ASC Z80
Parent Committee Meeting
February 27, 2018, 8:30 AM-12:00 Noon
Sheraton Sand Key Resort, Beach Room
Clearwater Beach, Florida

Minutes

Attendees	Representing
Dr. Tom White* (chair)	American Academy of Ophthalmology
Neil Roché (vice chair)	The Vision Council/Essilor
Dr. Karl Citek* (fill-in secretary)	American Optometric Association
Rick Van Arnam (legal counsel)	The Vision Council
Michael Vitale* (secretariat)	The Vision Council
	US Sub-Leader to ISO TC172/SC7
	Advanced Medical Technology Association (proxy)
	Opticians Association of America (proxy)
	Sunglass Association of America (proxy)
Ramzi Ari	Essilor
Lauren Bianchi	Marchon
Dr. Bill Brown	American Optometric Association
Carl Buckholt	Luxottica
Donald Calogero*	FDA CDRH/Division
Charlie Campbell	
James Cook	J&J Vision
Manal Gabriel	Alcon
Sanjeev Kasthurirangan*	J&J Vision
Adam Mancuso	Marchon
Nick Mileti*	National Association of Optometrists & Opticians/ Luxottica
Mary Mowrey-McKee	RP Stone Consulting
Dale Pfriem	ICS Labs
Lyle Rubin*	American Ceramic Society/Corning
Dr. Ralph Stone*	RP Stone Consulting
Jennifer Streza	CooperVision
Raj Suryakuma	Alcon
Neil Torgerson*	Optical Laboratory Association (proxy)/Walman
Dr. Carl Tubbs	American Academy of Ophthalmology
Paul Wade	The Vision Council
Dick Whitney	Carl Zeiss Vision
Greg Williby	J&J Vision

*voting member or proxy

1. Call to order – Dr. White

8:32 AM

Introduction of attendees

2. Roll call – Mr. Vitale

13 of 20 voting members or proxies present.

3. Acceptance of Agenda – Dr. White

Change "Spring" to "Fall" in Item 4. Slight change in order of Subcommittee reports to allow for early departures. Amended agenda accepted.

4. Acceptance of minutes from the Fall 2017 Parent Committee meeting – Dr. White

Minutes accepted.

5. Chairman's comments – Dr. White

Welcome and thank you to everyone for their participation in the standards process. Work and efforts of all are appreciated. Best wishes to Dr. Joe Benjamin, who could not attend this meeting.

6. Vice Chairman's comments – Mr. Roché

Thank you for a good meeting, lively discussions, and good, effective governance.

7. Legal Counsel's report – Mr. Van Arnam (see Annex 1)

Highlighted procedure changes following audit by ANSI. Recommendations include calling roll at meeting, allowing for proxies, opening ballots for 30 calendar days rather than 6 weeks, conforming ASC Z80 procedures with those of ANSI, e.g., appeals process, patent policy, antitrust compliance policy.

8. Secretariat's report – Mr. Vitale

20 voting members. 7 past due invoices from 2017, but The Vision Council had not followed up prior to this meeting; all have now been notified and are in the process of paying their dues.

190 standards sold last year. Royalties of about $30K, member dues about $16K; ANSI & ISO dues of about $16K, meeting expenses of about $13K, Z80 administration and other expenses about $16K; net loss of $100 for 2017.

Proposed budget for 2018 provides for net income of $2K. For the first time in many years, member dues will increase, going from $1,550 to $1,800 per year. The intent is to not have another increase for several years.

Press releases will now be issued for any standard that is published; one went out today highlighting 8 standards published or reaffirmed in 2017. The press releases can be found at Vision Monday's website, www.visionmonday.com.

Audit by ANSI went very well. Auditor spent only 6 hours in the office, since Mr. Vitale and Ms. Stolberg either had all requested materials available or readily accessible. In addition to procedural changes mentioned by Mr. Van

Arnam, an improperly documented negative vote on a standard has been addressed and is in the process of being rectified.

OEOSC TAG update: ISO TC172/SC7/WG3 held interim meeting in Southbridge, MA, in September 2017. Over 30 attendees from all over the world. Mr. Whitney and Carl Zeiss Vision were phenomenal hosts.

For upcoming ISO TC172/SC7 meeting in Berlin, Germany, May 14-18, 2018, all SC chairs are requested to forward to Mr. Vitale names of delegates and observers by March 9, 2018.

9. Subcommittee reports

1. SC3 – Mr. Mileti (see Annex 2)

Items in addition to written report:

Since ISO frame standards are now our standards as well, there will be New Work Item Proposals at ISO to begin review and revision of them. Included will be a recommendation for Claim of Dimensional Control and frame marking for proper mounting of lenses.

2. SC6 – Mr. Campbell (see Annex 3)

Items in addition to written report:

MOTION: Reaffirm Z80.17 without revision. Second by Mr. Mileti. Motion passes.

MOTION: Circulate completed Z80.23 for vote. Second by Mr. Mileti. Motion passes.

MOTION: Circulate completed Z80.10 for vote. Second by Mr. Calogero. Motion passes.

3. SC1 – Mr. Whitney (see Annex 4)

No additions to written report.

4. SC2 – Dr. Citek (see Annex 5)

Item in addition to written report:

MOTION: Request PINS to begin review of Z80.3. Second by Mr. Rubin. Motion passes.

5. SC4 – Dr. Tubbs (see Annex 6)

Items in addition to written report:

MOTION: Request PINS to begin review of Z80.12. Second by Mr. Kasthurirangan. Motion passes.

