American National Standards Institute
Z80 Committee on Ophthalmic Products

SHERATON SAND KEY HOTEL

ANSI Z80 PARENT COMMITTEE MEETING MINUTES

Wednesday, March 4, 2015: 8:30 am – 11:30 am

- **Call to Order and Instructions.** Dr. Tom White, Chair of the Z80 Committee, called the meeting to order at 8:30 am, Wednesday, March 4, 2015. 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 2014 Meeting Minutes**. The minutes of the last meeting of the Parent Committee that had been distributed were unanimously accepted without modification.

- **Chairman's Nomination**. Jeff Endres conducted an election for Chair of the Z80 Committee. Dr. Tom White was the sole nominee. Dr. White was unanimously approved.

- **Chairman's Comments**. Dr. White spoke about the early history of spectacles in Italy that led to the ability of presbyopic individuals to read, and how this led to education of those that had accumulated the resources and had time available for educational pursuits. Therefore, the field of ophthalmic optics was important in human history and standards became important for continued development.

- **Vice-Chairman's Comments**. Mr. Quido Cappelli, Vice-Chair of the Z80 Committee, stated that he had no comments to report.

- **Legal Counsel's Report**. Mr. Rick Van Arnam, Legal Counsel for the Z80 Committee, reviewed the status of Office of Management and Budget (OMB) Circular A-119 and covered key points in the Discussion Draft of the House Subcommittee which is approximately 400 pages long. He will monitor the development of Circular A119 and report back at the next meeting of the Z80 Committee. The Z80 Committee is hereby referred to the Legal Report included as a portion of these minutes.

- **Secretariat's Report**. Mr. Jeff Endres, representing the Secretariat, stated that the number of members of the Z80 Committee had remained stable: the Association of Vision in Research and Ophthalmology (ARVO) had dropped its membership and Abbott Medical Optics (AMO) had become a new member. The American Schools and Colleges of Optometry (ASCO) was considering membership. The dues for membership at $1,550 per year were unchanged. Four ANSI Z80 standards have been approved already in 2015 and five standards are in the voting process. A Z80 Standards Development Status spreadsheet, the Z80 Committee Budget summary for 2014, and the proposed budget for 2015 are included with these minutes.

- **Subcommittee Reports**.

  SC1: Mr. Richard Whitney, Chair of Subcommittee (SC) 1, reported on the PINS voting and status of the revision to ANSI Z80.1 on Prescription Spectacle Lenses. The written subcommittee report was projected for view by the Z80 Committee and key points were covered by Mr.

Whitney. The Z80 Committee is hereby referred to the SC1 Subcommittee report included as a portion of these minutes.

SC2: Dr. Karl Citek, Chair of Subcommittee 2, projected the written subcommittee report for view by the Z80 Committee. Key points were covered by Dr. Citek. The Z80 Committee is hereby referred to the SC2 Subcommittee report included as a portion of these minutes.

SC3: Mr. Nick Mileti, Chair of Subcommittee 3, had to leave the meeting and Dr. Karl Citek gave the SC3 report in his stead. The Z80 Committee is hereby referred to the SC3 Subcommittee report included as a portion of these minutes.

SC4: Dr. Carl Tubbs, Chair of Subcommittee 4, projected the written subcommittee report for view by the Z80 Committee. Key points were covered by Dr. Tubbs. The Z80 Committee is hereby referred to the SC4 Subcommittee report included as a portion of these minutes.

SC6: Dr. William Brown, Chair of Subcommittee 6, projected the written subcommittee report for view by the Z80 Committee. Key points were covered by Dr. Brown. The Z80 Committee is hereby referred to the SC6 Subcommittee report included as a portion of these minutes.

SC7: Mr. Quido Cappelli, Chair of Subcommittee 7, projected the written subcommittee report for view by the Z80 Committee. Key points were covered by Mr. Cappelli. The Z80 Committee is hereby referred to the SC7 Subcommittee report included as a portion of these minutes.

Because important meetings in the contact lens field will conflict with the ANSI Z80 meetings of the coming August, the CL Subcommittee agreed to meet in the Washington, D.C. area on July 31 and August 1, 2015. Dr. Benjamin would report the results of this meeting of SC7 at the ANSI Z80 Plenary session on August 25. Mr. Jeff Endres volunteered the conference room at the Vision Council in Alexandria for the site of the SC7 meeting. Dr. Benjamin will follow up on this offer for SC7.

Mr. Charles Campbell discussed his reservations regarding a proposed addition on the measurement of multifocal contact lenses to ANSI Z80.20, and Dr. William J. Benjamin joined in on the discussion.

