Z80 Accredited Standards Committee for Ophthalmic Optics
The Vision Council
225 Reinekers Lane, Suite 700
Alexandria, VA 22314
P: 703.548.4560 F: 703.548.4580

American National Standards Institute
Z80 Accredited Standards Committee for Ophthalmic Optics

SHERATON SAND KEY, CLEARWATER BEACH, FLORIDA

ANSI Z80 PARENT COMMITTEE MEETING MINUTES

Tuesday, August 21, 2018: 8:30 am – 11:00 am

- **Call to Order and Introductions.** Dr. Carl Tubbs, Chair of the Z80 Committee, called the meeting to order at 8:30 am, Tuesday, August 21, 2018. 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.

  It was ascertained that twelve (12) voting representatives or their designees of the twenty (20) member organizations were present and that, therefore, a quorum existed.

- **Acceptance of the Agenda**. The agenda that had been distributed was unanimously accepted without modification.

- **Acceptance of the Spring 2018 Meeting Minutes**. The minutes of the last meeting of the Parent Committee that had been distributed were unanimously accepted.

- **Chair's Comments**. Dr. Tubbs welcomed everyone to the Z80 meeting and thanked them for their support of the standards process. He thanked Dr. Tom White for his many (21) years of service as the Chair of the ANSI Z80 Committee. Dr. Tubbs next introduced the Vice Chair, Mr. Neil Roche.

- **Vice Chair's Comments**. Mr. Neil Roche announced his retirement from the ANSI Z80 Committee, having been glad to have worked on standardization since 1990, and was honored to have acted as the Z80 Vice Chair.

  Mr. Michael Vitale took the opportunity to describe the process for selection of a new Vice Chair and invited nominations in writing to him at The Vision Council.

- **Legal Counsel's Report**. Mr. Rick Van Arnam, Legal Counsel for the Z80 Committee, spoke about the Development Organization Advancement Act of 2004. He recommended that the Z80 Committee publish a notice in the Federal Register that would provide protection from treble damages. He would pursue this over the next several months and report back at the spring meeting of the Z80 Committee. The Z80 Committee is referred to the overview of this topic supplied by Mr. Van Arnam with these minutes.

- **Secretariat's Report**. Mr. Michael Vitale, representing the Secretariat, reminded the Z80 Committee about timely voting to ANSI and ISO Standards, if only to "Abstain." Abstentions help increase the vote count. 135 standards had been sold so far this year. A status list of the Z80 Standards is included in the Secretariat's Report included with these minutes.

  Mr. Vitale showed a PowerPoint presentation detailing the process of forming an ANSI standard by the Z80 Committee. He mentioned that every member of a subcommittee can obtain a "Committee Copy" of a new standard that the subcommittee produced by contacting Mr. Vitale.

  He described the audit by ANSI that the Secretariat had undergone and reported that accreditation had been achieved. He said that ANSI was very pleased with the operation of the Z80 Committee and no small thanks for this went to Ms. Michele Stolberg who was simply fantastic in organization of Z80 activities.

- **Subcommittee Reports**.

  SC1: Mr. Richard Whitney, Chair of Subcommittee (SC) 1, reported on the activity of SC1. Key points were covered by Mr. Whitney. SC1 will check the standards on contact lenses and intraocular lenses to see if the ultraviolet transmittance specifications and methodology can be harmonized within Z80. He also mentioned that SC1 is looking at Contact Angles for specification of the hydrophobicity/hydrophilicity of spectacle lens coatings. [The Secretary later sent Mr. Whitney a copy of the clauses on Contact Angles in ANSI Z80.20.] The Z80 Committee is 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 referred to the SC2 Subcommittee report included as a portion of these minutes.

  SC3: Mr. Nick Mileti, Chair of Subcommittee 3, projected the written subcommittee report for view by the Z80 Committee and key points were covered by Mr. Mileti. The Z80 Committee is referred to the SC3 Subcommittee report included as a portion of these minutes.

  SC4: Dr. Carl Tubbs, standing in for Dr. Raj Suryakumar, the new 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 referred to the SC4 Subcommittee report included as a portion of these minutes.

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

  SC7: Dr. Ralph Stone, the new Chair of Subcommittee 7, reported on the activity of SC7. Key points were covered by Dr. Stone. Dr. Karen Sentell had noted during the SC7 meeting that editorial corrections were recently made by to ISO 18369-1, 18369-3, and 18369-4. Mr. Angelo Greene noted that the U.S. Food & Drug Administration had recognized the ISO 18369 series of standards on June 7, 2018. He further reported that ANSI Z80.18 and ANSI Z80.20 had been recognized by the FDA on August 21, 2017. The Z80 Committee is referred to the SC7 Subcommittee report included as a portion of these minutes.

  SC8: Mr. Michael Vitale, standing in for Mr. Paul Wade, Chair of Subcommittee 8, briefly covered SC8 activities. There had been no meeting of SC8 on the previous day. The Z80 Committee is 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, summarized the activity of ANSI Z87. The Z80 Committee is referred to the ANSI Z87 Liaison report included as a portion of these minutes.

  U.S. Food & Drug Administration: Ms. Claudine Krawczyk, representing the U.S. Food & Drug Administration, summarized the activity of the FDA over the last 6 months relevant to ophthalmic products. She mentioned the recognitions of Part 8 of ISO 11979 on intraocular lenses and the ISO 18369 series of standards on contact lenses. A photochromic contact lens by Johnson & Johnson Vision Care had been approved by the FDA. The Z80 Committee is referred to her FDA report included as a portion of these minutes.