MOTION: Circulate completed Z80.35 for vote. Second by Mr. Suryakuma. Motion passes.

MOTION: Request PINS to begin review of Z80.7. Second by Mr. Kasthurirangan. Motion passes.

Per Mr. Vitale: Z80.30 is completely approved, out for public review, which ends April 2, 2018.

Per Mr. Vitale: with regard to referencing FDA Guidance documents, ANSI responds: "ANSI's procedures do not address what may be referenced or how,

only that the content of the proposed ANS be processed in accordance with a developer's procedures and the ANSI Essential Requirements (www.ansi.org/essentialrequirements). . . [R]efer to other documents published by your organization to determine any past precedent (if this is not addressed in your procedures) and be sure to sufficiently identify the document so that a reader/user understands and can find the document that is referenced. You may also wish to consult the FDA in case there are any government-related rules associated with the document at issue."

6. SC7 – Dr. Stone (see Annex 7)

Items in addition to written report:

Dr. Benjamin is on the road to recovery.

Requirements for European Medical Devices are in the process of being changed, this may affect the US as well. The SC requests that Legal Counsel look into the changes and inform the Committee accordingly.

7. SC8 – Mr. Vitale (see Annex 8)

No additions to written report.

BREAK: 9:59 AM
RECONVENE: 10:20 AM

10. Informational reports

1. ANSI Z87 – Mr. Whitney

Work on new standard Z87.62 on safety eyewear for biohazards is progressing.

Z87.1 has more stringent optical requirements for plano protectors and shields than Z80.1. The Z87 Committee is considering a second level of optical test performance.

2. FDA – Mr. Calogero

Since last meeting, FDA recognized two contact lens standards: Z80.18 in full; Z80.20, all but Clause 5.1 Paragraph 2.

Reorganization of CDRH: ophthalmic devices will merge with other groups, director will be chosen later this year, ophthalmics will include four divisions.

3. ISO/TC94/SC6 – Mr. Pfriem (see Annex 9)

No significant activity since last meeting. Interim meeting was held in December 2017, no dates set yet for another meeting.

4. ISO/TC172/SC7 – Mr. Vitale

Nothing further to report that has not already been mentioned in the Secretariat report.

11. Next meetings – Dr. White

ASC Z80

Fall 2018 – August 19-21 in Clearwater, Florida

Spring 2019 – TBD

ISO/TC172/SC7 – Plenary Meetings

Spring 2018 – May 14-18 in Berlin, Germany

Fall 2019 – US has agreed to host; details forthcoming

12. New business

Dr. White will be stepping down as Chair at the end of this meeting. He thanks everyone for the progress that has been made, for the education he has received, and for the friendships he has forged.

Process for determining new Chair will be provided soon.

(Secretary's note: Thank you, Dr. White, for your many years of service and dedication to this Committee, for the collegiality that you have demonstrated and fostered to all, and for the education that you have provided to us in your role as Chair. You will definitely be missed. We wish you all health and happiness.)

13. Adjourn – Dr. White

10:35 AM

Respectfully submitted,
Karl Citek, OD, PhD
Fill-in Secretary

Annex 1

Legal Counsel's Report
Rick Van Arnam
February 26, 2018
Clearwater Beach, FL

Changes to Official Operating Procedures of Z80

I. Added a reference to proxies, specifically allowing them.

   a. Proxies will be counted toward quorums at specific meetings.

   b. Allow someone to represent another

   c. Form proxy will be incorporated into the Operating Procedures

      i. Allow you to give qualified proxy, directing how to vote on certain issues.

      ii. Or, give unqualified proxy.

   d. Only good for that meeting.

II. Made some time changes.

   a. Letter ballot now due within 30 days from the date of issue; it had been 6 weeks;

   b. Reminder to vote on a ballet will now be sent out 10 calendar days before the ballot closes, not 10 working days.

III. Clarified that replies for requests for an interpretation of a standard would be in writing.

IV. Revised the procedures to be consistent with the ANSI *Essential Requirements* so that appeals will be limited to questions of procedural action or inaction.

   a. No longer will it include appeals based on substantive or technical disagreements.

V. Revised procedures to incorporate by reference the ANSI version of the:

a. Patent Policy

b. Antitrust Policy

c. Commercial Terms and Conditions.

d. This is being done to ensure that our document is consistent with the latest version of the language found in the *Essential Requirements* document.

e. Our document always had these policies.

f. Keeping our antitrust policy document as an annex to our procedures as a ”guidance document” provided for members’ convenience.

VI. Other changes made to conform our document with the ANSI *Essential Requirements* document.

a. Eliminated unnecessary language.

b. Clarified that Z80 will remain reasonably diverse.

i. Expanded reference to avoiding “dominance by a single interest category” to expressly include individuals and organizations.

