



To be submitted no later than January 31 of the year following the reporting period.
Submit to: psa@ansi.org.

2009 Annual Report for the U.S. Technical Advisory Group (TAG) To ISO 172 Optics and Photonics

TC/SC/WG/PC # and title

Please provide the information requested herein in accordance with the requirements contained in 2.5.5 Maintenance of Accreditation as found in the ANSI International Procedures.

1. TAG Administrator Organization Name: Optics and Electro-Optics Standards Council
2. Scope of the U.S. TAG: Standardization of terminology, requirements, interfaces and test methods in the field of optics and photonics.
This includes complete systems, devices, instruments, ophthalmic optics, optical and photonic components, auxiliary devices and accessories, as well as materials. Optics and photonics are used in the meaning of generation, handling and detection of optical radiation including signal processing.
Excluded :
Standardization for specific items in the field of cinematography (ISO/TC 36), photography (ISO/TC 42), eye protectors (ISO/TC 94), micrographics (ISO/TC 171), fibre optics for telecommunication (IEC/TC 86) and electrical safety of optical elements, and general lighting.
3. Please attach current TAG membership list, including: Name, affiliation, voting status, interest category and complete contact information for each member, including the Chair and other officers
4. Please provide the definitions of interest categories applicable to TAG members
5. Meetings:
 - Dates and locations (domestic and international) of all meetings of the TAG, TC and/or SC that took place in the past year:
 - If no meetings were held, please explain:
 - Dates and locations of all meetings of the TAG, TC and/or SC scheduled for the upcoming year:
6. If applicable, this confirms the status of Head of Delegation Reports for the past year:
 - Not applicable, no international meetings were held
 - Reports have already been submitted to ANSI
 - Reports are attached
 - Reports will be submitted by _____

7. Please list any problems encountered during the past year in the functioning of the U.S. TAG or U.S. TAG Administration, and any areas in which the U.S. TAG Administrator requires ANSI's assistance. *Note: for immediate assistance, please contact ISOT or psa@ansi.org.*

See individual SC reports.

8. Complaints/appeals:

- No complaints/appeals were submitted during this reporting period
- The following complaints/appeals were submitted during this reporting period; the status of each is described below:
The FDA

9. Self-audits: Were any self-audits conducted?

- Yes, the results are attached
- No

10. Annual Compliance Forms: A TAG Compliance Form will be issued in January of each year. It must be returned in accordance with the established deadline to confirm that the TAG's procedures are in compliance with the current edition of the *ANSI International Procedures*. Overdue Compliance Forms and Annual Reports from previous years, as well as any revisions to the procedures under which the TAG is accredited, are required to be submitted to ANSI as a condition of maintaining accreditation. If you have not already done so, please submit them now to psa@ansi.org.

Certification Statement

I, the undersigned, on behalf of the U.S. TAG to ISO TC 172 certify that the TAG has been operating in a manner that complies with all applicable ANSI and ISO Procedures.

Gene Kohlenberg
(Name of TAG Administrator)

Executive Director
(Title)

Optics and Electro-Optics Standards Council
(Organization)

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(Street Address/P.O. Box)

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(City, State, Zip)

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Roster of ANSI/OEOSC TAG to ISO/TC 172/SC 1

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SC 1/WG 1
SC 1/WG 2
Interest Type: General Interest
TAG/SC 1 Leader

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SC 1/WG 1
SC 1/WG 2
SC 1/WG 3
Interest Type: Producer

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SC 1/WG 1
SC 1/WG 2
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Interest Type: Producer

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SC 1/WG 1
SC 1/WG 2
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Roster of ANSI/OEOSC TAG to ISO/TC 172/SC 1

Interest Type: Producer

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SC 1/WG 1

SC 1/WG 2

SC 1/WG 3

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Interest Type: Industrial User

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SC 1/WG 1

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SC 1/WG 1

SC 1/WG 2

Interest Type: General Interest

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SC 1/WG 1

SC 1/WG 2

Interest Type: Producer

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SC 1/WG 1

SC 1/WG 2

SC 1/WG 3

SC 1/WG 4

Interest Type: General Interest

Roster of ANSI/OEOSC TAG to ISO/TC 172/SC 3

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Roster of ANSI/OEOSC TAG to ISO/TC 172/SC 4

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Interest Type: Producer
TAG/SC 4 Leader

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Interest Type: General Interest

Roster of ANSI/OEOSC TAG to ISO/TC 172/SC 5

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SC 4/WG 6
SC 4/WG 8
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Roster of ANSI/OEOSC TAG to ISO/TC 172/SC 7

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SC 7/WG 2
SC 7/WG 3
SC 7/WG 8
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Roster of ANSI/OEOSC TAG to ISO/TC 172/SC 7

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SC 7/WG 6
Interest Type: Industrial User

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SC 7/WG 6
Interest Type: General Interest

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SC 7/WG 3
Interest Type: Industrial User

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SC 7/WG 6
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SC 7/WG 9
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SC 7/WG 2

Roster of ANSI/OEOSC TAG to ISO/TC 172/SC 7

SC 7/WG 8
Interest Type: Industrial User

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SC 7/WG 6
Interest Type: General Interest

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SC 7/WG 9
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SC 7/WG 3
Interest Type: Producer

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SC 7/WG 1
SC 7/WG 6
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SC 7/WG 8
Interest Type: Industrial User

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SC 7/WG 3
SC 7/WG 6
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SC 7/WG 9
Interest Type: General Interest

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SC 7/WG 2
SC 7/WG 3
Interest Type: Producer

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SC 7/WG 7

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Roster of ANSI/OEOSC TAG to ISO/TC 172/SC 7

