

**American National Standards Institute  
Z80 Committee on Ophthalmic Products**

SHERATON SAND KEY HOTEL

<b>ANSI Z80 PARENT COMMITTEE MEETING MINUTES</b>
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Tuesday, February 25, 2014: 8:30 am – 11:30 am  
[Amended 08-26-2014]

- **Opening of the Meeting of ANSI Z80 Parent Committee.** Dr. Tom White, Chair of the Z80 Committee, called the meeting to order at 8:30 am, Tuesday, February 25, 2014. A sign-in sheet was distributed for attendees to document their participation. A roll call of ANSI Z80 member representatives in attendance was made. Each person identified themselves to the group in turn around the meeting room.
- **Acceptance of the Agenda.** The agenda that had been distributed was unanimously accepted without modification.
- **Acceptance of the Fall 2013 Meeting Minutes.** The minutes of the last meeting of the Parent Committee that had been distributed were unanimously accepted without modification.
- **Chairman’s Comments.** Dr. White brought forward Dr. Robert Rosenberg and presented him with a standing plaque in appreciation for 27 years as Secretary of the ANSI Z80 Committee. A round of applause ensued.

Dr. White then introduced Dr. William J. Benjamin (“Joe”) who had assumed the role of ANSI Z80 Secretary for his first meeting, after having been unanimously approved by the voting members of the Z80 Committee since the last meeting. Applause also greeted this announcement.

The Chairman reminded the representatives that the ANSI Z80 Committee wrote functional or performance-based standards by consensus, not design-based standards. The standards, when originally written or revised, should not exclude existing products from the marketplace.

- **Vice-Chairman’s Comments.** Mr. Quido Cappelli, Vice-Chair of the Z80 Committee, reminded the member representatives that delegates appointed from the Z80 Committee to attend meetings of the International Organization of Standardization (ISO) promise to represent consensus opinions of the ANSI Z80 Committee when attending project group and working group meetings at the ISO.
- **Legal Counsel’s Report.** Mr. Rick Van Arnam, Legal Counsel for the Z80 Committee, reminded the Z80 Committee of the 1995 National Technology and Transfer Act (NTTA), which directed US government entities to adopt existing consensus standards, where appropriate, instead of writing their own.

He then referred to the 1998 Office of Management and Budget (OMB) Circular A119 that reiterated the general concept noted in the 1995 NTTA, and added that consensus standards or portions of standards adopted and written into guidance documents have the force of law.

It has recently been brought to his attention, from the Federal Register of last year, that the government has proposed for review a revision to OMB Circular A119 that further reiterates and more firmly states the directive that federal entities make use of voluntary consensus standards such as those produced by the ANSI Z80 Committee. Further, it was proposed that federal agencies participate in greater capacities in standards bodies outside the government.

A potential complication for the Z80 Committee is that, as proposed, the revised OMB Circular A119 would require standards cited in federal guidelines and regulations to be made available free of charge to members of the public who wish to review the standards.

Mr. Van Arnam will obtain the closing date for comments on the proposed revision and Mr. White will solicit comments from the ANSI membership to be included in a letter of response from the ANSI Z80 Committee.

- **Secretariat's Report.** Mr. Jeff Endres, representing the Secretariat, had distributed a page including figures for the 2013 Proposed Budget, 2013 Actual Budget, and 2014 Proposed Budget. Notable was the extent to which sales of Z80 standards contributed to the budget, a concern if the revised OMB Circular A119 required free supply of Z80 standards. Also notable was the reduced expense of Z80 meetings at the Sheraton Sand Key, the return of one meeting per year to Alexandria would increase meeting expenses, and that for 2013 there had been a significant budgetary surplus.

By unanimous vote after discussion, the membership dues for the ANSI Z80 Committee were held constant for the coming year.

Also distributed by Mr. Endres was a summary of the voting history of the Z80 member organizations. Member organizations were highly encouraged to vote in a timely manner when the opportunities for voting were presented.

A Z80 Standards Development Status Summary as of 30-Jan-2014 had also been distributed. It included the dates by which standards should be renewed or revised. Subcommittee chairs were to take note of the renewal dates of standards falling within the work of their subcommittees.

- **Subcommittee Reports.**

**SC1:** Mr. Richard Whitney, Chair of Subcommittee (SC) 1, reported that SC1 was working on a revision to ANSI Z80.1 on Prescription Spectacle Lenses due for renewal in 2015. The standard needs a definition for prescription lenses that is being crafted. The scope is being reconsidered due to new technology in the form of spectacle lenses having adjustable power. Some discussion among experts occurred wondering if such lenses would rather fall within the scope of SC2 on Non-prescription Spectacle Lenses. Also briefly discussed was the potential concept of "self-refraction" and ordering spectacles on the internet using the self-refraction.

**SC2:** Dr. Karl Citek, Chair of Subcommittee 2, reported that SC2 would invite a traffic safety expert to speak on the visibility of traffic signals to the next meeting of the subcommittee. SC2 was currently comparing the ISO and ANSI standards such as Z80.3 on Non-prescription Sunglasses and Fashion Eyewear. The subcommittee was working on a revision of Z80.3 with the expectation of having a draft revision ready for voting by the deadline in 2015. It was also working on a revision of ANSI Z80.31 on Ready Readers to include lenses having bifocal additions.