  TC94/SC6: Mr. Dale Pfriem, the US TAG Chair for ISO/TC94/SC6, summarized the activity of this TC94/SC6 Subcommittee. The Z80 Committee is referred to Mr. Pfriem's ISO/TC94/SC6 Liaison Report included as a portion of these minutes.

  US TAG for ISO/TC172/SC7: Mr. Michael Vitale, the US TAG Leader for SC7, described the meetings of ISO/TC172/SC7 on May 14-18, 2018. He mentioned that The Vision Council would be seeking sponsors for the upcoming meeting of ISO/TC172/SC7 in Dallas on November 4-8, 2019. The ANSI Z80 Committee is referred to Mr. Vitale's TAG Update in the Secretariat's Report included as a portion of these minutes.

- **Next Meetings**:

  The ASC Z80 Steering Committee unanimously agreed to keep the next two Z80 meetings in Clearwater Beach to keep costs down. This is due to hosting of the Fall 2019 ISO TC172/SC7 meetings by the USA.

  ANSI Z80: February 10-12, 2019; Sheraton Sand Key, Clearwater Beach, Florida.
  ANSI Z80: August 18-20, 2019; Sheraton Sand Key, Clearwater Beach, Florida.
  ISO/TC172/SC7: November 4-8, 2019; Dallas, Texas.

- **New Business**: No new business was proposed.

- **Closure of the Meeting:** Dr. Tubbs again thanked everyone for their participation, wished them safe travels, and brought the meeting to a close at 11:00 am.

Respectfully submitted,
WJB

Legal Counsel's Report
Rick Van Arnam
August 21, 2018
Clearwater Beach, FL

Antitrust Limitations and the Standards
Development Organization Advancement Act of 2004

1 The Standards Development Organization Advancement Act of 2004, which was signed by President George W Bush. It amended the National Cooperative Research and Production Act of 1993.

   a. This amendment was important for two reasons. First, it extended the anti-trust's rule of reason test to standards developing organizations when engaged in standards development activities.
      i. This means that standards writing activity would be deemed illegal only if it unreasonably restrains trade.
      ii. The other antitrust test is per se illegality, meaning something is illegal on its fact. That test does not apply to standards writing activity.

   b. Second, the amendment eliminates the trebling of damages in any successful antitrust action against a standards development organizations.

   c. In order to get the protection against the trebling of damages, the standards developing organization must file notices with the Department of Justice and the Federal Trade Commission
      i. Identifying the standards developing organization and the nature of the scope of its standards development activity.
      ii. Provide a notice to be published in the Federal Register. This notice will alert the world to the SDO's activity in a particular space. In our case, ophthalmic optics.

2 The reason I have discussed this topic is that during the recent audit the auditor recommended that we pursue such status

   a. This law was passed in 2004 and SDOs were invited at that time to seek the protection against treble damages. Based on my search of the Federal Register, ASC Z80 committed did not file for such protection at that time.

   b. So, I am looking into doing this, and will be working with the DOJ and FTC to implement this protection.

   c. It will cover our activity going forward, but it has not retroactive application because to have gotten that, we would have had to file for such relief within 90 days of when the law passed in 2004.

Z80 Accredited Standards Committee for Ophthalmic Optics
The Vision Council
225 Reinekers Lane, Suite 700
Alexandria, VA 22314
P: 703.548.4560 F: 703.548.4580

ASC Z80 Committee Secretariat's Report
August 2018

Member Status and Dues
- 20 Voting members
- 1 Member Past Due

National Standards Approved in 2018 through June
- 3 National Standards have been approved or reaffirmed in 2018
  - Z80.3-2018 Nonprescription Sunglass and Fashion Eyewear Requirements
  - Z80.17-2013 (R2018) Focimeters
  - Z80.30-2018 Toric Intraocular Lenses

ANSI Audit 2017-12
- The 5-year audit is now closed. There was only one significant item that needed re-balloting. (Z80.28)
- Michele and I were both pleased with the audit results
- I would like to thank Michele for all her efforts in executing this audit. Having her on board made this process run very smoothly.

Standards Tracking

Number	SC	Chair	Title	Date of last review	Date of next review	PINS date	Current review status
Z80.1	1	Dick Whitney	Prescription Spectacle Lenses	2015	2020	September 2017	Published
Z80.3	2	Karl Citek	Nonprescription Sunglass and Fashion Eyewear Requirements	2018	2023	March 2018	Published
Z80.31	2	Karl Citek	Specifications for Ready-to-Wear Near-Vision Spectacles	2017	2022	N/A	Published

Z80.5	3	Nick Mileti	Frames	2010	N/A - Withdrawn	N/A	This item has been replaced by the ISO7998/8624/12870 Standards Set (Dec 2016); On 6/9/17 this item was obsoleted by ANSI (Sharon Roth), and a note was placed with the 3 Optics Set listing
N/A	3	Nick Mileti	ISO Adoptions	N/A	Three Optics Set - next revision due in 2021, or when ISO revises these three items prior to the five year rev cycle	N/A	Published
Z80.7	4	Carl Tubbs	Intraocular Lenses	2013	2018	March 2018	In process for reaffirmation; PC vote complete (Approved); Out for public review/BSR8 (closes 9/10/18)
Z80.11	4	Carl Tubbs	Laser Systems for Corneal Reshaping	2017 (Reaffirmed)	2022	June 2014	Published
Z80.12	4	Carl Tubbs	Multifocal Intraocular Lenses	2017 (Reaffirmed)	2022	N/A	Published
Z80.13	4	Carl Tubbs	Phakic Intraocular Lenses	2017 (Reaffirmed)	2022	N/A	Published

