), David Shaffer (WG6), Jurgen Zobel (WG6). This team is highly motivated, was well prepared and enjoys working together.

The strong US delegation of 5 members representing WG6 Endoscopes; contributed significantly to the high work-load of WG6 and demonstrated superb leadership and expert advice. China sent a large number of delegates; several were observers from the China version of the FDA. The UK and Sweden sent regrets and could not send delegates this year.



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

Working Group Name and Conveners:

WG3 “Terms and definitions” Mr. Reto Zuest Leica, Germany

WG6 “Endoscopes” Mr. Toshi Nakamura Olympus, Japan

WG9 “Optical performance of microscope components” Mr. Katsuyuki Abe Olympus, Japan (new convener replacing Mr. Kimiaki Yamamoto)

WG10 “Confocal Microscope” Dr. Helge Eggert Leica, Germany (new working group and convener).

Overall, this meeting was very well run, extremely productive, the meeting site was well located with excellent facilities. It is noted that SC5 work performance statistics are on time, at 100% in all areas and has an average standard development time of 20.4 months. We are very proud of this work effort.

The Japanese delegation were excellent hosts, with the help and support of Mr. Tetsuro Kobayashi from the hosting JMMA and JMOIA.

Since there were no delegations that offered to host the next meeting, The DIN representatives again offered to host the 2017 meeting in Berlin, Germany in early November 2017.

**List any significant accomplishments for ANSI/OEOSC TAG/SC 5 this year (2016).  
Significant Progress of Work**

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

**Liaisons**

<b>Liaison committee</b>	<b>Title</b>	<b>Liaison officer (their)</b>	<b>Liaison officer (our)</b>
ISO/TC 172/SC 7 (Res. 265/2014)	Ophthalmic optics and instruments	Elisabeth Leitner (Sec.)	Christian Thomas; Sabine Pintaske (Sec.)
ISO/TC 121/SC 2 (Res. 266/2014)	Airways and related equipment	Robert Virag (Sec)	Sabine Pintaske (Sec.)
ISO/TC 210 (Res. 268/2014)	Quality management and corresponding general aspects for medical devices”		Felix Bitrolf; Sabine Pintaske (Sec.)
<b>ISO/ IEC committees in liaison</b>			
IEC/SC 62D (Res. 93/2004) (Res. 267/2014)	Electromedical equipment	Mike Schmidt (Sec.)	Sabine Pintaske (Sec.)

**Important NEW Liaison activities taking place**

**ISO/TC 172/SC 7 – Ophthalmic optics**

Important project: **ISO 10936**

**“Optics and optical instruments – Operation microscopes“**

Part 1: 2000 Requirements and test methods – belongs to SC 5

Part 2: 2010 Light hazards from operation microscopes used in ocular surgery – belongs to SC 7

No actions in ISO/TC 172/SC 7 regarding Part 2 at the moment, but after the publication of ISO 15004 “Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection“ ISO 10936-2 would need most likely adoptions.

**Liaison officer from SC 7:** Elisabeth Leitner (Sec.)

**Liaison officer from SC 5:** Christian Thomas

**ISO/TC 121/SC 2 – Airways and related equipment**

**Formal liaisons with ISO/TC 172/SC 5/WG 6 with:**

**ISO/TC 121/SC 2 “Airways and related equipment“**

**Liaison officer from SC 2:** Robert Virag (Sec.)

**Liaison officer from SC 5:** Sabine Pintaske (Sec.)

**Liaison officer from SC 5:** TBN

**ISO/TC 210 – Quality management and corresponding general aspects for medical devices  
- ISO/IEC JWG4, Small bore connectors**

**Liaisons with ISO/TC 172/SC 5/WG 6:**

**ISO/IEC 80369 series “Small-bore connectors for liquids and gases in healthcare applications “**

## 5 Newly published standards

- ISO 18221:2016 Microscopes - Microscopes with digital imaging displays - Information provided to the user regarding imaging performance 60.60 1st edition
- ISO/TS 18339:2015 Endotherapy devices - Eyepiece cap and light guide connector 60.60 1st edition
- ISO/TS 18340:2015 Endoscopes - Trocar pins, trocar sleeves and endotherapy devices for use with trocar sleeves 60.60 1st edition
- ISO 8600-1:2015 Endoscopes - Medical endoscopes and endotherapy devices - Part 1: General requirements 60.60 4th edition
- ISO 9344:2016 Microscopes -- Graticules for eyepieces 60.60 revised