**SC3:** Mr. Nick Mileti, Chair of Subcommittee 3, reported that SC3 has continued work on the revision of ANSI Z80.5. SC3 determined to incorporate ISO frame standards ISO 12870 – Spectacle Frames Requirements and Test Methods, ISO 8624 – Spectacle Frames Measuring System and Terminology, and ISO 7998 – Spectacle Frames Terms and Vocabulary into the document. The draft revision of Z80.5 will be ready for SC3 to review at the fall meeting of SC3.

**SC4:** Dr. Carl Tubbs, Chair of Subcommittee 4, was absent for the Parent Committee meeting. Thus, Dr. White reported the results of the SC4 Subcommittee meeting held by Dr. Tubbs. Dr. White reported that Z80.27 on Implantable Glaucoma Devices was in the process of publication by ANSI. SC4 is working on Z80.29 on Accommodative Intraocular Lenses, would have an interim teleconference, and expected to have a draft standard for review by the fall meeting. ISO standards within the scope of SC4 were being watched.

**SC6:** Dr. William Brown, Chair of Subcommittee 6, reported that SC6 reviewed the extensive comments of the Food & Drug Administration (FDA) regarding ANSI Z80.10 on Tonometers. These were based on the FDA's Supplemental Information Sheet (SIS) for the tonometry standard.

Having considered these comments, the revision of ANSI Z80.10 was unanimously recommended by those present to be sent out for voting by the Secretariat prior to the next meeting.

**SC7:** Mr. Quido Cappelli, Chair of Subcommittee 7, turned the presentation of the SC7 report over to Dr. Benjamin, who had conducted the SC7 meeting in the sudden absence of Mr. Cappelli on the previous day. The written subcommittee report was projected for view by the Z80 Committee and key points were covered by Dr. Benjamin. The Z80 Committee is hereby referred to the detailed SC7 Subcommittee report.

**SC8:** Mr. Jeff Endres, Chair of Subcommittee 8, reported that SC8 had no new work left over from 2013. It would be drafting a New Work Item Proposal (NWIP) on Electronic Data Interchange for Billing and Reimbursement, for which technical experts from the National Association of Vision Care Providers would be at the next meeting of SC8.

▪ **Information Reports.**

**ANSI Z87:** Mr. Richard Whitney, the Z80 representative for the ANSI Z87 Committee, reported that the current ANSI Z87.1 on Occupational and Educational Eye and Face Protection Devices had been issued in 2010. The Z87 Committee is working on the revision for 2015. The next meeting of Z87 will be in April of 2014.

The Occupational Safety and Health Administration (OSHA) currently recognizes the 2003 version of ANSI Z87.1 and hasn't yet adopted the 2010 version. The ANSI Z87 Committee has tried and is currently trying to have this oversight addressed.

**FDA:** Mr. Don Calogero, lead representative for the US Food & Drug Administration, reported that the February 14 panel meeting on Toric Intraocular Lenses (Toric IOLs) had been snowed out and the work would be rescheduled. A number of technologies were emerging that would require consideration by more than one group within the FDA. The FDA and the American Glaucoma Society were co-hosting a workshop on minimally invasive surgery in the next few days.

**TC94/SC6:** Mr. Dale Pfriem, the US TAG Chair for ISO/TC94/SC6, covered key points on his written report as it was projected for view by the Z80 Committee. The Z80 Committee is hereby referred to Mr. Pfriem's detailed ISO/TC94/SC6 Liaison Report.

According to the Vienna Agreement, ISO standards must become European standards and the process of doing this is often 4 or 5 years long. Further, the adopted standards have the force of law. Of major concern was a very early adoption into law by the European Union of the recently published ISO 12609-1 and ISO 12609-2 on Sunglasses as European Committee for Standardization (CEN) standards. Adoption of these standards took only about 6 months! Mr. Jeff Endres then pointed out the huge impact that this could have on manufacturers of sunglasses that are marketing product in Europe. The Vision Council is writing a strong letter due Wednesday, February 26, with supporting statements by various ophthalmic and professional groups in Europe and the USA.

**US TAG for ISO/TC172/SC7:** Mr. Jeff Endres, the US TAG Leader for SC7, reported that a brief meeting of TAG leaders occurred in San Francisco in January of this year. He also noted that the next meeting of ISO/TC172/SC7 is tentatively set for Shanghai, China, in the spring of 2016. [Later, the SC7 Secretariat announced that the Shanghai meeting would be May 11-15, 2015.]

▪ **Next Meetings:**

ANSI Z80: August 24-26, 2014; Westin Hotel, Alexandria, Virginia.

ANSI Z80: March 2-4, 2015; Sheraton Sand Key, Clearwater Beach, Florida.

ISO ISO/TC172/SC7: May 11-15, 2015; Shanghai, China.

▪ **New Business:** No new business was brought forward by the Z80 Committee.

▪ **Closure of the Meeting.** The meeting was brought to a close at 11:30 am.