Z80.14	4	Carl Tubbs	Ophthalmic Viscosurgical Devices	N/A	NEW	N/A	Originally in SC6 and moved to SC4 in 2018. Possible NWI not needed- can reference ISO.
Z80.27	4	Carl Tubbs	Implantable Glaucoma Devices	2014	2019	November 2017	Published; Revision pending updated draft
Z80.29	4	Carl Tubbs	Accommodative Intraocular Lenses	2015	2020	N/A	Published
Z80.30	4	Carl Tubbs	Toric Intraocular Lenses	2018	2023	N/A	Published
Z80.32	4	Carl Tubbs	Methodology for Representation of Optically-Induced Phenomena	N/A	NEW	2009	Lack of funding and interest circa 2013 - no action at this time.
Z80.35	4	Carl Tubbs	Extended Depth of Focus (EDF) Lenses	N/A	NEW	2014	BSR 8 filed for public review (closes 9/10/18)
Z80.39	4	Carl Tubbs	Non-Accommodative Multi-Range Intraocular Lenses	N/A	NEW	May 2018	Pending initial draft
Z80.9	6	Charlie Campbell	Devices for Low Vision	2015 (Reaffirmed)	2020	August 2018	Published
Z80.10	6	Charlie Campbell	Tonometers	2014	2019	September 2017	BSR9 in process for final ANSI approval
Z80.17	6	Charlie Campbell	Focimeters	2018 (Reaffirmed)	2023	N/A	Published

Z80.21	6	Charlie Campbell	Visual Acuity Charts	2015	2020	August 2018	Published
Z80.23	6	Charlie Campbell	Corneal Topography Systems	2013	2018	September 2017	Under comment resolution/appeal
Z80.28	6	Charlie Campbell	Standard for Reporting Optical Aberrations of the Eye	2017	2022	N/A	Published
Z80.36	6	Charlie Campbell	Light Hazard Protection for Ophthalmic Instruments	2016	2021	N/A	Published
Z80.37	6	Charlie Campbell	Slit-lamp Microscopes	2017	2022	N/A	Published
Z80.38	6	Charlie Campbell	Light Hazard from Operation Microscopes Used in Ocular Surgery	2017	2022	N/A	Published
Z80.18	7	W. Joe Benjamin	Contact Lens Care Products	2016	2021	N/A	Published
Z80.20	7	W. Joe Benjamin	Contact Lenses	2016	2021	N/A	Published
Z80.24	8	Paul Wade	Information Interchange for Ophthalmic Optical Equipment	2017 (reaffirmed)	2022	February 2018	Published
Z80.34	8	Paul Wade	Information Interchange Billing & Billing Reimbursement	N/A	NEW	2014	PINS submitted in 2014

Sales of ASC Z80 Standards as of June 2016

- 135

Member Voting Information

- ANSI and ISO voting logs continue to get better due to increased reminders from Michele

OEOSC TAG Update

- ISO/TC172/SC7 Plenary meeting was held May 14th-18th, 2018 in Berlin Germany.
- US sent 24 members to participate in these meetings
- There were no serious conflicts or concerns

SC1 - ANSI Z80.1 Spectacle Lens Meeting
Minutes

Monday, August 20, 2018 (8AM – 11AM)
Sheraton Sand Key, Clearwater Beach, Florida

Dick Whitney – Chair
Rick Tinson – Vice Chair

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

2. Introductions & Introductory Comments / Roster
The following experts participated in the SC1 meeting. At the start of the meeting, each member introduced themselves and their industry affiliation.

	First Name	Last Name	Company
1	Ramzi	Ari	Essilor of America, Inc.
2	Bill	Brown	Mayo Clinic
3	Carl	Buckholt	Luxottica North America
4	Karl	Citek	American Optometric Association
5	Keith	Cross	PPG
6	Alfredo	Duenez	Carl Zeiss Vision
7	Tom	Hicks	Oxford Opticians
8	Daniel	Lahousse	FGX International
9	Adam	Mancuso	Marchon
10	Nick	Mileti	Luxottica Retail
11	Dale	Pfriem	ICS
12	Neil	Roche	Essilor of America, Inc.
13	Lyle	Rubin	Corning Incorporated
14	Robert	Shanbaum	Occuco
15	Johnathan	Schwartz	Demeter Technologies
16	Rick	Tinson	Hoya
17	Neil	Torgersen	Walman
18	Michael	Vitale	The Vision Council
19	Richard	Whitney	Carl Zeiss Vision
20	Greg	Williams	Colts Laboratories

3. **Acceptance of February 26, 2018 Meeting Minutes**
– The meeting minutes were accepted without corrections or additions.

4. Administrative
Annex E of the April 2017 Revision of the ASC Operating procedures was reviewed as a reminder that all must adhere to the Anti- trust compliance document code of conduct.

5. ISO TC172/SC7/WG3 meetings in Berlin (May 2018)

a.) Report on actions from ISO TC172/SC7/WG3
TR 21958 Abrasion document – Presently out for Vote

The subcommittee decided to release ISO/WD TR 21958,as revised at the Berlin meeting, for circulation as a Draft Technical Report (Project leader: Neil Roché)

b.) **8980-6 (Product Claims)-**

- Index / Abbe- reviewed desire by China to have non – destructive method of determining the category of index of refraction in order to determine if product sold matches claims. Difficulties arise when measuring curves accurately enough on non spherical product in order to back calculate the index category (ie- Poly, 1.6, 1.67…). Alfredo Duenez (Zeiss) indicated he is worked on test samples to demonstrate how practical this may be. He expects to to share results by VEW 2019 LTC meeting.