Annex 2

Frame Subcommittee Agenda
Meeting Minutes
February 26, 2018
Sheraton Sand Key

Meeting call to order

Acceptance August Meeting Minutes

Acceptance of Agenda

- **Review of Interim Southbridge & London ISO TC/172 / WG2 Meeting**
- **N101 A 3D Frame Measurements**


N101 A_3-D measurement.pdf


ISO-TC172-SC7-WG 2_N0245_measureme

- **Review of comments N244**


ISO-TC172-SC7-WG 2_N0244_New_Japar

- **Review of comments related to logo fade**


ISO-TC172-SC7-WG 2_N0243_Fading_of_

- **Dimensional Control Proposal update**
- **Face Form new drawings**


ISO-TC172-SC7-WG 2_N0246_Proposal_t

- **Delegates to ISO – Berlin (2 delegate rule, observer)**

New Business

Adjournment

Meeting Minutes

Meeting called to order, acceptance of August meeting minutes and modification to the Agenda

Review of comments of NWIP for 12870 and 8624:

Frame Labeling

Europe has considerable number of objections for on the frame marking due to Medical Device directives that will impact the proposal. There is consensus to adopt labeling/warning for users of the product in the value stream. The US to provide optional requirement for on the frame label. Additionally, US to propose manufacturers establish value stream users a web site to contain necessary documentation for the frame.

Lens Retention

One country voice opposition to the proposed lens retention test. In discussions with the SC, a recommendation to propose Equivalent Test Method vs. additional test method to be employed.

Effective Diameter

On the whole acceptance of definition of effective diameter, with some editorial comments.

In addition to the three NWIP on the above, SC3 put forward a query to WG2 in August of 2017, on the subject of Frame Dimensional Control.

Response

Overall, WG2 reluctance to add the circumference controls for frames.

SC3 agreed to submit a NWIP 'Claim for Dimensional Control'. This will provide allowance for an optional participation with established tolerances by frame manufacturers.

Additional item being brought up WG2 is around Perspiration Test on Frames 12870, 4.7. Clarification on test process around frame 'logo' – 8 hour (cosmetic) vs material coating / skin contact after 24 hour bio impact. SC3 to provide response on subject indicating the need to provide language to separate the two.

There was a call for New Business – none given.

Meeting adjourned.

Minutes
ANSI Z80 SC6
Instruments & Low Vision Devices Subcommittee Meeting
February 26, 2018
Clearwater Beach, FL

1. Meeting was called to order at 1:00 p.m.
2. Those in attendance in person and via teleconference:
   Charles Campbell, Bruce Drum (FDA) William Brown (AOA), Karl Citek and David Sliney. Dexiu Shi (FDA) joined by teleconference.
3. Agenda was accepted as posted.
4. ANSI Standards published since that last meeting
   Z80.37- 2017 – Slit-lamp microscopes
   Z80.38 -2017 – Light hazards for operation microscopes
   Other ANSI Standard under consideration
   Z80.17- 2018 – Focimeters (re-issued without revision)

5. Revision of Z80.23 –Corneal topography systems

   Work continued on the draft of revision Z80.23 – Corneal topographers – that was started at the August 21, 2017 meeting. The scope of the standard has been changed to include instrument that use interferometric means to measure the corneal surface. The title and scope have been changed to clearly state that this standard covers two basic methods for measuring the corneal surfaces and to give each method a separate name. 'Corneal topographers' are those instruments that use light rays reflected off the anterior corneal surface to make their measurements. 'Corneal tomographers' are those instruments that directly measure the axial height of the corneal surfaces – the anterior surface and for some posterior surface – and use these height measurements to make calculations of the corneal shape. The standard will now be titled Z80.23 – Corneal Topography and Tomography Systems – Standard Terminology and Requirements.

   Some of the wording in the definitions was revised. The word 'elevation'- where it was used to designate the position of the corneal surface - was changed to 'height' because the word elevation has been given a special meaning in the corneal topography field and in this standard. The definition for 'corneal topographer' was revised to more clearly define what and how these instruments measure.

   A specification for test surface for corneal tomographers that measure using interferometric methods was added. These instruments include optical coherence tomographers (OCTs).

   The sub-committee now is of the opinion that the revised version of Z80.23 is ready for a vote by the ACS Z80 membership. However, there is some textual repair that is needed to several of the equations as they were corrupted in some way when a Word document was created from a .pdf document.

6. Revision of Z80.10 – Tonometers

Work began on a revision of Z80.10. Bruce Drum informed the sub-committee that the main problem that the FDA has with the current standard is a provision of repeated testing of the eye with intraocular pressure values of over 23 mmHg. Upon discussion, it was decided that this paragraph in B.5.3 be removed.

Bruce Drum also asked that the requirement in B.5.3 for an addition 10 eyes with corneal astigmatism of over 3 D be changed to a requirement that only applied when a manufacturer wish to claim that their tonometer could measure high astigmatism cases as well as it could measure eyes with normal amounts of astigmatism. The sub-committee agreed to change this requirement in this way.

The FDA was also uneasy with the provision to allow a replacement investigator to be used if the initial investigator had to with draw. Karl Citek suggested that the standard require that for a given eye the same investigator must make both the measurement of intraocular pressure with the reference tonometer and with the tested tonometer. With this addition to the requirements for investigators– as B.2.3 – the objection of the FDA was removed.

With these changes, the sub-committee is of the opinion that Z80.10, as revised, should be circulated for ASC Z80 member voting.

7. SC 6 delegates to the ISO TC172/SC7/WG6 meetings in Berlin in May 2018.

Karl Citek – project leader – Devices for enhancing low vision
Bruce Drum – project member for the revision of ISO 15004-2 - Light hazard protection
David Sliney – project member for the revision of ISO 15004-2 - Light hazard protection

8. The sub-committee discussed the on going work for the revision of ISO 15004-2 Light hazard protection. The project group is meeting with week on Thursday March 1 and Friday March 2, hosted by the FDA at their facilities.