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SC 7/WG 6
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SC 7/WG 3

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SC 7/WG 9
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SC 7/WG 6
SC 7/WG 7
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SC 7/WG 3
Interest Type: Producer

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SC 7/WG 2
SC 7/WG 3
SC 7/WG 8
Interest Type: General Interest

Roster of ANSI/OEOSC TAG to ISO/TC 172/SC 9

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SC 9/WG 7
Interest Type: General Interest

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SC 9/WG 1
SC 9/WG 2
Interest Type: General Interest

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SC 9/WG 1
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SC 9/WG 1

Interest Type: Producer

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SC 9/WG 1
SC 9/WG 2
SC 9/WG 3
SC 9/WG 4
SC 9/WG 5
SC 9/WG 6
SC 9/WG 7
Interest Type: General Interest

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SC 9/WG 4
Interest Type: Industrial User

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SC 9/WG 1
SC 9/WG 5
Interest Type: Producer
TAG/SC 9 Leader

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SC 9/WG 4

Roster of ANSI/OEOSC TAG to ISO/TC 172/SC 9

Interest Type: General Interest

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SC 9/WG 1
SC 9/WG 7
Interest Type: Producer

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SC 9/WG 1
Interest Type: Producer

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SC 9/WG 1
SC 9/WG 7
Interest Type: Producer

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E-mail: wroyall@rochester.rr.com
SC 9/WG 1
Interest Type: General Interest

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SC 9/WG 1
Interest Type: Producer

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ANSI/OESC TAG to ISO/TC 172/SC 1 Annual Report for 2009

Prepared by TAG/SC 1 Leader: Dave Aikens

Number of Meetings Held during 2009: 1

Date: November 2, 2009

Location: DIN Headquarters, Berlin, Germany

Number of Meetings Scheduled for 2010: 1

Date: TBD, probably September or October, 2010

Location: TBD, probably Wien, Austria.

List any significant accomplishments for ANSI/OEOSC TAG/SC 1 this year.

ISO 10110-8 for surface texture, waviness and lay has been revised and will be published in 2010. The new version of the standard is in compliance with the latest revision of ISO 1302, and adds notations for Waviness, Slope, and Lay.

We began an effort to revise ISO 10110-1 and -10 to allow the use of color, and to fix other issues in the current version to bring it more in line with the US standard practices. This project will be led by the US and Romania.

We have kicked off an effort to withdraw ISO 10110-2,3, and 4 and replace them with a single standard. We have also launched an effort to create a notation for raw optical glass, but it remains unclear if these two efforts can be combined. Both efforts will be led by Allen Krisiloff of the US.

The next version of ISO 10110-6 for centring will include a notation for runout and beam deviation, in addition to the existing notation for surface tilt, which brings it in line with standard practice in the US.

We fixed ISO 15529 Principles of modulation transfer function, bringing back much of the language of the original version. The corrections will be released as a corrigendum.

List any problems encountered by the ANSI/OEOSC TAG/SC 1 during the year

WG1 seems to have completely stalled, with only the USA contributing any significant work. This is because most of the vested members have retired or are no longer active. Since we are now required to have separate notations and measurement standards, this can create problems in the future with consistent validation methodologies.

The USA continues to have no delegates in WG4, where the development of both the reference dictionary and the optical electronic interface protocol came from. This could have

a significant impact on US industries. Specifically, ORA, Zemax and Lambda Scientific, the US manufacturers of lens design software, could be at a competitive disadvantage if this interface is created without their input.

There are significant potential issues associated with the reference dictionary project, which has now advanced to the demonstration level for the concept database, and has been elevated to TC172 for management, and distributed to the SC's for input of technical content.

The notion that ISO could or should own copyright on something so simple and public as the definition of, say, wavelength or refractive index gives us pause. We believe that ANSI should oppose any such claim of ownership, and in no way abet such an enterprise. For this reason, we recommend ANSI request that all work on the database be suspended until these commercial issues are resolved. We have referred this matter to the TC172 TAG for consideration, and look to ANSI and TAG for further guidance.

ANSI/OESC TAG to ISO/TC 172/SC 3 Annual Report for 2009

Prepared by TAG/SC 3 Leader: Gordon Boulton

Number of Meetings Held during 2009: 1

Date: November 4, 2009

Location: Berlin Germany, prior to ISO TC 172 SC 1 and SC 3 meetings.

Number of Meetings Scheduled for 2010: 0

The expectation is that SC 3 TAG business will be conducted via email correspondence only.

List any significant accomplishments for ANSI/OEOSC TAG/SC 3 this year.

Provided US comments on WG 1 project ISO DIS 12123 for *Raw optical glass*.

Provided US comments on WG 2 project ISO 9211-4 DAmtd. 1 for *Optical coatings — specific test methods*. The US chaired this project.

Provided US comments on WG 3 ISO DIS 11382 for *Characterization of optical materials used in the spectral range from 0.78 μm to 25 μm* .

List any problems encountered by the ANSI/OEOSC TAG/SC 3 during the year

SC 3 succeeded in getting some inputs on WG 3 ISO DIS 11382 from IR materials suppliers, but some of the comments were received after the US requested deadline, and some were received after the Berlin SC 3 WG 3 meeting. As of the date of this report, none of the IR materials suppliers had joined OEOSC.