- Contact Angle – After some discussion of various means to quantify claims for performance levels for AR Coatings, members discussed variations that are inherent in this test. There was discussion in the committee of how to quantify of the need to avoid ranking of product, and if this test is adopted that an categorization be limited to <90 or >90 degrees.

- Claims for Transmittance cutoff up to and including 400nm
  A method for describing claims for product transmission cutoff properties for wavelengths up to 400nm was reconsidered, following an update to the group on the Feb 2018 work at ANSI Z80.1 and Z80.3. A proposal was made by Kevin O'Conner and agreed to at the 8980-6 May meeting. This was subsequently agree to in Aug 20 Z80.1 and Z80.3 Meeting; see item 6 (below).

c. Ad Hoc Power and Prism Measurement

- Global Questionnaire update

  Mike reported that in Berlin the final logistics were agree to in disseminating a power and prism questionnaire. The purpose was to get assess real life practices on methods used globally. The Vision Council agreed to coordinate this anonymous questionnaire. It is now underway and expected to continue through the end of Sept. Mike reported the following breakdown on responses by country to date:

  USA – 1016
  Portugal – 101
  Switzerland- 94
  France 85
  Under 50 – Australia, Japan, Germany…

  The committee will review reponses, but each country will control their country responses and what is made public.

6.) ANSI Z80.1 – 2020 Draft Document Key additions discussed

- **Transmittance and Attenuation Product claims and requirements**

5.1.1 Claims for selective transmittance attention in visible range

If a manufacturer is claiming attention, the following is to be supplied:

1.) Range of wavelengths attenuated
2.) Amount of attenuation within that range
3.) Whether values are spectral or weighted

Claims for Attenuation for wavelengths <= 400nm

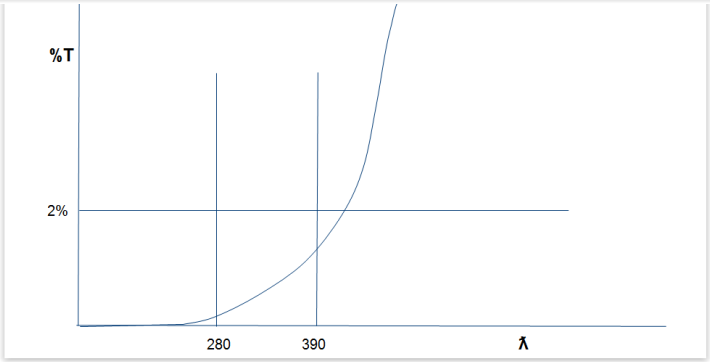
May 2018 ISO proposal in 8980-6

Draft alternative proposal.....

Transmittance cutoff

For lenses claimed to have a transmittance cutoff at a nominated wavelength, the spectral transmittance shall be less than x% at the nominated wavelength and at all wavelengths below it to 280nm.

Note: The starting proposal is that x could be 2%.



d. New Business – Meeting dates

a. **Interim ISO meeting planned for WG3 in China (Nov 7-9 2018)**

b. **ISO TC172 Plenary Meeting**, Fall 2019 Nov 4-8 (Dallas Tx). Mike Vitale advised members that there will soon be a request sent out by Z80 via the Vision Council for sponsorship to help defer meeting costs. Donations of up to $10,000 will be requested

e. Meeting dates for ANSI Z80 –Clearwater

- Feb 10-12, 2019 (Winter meeting),
- Aug 18-20 (Summer) in Clearwater beach

f. **Adjournment – 10:55 AM**

ANSI Z80 SC2
Non-Prescription Eyewear Subcommittee Meeting
August 20, 2018, 1:30 PM-3:30 PM
Sheraton Sand Key Resort, Sand Key Room
Clearwater Beach, Florida

Minutes

Attendees: Karl Citek (chair), Ramzi Ari, William Brown, Carl Buckholt, Keith Cross, Alfredo Duenez, Tom Hicks, Daniel Lahousse, Adam Mancuso, Nick Mileti, Dale Pfriem, Neil Roché, Lyle Rubin, Jonathan Schwartz, Neil Torgersen, Mike Vitale, Dick Whitney, Greg Williams

1) **Call to order: 1:32 PM**
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**
4) **Acceptance of minutes from the February 26, 2018, meeting – No changes**
5) **ANSI Z80.3**
   a. **ANSI Z80.3-2018, with amendment to Section 5.8, was approved and published March 13, 2018.**
   b. **PINS to begin next revision was filed March 27, 2018. 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.**

   c. **Draft work completed today includes harmonization with SC1, ANSI Z80.1, with regard to spectral (blue) light and UV attenuation claims.**
   d. **Axis of Polarization: Dale Pfriem and Nick Mileti will draft language regarding minimal or acceptable test method.**
   e. **Draft revision will be circulated to SC2 members for review prior to next meeting.**
6) **Other business – none**
7) **New business – none**
8) **Next meetings: ASC Z80 will meet February 10-12, 2019, and August 18-20, 2019, both at Sand Key Resort, Clearwater, Florida; ISO TC 172/SC 7 will meet November 4-8, 2019, in Dallas, Texas, venue TBD.**
9) **Adjourn: 2:41 PM**

Frame Subcommittee 3
August 20, 2018
Sheraton Sand Key
Meeting Minutes

Meeting call to order

Acceptance February Meeting Minutes – *Approved*

Acceptance of Agenda – *Approved Amended Agenda*

- **Review of ISO WG2 Activities**
  - ISO/TC 172/SC 7/WG 2 – Berlin Report

    N12 Report Berlin meeting 2018.pdf
  - ***Ad hoc group defined specific steps to determine the gaps that exist with current standards and report back to WG2, WG3 and WG8***