9. The meeting adjourned at 4:30 PM.

Annex 4 SC1 - ANSI Z80.1 Spectacle Lens Meeting Minutes

Monday, February 26, 2018 (8AM – 10AM)
Sheraton Sand Key, Clearwater Beach, Florida

Dick Whitney – Chair
Rick Tinson – Vice Chair

1. **Call to Order – the meeting was called to order at 8:05 AM**

2. **Introductions & Introductory Comments / Roster**

	26-Feb-18			
	First Name	**Last Name**	**Company**	**Email**
1	Ramzi	Ari	Essilor of America, Inc.	
2	Lauren	Bianchi	Marchon	lbianchi@marchon.com
3	Carl	Buckholt	Luxottica North America	cbuckhol@luxotticaretail.com
4	Karl	Citek	American Optometric Association	citekk1@pacificu.edu
5	Tom	Hicks	Oxford Opticians	thref@aol.com
6	Daniel	Lahousse	FGX International	dlahousse@fgxi.com
7	Adam	Mancuso	Marchon	amancuso@marchon.com
8	Nick	Mileti	Luxottica Retail	nmileti@luxotticaretail.com
9	Dale	Pfriem	ICS Labs	
10	Neil	Roche	Essilor of America, Inc.	nroche@essilorusa.com
11	Lyle	Rubin	Corning Incorporated	rubinlk@corning.com
12	Robert	Shanbaum	Occuco	
13	Daniel	Simonetta	Shamir	
14	Dr. David	Sliney		
15	Rick	Tinson	Hoya	
16	Neil	Torgersen	Walman	ntorgersen@walmanoptical.com
17	Michael	Vitale	The Vision Council	mvitale@thevisioncouncil.org
18	Paul	Wade	Vision Council	pwade@thevisioncouncil.com
19	Richard	Whitney	Carl Zeiss Vision	dick.whitney@zeiss.com
20	Greg	Williams	Colts Laboratories	gwilliams@coltslabs.com

3. **Acceptance of Agenda – accepted as proposed**

4. **Acceptance of August 21, 2017 Meeting Minutes**

5. **Administrative**

   Anti- trust compliance document for ANSI ASC Z80

   members are encouraged to review Annex E of the operating procedures in ASC Z80 Operating procedures. (www.z80asc.com)

6. **ANSI Z80.1-2020 revision**

   a.) **ANSI Z80.1 PINS Processed 9/17 by Michele**

   The following PINS was processed last September, which permits this committee to discuss details of the planned 2020 ANSI Z80.1 committee. Mike reminded SC chairs as to the importance of having this done before work is done on any revision. Dick thanked Michele Stolberg for her work on this and seconded Mike Vitale's complements on her professionalism and attention to detail.

Monday, February 26, 2018 (8AM – 10AM)
Sheraton Sand Key, Clearwater Beach, Florida

Dick Whitney – Chair
Rick Tinson – Vice Chair

PINS Standard Action Request Form

Complete the form below for each Standards Action Request. Hit ADD REQUEST to add each additional standard to your submittal

Designation of Proposed Standard	Title of Standard		
Z80.1	Prescription Ophthalmic Lenses		
Project Intent			Supersedes or Affects
Revise current ANS			Z80.1-2015
Project Need			Identify ISO or IEC standard to be adopted
Begin updating for ANSI 5 year review			
Identify Stakeholders			Includes text from ISO or IEC standard?
All involved in Spectacle Lens eyewear production, distribution and use. Manufacturing, Labs, ECP's, FDA, Consumers, etc.			No
Scope summary			
This standard reflects the shift in utilization from mass-produced lenses to a basic dependence upon custom-processed lenses at the laboratory level. It does not represent tolerances that describe the state-of-the-art of the ophthalmic laboratory, but provides quality goals for new lenses prepared to individual prescription. The individual performance parameters listed in this standard can be achieved reliably.			
Consumer Product	Unit of Measure	Revised a previous PINS submittal?	
yes	Metric	no	
Notes			
Request an Announcement in Standards Action to Solicit New Consensus Body Members			
No			

b.) Overview of Draft Document – Content / format

A draft document was started where specific areas of the 2015 standard were reviewed with the intent of identifying areas to revise / modify. The definitions section was first were examined and the ISO Freeform TR mentioned as a possible source for excerpting / referencing. As worn correction and the term "verification power" was also mentioned by Robert Shanbaum as needed.

The Focimeter discussion paper that was endorsed last year by SC1 /SC6 may be excerpted for inclusion in relevant sections. One example pertained to the recommended inspection method in 5.1.6 and 8.1.2 which requires use of a visual focimeter as the final arbiter for pass/fail Equivalency of alternate test method from the visual focimeter may be added.

A review of the 0.16 Tolerance for Progressives occurred, where the history and need was discussed. It was originally added in 2005, at a time when concerns were raised at the disconnect between tolerance for blanks and the allowable 1/8 Diopter value that left little room for the processing of the blank. While discussed, there was not a clear decision on its continuation and will be reviewed further.

Action: The following people agreed to participate starting the editorial work in a new draft document: Karl Citek (Editorial committee head), Mike Vitale, Rick Tinson, Neil Torgersen. It was agreed that after vision Expo, Dick Whitney would schedule a conference call to begin editing the document with specific input from the committee.

"UV 400 claims"

Another content issue that was discussed pertaining to revisiting the issue of claims with regard to product performance for "UV 400" product. Dick Whitney indicated that while Ophthalmic lenses use 380nm as the cutoff for UV, he indicated we may wish to revisit defining how the cutoff claims are handled and defined as this topic continues to be an issue and should be re-examined.