ANSI/OESC TAG to ISO/TC 172/SC 5 Annual Report for 2009

Prepared by TAG/SC 5 Leader: Lee C. Shuett

Number of Meetings Held during 2009: 1

Date: Sept 13-18, 2009

Location: Carl Zeiss Imaging Solutions GmbH, Kistlerhofstraße 75, Region Bavaria, 81379, Munich, Germany Date: January 1, 2009

Number of Meetings Scheduled for 2010: 1

Date: September 14-17, 2010

Attending: 26 delegates representing China, Germany, Japan, UK, Switzerland, USA

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

Accomplishments:

1) Standards revisions undertaken during systematic review process:

Alert Reference	Document title	Reg. date	Stage date
ISO 8036:2006	Optics and photonics --Microscopes -- Immersion liquids for light microscopy	2003-08-19 90.60	2009-06-17
ISO/CD 8038	Optics and photonics --Microscopes -- Screw threads for objectives and related nosepieces	2009-01-30 30.60	2009-05-05
ISO/CD 8255-1	Optics and photonics --Microscopes -- Cover glasses -- Part 1: Dimensional tolerances, thickness and optical properties	2008-09-09 30.60	2009-05-05
ISO/CD 9344	Optics and photonics --Microscopes -- Graticules for eyepieces	2008-08-21	2009-07-10
ISO 11884-1:2006	Optics and photonics --Microscopes -- Minimum requirements for stereomicroscopes -- Part 1: Stereomicroscopes	2003-09-17	2009-06-17

	for general use		
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Accomplishments:

2)Standards Published:

ISO 19012-2:2009

Optics and photonics -- Designation of microscope objectives -- Part 2: Chromatic correction

ISO 10935 Microscopes – Interfacing connection type C

3) ISO/NWIP

NWIP 8600-1 Revision of ISO 8600-1:2005 Optics and photonics – Medical endoscopes and endotherapy devices – Part 1: General requirements

NWIP 8600-xx Optics and photonics – Medical endoscopes and endotherapy devices – Part xx: Requirements for medical endoscopes of water resistant type (proposed ISO 8600-7)

List any problems encountered by the ANSI/OEOSC TAG/SC 1 during the year

Problems or Concerns:

TC172/ SC5 mdelegates at 2008 and 2009 meetings received reports from SC1/SC5 delegate Dr Yamamoto, about the progress, and future implications to SC5 of the Reference Dictionary. SC5 has not yet reached a consensus on many issues involved in the Dictionary and would appreciate more feedback from other SC heads in the USA TAG about the value of the TAG recommending whether or not to move forward with our participation.

December 31, 2009

ISO/TC 172/SC 7 - Ophthalmic Optics and Instruments

Annual Report for 2009

Prepared by

Charles Campbell, SC7 US Delegation Leader

ISO/TC172/SC7 meetings in 2009

ISO/TC172/SC7 and its constituent working groups met on May 25 through May 29, 2009 in Berlin, Germany.

The Head of Delegation report for the Berlin meetings is attached to this report to give the details on the meetings held.

ISO/TC172/SC7 meetings in 2010

ISO/TC172/SC7 and its constituent working groups will meet on September 27 through October 1, 2010 in Las Vegas, Nevada, USA.

WG9 – Contact lenses – will meet on April 30, 2010 in Toronto, Canada.

Work of SC7 in 2009

During the course of the year the work of the various working groups, as represented by the documents prepared and voted on, was as follows;

NWIP (new work item proposals) –

WG6– 1

WG10 – 1

CD (committee draft) - 6

WG2 agree- 3

WG7 agree – 1

WG9 agree with comment –1

WG10disagree –1

DIS (draft international standard) – 7

WG3 agree- 1/disagree - 1

WG6 agree –2
WG7 disagree –1
WG9 agree -2

FDIS (final draft international standard) - 12
WG6 agree – 11
WG7 agree - 1

Systematic 5-year review – 19
WG2 – 2 confirm
WG3 – 3 confirm
WG6 – 4 confirm
WG7 - 2 confirm /2 revise
WG8 - 1 revise
WG9 - 1 confirm/4 revise

It can be seen that the work of SC7 in 2009 includes work at all stages of the standardization process and similar to the activity of 2008. Even more issued standards came up for systematic review in 2009 than in 2008. This will to be the trend in SC7 due to the large number of standards the subcommittee has created over that last 25 years.

Work by the various working groups within SC7

WG2 –Work, begun in 2007, on a new work item to create a standard for a spectacle frames electronic catalog and identification continued in 2009. This work is being done as a joint effort with WG8.

WG3 – The major issue being addressed by WG3 was the standardization of finished spectacle lenses. This work was finished in 2009. The United States does not agree with the tolerances set in this new International Standard and abstained from the final vote on it. The United States national standards will not be changed to reflect the tolerances in this new International Standard.

WG6 –2009 was an active and productive year for the Ophthalmic Instruments and Test Methods working group. Many projects within WG6 were brought to completion in 2009 – as is reflected by the large number of FDIS votes cast. 7 International Standards resulting from WG6 work were published in 2009.

WG7 – The working group continues to work on standards relating to multifocal intraocular lenses and accommodating intraocular with the view to revising the various parts of the current intraocular lens standard to incorporate these types of intraocular lenses into them - types that the current standard does not cover. Based on some reported problems with endotoxins that inadvertently made their way in some IV fluids and subsequently caused some eye inflammation following their use in ophthalmic surgery, the FDA became concerned about the tolerances for endotoxins found on interocular lenses following manufacture. This issue continues to be under review by the working group.

WG8 – Data Interchange – Work continued to create a standard for an electronic catalog for

spectacle frames and their identification. This work is being done as a joint effort with WG2. The primary International Standard in this area came up for systematic review in 2009 and the United States voted to revise this standard to keep it in line with current electronic data transfer technology – a field in which there is rapid change.