    ISO-TC172-SC7-WG 2_N0261_2018-06-12
  - ***DIS vote of 8624:2018 incorporating a number of changes. Plus the NWIP put forth by SC3 on Frame Effective Diameter***

    ISO_FDIS_13666-Character_PDF_docume
  - ***Review of FDIS of 13666 – noting the additions of Position of Wear – recommending affirmative vote***
  - **Frame Marking**- ***NWIP as presented was not supported by Germany and Italy. We are scaling back our request to standardization of:***
    - ***Heat Ranges (high, medium, low, no heat)***
    - ***Chemistry – what chemicals to avoid***
    - ***Cleaning Requirements***

New Business - *No new business*

Adjournment

ANSI SC4 Meeting Report
Clearwater, Florida
August 20, 2018
Dr. Tubbs
(For Raj Suryakumar, new SC4 Chair, in absentia)

SC4 Glaucoma Meeting Z80.27
August 20th , 8AM to 5 PM
Attendees in Person and by Phone (see attendance sheet)
Representing: FDA, Clinical Practice, Research and Industry
New Leader of Project: Jane Ellen Giamporaco
Compliments to Jane Ellen for running a very smooth and lively meeting!

Current revision is 45 pages (second revision of original 2014 publication)
There are 59 pages of comments from last meeting and from interim comments-
The majority are reviewed and discussed.
Specifics are listed below, but final text and compilation of comments to distributed

Body of Normative Section:

3.0 Definitions:
"Drainage tube" and "flow restrictor" are revised,
"outer diameter of drainage tube" definition deleted

4.2 General Guidelines:
Second paragraph removed (not needed)
Fourth paragraph modified- clarification of material to be used in testing for biocompatibility and reasons to be given if material used in testing substantially different from finished product

5.1 Scope:
Include aqueous shunts and MIGS devices: (this does not change the overall scope or purpose of the document but clarifies what is included in context of newer deices)

5.5 Pressure/flow characteristics:
Revised to recommend direct evaluation of devices from a testing standpoint (under physiologic or simulated physiologic conditions) but to allow calculation of dynamics when such testing is not practical or possible.

6.2 General Guidelines:
Revised paragraph to clarify testing materials (similar to 4.2)
Delete second paragraph: USP standards (superfluous)
Delete last paragraph: (not needed for clarity)

6.3.7 Rabbit Pyrogen Test
Clarification of reference and when needed for use (per FDA guidelines)

6.4.1 Extractables by exhaustive extraction:
Change to section – no need to evaluate mass loss during extraction

6.4.2 Hydrolysis testing:
Detect both physical and material properties of device after degradation
Examine liquid medium after testing for resultant chemicals

7.3 Validation of sterilization tests:
Revised to link appropriate testing to references- delete gamma sterilization

7.5 Bacterial Endotoxin:
Refer to FDA guidance document rather than listing limits in text (prevents future conflicts)

8.2 Requirements:
Examine/evaluate device and device related materials after simulated shipping

9.1 Insertion method:
Discussion of need to perform at all, given some injector forces and tissue forces are much less that might be needed to degrade a device or system- agree to use this test. Discussion as to why 10 devices tested- explanation from FDA given as to this number

9.3 Metallic devices:
Agree to assess for MRI and corrosion safety (where applicable)
See FDA reference in note-

10.2 Clinical Investigation Plans:
Clarification of need to "follow" subjects at each reporting period- meaning there is a contact with patient and Form completed for each scheduled visit (not that subjects are required to present at each visit physically, as this is sometimes not possible) Clarification of recording patient visits not in original protocol plan. Deletion of 7th paragraph in entirety, dealing with staged inclusion of non-refractory glaucoma patients.

11. Labelling:
Change "aqueous shunt" to "device"
Add Summary of clinical results (including AE's)
Add MRI safety and compatibility

Annex A

No changes

Annex B

B.2 Rational for selection of animal model:
Add bullet point: Ocular anatomy and/or structural integrity

B.4 Test material:
Clarification of material to be used in testing and relationship of this sample to the finished and sterile final product

Annex C

Refractory Glaucoma:

Held lively discussion re: updated newer definitions of "refractory glaucoma" presented by from AGS. (Traditional "refractory" patients defined as glaucoma patients failing maximal tolerated medical therapy AND a traditional glaucoma surgery, or having more aggressive glaucoma disease etiology such as inflammatory or neovascular glaucoma). Revision of the "refractory" term puts the definition and included patient type more in line with what is encountered in daily glaucoma practice at the current time and also allows inclusion of additional patients safely and effectively into research using newer "less traumatic" devices to lower IOP (for which there is increasing safety and efficacy history). For example many patients are using maximal medications are uncontrolled and need surgery, generally more than trabeculoplasty but not necessarily filtration surgery or tube shunt surgery. However inclusion of the latter type of "refractory" patient does not meet the FDA requirements for regulations allowing inclusion into "refractory" category with respect to surgical research- discussion is ongoing as how to align FDA research requirements with practical nature of glaucoma - good progress made in this area and interim work planned.

Discussion also revolved around the documentation of AE's in refractory and non- refractory groups, and how risk analysis of particular devices in these categories would be applied for safety.