Dr. Benjamin brought up a discussion regarding a common problem evident in the reports of today, discussed also in the SC7 meeting, about the proper manner in which to date standards as normative references. That is, in the report of SC1, SC3, and SC7, there was an inconsistency in citing the exact date of the standard or leaving the standard undated. In the former, the normative reference would be limited to the standard as of the date cited; and in the latter, the normative reference would automatically update with the publishing of updated versions of the standard. The latter would apply, as well, to updated normative references of standards cited as normative references. Dr. White took on this issue as a topic for review by the ANSI Z80 Steering Committee.

SC8: Mr. Jeff Endres, Chair of Subcommittee 8, reported on the activities of SC8 and the importance of data interface exchange. The Z80 Committee is hereby referred to the SC8 Subcommittee report included as a portion of these minutes.

- **Information Reports**.

ANSI Z87: Mr. Richard Whitney, the Z80 representative for the ANSI Z87 Committee, reiterated that the Occupational Safety and Health Administration (OSHA) had recognized the 2010 version of ANSI Z87. The Z87 Committee is now revising the 2010 standard to have it ready for voting later on this year. One modification being made is regarding the thickness requirements for test specimens.

FDA: Mr. Don Calogero, lead representative for the US Food & Drug Administration, reported that the FDA had recognized ANSI Z80.27 on Implantable Glaucoma Devices. He was very concerned with the ISO Draft International Standard (DIS) on endotamponades that had gone to a Final DIS (FDIS) still needing much substantive attention.

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 ISO/TC94/SC6 Liaison Report included as a portion of these minutes.

US TAG for ISO/TC172/SC7: Mr. Jeff Endres, the US TAG Leader for SC7, reported that he had heard of nobody that had received a letter of invitation from China, a necessary requirement for obtaining a VISA and attendance of the SC7 meeting in Shanghai, China, on May 11-15, 2015. This problem is not only happening in the USA because the French and Germans have not received invitations either. This is of great concern and he will be checking on this repeatedly upon his return to the Vision Council offices following this meeting.

Regarding the requirement for a copy of one's passport in order to obtain a VISA, there has been a question about the extent of the copy that is needed. That is, must one supply a copy of the entire VISA or merely of the front photo page? Mr. Endres reported that he had recently been to China and he obtained a VISA using only the copy of the front photo page. Those requiring a VISA for China will have to judge their submission accordingly.

- **Next Meetings**:

  ISO ISO/TC172/SC7: May 11-15, 2015; Shanghai, China.
  ANSI Z80: August 24-26, 2015; Westin Hotel, Alexandria, Virginia.
  ANSI Z80: March 6-8, 2016; Sheraton Sand Key, Clearwater Beach, Florida.

- **New Business**: Dr. Citek called for a motion to have the draft revision of Z80.3 voted on by the ANSI Z80 membership. A summary of the changes to the current Z80.3 is included with these minutes. The motion was made by Mr. Calogero, seconded by Dr. Tubbs, and unanimously approved. No other new business was brought forward by the Z80 Committee.

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

Respectfully submitted,
WJB

Spring Meeting ASC Z80; March 2-4, 2015
Legal Report
Rick Van Arnam, Esq.
Counsel to ASC Z80

A. CIRCULAR A-119

1. Circular A-119, the document issued by the Office of Management and Budget that states that federal administrative agencies, like the FDA, are to favor voluntary standards over those written by the government, is being revised.

    a. The revisions, which were published for comment, as drafted seek to state a preference for voluntary consensus standards over voluntary non-consensus standards.

    b. The revisions also seek to improve transparency in the standards making process and to get more involvement from the federal agencies.

2. About a week ago I spoke with the person at OMB handling the revision process:

    a. The comments (including ASC's comments) are still being reviewed.
    b. Expect the revisions to be published in final form this summer.

B. FDA'S 21ST CENTURY CURES LEGISLATION

1. This is a piece of proposed legislation that could have an impact on our standards writing activity. The legislation seeks to alter the way that medical devices and pharmaceutical products are regulated in the U.S. by promoting the discovery, development and delivery of new treatments and cures.

2. In January 2015, the US House of Representatives' Energy and Commerce committee released a "discussion draft" of the bill.

    a. http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Analysis/Cures/20150127-Cures-Discussion-Document.pdf

    b. This is a 400 page document, and is chock full of various proposals, clearly not all of which will make it into a final bill.
    c. The discussion draft was circulated by Fred Upton R-MI. While the concept of FDA reform is supported by both parties, Diana DeGette, D-Co, the intended co-sponsor, did not sign off on the release of the discussion draft.

3. In a nutshell, and as it relates to medical devices (which will include ophthalmic optics medical devices) the goal at this time is to get agreement on legislation that will do a number of things. One example found in the draft document is proposed language whereby the assessment process of low risk devices could be moved from the FDA to independent 3rd party review boards.

    a. Thus, it would be similar to the European process, which utilizes independent and authorized "notify parties" for CEN compliance.

