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

Annual Report for 2011

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ISO/TC172/SC7 meetings in 2011

WG3 – Spectacle lenses – project groups met in Clearwater, Florida on June 17, 2011

WG7 - Ophthalmic implants – met in Brussels, Belgium on May 10 through 12, 2011 and in Vienna, Austria on September 15 and 16, 2011

WG9 – Contact lenses - met in London, UK on May 11 through May 13, 2011

WG10 – Devices for dioptric power measurement of lenses –met in Sydney, Australia on May 31 through June 2, 2011

Work of SC7 in 2011

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) – 1
- WG3– 1
- WG6 – 2

CD (Committee Draft) - 9
- WG3 agree- 1, agree with comment – 2
- WG6 agree with comment – 1
- WG7 agree -2
- WG9 agree–2, agree with comment – 1

DIS (Draft International Standard) – 9
- WG6 agree – 2

WG7 agree with comment - 1
WG8 agree- 2

WG9 agree with comment - 2
WG10 agree with comment – 1, disagree –1

FDIS (Final Draft International Standard) – 5
WG6 agree - 1
WG7 agree - 4

Systematic 5-year review – 4
WG6 – 2 confirm
WG7 - 1 confirm
WG9 - 1 confirm

It can be seen that the work of SC7 in 2011 includes work at all stages of the standardization process and similar to the activity of 2010. Only 4 issued standards came up for systematic review in 2011, the same number as in 2010.

Work by the various working groups within SC7

WG2 – Spectacle frames –Work, begun in 2007, on a new work item to create a standard for a spectacle frames electronic catalog and identification continued in 2011. This work is being done as a joint effort with WG8. The first part of the International Standard was issued this year.

WG3 – Spectacle lenses – The spectacle lens working group has project groups working on the revision of the International Standards; ISO 8980-3: Transmission specification and test methods, ISO 10322-1: Specifications for single-vision and multifocal lens blanks, ISO 10322-2: Specifications for progressive power lens blanks, ISO 13666: Spectacle lenses – Vocabulary, and ISO 14889: Spectacle lenses - Fundamental requirements for uncut finished. There also project groups working technical reports on Abrasion resistance of spectacle lenses and Short wavelength visible effects. All these project groups held meetings at the Clearwater meeting.

WG6 - Ophthalmic instruments and test methods – The active work in Working group 6 is on the revision of ISO 10938 – which now includes not only visual acuity chart projectors but other more modern methods of visual acuity testing plus an annex on correlating optotypes to the standard optotype – and the revision of ISO 15004-2: Light hazard protection. In 2011 it was decided to standardize a new class of instruments – optical coherence tomographs – and this work will start in 2012.

WG7 – Ophthalmic implants – The working group continues to work on the revision of various parts of the International Standard for intraocular lenses with the view of incorporating requirements for multifocal intraocular lenses and accommodating

intraocular lenses – types of intraocular lenses 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 intraocular lenses following manufacture. This issue continues to be under review by the working group.

WG8 – Data Interchange – The first part of a three part standard for an electronic catalog for spectacle frames and their identification was issued as an International Standard this year. This work is being done as a joint effort with WG2. The second and third parts progressed through the DIS stage.

WG9 – Contact Lenses -

There were 9 project groups with in WG9 in 2011. The United States provided the leadership in 6 of these 9 projects.

4 projects dealt with various matters having to do with contact lens care products. Work continued 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.

Work continued on the revision of several parts of the 4 part standard for contact lenses, ISO 18369.

WG10 - Devices for dioptric power measurement of lenses – the primary work of WG10, the revision of ISO 8598 – Focimeters. It has been difficult to get agreement on Part 1, which standardizes general purpose focimeters, and second and third Draft International Standard was needed. Although sufficient positive voting were received on the third draft it will be further discussed at the Milan meeting and undoubtedly there will be some changes made before it goes to the Final Draft International stage. The United States disagreed with third draft for several fundamental reasons. In the first place, this draft includes a requirement to calibrate focimeters that are exclusively used to measure contact with a test lens set that is known to exhibit a large amount of spherical aberration for the higher powers. When this is the case, there is no single definable power for the lens over only reasonably sized aperture and so such lenses are inappropriate to use as standardized lenses to define dioptric power. In the second place, a special test of ability of automatic focimeters to measure astigmatism was incorrectly specified in the draft.

Due to lack of progress, it was proposed at the Sydney meeting to suspend work on Part 2 of the standard – the portion dealing with test lenses for focimeters – and to refer in Part 1 to the two existing International Standards for test lenses for focimeters. The initial plan

was to include these standards in the focimeter standard as Part 2 and this would have been comparatively simple had the work been managed in a proper way. But since this was not the case, this consolidation has been delayed until some future revision of the focimeter standard. SC7 subsequently voted to accept this proposal.

It was also proposed at the Sydney meeting to disband the project group formed to create Part 3 of the focimeter standard on special purpose focimeter and to delete this work item thus deleting Part 3 of the standard. SC7 subsequently voted to accept these proposals.

ISO/TC172/SC7 publications in 2011

During 2011, 1 new International Standard originating in SC7 was published. It came from the WG8 working group.

Other SC7 TAG activity in 2011

Some time in the past Bausch & Lomb, Inc. contacted the ANSI central office directly on a matter associated with their on going difficulties in China with the dioptric power measurement of their hydrogel contact lenses and asked for help in presenting their case to officials in China. This did not come to my attention as leader of the U.S. TAG for ISO TC/172/SC7 until 2011 when Bausch & Lomb made an additional request that a vote be taken to establish the United States position on the calibration of focimeters used for measuring contact lenses. This request was made directly to the administrator of the U.S. TAG for ISO/TC172. It was then referred to Quido Cappelli, who is the sub-leader for the U.S. TAG for ISO/TC172/SC7/WG9 – Contact lenses. Mr. Cappelli was of the opinion that the position of the United States on this matter had been made quite clear at the combined ANSI/TAG meeting for contact lenses just held – an opinion that supported the view of Bausch & Lomb and that no vote was needed. After some discussion, in which I participated, it was pointed out that at the May 2011 Sydney meeting of WG10 dealing with standardization of focimeters the position of the United States had been recorded in writing and distributed to all national bodies via an updated comment sheet on the draft of the focimeter standard. Thus the official United States position was already established in an official manner. Bausch & Lomb then withdrew their request for a vote and it was decided that the central ANSI office would send a letter to other national bodies pointing out our opposition to the special calibration requirements, the reasons for our opposition and asking them to join us in disapproving of the draft standard. I prepared a statement for the central ANSI office to use but do not know if it was sent to other countries. In the voting on the third Draft International Standard for general purpose focimeters only the United States and the United Kingdom disapproved.

Meetings for 2012

ISO/TC172/SC7, it working groups and project groups, will meet in Milan, Italy on March 12 through March 16, 2012.