MIGS:
Terminology and definitions- The FDA has guidance and a definition of "MIGS" from prior outreach workshops. However such definitions do not include the classification of the anatomic placement of the device or mechanism of IOP lowering function-, and discussion revolved around modifying classification of such devices for better historical and comparative data collection as well as description and risk analysis of safety and efficacy.
Given some "MIGS" are procedures and not implantable devices (ABiC, trabectome, goniotomy for example) we are reminded that this standard is for implantable devices only - not procedures.

Annex D

D.3 Design of clinical study:

FDA and AGS agree that historical clinical safety data can be used when the previously tested and accepted device and the new devise have similar effect- in that an AE grid may be compiled and used (as in the case of IOL's) as such data becomes available.

Discussion of adverse event testing to pick up a 1% AE rate: review that filters and tubes have a 5-8% AE effect so should we loosed the 1% number- but when newer devices are being used in less sick eyes or to lower IOP (or replace meds) perhaps we Do want to keep a tighter AE control in clinical design-

Revision of percentage subjects allowed in each center and from each surgeon- to 25%

Size study to allow for 10% loss over lifetime of investigation for *implanted* subjects

Addition of instructions to surgeons (see text bullet points)

D.4 Study Duration:

Discussion of 12 versus 24 month study requirement; settle on 12 months with possible extension from risk analysis of device and eyes used in investigation

Table D.2:

Revisions as noted for gonioscopy and specular microscopy

FDA to check with Spec micro expert to determine need and timing

Annex E

E.2 Best corrected visual acuity:

Include testing with "Best Distance Corrected Visual Acuity" listed (consistent with AAO terms)

Use EDTRS testing throughout all centers

E.5 Crystalline Lens status:

Allow additional lens assessment (objective)

E.10 Specular micsoscopy:

FDA to check on need and timing-

A 30% drop is significant

no additional sections in Annex E covered

Annex F

Statistics- not covered

Annex G

Analysis:

Change terms "efficacy" to "effectiveness" (effective has to do with a device)

Annex H

Labelling: Add MRI safety and compatibility

Annex I

Computational modelling for MIGS devices- outline written
(need to review next time- not covered)

Confirmed comments are to be incorporated into new document that will be distributed for additional review in interim, and work continuing through interim to next meeting. Interim work planned on action items and definitions for clinical application. Expect full day needed in February 2019 ANSI meeting for additional review.

Additional draft items for ANSI-
Planning for spring meeting 2019:
Start work on Z80.39 (combining MIOL and EDF IOL standards)
PINS ready

Next meetings are both in Clearwater FL for 2019:
February 10-12
August 18-20

Ongoing updates for ISO- TAG group SC7/WG7:
11979-1 Vocabulary
11979-5 Biocompatibility
11979-7 IOL standard (revision to include EDF)
Endotamponades

Upcoming ISO meetings

Interim meeting SC7/WG7	Late February in Netherlands
US Hosted Plenary	November 4-8, Dallas Tx area

Note: per legal counsel, we will add Antitrust issues to every meeting-
Refer to Z80 website- for Z80 Operations Manual

Respectfully submitted-

Dr. Tubbs

Minutes
ANSI Z80 SC6
Instruments & Low Vision Devices Subcommittee Meeting
August 20, 2018
Clearwater Beach, FL

1. Meeting was called to order at 10:00 A.M.

2. Those in attendance in person and via teleconference:
Charles Campbell, Bruce Drum (FDA) William Brown (AOA), Karl Citek (AOA) and Stephen Klyce (ASCRS). Dexiu Shi (FDA), Maryam Molchtarzadeh (FDA) and Stephen Farrar (J&J) joined by teleconference.

3. Agenda was accepted as posted.

4. ANSI Standards in voting since that last meeting

   Z80.10 – Tonometers – standard has been approved by vote of ASC Z80 and has passed the public review period
   Z80.23 – Corneal topography and tomography systems was approved by ASC Z80 with one negative vote. This negative vote has been resolved and the document will now go into the public review stage.

5. Report of recent ISO meeting in Berlin

   Dr. Drum reported on the ISO/TC127/SC7/WG6 meeting in Berlin May 2018. It was decided to do minor revisions to correct errors in ISO 8596 Visual acuity testing – Standard and clinical optotypes and their presentation and ISO 24157 – Reporting aberrations of the human eye. The project group working on ISO 15253 – Low vision devices, under the leadership of Dr. Citek, produced a Committee Draft that is now in circulation for voting. A project group to revise ISO 19980 – Corneal topographers will be formed and led by Mr. Kirchhubel. It was decided to create a Visual Acuity standard to address visual acuity presentations used clinically. Dr. Citek will lead this group. Dr. Wolffe from the UK will create an initial draft for the group to use. The project group to revise 15004-1 – Fundamental requirements for ophthalmic instruments met. It was decided to expand the scope of this project to harmonize the portion of the standard on environmental standards with IEC 60601. A second CD will be created for this work. The project group to revise ISO 15004 –2 Light hazards met. This project group will meet again in London on November 12-13, 2018.

6. Revision of Z80.9 –Low Vision Devices

   A PINS has been issued for a review of Z80.9 Low Vision Devices with the view to use current work on ISO 15253 as a basis for revision of the ANSI standard, which covers the same material. The CD of ISO 15253 was reviewed by the committee under the guidance of Dr. Citek, the ISO project leader, taking into account comments received by various committee members. Dr. Citek informed the committee that in his view the changes we feel need to be made to the ISO CD will be in the document before our next committee meeting and that most likely an ISO DIS will be issued by that time. The committee then concluded that the ISO text could be used as is for a revised version of ANSI Z80.9 with the exception that we would wish to refer to the ANSI sunglass standard, ANSI Z80.3, for details on tints and impact resistance instead of using the ISO version. This revision to Z80.9 can take place at the next SC 6 meeting.