4. The discussion draft includes some important language that will impact performance standards necessary to promote safety.

    a. The draft language would require the FDA to recognize the utility of a privately-developed standard necessary to promote safety within 60 days of the publication of the standard.

    b. Or, if the agency determines not to recognize the standard, then it also has 60 days to publish in the Federal Register its reason for not recognizing the standard

c. The goal is to make it easier for device manufacturers to look to established standards when developing products

d. But, is 60 days a reasonable amount of time to give the FDA to review the standard?

5. The discussion draft also includes language calling for the FDA to provide training to its employees on the use of standards. This training would occur upon being hired, and annually thereafter.

6. What is the likelihood of this draft making its way to final form?

    a. As mentioned above, the draft is 400 pages long and has lots of different proposals in it. So the bill is likely to be changed before moving forward.

    b. The changes would need funding, so that is a stumbling block.

    c. And you'll need the votes. Need I say more with today's Congress?

Z80 Standards Development Status Details Spring 2015

Number	Title	Publication Date	Next Action Date
Z80.1	Prescription Spectacle Lenses	4/28/2010	4/28/2015
Z80.2	Physical, Mechanical Properties	NEW	TBD
Z80.3	Sunglasses and Fashion Eyewear	6/7/2010	6/7/2015
Z80.5	Frames	4/20/2010	4/20/2015
Z80.7	Intraocular Lenses	08/02/13	08/02/18
Z80.9	Low Vision Devices	5/13/2010	5/13/2015
Z80.10	Tonometers	10/30/2009	10/30/2014
Z80.11	Laser Systems for Corneal Reshaping	8/9/2012	8/9/2017
Z80.12	Multifocal Intraocular Lenses	4/20/2012	4/20/2017
Z80.13	Phakic Introcular Lenses	4/20/2012	4/20/2017
Z80.14	Ophthalmic Viscosurgical Devices	NEW	TBD
Z80.17	Focimeters	03/14/13	03/14/18
Z80.18	Contact Lens Care Products	10/25/2010	10/25/2015
Z80.20	Contact Lenses	12/6/2010	12/6/2015
Z80.21	Visual Acuity Charts	5/27/2010	5/27/2015
Z80.23	Corneal Topography Systems	11/29/2013	11/29/2018
Z80.24	Information Interchange for Ophthalmic Equipment	4/16/2012	4/16/2017
Z80.27	Implantable Glaucoma Devices	1/31/2014	1/31/2019
Z80.28	Standard for Reporting Optical Aberrations of the Eye (Instrument SC)	3/12/2010	3/12/2015
Z80.29	Accomodative Intraocular Lenses	NEW	x
Z80.30	Toric Intraocular Lenses	3/24/2010	3/24/2015
Z80.31	Ready Readers	7/25/2012	7/25/2017
Z80.32	Methodology for Representation of Optically-Induced Visual Phenomena	NEW	x
Z80.34	Information Interchange Billing and Billing Reimbursement	NEW	x
Z80.35	Extended Depth of Focus	NEW	x

	Officer Elections	Elected	Re-Election
Chair	Tom White	Feb-12	Mar-15
Vice-Chair	Quido Cappelli	Oct-11	Oct-14
Secretary	Joe Benjamin	Feb-14	Feb-17

ASC Z80 Committee Budget 2014/15

Income	2014 Proposed Budget	2014 Actual	2015 Proposed
Z80 Member Dues x19	$ $27,000.00	$ 26,803.00	$29,450.00
Standard Sales Royalties	$ $8,000.00	$ 5,447.00	$5,000.00
Total Income	$ $35,000.00	$ 32,250.00	$34,450.00
Expenses			
ANSI and ISO Dues	$ $19,000.00	$ 13,395.	$19,000.00
Z80 Mtg Expense	$ $9,000.00	$ 8,509.00	$9,000.00
Z80 Travel Expense	$ $2,500.00	$ 3,309.00	$2,500.00
Z80 Legal Counsel	$ $2,500.00	$ 3200.00	$2,500.00
Z80 Insurance Expense	$ $1,000.00	$ 1000.00	$1,000.00
Z80 Misc.	$ $1,500.00	$ 636.90	$1,500.00
Total Expense	$ $35,500.00	$ 30,049.90	$35,500.00
Net Income	**$ -500.00**	**$ +2201.00**	**$ 950.00**

ANSI Z80.1 Spectacle Lens Subcommittee
Sheraton Clearwater Beach Hotel, Clearwater Florida
Bay Room

Tuesday, March 3, 2015

8AM – 11AM
Dick Whitney – Chair
Rick Tinson – Vice Chair

Status of ANSI Z80.1-2015

1.) PINS vote extended to March 11 by Dr. White due to lack of votes
2.) 7/20 voted, 11 are needed.to proceed to vote on Standard
3.) Reviewed Jan 2015 working document of ANSI Z80.1 provided by Drafting committee (Rick Tinson, Karl Citek, Tom Hicks);
4.) The committee made additional modifications in SC1 Mar 3, 2015 meeting.
5.) Final document completed by SC1 to be provided to Amber within 30 days
6.) April 28, 2015 originally the goal but we are permitted to extend
7.) Expect voting and ANSI processing to mean that the ANSI Z80.1 -2015 Standard will likely be published by July of this year.