WG9 – Contact Lenses - Dr. William Benjamin, USA resigned in 2009 as convener of WG9 after serving in this position for 15 years. He was replaced as convener by John Parker, UK. WG9 has been addressing issues raised in the area of care solution compatibility with contact lens materials due to introduction into the business of silicon hydrogel materials. In addition, due to ocular infections involving the acanthamoeba organism, much work has been devoted to devising an appropriate method of assessing the ability of various contact care solutions to provide protection against this disorder. The primary International Standard for contact lenses – a 4 part standard – will come up for systematic review in 2010 and work has begun to be prepared for revisions known to be needed. It was also discovered that a part of that standard dealing with a method to measure the curvature of contact lens surfaces using an ophthalmometer is in conflict with the International Standard for these instruments, which was developed by WG6. So at the Plenary meeting of SC7 an Ad Hoc committee, consisting of experts from WG6 and WG9, was established to study this issue and advise SC7 on a method of resolution. This Ad Hoc committee, after consultation, has recommended that the part of the main Contact Lens standard be revised to bring it into harmony with the instrument standard and that the instrument standard be revised to insure that the needs of the contact community are addressed properly by instruments conforming to the standard. One International Standard originating from the working group was published in 2009. In addition, there was an amendment to an existing International Standard published.

WG10 – the primary work of WG10, the revision of ISO 8598 – Focimeters, progressed to the DIS stage for Part 1 of the standard – the portion dealing with general purpose focimeters. Work on Part 2 of the standard – the portion dealing with test lenses for focimeters – progressed to a stage that a New Work Item Proposal was circulated to move this project from preliminary status to active work item status. In fact, the committee draft for this part of the standard is already drafted.

ISO/TC172/SC7 publications in 2009

During 2009, 8 new International Standards and one amendment to an International Standard originating in SC7 were published. It came from the following working groups.

WG6 7 standards

WG9 1 standard, 1 amendment

Organization of U.S. TAG for ISO/TC172/SC7

To clarify the procedures of this Technical Advisory Group and its membership, the TAG leader prepared and circulated two documents to the TAG members in 2009. The first document, entitled “The United States Technical Advisory Group (U.S. TAG) for ISO/TC172/SC7 – Ophthalmic Optics and Instruments - Organization and Procedures”, sets forth the organization of the TAG and its procedures for forming the position of the United States on various matters that come before the TAG and for voting on these matters. The second document is the roster of the U.S. TAG for ISO/TC172/SC7. The U.S. TAG for

ISO/TC172/SC7 is composed of sub-groups – one for each working group within SC7 – and the roster is organized by sub-group, giving the individual experts in the sub-group and the organizations that are part of the sub-group. The roster gives a contact person for each organization within the sub-group. It should be noted that members in one sub-group are not necessarily members in other sub-groups.

Complaint by the U.S. Food and Drug Administration (U.S. FDA)

The U.S. FDA, a member of sub-groups WG6, WG7 and WG9 within the U.S. TAG for ISO/TC172/SC7 complained that the TAG has acted improperly with regard to a matter that came before SC7 2009. The complaint was that the United States had voted without properly considering the opinion of the sub-group members, i.e. the opinion of the FDA. However, the FDA did not understand this matter clearly. There was in fact no vote the matter in question so their complaint was spurious. The matter involved a proposal by the United Kingdom to form a new working group on Light Hazards to the Eye. In the matter of forming new working groups for a sub committee within an ISO technical committee, member nations do not get a vote as the formation of a working group is an administrative matter solely under the jurisdiction of the sub committee secretariat. In this matter, the various member countries were asked by the SC7 secretariat only for their opinions. This proposal was considered by the leader and sub-group leaders of the U.S. TAG for ISO/TC172/SC7 and was found to be in violation of the procedures of ISO/TC172/SC7 for several reasons. In addition, even if the formation of such working group were to be in order, it would not be needed to do the work of SC7 in the opinion of leader and sub-group leaders of the U.S. TAG for ISO/TC172/SC7. (see the attached HoD report for details)



HEAD OF DELEGATION (HoD) REPORT

U.S. Member Body of the
International Organization
for Standardization (ISO)



U.S. National Committee of
the International
Electrotechnical Commission
(IEC)

Please return this report within one month of the completion of the international meeting and submit it to the appropriate ANSI Department as follows:

ISO

USNC

ISOT@ansi.org

USNC@ansi.org

HoD Reports can be used for a variety of purposes. For example:

- To report results of a TC/SC meeting to the related TAG
- To publicize the work of the TC/SC to the related US constituency via the ANSI Reporter, ANSI On-line, USNC News and Notes, or other media
- To suggest areas for possible development of featured articles
- To address specific challenges and concerns that the HoD may bring to the attention of related ANSI and/or USNC/IEC management

PLEASE REMEMBER: Your HoD Report is NOT filed as a confidential, password protected document and, therefore, may have broad, unintended distribution. Keep this in mind when preparing the Report and, if appropriate, use a more secure form of correspondence to bring attention to sensitive issues.

Completed by:

Head of Delegation: (Please print)	Charles E. Campbell
Telephone/Telefax:	(510) 612-1990
Email:	charles.e.campbell@mac.com
Date:	June 17, 2009

Meeting of ISO/TC172/SC7 – Ophthalmic optics and instruments (Designation/Title)
Date(s) May 25 through May 29, 2009

Location Berlin, Germany

1. MEETING ATTENDANCE

Please indicate, if available, both the number of delegates and the countries represented at the Meeting:

155 experts, 16 countries

30 Meeting attendance roster and meeting resolutions attached, if available

Please comment on significant or unusual attendance issues (e.g., new member bodies, regular members not in attendance, new Chairman or Secretariat, non-accredited U.S. persons, etc.).