The following wording was agreed to during the joint discussion with SC1 & SC3 regarding UV absorption claims of clear lenses:

With the understanding that UVA and Visible Light overlap between 380 and 400 nm, SC1 & SC2 recommend including in any standard an additional definition and potential related test procedure. This would not be a requirement for all lenses, but addresses claims about specific lenses. Two possible definitions, of which we will settle on one by consensus, are

Claims for extended UV attenuation up to 400 nm

For mean transmittance value beyond the UVA zone, apply the claimed wavelength as the limit in the equation. For example, if absorption is claimed to 390 nm, use λ_2 = 390 nm.

OR

Spectral transmittance of any wavelength at and below the stated wavelength shall be no greater than the claimed value supplied by the manufacturer.

Note: The recognized UVA limit for clear lenses is 380 nm.

Action: It was decided to continue the discussion at SC2 in terms of how this might be defined for both Z80.1 and Z80.3.

c.) Distribution options: ANSI "App" prototype format discussion

Dick Whitney reported that as agreed upon at the August 2017 meeting, a task group has been working on scoping out the details of a proposed ANSI App". The practicality and for an "app" and details of what it might entail have been discussed by a task group in detail. Dick Whitney, Alfredo Duenez and Neil Torgersen initially met and scoped out a rough proposal. Mike Vitale, Paul Wade and Brent McCardle (Zeiss/ App author) subsequently got involved. **It is planned that the Vision Council Lens division will further review the need/ possible content/ practicality / cost.**

In general, there was support to proceed and several committee members provided feedback and ideas on what might be included. With regard to partial funding for such a development/ distribution Tom Hicks mentioned that it would be worthwhile to consider applying for an OAA grant to help supplement any cost for such an app.

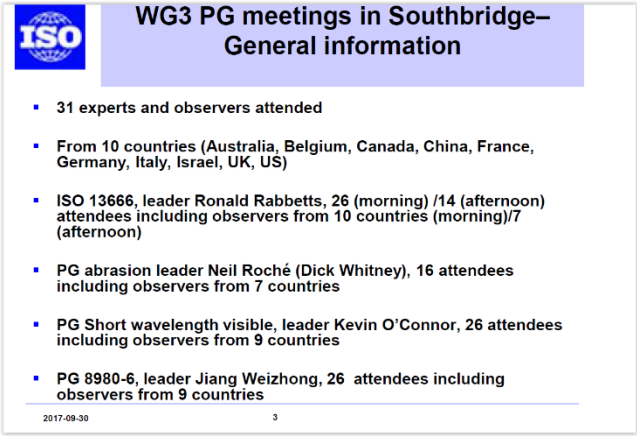
On a related topic, Mike indicated that he polled 160 Opticianry experts and asked how many bought the 2015 ANSI Z80.1 Standard and 6 raised their hands. Some indicate they do not need the whole standard and only seek to have what is provided in the summary tolerance table.

Dick indicated that he hoped this would be an effective way to educate, and an app would likely help provide information and purchase information for some who might want to learn more.

7. ISO TC172/SC7/WG3 Updates

a) ISO TC172 WG3 – Sept 2017 Interim meeting feedback / issues – Southbridge, MA

The interim WG3 meetings were successful, and Mike thanked the Optical Heritage Museum / Dick Whitney / Zeiss who were its sponsors. There was a good turnout as shown from this meeting summary slide:



b) **ISO TC172 Plenary Meeting**, Spring (May 14-18, 2018) in Berlin

- Experts to be nominated to attend ISO Berlin Meeting

It was requested that those SC1 Members who wish to be nominated by ANSI to attend the ISO Berlin meeting notify Dick who in turn will provide this to Mike by the end of next week.

- Experts for specific committees / ad hoc groups

The following experts were listed in the Jan ISO PG members document and was shown to the committee for discussion. A final listing will be prepared for submittal. Experts who are approved by ANSI to attend must also register with ISO. Also, all are encouraged to soon make their hotel Reservations.

WG3	8980-6 Claims	USA- Neil Roche, David Sliney, Dick Whitney
WG3	13666 Vocabulary	USA ~~-Jeff Endres?~~ / Dick Whitney/ Michael Vitale
WG3	TR 21958 Abrasion	USA Neil Roche /Dick Whitney / Daniel Simonetta
~~WG3~~	~~TR 20772 SWV~~	~~USA Karl Citek, Herb Hoover, Neil Roche, Dick Whitney~~
WG3	Power and Prism WG	USA Michael Vitale, Alfredo Duenez, Dick Whitney
WG3	3 D Measuring system	USA Nick Mileti, Michael Vitale

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Dick Whitney – Chair
Rick Tinson – Vice Chair

c) **ISO TC172 Plenary Meeting**, Fall 2019 (USA);

8. Old Business - None

9. New Business - None

10. Next Meeting – August 20, 2018 in Clearwater Fl.

11. **Adjournment – The meeting adjourned at 10. Further discussion was planned at the SC2 meeting on the topic of claims and "UV 400".**

Annex 5

ANSI Z80 SC2
Non-Prescription Eyewear Subcommittee Meeting
February 26, 2018, 10:00 AM-Noon
Sheraton Sand Key Resort, Beach Room
Clearwater Beach, Florida