Overview of changes agreed upon in SC1 Mar 3 meeting included:

- Summary of changes table modified for easier read
- Scope and Purpose – some editorial changes made but not impacting meaning or PINS voting (copied below)
- Modified cyl axis tolerance table to align with ISO, where cyl powers <.12 are explicitly noted as having no axis tolerance
- Drawings for Impact Fixtures and Inspection method updated with clean newer identical versions provided by Mike Vitale
- Reviewed and confirmed wording on tolerances for Compensated Rx
- Updated Appendix D (Summary Table)

Excerpts from SC1 committee approved 3/Mar/15 document:

Summary of Changes to ANSI Z80.1 for 2015

This 2015 revision represents the most current consensus of experts in this field. The changes from the 2010 standard are the result of a thorough study by the ANSI Z80.1 committee of the relevance and applicability of its contents.

This publication includes modifications to several portions of the standard that had not been updated for some time:

- *The Scope and Purpose sections were both reworded to better reflect how the committee believes the standard should be used in today's environment.*
- *The definitions area was reviewed with changes and modifications.*
- *"Position of Wear" definitions were added in a new annex E for informational purposes, in order to help instruct others on 3 terms commonly used in this area. These terms are becoming more commonplace with growing popularity of newer fabrication technologies and lens designs.*
- *A further clarification of how tolerances should be applied to compensated lenses was added in the optical requirements section.*
- *A voluntary permanent lens marking standardized character (^) was added as a recommendation, to be applied on lenses that contain such compensation.*
- *Other modifications to the marking guidelines were also made.*
- *Another new addition to the standard was included in the area of transmittance, where a recommendation for minimum transmittance when driving was added. The new section provides guidance and is intended to harmonize with ANSI Z80.3 requirements in this area.*
- *Reference to orientation of polarization axis was added.*
- *The "FDA Impact" guidelines were again included, with an additional sentence added to refer the reader to the specific authoritative source which should be referenced on this topic, the Federal Register.*

Scope and Purpose

Scope

This standard applies to all prescription dress ophthalmic spectacle lenses in edged or assembled form. It is a guideline for entities that fabricate, assemble or process dress eyewear or lens components. Relevant optical and physical specifications and tolerances of this standard also apply to uncut lenses.

This standard does not apply to products covered by

- *American National Standard for Ophthalmics – Nonprescription Sunglass and Fashion Eyewear Requirements, ANSI Z80.3*
- *American National Standard for Ophthalmics – Specifications for Single Vision Ready to Wear Near Vision Spectacles, ANSI Z80.31*

- *American National Standard for Occupational and Educational Personal Eye and Face Protection Devices, ANSI Z87.1*
- *ASTM F803, Eye Protectors for Selected Sports*

Purpose

This standard reflects the shift in utilization from mass-produced lenses to a basic dependence upon custom-processed lenses. It provides minimum acceptable tolerances for new lenses prepared to an individual prescription.

The power, prism, and axis tolerances established in this standard are subject to measurement limitations associated with the accuracy and repeatability of the current state-of-the-art focimetry and other measurements commonly in use by laboratory technicians and eyecare professionals. Users should therefore take into account the measurement capability of the devices (and methodology) when applying tolerances to the spectacle lens. As such, this voluntary standard expresses technical concepts that provide a frame of reference for safety and effectiveness.

ANSI Z80 SC2
Non-Prescription Eyewear Subcommittee Meeting
March 3, 2015, 11:00 AM-3:00 PM
Sheraton Sand Key Resort, Bay Room
Clearwater, Florida

1) Call to order: 11:22 AM — Karl Citek

2) Introductions & introductory comments — Karl Citek

3) Acceptance of Agenda — Karl Citek

4) Minutes from the August 25, 2014 meeting accepted — Karl Citek

5) Review and discussion of Z80.3 draft — Karl Citek
   Revisions reviewed, discussed, and approved

6) Other business — Karl Citek
   Considerations for review of Z80.31 at Fall meeting:
   a) Incorporate "plano carrier readers"
      i) non-prescription plano carrier which complies with applicable sections of Z80.3
      ii) segmented add which complies, for each lens and for the complete spectacle, with applicable sections of Z80.1
   b) Incorporate "sun readers", either as single vision or plano carrier reader, complying with applicable sections of Z80.3
   c) Investigate incorporating "progressive readers"

7) New business: None

8) Adjourn: 2:32 PM — Karl Citek

SC3 Meeting Minutes – Mr. Nick Mileti Chair
March 3, 2015

- Call to order: 2:30 PM EST
- Introductions
- Acceptance of agenda
- Meeting minutes August 2014 accepted
- Review for new attendees of the adoption vote for ISO 12870, 7998 and 8624.
- Committee completed three applications to adopt the above standards.
- No new business was brought up
- Adjourn: 3:30 PM

March 3rd, 2015
ANSI SC4 Subcommittee Report-
Clearwater, Florida
Dr. Carl Tubbs, SC4 Chair
Z80.30 (toric) and Z80.35 (Extended Depth of Field) Lenses

The SC4 subcommittee met on Tuesday March 3rd from 8 AM to 5 PM.
The mainstay of discussion concerned EDF lenses (Extended Depth of Field), which is a novel standard without any ISO counterpart. Also, a discussion of and plan for revision of Z80.30 (toric IOL standard) was set.