5 U.S. experts were unable to attend the meetings due to the current economic conditions, prior commitments or ill health.

2. MEETING OBSERVATIONS

2a. Overall, how well did the U.S. meet its objectives on policy or technical matters?

Very Successful -- U.S. positions were accepted in whole
 Successful -- Compromises were reached which are acceptable to the U.S.
 Not Successful -- U.S. positions were not accepted

Since work of standardization within ophthalmic optics is divided to the 7 areas within the field of ophthalmic optics, the results are given for the ASC Z80 sub-committee for which a corresponding ISO/TC172/SC7 working group met.

SC7 has 7 working groups. Following are the overall results of each of these

WG2 – Frames - Successful

WG3 – Spectacle Lenses – Successful

WG6 – Ophthalmic Instruments and Test Methods – Successful

WG7 – Implants – Successful

WG8 – Data Interchange – Successful

WG9 – Contact Lenses – Successful

WG10 – Devices for Measuring the Dioptric Power of Lenses – Successful

2b. Please comment on any issues of significance which might have an impact upon materially affected or interested U.S. parties.

Contentious issues that arose at the Berlin meetings

1) The United Kingdom proposed that an existing task group within ISO/TC172/SC7, the Light Hazards Task Group, be upgraded to a working group thus creating a new working group within ISO/TC172/SC7 to be entitled Light Hazards. The United States and several other P-members (Participating member countries) opposed this proposal. The United States opposed the proposal for the following 3 reasons.

11. The United Kingdom proposal was not in accord with the ISO directives for the formation of working groups in that;

a) ISO working groups can only be formed once a work item has been proposed and authorized by P- member vote. No work item was associated with the proposed Light Hazards working group.

b) The creation of working groups is the sole prerogative of an ISO sub-committee, once a work item has been authorized for that committee. Thus a working group cannot be created by vote of the P-members.

12. The creation of standards with light hazards requirements and the revision of standards with light hazard requirements within the designated working group of ISO/TC172/SC7, i.e. Working Group 6 – Ophthalmic instruments and test methods, has proceeded in the 10 years since the Light Hazards Task Group was formed with out specific need for guidance from this group. The work of Working Group 6 has been done following the normal ISO procedure of forming project groups with project group leaders as authorized by ISO/TC172/SC7, dealing with the work in these project groups and then disbanding the project groups when the work was done. Thus there has been no need for the Light Task Group to date nor for a special Light Hazards Working Group in the future for proper care and creation of standards with light hazard requirements.

13. There is no need, in general, for the existence of special working groups within ISO/TC172/SC7 to advise other working groups in the sub-committee on areas of hazard in the field of ophthalmic optics. Working groups within ISO/TC172/SC7 other than Working Group 6 – Ophthalmic instruments and test methods – , such as Working Group 7 – Ophthalmic Implants – and Working Group 9 – Contact lenses - , have to deal with ocular hazards and they have demonstrated that the normal procedure of forming project groups with the proper experts included works very well in cases where ocular hazards must be considered within standards created by ISO/TC172/SC7.

The position of the United States was upheld by the Secretariat of ISO/TC172/SC7 and the proposal of the United Kingdom was ruled out of order as not being in accord with the Directives of ISO.

2c. Was there any discussion for which the United States was unprepared? (e.g., late document distribution, addition of new items, etc.)

There were some ballots submitted prior to the meetings whose results were discussed during the meetings for which the ballots of the United States did not have the associated comments included. This seems to have been an administrative problem with the ballot submission process. While the United States experts were fully prepared to discuss the issues raised, other experts were not as they did not have the U.S. comments prior to the meeting.

2d. Did the U.S. extend an offer to assume any new TC/SC Secretariat or management positions?

Yes No
(If yes, please indicate which position and provide Officer contact information.)

2e. Did the U.S. extend an offer to host any future TC/SC meetings?

Yes No
If yes, please identify:
The United States offered to host the meeting of ISO/TC172/SC7 in the Fall of 2010 and this offer was accepted by SC7.

2f. Were any new issues raised which require, or might involve, coordination with other U.S. bodies? (Include coordination items with other U.S. TAGs, ANSI policy-level committees (AIF, AIC), the USNC TMC and/or Council, etc.)

Yes No
If yes, please identify:

2g. Did the U.S. put forth/agree to put forth any New Work Items?

Yes No
If yes, please identify:

2h. Was there any evidence of "bloc" or "alliance" voting by participating countries?

Yes No
If yes, please identify any significant issues or concerns:

2i. Are work items in the TC or SC being affected by related work in regional standards bodies (e.g., CEN, CENELEC, ETSI, PASC, NAFTA, COPANT, etc.)?

Yes No
 No related regional activity
If yes, please explain:
As a result of what is known as the 'Vienna accord' standardization in the field of ophthalmic optics within the European Union (CEN) is to be created as a joint effort with ISO/TC172/SC7. As a result, the various nations within the EU, knowing that they will have to accept the standards created by ISO.TC172/SC7 as CEN standards, which have, within the EU, the force of law, work essentially as a block in these matters and have a somewhat different view of the work than do nations such as the United States where standards in this field are of a consensus and non-regulatory nature. Countries such as Japan and China have a situation where national standards are mandatory but they are under no obligation to accept ISO standards in toto thus they also approach the work of ISO.TC172/SC7 from a different point of view than do members of the EU.