Minutes

Attendees: Karl Citek (chair), Ramzi Ari, Lauren Bianchi, Carl Buckholt, Tom Hicks, Daniel Lahousse, Adam Mancuso, Nick Mileti, Dale Pfriem, Neil Roché, Lyle Rubin, Dan Simonetta, David Sliney, Rick Tinson, Neil Torgersen, Mike Vitale, Paul Wade, Dick Whitney, Greg Williams

1) **Call to order: 10:17 AM**
2) **Introductions & introductory comments**

   Reminder about Antitrust Compliance, requirements can be reviewed at ANSI Z80 website, www.z80asc.com, under Operating Procedures Annex E.
3) **Acceptance of Agenda – Addition of Items 7b and 7c.**
4) **Acceptance of minutes from the August 21, 2017, meeting – No changes**
5) **ANSI Z80.31**

   Standard has been published. Thank you to all who participated in the review, including Dan Lahousse (we will be sure to get your name on the next revision!).

   Related ISO standard will be up for discussion at upcoming ISO TC172/SC7 meeting. Anyone from SC2 attending is encouraged to participate and present our published standard for consideration.
6) **ANSI Z80.3**

   Voting on ANSI Z80.3-2015 amendment of Section 5.8 is complete, and should be in the final stage of approval by ANSI. Once that occurs, SC2 will request a PINS to begin review of the entire standard:
   Motion by Tom Hicks, second by Dick Whitney. Scope of work will include
   - **providing test procedures for prism testing**
   - **further clarifying requirements for photosensitive and gradient tint lenses**
   - **continued harmonization with relevant ISO standards, such as ISO 12312-1**
   - **reviewing color transmittance requirements for traffic signal detection**
   - **incorporating claims with respect to side protection, such as sideshields or high wrap**

   Motion passes.

7) **Other business**

a) Anyone wishing to attend ISO TC172/SC7 will need to make request to SC chair in time to be forwarded to Mr. Vitale by March 9.

b) Update from ISO TC94/SC6 – no back-to-back meeting this May with TC172/SC7. No other update.

c) Joint discussion with SC1 regarding UV absorption claims of clear lenses

With the understanding that UVA and Visible Light overlap between 380 and 400 nm, SC1 & SC2 recommend including in any standard an additional definition and potential related test procedure. This would not be a requirement for all lenses, but addresses claims about specific lenses. Two possible definitions, of which we will settle on one by consensus, are

Claims for extended UV attenuation up to 400 nm
For mean transmittance value beyond the UVA zone, apply the claimed wavelength as the limit in the equation. For example, if absorption is claimed to 390 nm, use λ_2 = 390 nm.
OR
Spectral transmittance of any wavelength at and below the stated wavelength shall be no greater than the claimed value supplied by the manufacturer.
Note: The recognized UVA limit for clear lenses is 380 nm.

Consideration and discussion will continue via e-mail and at the Fall 2018 meeting.

8) **New business – none**

9) **Next meetings: ISO TC172/SC7, May 14-18, 2018, Berlin, Germany; August 19-21, 2018, Sand Key Resort, Clearwater, Florida**

10) **Adjourn for lunch: 11:54 AM (sorry, no eclipse today!)**

SC4 Medical Devices
ANSI Subcommittee Report
February 25th -27th 2018
Clearwater, Florida

ANSI Items and Process:

1. Z80.27 Implantable Medical Devices:

The glaucoma group is beginning revision of the standard, previously published in 2014.
Revision is directed at general comments and updating to incorporate MIGS (Minimally Invasive Glaucoma Surgery) devices
The group met from 08:00 until 16:30.
Polycom and WebX allowed attendees to participate remotely
13 out of 21 pages of comments were reviewed and good progress made
Small work groups were formed for completion of assigned action items
The standard will be modified within 6-8 weeks and redistributed for additional progress

2. Z80.35 Extended Depth of Focus IOL:

The group met from 08:00 to 17:00 to review the 7th iteration of the standard
Optical and clinical sections were revised and updated to incorporate comments from previous meetings and interim phone conferences.
The standard will be updated to incorporate prior comments, and finalized.
It should be ready for submission for voting in 2-3 months.

3. Z80.12 Multifocal IOL:

The standard has been reaffirmed, and we now desire to begin work this fall.
The plan is to open the MIOL standard in order to incorporate the EDOF standard into the MIOL standard (similar to the ISO standards that are incorporating the two).
A PINS is requested at the Parent meeting today. However we may instead consider a new Z80 number to prevent confusion, because we will need a new scope for the combined draft standard, and then retire the MIOL Z80.12 and the EFOF Z80.35 documents.

4. Z80.7 General IOL:

This standard will be opened in the future to incorporate changes from above work.
A PINS was asked for at the Parent meeting today to revise the standard to include changes in the related documents (Z80.7 is the very general parent document). Work may possibly not begin on Z80.7 until next spring, because we need to follow ISO work on the EDOF document as well as the biocompatibility document 11979-5.

5. Z80.30 Toric IOL:
Was completed in late 2017 and sent to vote. The standard was approved, and is currently out for public comment before publication, possibly in June or July.
Results: 13 Approve, 0 Disapprove, 2 Abstain, 5 Did Not Vote

ISO Items for Berlin May Meeting SC7/WG7:

11979-1 IOL Vocabulary is in process of revision
11979-7 Clinical IOL has gone through FDIS stage and is due to be published
11979-7 EDF IOL is in WD.2 stage and is incorporating the EDF IOL materials into the MIOL section of the clinical standard.
11979-10 Phakic IOL has gone through FDIS stage and is due to be published
11979-5 IOL Biocompatibility is in process of revision
11672 Ocular Endotamponades is in process of revision

The SC7/WG7 team will attend related Berlin meetings Tuesday through Thursday, and have a US delegates meeting on the Monday evening prior to the main Tuesday meeting, location and final time yet TBD. Current member list needs to be finalized and sent to Mike Vitale by March 9th.