The meeting was opened, introductions and sign-in sheets were completed, callers-in by phone identified, and the meeting started.
See attached sheet for participants present in the meeting room. Phone attendees will email Amber to confirm their attendance and contact information.

Z80.30:
The toric standard is up for a normal 5 year review. As such, a PINS was requested and approved at the Fall 2014 ANSI meeting. There have been no requests to open the Z80.30 standard otherwise. To address the standard renewal, the EDF group decided to ask Amber to send each member of the EDF group a copy of the Z80.30 standard in order to review it to see if changes need to be made, or if the standard can be reaffirmed as is. There will be established a sub-group of the EDF members who will be active in evaluating Z80.30. If the group elects to reaffirm the standard, then the standard will be sent to additional IOL experts for review. If there is no request to review, the standard will be sent to vote to reaffirm; otherwise, Z80.30 will be opened for revision.

Z80.35:
A leader and sub-leaders were elected. Sanjeev K. will lead the main group, while Charles Campbell will manage the optical objective testing workgroup, and Raj Suryakumar will lead the clinical optical assessment group. It is expected that most of the work will involve bench and clinical testing and definitions of IOL function, with the expectation that optical testing will assist in predicting clinical functioning.

There was some discussion on minor changes in the scope of the draft. It was felt that such changes would not be material enough to require re-vote on the project itself.

Don and Gene from the FDA were kind enough to take the accommodative IOL standard as a starting point, and design a framework for the EDF standard. Don relayed specific recommendations from the AAO taskforce (formed to deal with premium IOL endpoints) that should be incorporated into the standard.

It was determined that the EDF standard would be attempted to be formulated so that it would, in many cases, allow a type "B" category for approval. For example, if there is a parent lens onto which an EDF modification were being made, and it was NOT expected to cause glare and flare issues (unwanted visual effects), then a smaller clinical study would suffice. If there is no parent IOL or if there is a risk assessment predicting significant potential unwanted visual effects, then a standard thorough clinical assessment would be needed.

The standard was then read through with discussion on each point. Workgroups were established to clarify and make recommendations on points that were unclear or needed additional revision. Interim meetings will be held before the next ANSI meeting in the fall of 2015.

Some Action Items- Minor adjustments in the Scope of the Document-

Review of clinical optics, testing methods and wavelengths, use of eye models
Review and clarification of clinical testing, methods and relevance
Revision of primary standard from today's review and discussion.
Distribution and receipt of comments on revised draft from EDF members.
Establishment of conference calls in interim before Fall 2015 meeting.

Concerning the AAO taskforce on premium IOL endpoints, Don asked the group to ask all industry members and corporate sponsors to send information to the AAO taskforce for consideration. Input is needed.

Contacts for this put to the AAO IOL taskforce are:

Mark Leahey	MDMA	mleahey@medicaldevices.org
Flora Lum	AAO	flum@aao.org

Respectfully,

Carl Tubbs, MD

ANSI Z80 SC6
Instruments & Low Vision Devices Subcommittee Meeting
March 3, 2015
Clearwater Beach, FL

1. **Attendees:** Charles Campbell, Bruce Drum (FDA), Priya Janakiraman (Abbott Medical Optics), Thomas White (Am Acad Ophthalmol), Sharon Miller (FDA – by conference call), Bill Brown (Am Optom Assoc)
2. **Status of Standards under SC6 oversight**
   - **Standards recently revised**
     - Z80.17-2013 Focimeters – revision deadline 3/14/18
     - Z80.23-2013 Corneal topography – revision deadline 11/29/18
   - **Standard just published**
     - **Z80.10 - 2014** Tonometers –Published 2/12/15
   - **Standards in approval process**
     - Z80.21- 2010 Visual acuity charts
       – Revision deadline 5/27/15
       – Committee reballoting closes 3/11/15
       – Public review closes 4/13
     - Z80.28 - 2010 Methods for reporting optical aberrations of eye - PINS ballot passed, document ready to submit for ballot
     - Z80.9 - 2010 Ophthalmics - Devices for low vision
       – Revision deadline 5/13/15
       – Public review ends 3/9
       – A few editorial comments received during balloting were accepted.
   - **Inactive standards**
     - Z80.19-Endoilluminators
     - Z80.25-Fundamental Requirements and Test Methods for instruments