<p>2j. Were any issues raised which relate to or impact existing U.S. regulatory matters?</p>
<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please explain:</p> <p>Due to the policy of the Food and Drug Administration of the United States on the use of standards whenever possible in the creation of regulations in the field of ophthalmic optics and due to their active participation in the work of ISO/TC172/SC7 as a result, the creation of ISO Standards in certain areas of ISO.TC172/SC7 always have a potential regulatory aspect. Just as the members of the EU know that ISO standards created by ISO/TC172/SC7 will be mandatory CEN standards, those who do business in the United States know that if an ISO Standard in the field of ophthalmic optics contradicts FDA regulations it will not be viable in the United States. Thus, while there were no explicit issues raised at the Berlin meetings of ISO/TC172/SC7 impacting U.S. regulatory matters, this issue is always present in the background.</p>
<p>2k. Please identify any IMMEDIATE U.S. TAG actions which will be required as a result of this international meeting.</p>
<p>none</p>
<p>2l. Please identify specific decisions which the U.S. delegation believes to be noteworthy for publication, publicity and/or development of a future article. If there are any, would you be willing to help develop an article for publication?</p>
<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
<p>2m. What might be done to further promote the ANSI Federation’s goal of “global standards that reflect U.S. interests?” (Consider such issues as how might the U.S. further promote acceptance of related American National Standards in international and, where applicable, regional fora?)</p>
<p>At the meeting of ISO/TC172/SC7 in Baden, Switzerland in April 2006 a resolution was taken to draft a letter to the Central ISO Secretariat asking for more support in getting ISO standards in the field of ophthalmic optics adopted universally as national standards. When this letter was drafted all national delegation leaders were asked to sign it. After consultation, the United States declined to sign and sent the following response.</p> <p>After consultation with the members of the Accredited Standardization Committee Z80 (ASC Z80) - Ophthalmic Optics, the American National Standards Institute credited body for the creation of national standards in the field of ophthalmic optics, I, as leader of the United States delegation to ISO/TC172/SC7, submit the following response to your request for a response to the letter draft created in accordance with ISO/TC 172/SC 7 Resolution 273 (national adoption and use of ISO standards).</p> <p>The United States declines the offer to sign the letter, as drafted, from ISO/TC172/SC7 to the ISO Central Secretariat on the matter of support for the national adoption of</p>

International Standards for the following reasons.

- 1) In the opinion of the United States, the letter from the ISO Central Secretariat to ISO/TC172/SC7 on the matter of the adoption of ISO standard by national bodies is quite correct and essentially in agreement with the position of the United States that optimally, ISO standards should be written so that they can be adopted by the national bodies but that there is no mandate that whatever is written and adopted must be so adopted at a national level.
- 2) To suggest that the United States automatically adopt ISO standards 'in toto' is contrary to the practice of the United States that national standards are to be of a consensus nature. Under ISO rules a draft ISO document can become an ISO standard with a negative vote by the United States. To make such a document a United States national standard destroys our basic consensus process.
- 3) To sign this letter is to endorse a position and seems to quite clearly commit the United States to vote for any mandatory adoption process that might be promulgated as a result. By not signing the United States clearly reserves our right to have a clear and thoughtful evaluation of any proposal that may be forthcoming and to not have our vote questioned if it were to be negative.

United States supports the goal of having harmonization of ISO and national standards to as great a degree as possible to foster trade and reduce unnecessary barriers. It is for this reason that we continue to work diligently and forthrightly with our international colleagues in the drafting of such ISO documents. Whenever ISO standards are formulated the United States works diligently bring them as fully as possible into the framework of our national standards as our consensus process will allow and, when it does not permit this completely, we bring our concerns and issues back to the international debate for consideration at the appropriate time for reconsideration.

The delegation from the United States trusts that this is a statement in line with general ANSI policy as is understood by ASC Z80. The members of ophthalmic community of the United States, as represented in the work of standardization by ASC Z80 ask for support of the ANSI Federation in general in this important matter for us.

2n. Has this report been provided to your TAG Administrator for US TAG distribution?

Yes No

2o. Other Comments

A full report of the activities of ISO/TC172/SC7 has been prepared and submitted to the TAG administrator as is customarily done prior to the annual TAG meeting which takes place at the end of January.

Item 8: Complaints/appeals:

The FDA filed a formal appeal to determine whether the TAG was following the model procedures in terms of establishing the US opinion concerning ISO ballots. The particular TAG/SC 7 issue turned out not to be a formal ballot, but request for opinions to be collected and shared at an upcoming international meeting. The solicited opinions were for a proposal put forth by the British Standards Institute, which was rejected by ISO on procedural grounds. However, the TAG to TC 172 Administrator realized that the documentation for TAG balloting was not being clearly maintained at the administration level so that a paper trail of voting results could be reviewed.

As a result a memorandum was distributed to the individual TAG/SC Leaders with a proposed expansion of the current balloting process. The TAG SC 7 Leader countered that the process is not workable. His e-mail follows.

This topic is on the agenda for the January 26, 2010 Annual TAG to TC 172 Meeting. All of the TAG Leaders will have input concerning ballot documentation.