Carl Tubbs, MD
SC4 Subcommittee Chair

Annex 7

Report of
ANSI Z-80 SC7
February 26, 2018

To: ANSI Z-80
From: Ralph P. Stone

The meeting of ANSI Z-80 SC7 was convened at 8:30 AM March 26, 2018 at the Sheraton Sand Key with 20 experts in attendance. The agenda comprised nearly 30 items to be considered. Due to the ongoing activities of this subcommittee, portions of the items in the agenda required no action by the committee.

The discussion of specific items included discussion of the active and pre-project work items. Mary Mowrey-Mckee discussed the issues relating to the ongoing ring test of ISO 19045-2 on Acanthamoeba trophozoites and the calculation between methods were discussed. Results of 3 of the 5 participating laboratories have been received. The results of the ring test will be up for the discussion for the ISO Berlin meeting.

The project group assigned for the generation of symbols from the contact lens areas was discussed and additional potential areas were suggested. This committee is being re-activated at the May ISO meeting.

The two pre-project teams for additions of test methods and standards for inclusion in ISO 18369-3 and ISO 18369-4 indicated that their teams were continuing evaluation in the development of new methods and standards.

The work on ISO 11981 and ISO 11986 has been completed and the ISO project teams disbanded.

Three standards were recently evaluated under provisions for periodic review. Each of these standards received votes to revise the standard including from the US, but received sufficient votes for confirmation of the current standard. Given that the US as well as some other countries provided comments, these standards will be discussed at the WG-9 meeting in May. The objective will be to determine if the comments have sufficient merit to request a project for revision of these standards give a review of the comments from all the voting countries.

The first standard was ISO 9394 Determination of biocompatibility by ocular study with rabbit eyes. It was determined that it would be advisable to include a statement as submitted on animal welfare. The final position will be circulated from M Gabriel and J Cook.

The second standard was ISO 11980, Clinical Investigations. It was determined that the comments to the standard were not substantial enough to support a request for

revision given the vote but the US will develop positions to support our comments. K. Sentell, C Lakkis and G Davies will provide the basis for the US Position and circulate.

The third standard was ISO 11987 Shelf life of lenses. It was determined that the base US position would include our comment 11. The key concern is how we include tolerances, what tolerance, and what should be used for the base value for the evaluation over shelf life. The scope of ISO 18369-2 indicates that the tolerances described in that standard may not apply to shelf-life. SC7 believes that a revision is in order for this standard.

There was discussion of ISO 11978 Labeling. Key was to request a revision of the standard for the determination of the required size of fonts. It was felt that we do not have sufficient justification for the current language and would like to avoid the requirement for testing of each labeling piece. In order to support the request for revision it was suggested that the use of color coding such as caps and labeling banners be included for products that cannot be used directly in the eye such as hydrogen peroxide. There were other areas that should be included and M Gabriel will circulate those areas. During the discussion it was noted that TC 159 SC4 was working in this general area and has a CD for ISO 21055. This CD has been requested.

ISO 19979 Hygienic Management of Multi-patient use of trial lenses was discussed. The US voted disapproval of this standard. The premise of the no vote was that it potentially required a violation of US HIPAA regulations. The response from the Secretariat was that if names were not included it was OK. Since this is a potential issue and requires potentially additional requirements for practitioners, this area has been discussed with the Steering committee and will be reviewed by legal counsel.

There was a short discussion of the impending changes in the European MDR and the potential to affect our work in ISO and its impact. Participants were requested to review these upcoming changes as they become available.

The committee received a request from the Scleral Lens Society with a proposal for a consolidation of standards in the nomenclature for scleral lenses. S Puig, G Davies and M Dalsing were asked to review the proposal in light of the definitions proposed with respect to the revision of ANSI Z-80 20 and ISO 18369-1 and to report at the ANSI meeting in August.

ANSI received from the WG-9 Convener a request for review of ISO 9342 for the use of focimeters. The discussion in ANSI Z-80 SC-7 was to support the British position to withdraw the standard for use with contact lenses because of the failure to provide usable values because of higher order aberrations. This standard is not the province SC7, but we would ask the ANSI subcommittee for this standard to support our position.

Finally a list of delegates for the May ISO meeting in Berlin was developed to be confirmed by the nominated individuals. The finalized list of the attendees will be provided to M Vitale by March 5. The final list is attached.