7. Z80.21 – General-Purpose Clinical Visual Acuity Charts

   A PINS has been issued to revise Z80.21. This standard is schedules for review in 2020. No action on this item was taken at this meeting. This standard will be discussed at the next meeting of SC 6. Committee member are asked to review Z80.21 and submit their thoughts on a revision prior to the next meeting of SC 6.

8. Z80.10 – Tonometers

   Dr. Drum asked for the tonometer standard Z80.10 be reopened so that requirements the FDA wishes to place in the standard could be considered. This will be taken under consideration by SC 6.

9. The committee was informed by Michael Vitale that next meeting of SC6 will take place in Clearwater Beach on February 11, 2018.

10. The meeting adjourned at 12:30 PM.

Subcommittee for Contact Lenses

Sheraton Sand Key, Clearwater Beach, FL

ANSI Z80 CONTACT LENS SUBCOMMITTEE: CONTACT LENSES and CARE PRODUCTS

Monday, August 20th, 2018: 9:00 am – 12:00 pm

1. **Opening of the Meeting of ANSI Z80 CL Subcommittee: Contact Lenses and Care Products:** The Z80 Contact Lens Subcommittee meeting was opened at 9:00 am, March 20th, 2017. A sign in sheet was distributed for attendees to document their participation. Dr. Benjamin opened the meeting and announce that he would be leaving the Chair of SC7 but retain his role as the secretary for ANSI Z80. Dr Stone was asked to assume the chair of SC7 and would take this role as of this meeting.

2. **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:

Manal Gabriel	Alcon Laboratories
Cindy Bach	Alcon Laboratories
Michael Pfleger	Alcon Laboratories
William J. Benjamin	American Optometric Association
Glenn Davies	Bausch & Lomb, Inc.
Angelo Green	Food and Drug Administration
Kelly Arnold	Johnson & Johnson Vision Care
James Cook	Johnson & Johnson Vision Care
Greg Williby	Johnson & Johnson Vision Care
Carol Lakkis	Johnson & Johnson Vision Care
Ralph Stone	R.P. Stone Consulting
Brian Loudermilk	Alcon Laboratories
Michelle Mundorf	Johnson & Johnson Vision Care
Karen Sentell	Alcon Laboratories
William Domm	Bausch and Lomb, Inc.
Kim Millard	Bausch and Lomb, Inc.
Ying Zheng	Alcon Laboratories
Melanie George	CooperVision
Heather Michaels	CooperVision
Monica Crary	Alcon Laboratories
Mary Mowrey-McKee	R.P. Stone Consulting

The following persons participated by speaker phone:

Paul Ludington	Bausch & Lomb, Inc.
Joshua Soane	Bausch & Lomb, Inc

3. **Review of the Agenda:** The agenda was reviewed. In item 13 the standard number was corrected from ISO 11979 (Labeling) to ISO 11978 (Labeling). There were no changes in the overall agenda. It was announced that going forward the list of activities would be circulated but the new agendas would only reflect those items to be discussed at the meeting. It was asked that those providing reviews of specific areas provide a summary to be attached to this report.

4. **Review of Z80.20: Contact lenses (Joe Benjamin):** A request received via the Scleral Lens Society has been received for consideration for addition/revision of the definitions relating to scleral lenses. This is an attempt to provide the field with a common set of definitions for this area. It was decided to circulate this request and to determine if a request for a PINS would be appropriate at our next meeting. G Davies, M. Dalsing, and S Puig were asked to provide additional input on the proposal. It was also to be determine at the meeting of ANSI Z80 if if we would request to ISO for a change in the ISO18369-1 standard.

5. **ANSI 18369**-1 thru 4: It was announced that errors have been corrected, effective February 14, 2018 and the revision is now available.

6. **FDA Acceptance of ANSI Z80-18 And ANSI Z80-20** Angelo Green announced that ANSI Z80-18 had been accepted in its entirety and that ANSI Z80-20 had been accepted with the exception of Subclause 5.1, paragraph 2.

7. **ISO 18369-1, ISO 18369-3 and ISO 18369-4** Angelo Green announced that these three standards ISO 18339-1, -3-and -4 had been accepted by FDA in their entirety.

8. **ISO 18369-2: Tolerances (Glenn Davies):** FDA announced that this standard was also accepted in its entirety with the following note as part of the rationale for recognition: "Note : Although the scope of the standard states that tolerances may not apply beyond time of manufacture, manufacturers may use this standard for the purpose of final product specifications and shelf life specifications."

9. **ISO 18369-3: Parameter measurement methods (Greg Williby):**

   The PWI Working Group on this topic that is considering multifocal contact lenses measurement of optical prism, and the correlation of in-air refractive power with wave sensor measurements in saline. The ring test is ongoing but preliminary indications are that the wavefront approach may be superior. We expect the final results for this effort by our next meeting. Other areas are under review including power mapping for lenses.

   It was noted that ISO 9342-2 withdrawal continues to be strongly supported by this committee.

10. ISO 18369-4: Physicochemical properties (Karen Sentell): The Development of test conditions recommendations for mechanical testing of hydrogels for when surveillance tensile testing is conducted by regional health authorities or regulatory bodies are under review Primary mechanical test parameters has been collected and summarized from four major contact lens manufacturers.

Round robin testing with each site using habitual measurement protocol is in progress. Preliminary data from two sites shows good agreement for modulus and center thickness; root cause for large differences in other tensile parameters under investigation. Sites are reporting difficulty in handling test lenses (very thin CT). Cooper Vision provided alternate test articles for round robin testing.
Action items: All sites will test new test articles as well as complete testing on initial samples. Sentell will compile data from both sets of test articles and measurement experts at each test site will discuss any disparities. Compiled data will be reviewed at interim WG meeting, with next steps for preparation of technical report to be decided therein.