Subcommittee for Contact Lenses

Sand Key, Clearwater FL

ANSI Z80 CONTACT LENS SUBCOMMITTEE: CONTACT LENSES and CARE PRODUCTS

Tuesday, March 3, 2015 9:00 am – 4:05 pm

Opening of the Meeting of ANSI Z80 CL Subcommittee: Contact Lenses and Care Products and the US TAG TC172/SC7/WG9.
The Z80 Contact Lens Subcommittee meeting was opened at 9:00 am, Tuesday, March 3rd, A sign in sheet was distributed for attendees to document their participation.:

Roll Call of ANSI Z80 Contact Lens Subcommittee Experts in Attendance. Each person identified themselves to the group in turn around the meeting table. The participants were:

Quido Cappelli,	Contact Lens Manufacturers Association
William J. Benjamin	American Optometric Association
Glenn Davies	Bausch & Lomb, Inc.
Paul Ludington	Bausch & Lomb, Inc
Denise Hampton	Food and Drug Administration
Steve Galas	Johnson & Johnson Vision Care
Richard Courtney	Johnson & Johnson Vision Care
Carol Lakkis	Johnson & Johnson Vision Care
Scott Durland	Johnson & Johnson Vision Care
Ralph Stone	R. P. Stone Consulting
Mary Mowry-McKee	Alcon Laboratories
Manal Gabriel	Alcon Laboratories
Karen Sentell	Alcon Laboratories
Roya Borazjani	Cooper Vision Corporation
Samuel Puig	Cooper Vision Corporation
Priya Janakiramon	Abbott Medical Optics

The following personnel from the Food and Drug Administration participated by conference phone

Jeffrey Brocious	Lamont Booker	Dan Fedorko
Chandramallika Ghosh	Angelo Green	Joseph Hutter
Scott Steffen		

1. **5 Year Review of Z80.20**
   An attempt was made to begin the process of reviewing the proposed changes to Z80.20. However, a number of the members of the subcommittee did not receive the proposed changes that were circulated by the Chairman and it was decided to delay this process until the end of the meeting.

2. **5 Year Review of Z80.18.**
   Mary Mowrey McKee then conducted a line by line review of a proposed revision to Z80.18. Comments and corrections were made. Without an agreement on the question of including the date to many references (mostly ISO Standards) it was the consensus of the subcommittee to recommend the resultant draft standard as a candidate for the revised version of Z80.18 after some minor questions were resolved. A show hands indicated that a small majority of the subcommittee favored proceeding with the standard by omitting the date of many standards in the Normative Reference section since new versions of those standards would greatly affect the revised Z80.18. It was left for further discussion with ASCZ80 to decide this question.

3. **Acanthamoeba Progression:**
Mary Mowrey McKee presented a draft of a Method for evaluating disinfecting efficacy by contact lens care products using trophozoites of *Acanthamoeba* species as the challenge organisms. The subcommittee reviewed and made changes to the draft and it was decided to offer the draft to ISO for inclusion in international standards.

4. **TC/172/SC7/WG9 Meeting in Shanghai, May 2015**
Joe Benjamin presented the list of expert delegates to the Shanghai meeting and reviewed the various personnel assigned to the Project Groups as follows:

ANSI Z80 CL Subcommittee Delegation to Shanghai, for May 11-15, 2015

ANSI Z80 CL Delegation Leader: Dr. William J. Benjamin

The following are named as Experts to ISO TC172/SC7/WG9:

Roya Borazjani
Glenn Davies
Manal Gabriel
Carol Lakkis
Samuel Puig
Ralph Stone
James Cook
Steven Galas
Joseph Hutter
Mary Mowrey McKee
Karen Sentell

The following are named as Observers to ISO TC172/SC7/WG9:

W. Joe Benjamin
Paul Ludington
Chandramallika (Molly) Ghosh
Shawn Lynch

The following table contains the names of the members from the lists of Experts and Observers who are authorized to serve in the designated Project Group in the capacity shown:

Project Group **FINALIZED** **Meeting Date & Time**	**Project Leader**	**ANSI Z80 CL SC Designated Experts**	**Project Leader Designated Expert**	**ANSI Z80 CL SC Observers**
PG 18369-1 Monday 05-11-2015 9:00am – 12:30pm	Michael Port	Steve Galas Joseph Hutter Karen Sentell Ralph Stone	Paul Ludington	W. Joe Benjamin Samuel Puig Manal Gabriel
PG 18369-2 Monday 05-11-2015 1:30 – 5:00pm	Michael Port	Glenn Davies Steve Galas Samuel Puig Karen Sentell	Paul Ludington	Joseph Hutter Carol Lakkis Ralph Stone Manal Gabriel
PG 18369-3 Tuesday 05-12-2015 10:30am–12:30pm and 1:30–5:00pm, if needed	Michael Port	Steve Galas Samuel Puig Ralph Stone	Paul Ludington	Glenn Davies Joseph Hutter Karen Sentell
PG 18369-4 Tuesday 05-12-2015 1:30 – 5:00pm	Michael Port	Steve Galas Joseph Hutter Ralph Stone	Paul Ludington	W. Joe Benjamin Samuel Puig Karen Sentell