The meeting closed at 2:30 PM

Annex 7

ISO TC 172/ SC7/WG9
Meeting May 14-18, 2018
Berlin Germany

Experts/Observers

Monday May 14, 9-12:30 AM WG-9 Symbols

Experts: Carol Lakkis
Jenifer Streza

Observers: Angelo Green
Kim Millard
Karen Sentell
Manal Gabriel
Ralph Stone

Monday May 14, 13:30-17:00 PG 19045-2
Project Leader: Mary Mowrey-Mckee

Experts: Manal Gabriel
Carol Lakkis

Observers: Wm. Domm
Kim Millard
James Cook
Ralph Stone

Monday May 14, 13:30-17:00 PG18369-4
Project Leader: Karen Sentell

Experts: Greg Williby
Samuel Puig

Observers: Angelo Green
Ralph Stone
Paul Ludington*

Tuesday May 15, 13:30- 17:00, PG 18369-3
Project Leader: P. Ludington*

Experts: Greg Williby
Samuel Puig

Observers: Karen Sentell
Angelo Green
JenniferStreza
Ralph Stone

Wednesday May 16 13:30-17:00 WG-9 meeting

Experts: Ralph Stone
Mary Mowrey-Mckee
Carol Lakkis
Samuel Puig

Observers: Greg Williby
Karen Sentell
Angelo Green
Manal Gabriel
Jennifer Streza
Wm. Domm
Kim Millard

*By conference call if available

Annex 8

ANSI Z80 SC 8 Report
Sheraton Sand Key, Clearwater, FL
February 26, 2018

ANSI Z80.24 – Information Interchange for Ophthalmic Optical Equipment

- **Overview**

  Z80.24 is based on the work done by The Vision Council's Data Communications Standard Committee. This committee meets at least twice per year to continually improve and expand the Data Communications Standard as the industry and technology evolves. Historically the Data Communications Standard has been adopted for Z80.24 and ISO 16284.

- **Status**

  Current version Z80.24-2012 is based on Data Communications Standard 3.03 published in 2011. The group completed reaffirmation of Z80.24 in October of last year and a PINS was approved to begin work on the update to the latest version of the DCS was approved in February 2018. The group has agreed to allow the Data Communications Standard Committee to approve the current draft 3.12 and use that approved version for the ANSI and ISO updates.

- **Action**

  Waiting for approval of 3.12 from the DCS Committee and then Paul Wade will edit for ANSI. We hope to distribute the first draft for review prior to the ISO meeting in Berlin.

ANSI Z80.34 – Billing Reimbursement – ON HOLD

- **Purpose and Scope**

  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, interoculars, consumables
  - Medicare/Medicaid, Federal and State governments, institutional employers

- **Status**

  There are currently data points lacking in X12 that prevent work on Z80.34 from proceeding. The work on this standard is on hold until X12 completes its work.

- **Action**

  None at this time.

Liaison Report of ISO/TC 94/SC 6 "Eye and Face Protection" to ANSI Z80 Sand Key, FL - 27 February 2018

The full committee of ISO/TC94/SC6 and its working groups last met in Sydney, Australia, October 17 - 21, 2016. Thirty delegates representing eleven countries (*plenary)* were present. Three delegates from the U.S. were present. An interim meeting of the Working Groups of SC6 was held the week of December 4 (2017) in Sand Key, FL. A firm date and place for the next meeting of SC6 has not been confirmed.

Work Group Activity Summary / Highlights

WG1 – Definitions:
ISO 4007, the SC6 terminology / definitions has progressed a revision of its document to DIS stage. The U.S. abstained with comment through ANSI as the TAG did not have consensus in the matter of 370 vs 400.

WG 2 – Test Methods:
Several (revised) test method documents to accompany sports eyewear requirement standards have progressed to DIS stage these being:
- ISO/DIS 18256-1 Occupational and Sports Geometric Optics Test Methods
- ISO/DIS 18256-2 Occupational and Sports Physical Optics Test Methods
- ISO/DIS 18256-3 Occupational and Sports Physical and Mechanical Test Methods
- ISO/DIS 18256-4 Headforms

WG 3 – Sunglasses:
ISO 12312-1: Eye and face protection – Sunglasses and Related Eyewear was revised and promulgated in October of last year (2016). Sections of the standard having revision(s) are:
- 5.2 Transmittance categories
- 5.3.2 Requirements for road use and driving
- 7.6 Impact levels
- 11.2 Temporal protection requirements
- 12.1 Information for users

WG 4 – Occupational Eye and Face Protection:
Four document (revisions) have been progressed within WG4 to DIS stage these being:
- ISO/DIS 16321-1 Occupational Eyewear – General Requirements
- ISO/DIS 16321-2 Occupational Eyewear –Protectors for Welding
- ISO/DIS 16321-3 Occupational Eyewear – Mesh Type Protectors

WG 5 – Eye and Face Protection for Sports:
Two documents (new) have been progressed within WG5 to DIS stage these being:
- ISO/DIS 18527-1 Eye and Face Protection for Sports – Skiing Goggles
- ISO/DIS 18527-2 Eye and Face Protection for Sports – Racquet Sports

The U.S. was forced to abandon its PG lead for the newly approved NWIP (May 2016) as the principle was unable to progress the work item. A new PG lead has been chosen from the U.K.

WG 6 – Guidance on Selection, Use and Maintenance
The initial document from WG6 has been progressed to DIS stage:
- ISO/DIS 19734 Eye and Face Protection – Guidance on Selection, Use and Maintenance.

JWG1 – Joint ISO/TC 94/SC 6 - IEC/76 WG on Eye and Face Protection against Laser Radiation. Debate between Work Group members in the current draft document (ISO/WD 19818) defining resistance class (RC) and optical density (OD) continues. As a result of continued nonconsensus, the committee has formally voted to backstage both ISO 19734 Eye and face

protection – Guidance on selection, use and maintenance and ISO 19818 Requirements of eye and face protection against laser radiation to the Preliminary Work Stage.
The JWG will meet in November in Milan in attempt to progress a position of mutual agreement.

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