## 9 Active work items

- ISO/NP 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 10.20 (NWIP vote by: 2016-08-26) Circulate revised WD for comments
- ISO/NP 8600-5 Dennis Leiner (US) WG 6 Endoscopes - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics 10.20 (NWIP vote by: 2016-08-26) Circulate revised WD for comments
- ISO/AWI 8600-6 Ryohei Sugihara (Japan) WG 6 Endoscopes - Medical endoscopes and endotherapy devices - Part 6: Vocabulary 20.00 (NWIP approved) Extended time frame Limit date DIS: 2019-06-23 Change project leader, circulate revised WD for comments
- ISO/WD 21073 Hilmar Gugel (Germany) WG 10 Microscope - Confocal microscopes - Optical data of fluorescence confocal microscopes for biological imaging 20.20 Limit date DIS: 2018-03-07 Circulate revised WD for comments
- ISO/WD 9345 Lei Mao (China) WG 3 Microscopes - Optically related dimensions for imaging system and mechanically related dimensions for imaging components 20.20 Limit date DIS: 2018-05-09 Change title, and revise document and circulate as CD
- ISO/WD 19056-2 Katsuyuki Abe (China) WG 9 Microscopes - Definition and measurement of illumination properties - Part 2: Illumination properties related to the color in bright field light microscopy 20.20 Limit date DIS: 2018-03-11 Circulate revised WD for comments
- ISO/DIS 10936-1 WG 9 Optics and photonics - Operation microscopes - Part 1: Requirements and test methods 40.00 (Submission to ISO/CS for DIS) DIS vote approved
- ISO/FDIS 8255-1 Microscopes -- Cover glasses -- Part 1: Dimensional tolerances, thickness and optical properties 50.00 37.020 (added from 2016 systematic review) Minor change then submit as FDIS
- ISO/WD 10934-2 Microscopes -- Vocabulary for microscopy -- Part 2: Advanced techniques in light microscopy 20.20 37.020 01.040.37 (added from 2016 systematic review) Circulate WD after comment period in February

## 4 New Work Items

- ISO 8600-8 "Endoscopes – Medical endoscopes and endotherapy devices -Capsule endoscopes"– Circulation of revised preliminary Working Draft
- ISO 19644 " Endoscopes - Determination of the color difference distinction ability and the color reducing properties" – Submission of NWIP for vote
- ISO 19645 Cancellation and Re-instatement of as NWIP "Endoscopes - Determination of the luminous energy transfer efficiency" Submission of NWIP for vote
- ISO 19646 " Endoscopes - Determination of relative effect of edge photometry" – Submission of NWIP for vote

## 5 Systematic Reviews for 2016

- ISO 8576:1996 Optics and optical instruments - Microscopes - Reference system of polarized light microscopy 90.93 [Confirmed](#)
- ISO 8037-1:1986 Optics and optical instruments - Microscopes - Slides – Part 1: Dimensions, optical properties and marking 90.60 [Review replies/comments draw conclusion. Result was confirmed](#)
- ISO 8040:2001 Optics and optical instruments - Microscopes - Dimensions of tube slide and tube slot connections 90.60 [Review replies/comments draw conclusion. Result was to withdraw standard due to non-usage.](#)
- ISO 10934-2:2007 Optics and optical instruments - Vocabulary for microscopy - Part 2: Advanced techniques in light microscopy 90.60 [Review replies/comments draw conclusion Result was no change in scope but to update and circulate WD for comments in February.](#)
- ISO 8255-1:2011 Microscopes - Cover glasses - Part 1: Dimensional tolerances, thickness and optical properties 90.60 [Review replies/comments draw conclusion. Result was minor change and submit as FDIS](#)