PG 19979 Trial Lenses Tuesday 05-12-2015 10:30am – 12:30pm	Imre Kovats	Roya Borazjani Manal Gabriel Carol Lakkis Mary M. McKee		Glenn Davies Shawn Lynch
PG 18189 Cytotoxicity Tuesday 05-12-2015 1:30 – 5:00pm	Molly Ghosh	James Cook Manal Gabriel Mary M. McKee Carol Lakkis	Shawn Lynch	Roya Borazjani Joseph Hutter
PG 19045/Microbiology Wednesday 05-13-2015 9:00am – 12:30pm	Mary M. McKee	Roya Borazjani James Cook Manal Gabriel Carol Lakkis		Molly Ghosh Shawn Lynch

It was explained that W. Joe Benjamin, Shawn Lynch and Molly Ghosh would not be able to attend the meeting and provision was made to substitute Mary Mowrey McKee wherever possible.

It was announced that Ralph Stone would act as the Leader of the Contact Lens delegation and the agenda items of the Shanghai meeting were briefly addressed. It was noted that questionable procedures in Working Group level have been noted and possibly some US comments were not handled correctly. Provisions were discussed to look into this matter and the US Delegation Leader will be consulted.

5. Proposed Measurement Method for Multi-Focal Contact Lenses

Paul Ludington presented a method to measure the add powers of various multi focal lenses. The subcommittee accepted the method and it was suggested to incorporate this method into Z80.20 at a later date after the method has been circulated. In the meantime the method will be proposed for ISO consideration.

6. Recognition of Z80.20

Richard Courtney brought the subcommittee up to date on the recognition by FDA of Z80.20 that had been withheld.

7. Closure of the Meeting.

The next meeting of the subcommittee was announced as August 24-26, 2015 in Alexandria VA. It was brought to the attention of the Subcommittee that a number of its members would be unable to attend due to date conflicts. W. Joe Benjamin proposed an Interim Meeting of SC7, July 31 – August 1 in the Washington, DC area. This was accepted pending the procurement of hotel space and a suitable number of attendees.

There being no further business, the meeting was brought to a close at 4:05 PM.

Report SC8 Information Interchange
ASC Z80 Spring 2015

1. ASC Z80.24/ISO Mirror "ISO 16284"
    - Currently in draft phase in preparation for Shanghai

2. ASC Z80.34 Billing Reimbursement

Executive Summary
To create a uniform communication standard for data interchange between participating entities as applies to the financial and benefits transaction, as well as manufacturing data, for the vision portion of medical services and under the auspices of ANSI X12 using an augmented ASC X12 837P EDI format.
Beneficiaries and effected parties to such a standard development include:

- Patients and Practitioners
- Insurance providers
- Service Providers – optical and testing laboratories
- Manufacturers and Material suppliers – frames, lenses, inter-oculars, consumables
- Medicare/Medicaid, Federal and State governments, institutional employers

Long Term Goal - Mirror Pharmacy
Over the last 15 years the pharmacy community has developed a highly organized and universally beneficial data communication scheme to the benefit of all users and patients. The goals for the program are to mimic this success and bring the following features to the community:

- Vision specific transaction
    - Fields for additional data, including manufacturing information
    - Formatting in a manner that allows for data (possibly in an XML format) to be inserted into X12 format. The technical feasibility of this remains under review.
- HIPAA compliance
- Improvement Of the Experience For all participants
- Creation of a new set of transactions that encompass member benefits and eligibility and today's data requirements
- Achieve framework for eventual "real-time" Dynamic Transaction experience without breaking our current methodology
    - This could include a small level of core benefit information such as co-pays, allowances and frequency
- Provide an electronic non-binding claim calculation that is the key to achieving our goal of dramatically improving the member experience while reducing the transactional cost associated with insured benefit adjudication

- With the pre-authorization received, the provider creates the order in detail, and a summary version of the 837V is sent to the insurer with all of the manufacturing information included in one of the currently accepted formats.
- The insurers system can then interpret the product that is being supplied to their member and calculate insured payment, member payment & contractual discount along with the insurer specific coding that their systems are expecting in order to adjudicate the claim.