Optics and Electro-Optics
Standards Council

Date: October 7, 2009

Document Number: ANSI/OEOSC TAG to ISO/TC 172 2009: 7

To: David Aikens, TAG/SC 1 Leader
Gordon Boulton, TAG/SC 3 Leader and OEOSC Director
Fritz Kaufman, TAG/SC 4 Leader
Lee Shuett, TAG Leader, TAG/SC 5 Leader and OEOSC Director
Charles Campbell, TAG/SC 7 Leader
Thomas Lieb, TAG/SC 9 Leader

CC: Allen Krisiloff, OEOSC Chairperson
Marla Dowell, OEOSC Past Chairperson
Hal Johnson, OEOSC Chairperson-elect
William Royall, OEOSC Treasurer
Walter Czajkowski, OEOSC Director
Kenneth Wood, Vision Council
Thomas White, Z80 Chairperson
Carol Herman, FDA
Michele Stolberg, TAG Administrator

Subject: ANSI/OEOSC TAG to ISO TC/172 Balloting Procedures

As you may recall, the FDA made a formal request to OEOSC to determine if the TAG was following ANSI procedures when forming the US position concerning ISO documents, particularly with respect to ISO/TC 172/SC 7. I went back to the procedures and discovered that, in general, we are not following them. The procedures can be found at <http://www.optstd.org/ISO/ANSI-OEOSC%20TAG%20to%20ISO-TC172%20Operating%20Procedures.pdf>.

I have also been advised that some leaders have difficulty getting responses from the SC or WG members in order to arrive at a US consensus position. Therefore, we are establishing a revised process for collecting and reporting the results of ballots that will be used to arrive at a consensus opinion. This process should make the Leaders' jobs easier and give OEOSC documentation that confirms the transparency of the procedure.

As in the past, Michele Stolberg will

1. obtain documents from ANSI and place them on the OEOSC website;
2. inform the members of the particular subcommittee or working group that the documents and any associated ballots are available and specify the due date;
3. indicate that comments or ballots are to be sent to her for processing and posting on the OEOSC website (SC 7 ballots will be sent to a person at the Vision Council. That person will process the ballots and send the results to Michele.);
4. monitor the return of ballots (or comments) and remind those who have not responded that their ballots are due by the posted date;

5. upload copies of the ballots to the OEOSC website;
6. notify the pertinent SC or WG members that the ballots have been posted.

The SC or WG Leader will

1. review the ballots and form the proposed US position (Please note that section A7.6 of the Procedures require that two-thirds of those voting, excluding abstentions, must vote “affirmative” or “affirmative with comments” in order for an NP, CD, DIS, or FDIS ballot to be approved. A majority of members must vote.);
2. submit the position to Michele for posting on the website.

Michele will

1. notify the pertinent SC or WG members that the position has been posted and ask them to send any comments concerning the US position to her;
2. remind them of the deadline for comments concerning the proposed US position;
3. Upload comments to the website and notify everyone that they are available.

If necessary, the SC or WG Leader will

1. negotiate the final US position with the members of the SC or WG;
2. notify Michele of the results.

Michele will

1. post the final results and;
2. submit them to ANSI for transmission to ISO.

We propose to begin this process in January starting with new documents that have not yet been received.

If you have questions or comments please send them to me.

On a related topic, Charles Campbell has published his procedure for handling ballots. I suggest that we all look at his method at the annual meeting in January to see if all SCs could follow it.

“The TAG sub-group leader will consider all votes and comments received, resolve any differences of opinion – if possible – between the TAG (SC)members, and form a unified United States position.

“Alternatively, the TAG sub-leader may decide to convene a meeting of the TAG sub-group and at that meeting form a unified United States position on the item under voting...

“Having taken either of the above actions, the TAG sub-group leader will complete the ballot form, fill in the comment form – if comments are to be submitted with the vote -, and forward these documents to the TAG (SC) leader.

“The TAG (SC) Leader will follow the following procedure when submitting the vote of the United States to (OEOSC for submission to) ANSI.

- 1) A valid vote will be one that is received by the TAG Leader from the TAG sub-group leader in the form of a filled out ballot – the ballot found in the OEOSC website.

- 2) Comments on ballots for AFFIRMATIVE votes from the United States will be included only if the comments are received by the TAG SC Leader from the TAG subgroup leader on the standardized comment form provided by ISO/TC172...
- 3) If the vote of the United States is NEGATIVE, the vote will only be valid if it is accompanied by a standardized comment form in which the reason for the negative vote is clearly stated and any conditions that would remove the negative vote.
- 4) Votes on Systematic Reviews of International Standards (a review occurs every 3 years following the issuance of an International Standard) will be valid only if they are received as filled out ballot forms, forms which are supplied on the OEOSC website.
- 5) If the TAG (SC) Leader receives no valid votes or comments from the TAG subgroup leader as per 1) through 4) above by the date that they must be transmitted to ANSI, the duty of the TAG SC Leader to insure that there be a position for the United States shall be fulfilled in the following way:
 - a) For Committee Drafts (CD) and Draft International Standards (DIS) for which no valid vote as defined in 1) is received, the TAG Leader will transmit an ABSTENSION for the United States.
 - b) For Committee Drafts (CD) and Draft International Standards (DIS) for which the TAG SC Leader receives a valid vote as defined in 1) that indicates that the United States has comments but for which a valid comment sheet as defined in 2) is not included, the TAG Leader will transmit an AFFIRMATIVE for the United States without comment.
 - c) For Committee Drafts (CD) and Draft International Standards (DIS) for which the TAG SC Leader receives a valid NEGATIVE vote as defined in 1) but for which a valid comment sheet as defined in 2) is not included, the TAG Leader will transmit an ABSTENSION for the United States.
 - d) For Final Draft International Standards (FDIS) for which no valid vote as defined in 1) is received, the TAG SC Leader will transmit an AFFIRMATIVE vote for the United States.
 - e) For Systematic Reviews for which no valid vote as defined in 4) is received, the TAG Leader will grade each query with the value 3 for a total evaluation of 9, vote to CONFIRM the standard for another 3 years, indicate that the standard has not been adopted by the United States and that there is no plan to do so, indicate that the United States will participate in any revision of the standard and that the experts who will participate are the experts from the United States to the cognizant working group.”