ISO/TC 172/SC 5 N 751: Report meeting Tokyo/JAPAN, 2016-10-26 and -28

ISO/TC 172/SC 5		stage	PL	Feb 16	Mar 16	Apr 16	May 16	Jun 16	Jul 16	Aug 16	Sep 16	Oct 16	Nov 16	Dec 16	Jan 17	Feb 17	Mar 17	Apr 17	May 17	Jun 17	Jul 17	Aug 17	Sep 17	Oct 17
3	18221	digital imaging displays	ISO	Reto Zuest																				
3	9345	imaging distance	WD	Lai Mao																				
3	10330-1	operation microscopes	DIS	Secretariat																				
9	9344	Grateules for epepeose	DIS	Katsuyuki Abe																				
9	10059-2	illumination properties	WD	Katsuyuki Abe																				
10	21073	confocal	WD	Himar Gargal																				
3	10334-2	Vocabulary-advanced techniques	SR	Reto Zuest																				
9	8037-1	Slides - dimensions, optical properties	SR																					
3	8040	Dimensions of tube	SR																					
9	8255-1	Cover glass - dimensions	SR	Secretariat																				
3	8570	polarized light microscopy	SR																					
6	8800-6	Vocabulary	AW	Ryoko Sugihara																				
6	8800-3	Determination of field of view and dia	AW	Denis Leiner																				
6	8800-5	Determination of optical resolution of	AW	Denis Leiner																				
6	8800-6	capsule endoscopes	PM	Yoshihiro Okada																				
6	15644	Determination of the color difference	NP	Kiao-Hang Jia																				
6	15645	Determination of the luminous energy	PM	Kiao-Hang Jia																				
6	15645	Determination of the relative effect of	NP	Kiao-Hang Jia																				
Secretariat																								
Project leader																								
ballot or commenting period																								
meeting																								
ballot date																								
EC/CS																								

## Significant Problems Encountered in 2016

### ISO Subcommittee

No problems encountered

### US TAG Subcommittee

WG 6 Endoscopes now has 6 members and represents the US TAG very well. Within WG 3, 9 & 10; again at this meeting there was only 1 US delegation member representing microscopes. One new microscope expert was added to support ISO 10934-2 Vocabulary part 2 from Nikon Instruments Inc. Additional experts should 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 will work with Allen Krisiloff to provide principal names and contacts to network at these companies for recruitment follow up. In addition academic experts are trying to be recruited with no success. This is due partly to perceived conflict of interest with active academics, time commitment and lack of budget. Now that new work items involving confocal and LED illumination standards are proposed it is even more critical to obtain additional US experts in microscopes. Additionally, the Trump administration, has indicated "Buy America" will become an issue, probably involving standards and in the case of Medical Devices, The FDA could play a more prominent role.

## Summary

- The US delegation attended a well run and productive annual meeting at the JMMA and JMOIA facilities in Tokyo, Japan at the end of October 2016.
- 5 standards were published in 2016
- 9 active work items continue
- 4 preliminary work items are being voted on
- 5 Standards were under systematic review with 2 confirmed and 1 withdrawn
- There were no additional items or future work items suggested to be added
- The Next meeting is in Berlin, Germany Nov 6-8, 2017

## Projections for 2017

### ISO Subcommittee

Based on the 9 active work items and 4 preliminary work items from above, SC 5 will be very busy, yet most of the work in progress will be move quickly and several items will move to publish stage.

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

### **There are 5 standards up for Systematic Review in 2017**

- ISO 8577:1997 Optics and optical instruments - Microscopes - Spectral filters By 2017-07-15
- ISO 11883:1997 Optics and optical instruments - Microscopes - Marking of stereomicroscopes By 2017-07-15
- ISO 11882:1997 Optics and optical instruments - Microscopes - Interfacing connection for 35 mm SLR photo cameras (T-thread adaptation) By 2017-07-15
- ISO 10934-1:2002 Optics and optical instruments - Vocabulary for microscopy - Part 1: Light microscopy By 2017-10-15

### **The TAG Subcommittee**

No new or additional projects or requirements are anticipated for 2017. We will focus on our work items and continue recruiting efforts for microscope experts / members.