Status

- The current phase of work resides in the X12 Committee
- Until such time as NWIP's are proposed and accepted by X12, the needed "touch points" do not exist such that the current ANSI Z80.24 standard can be made to "pair" with the X12 as it now exists
- This effort is now lead by the NAVCP who has joined the X12 group
- We are looking at 18 months until additional work can be done

ICS® INC. LABORATORIES

Liaison Report of ISO/TC 94/SC 6 "Eye and Face Protection" to ANSI Z80

Sand Key, FL, March 4, 2015

The full committee of ISO/TC94/SC6 and its working groups last met in London, UK June 16 – 20, 2014. Thirty six delegates representing ten countries (*plenary)* were present. Six delegates from the U.S. were present. The next meeting of SC6 and its working groups is scheduled the week of June 22nd, 2015 in Paris, France.

WG Activity Summary
WG1 – Definitions:
Editorial and technical comments are being collected on ISO 4007 for future revision
UV-A is still being debated as to included 400nm as "an alternate"

WG 2 – Test Methods:
With ISO 12311 being promulgated, the WG is focusing their support on product standard documents from WG4 (Occupational) and WG 5 (Sports and Recreation).
Three supporting test method documents are currently being worked on:

- ISO 18256-1 Occupational and Sports Geometric Optics Test Methods
- ISO 18256-2 Occupational and Sports Physical Optics Test Methods
- ISO 18256-3 Occupational and Sports Physical and Mechanical Test Methods

WG 3 – Sunglasses
The WG is currently finalizing ISO12312-2 - Eye Protection for Direct Observation of the Sun (FDIS vote)

WG 4 – Occupational Eye and Face Protection:
Work has resumed on ISO/CD 16321 under a new convenor. The PWI draft is being revised according to comments received and meetings held in December of 2014.
Work continues within the joint IEC/ISO WG for eye and face protection against laser radiation.
The WG met last in Tokyo in November.

WG 5 – Sports Eye and Face Protection
The newly reformed WG has two standard to be released as NWI proposals:
- ISO/PWI 18527-1: Draft Standard for Skiing Goggles.
- ISO/PWI 18527-2; Draft Standard for Eye Protection for Racquet Sports.

Respectfully submitted,
Dale B. Pfriem
Chair, US TAG to ISO/TC94/SC6
c/o ICS Laboratories, Inc.

Summary of Changes to Z80.3 for Voting in 2015

Foreword

Inclusion of all organizations and representatives on ASC Z80, and all who participated and contributed to SC2 since the last revision (consistent with SC1 for Z80.1).

1.1 Scope

Reference to ASTM F08.57 Committee, rather than individual ASTM standards (such as F803) for sports protective eyewear.

1.2 Purpose

Previously accepted (Spring 2014) change in language to lenses used for driving.

Included lenses for observing the sun as not being covered by this standard (consistent with ISO 12312).

Reference to ASTM F08.57 Committee, rather than individual ASTM standards (such as F803) for sports protective eyewear.

2 Normative References

References updated to be more inclusive.

Publication dates removed to encourage reliance on most recent editions, rather than specific versions (consistent with draft for Z80.1).

3 Definitions

Removed definition of, and reference to, optical density throughout standard; replaced with reference to luminous transmittance.

3.2 Geometric center

Added determination of geometric center location for one-piece or goggle lenses.

3.4.5 Special purpose lenses

Added definition of very dark lens.

3.8.3 Ultraviolet mean transmittance

Included “ultraviolet” in the heading, since that is the only radiation to which “mean transmittance” is applied in this standard.

3.10 Uncut lens

Changed heading to a more general term. Changed definition to be consistent with Z80.1.

4.4 Frame finish

New section, based on discussion in Fall 2014.

4.5 Frame corrosion

New section, based on discussion in Fall 2014.

4.6 Frame material safety to health of wearer

New section, based on discussion in Fall 2014.

4.7 Frame deformation and retention of lenses

New section, based on discussion in Fall 2014.

4.8 Cosmetic quality of lenses

Changed to be consistent with Z80.1.

4.9.3 Prismatic power imbalance

Removed reference to prism power for individual or unmounted lenses.

Included reference to ISO 12311 for prism imbalance determination in finished eyewear.

Retained tighter US tolerances.

4.10.3 Ultraviolet mean transmittance

Same as 3.8.3.

4.11.3 Gradient tint lens

Changed tolerances to relative percentages.

Increased minimum transmittance requirements.

4.11.4 Uniform tint lens

Changed tolerances to relative percentages.

4.12 Tint imbalance between lenses

Changed tolerances to relative percentages.

4.13 Axis of polarization

New section, similar to section in Z80.1 draft.

5.3 Ignition test

Changed heading name, based on discussion in Fall 2014. Changed test procedure to be consistent with ISO 12870 (“hot rod test”).

5.4 Corrosion resistance test

New section, based on discussion in Fall 2014.

5.5 Cosmetic quality test

Changed wording to be consistent with Z80.1.

5.7.3 Ultraviolet mean transmittance

Same as 3.8.3.

Figure 5 – Recommended system for visually inspecting lens for defects

New figure, consistent with Z80.1.