Think about this process and be ready to discuss it at the upcoming annual meeting on January 26, 2010 in San Francisco, CA.

Regards,



Gene Kohlenberg

OEOSC

Subject: New voting procedure

From: Charles Campbell <ceccec@pacbell.net>

Date: Thu, 3 Dec 2009 10:09:53 -0800

To: Gene Kohlenberg <gene.kohlenberg@toast.net>

CC: Nick Mileti <nmileti@luxotticaRetail.com>, William Brown <brown.william2@mayo.edu>, Jeff Endres <jendres@thevisioncouncil.org>, Dan Torgersen <dtorgersen@walman.com>, Robert Rosenberg <rrosenbergod@verizon.net>, Thomas White <twhite@usd.edu>, Quido Cappelli <qcappelli@tampabay.rr.com>, Carl Tubbs <c2k2tubbs@msn.com>, Michele Stolberg <michlisa@frontiernet.net>

Gene,

The new voting procedure for the U.S. TAG for ISO/TC172/SC7 - as it currently seems to be implemented as of January 1, 2010 - will not work well because;

- 1) There is no date established for the SC7 TAG sub group leaders to send the U.S. position to the SC7 TAG leader and
- 2) There is no date established for the SC7 TAG leader to submit the vote of the United States to the ANSI Central Secretariat via OEOSC.

The Vision Council has agreed that Amber Robinson will collect the votes and comments TAG sub-group responsible for any voting action, collate them and send this collated results to the TAG sub-group leader. This is being done, so I am informed, because Michele does not have time for this extra work. I am arranging with Amber to assemble all the comments on a single ISO comment sheet organized by clause in the standard. This will make the task of all much easier as a unified United States position is created. The votes themselves will be recorded on a tally sheet so that all can see how the vote went in a very easy fashion.

As most votes have 3 choices - agree, disagree and abstain - the tally sheet needs to have only 4 options - these 3 choices plus 'did not vote'. Amber currently does this for national standards votes within Z80 and it works well. I will supply her with forms for each TAG sub-group so all she has to do is put a title on the tally sheet and put crosses in the appropriate boxes for each member of the TAG sub group.

There is no other role for The Vision Council in this matter. The unified position of the United States on any matter will be created using exactly the same procedure we in SC7 have been using for years - the one set forth in my document on the organization and procedures of the U.S. TAG for ISO/TC172/SC7. When I submit the vote of the United States and associated comments, I am now copying all members of the TAG sub-group. Of course posting these documents on the OEOSC website is good but I think it best to notify all member immediately as I am doing because they may not always take the time to go to the website and certainly will not know exacting when the vote was cast. My method removes any confusion on this matter.

I would like you to change the notifications Michele is now sending out to reflect the above procedure with the next notification she sends.

We will see how this new collection method works. However, I am concerned in that the TAG sub-group leaders will not have as much time as they do now to start forming a unified position because now they get ballots and comments often before the deadline for submission and so can see conflicts that need to be resolved early and start working on them as soon as

they become evident. Under the new plan the TAG sub group leaders will be essentially blind to problems until after the submission deadline and then will have very little time to resolve conflicts.

Charles Campbell
Leader, U.S.TAG for ISO/TC172/SC7
2908 Elmwood Court
Berkeley, CA 94705
(510) 612 1990

Subject: Re: New voting procedure

From: Michele Stolberg <michlisa@frontiernet.net>

Date: Thu, 03 Dec 2009 16:42:33 -0500

To: Charles Campbell <ceccec@pacbell.net>, Gene Kohlenberg
<gene.kohlenberg@toast.net>

CC: Nick Mileti <nmileti@luxotticaRetail.com>, William Brown
<brown.william2@mayo.edu>, Jeff Endres <jendres@thevisioncouncil.org>, Dan Torgersen
<dtorgersen@walman.com>, Robert Rosenberg <rrosenbergod@verizon.net>, Thomas White
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<c2k2tubbs@msn.com>

Charlie-

The dates for the next stage of ballot due dates requested in your note below (WG Leaders to you, you to me/OEOSC) will come out in the next round of emails about the items out for vote. Under the new voting procedure, the items go first to Amber, who copies them to the SC7 WG Leader (if they have not already been copied). The WG leaders can start working on their US positions right away. She has a list of all the US SC7 WG experts (your list from October) and will also forward reminders to those that she has not heard from, to attempt to secure a vote from each WG member. She will generate a log sheet I can post to the OEOSC website.

Once the due date to Amber has arrived, I will send an email to each WG leader, asking them to provide a draft US position to me by a certain date, and indicate that it will be posted to the OEOSC site for a period of 4-5 days for any WG members to comment. The WG members will be emailed that the draft position is available for review, and will be asked to send in any additional comments to the WG Leader before he sends the finalized US position on to you. The WG Leader will be provided with a due date to get the finalized vote to you, and then you to me, for ANSI to receive it in a timely manner.

The first step in this new voting process is a log of each member vote/comments to be posted to the website per OEOSC's new procedure, with the follow-on dates issuing from there. I've tried to make this transition as easy as possible, the new system is certainly more cumbersome than the old-- and a sheaf of dates issued all at once didn't seem to help with that. I can certainly do that if you prefer. Amber is only being asked to track the votes, and send the reminders to the experts and a log sheet to me for posting to the OEOSC website. I'm sure whatever format you already have in place for this will be fine. The WG Leaders will still be working on the US positions as soon as comments begin to come in.

I was also concerned about the shortened lead time for the experts to review the items, but have been advised that OEOSC must become more accountable for the votes cast even if it means less time for review. I'll do my best to send items around as quickly as possible.

Michele
(510) 612 1990