We continue to optimize / standardize methodology for wet lens blotting - Round robin study to be conducted by Alcon, JJVC, Cooper Vision and Menicon on -3.00 D high water content lenses to determine degree of variability for wet lens weights and thereby degree to which wet lens blotting methods require standardization. Wet lens weights are to be compared for individual lenses for habitual blotting methods at each test site vs. "more standardized" methodology. Final details of test protocol discussed and agreed upon. Action items: Finalization of test protocol by August 30. All sites will test all three groups of test articles. Sentell will compile data from all sets of test articles and measurement experts at each test site will discuss any disparities. Compiled data will be reviewed at interim WG meeting, with next steps to be decided therein.

11. ISO 11980: Clinical investigations (Carol Lakkis): It was reported that given the number of comments an attempt is being made by Dr Lakkis and Dr Josephson to bring forward the key areas of concern for discussion at project team at the WG-9 meeting in November. The list will be circulated by mid-September and members are encouraged to add any additional topics that they believe should be discussed by the ISO project team. This will be on the agenda for the Pre-meeting of ANSI experts prior to the WG-9 interim meeting in November.

12.ISO 19979: Hygienic management of multi-patient use trial contact lenses (Carol Lakkis): The standard has been reconfirmed, and it is our understanding that the concern raised under HIPPA is not a concern.

13.ISO 11978: Labelling: Greg Williby present an approach to ta revision to the language to provide determining acceptability of font size and contrast. This was accepted by the committee and the proposal will be attached to this report. This will be our proposal to ISO WG-9.

14.ISO 11978 Symbols and ISO 15223-1: Medical Symbols: The PWI team is considering 13 possible symbols and trying to obtain appropriate graphic design images for discussion and testing. It was suggested that activities relating to symbols be combined under this topic and it was agreed. Assistance for graphic design assistance from the Vision Council has been requested.

15. ISO 19045-2 **Acanthamoeba Trophozoite Biocidal. Standard (Mary Mowrey-Mckee)** There was a review of the data obtained from the initial ring tests and discussion was carried out. It was decided to initially look at control of the inoculum. Future testing was discussed as there are attempts to control the variables in the testing protocols. The initial testing will be carried out by the interim WG-9 meeting in November 2018. A second full ring test will be attempted with a target of results for the ISO TC 172 meeting in November 2019.

16. Next Meetings of ANSI Z80.20 CL Subcommittee and ISO TC/172/SC7/WG9:

ISO WG9	Novemeber 14-18	Jacksonville FL
ANSI Z80	Feb 10-12, 2019	Sheraton Sand Key, Clearwater Beach FL
ANSI Z80	August 18-20, 2019	Sheraton Sand Key, Clearwater Beach FL
ISO SC7	November 4-8, 2019	Anticipated to be Dallas/Forth TX

17. Delegates for the Interim Meeting of WG9 in November 2018(Ralph Stone):
It was explained that we have been directed by ISO Central that only qualified experts would be allowed to register for the ISO meeting, and that the designation a an "observer" is not appropriate for the purpose of registration. At the ISO meeting the registered experts may attend other project team meetings at the discretion of the Project leader.
The following have been nominated as experts for the interim meeting.

ISO 19045-2 Mary Mowrey-Mckee Project Leader'
- Carol Lakkis
- Manal Gabriel
- William Domm (expert at request of the Project leader

ISO 11980
- Carol Lakkis
- Glenn Davies
- ISO11978
- Gregg Williby
- Glenn Davies

ISO 11978 Symbols (PWI) C Lakkis Project leader
- J Streza
- A green
- M Gabriel (at request of the project team leader)

ISO 18369-3(PWI0 Paul Luddington Project Leader
- Gregg Willigby
- Karen Sentell

ISO 18369-4 (PWI) Karen Sentell Project Leader
- Paul Luddington
- Sam Puig

WG-9 Experts
- Ralph Stone
- Mary Mowrey-McKee
- Wm J Benjamin
- James Cook

18. Miscellaneous Business and Call for New Work Items:
The reception on Dr Thomas White retirement was announced, to be at 5:30-7:30 pm in the Beach room.

19. **Revised Administrative Structure of ANSI Z80 CL Subcommittee:** The administrative structure will be reviewed given our changes in organization.

20. **Closure of the Meeting:** The meeting of the ANSI Z80 Contact Lens Subcommittee came to an end at 12:00 pm, March 20, 2017. A committee of those involved and or interested in the ISO 19045-2 discussion met and continued their technical discussions from 1:30-3:30 PM.

Respectfully submitted,
RPS

ANSI Z80 SC 8 Report
Sheraton Sand Key, Clearwater, FL
August 21, 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 DCS Committee approved version 3.12 on 8/8/18.
- **Action**
  ANSI document is currently being drafted by Paul Wade for distribution to SC8 members. We hope to complete the first draft by the end of September and hold a remote meeting prior to the fall ANSI meeting.

ISO 16284 – Information Interchange for Ophthalmic Optical Equipment

- **Action**
  ISO 16284 is also in active drafting status in parallel with Z80.24. The call for experts was completed on 7/11/2018.

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 currently.

Status report for ANSI Z87.1 Standard Occupational and Educational Personal Eye and Face Protection Devices

Dick Whitney – ANSI Z80 liaison to ANSI Z87.1

1. A draft of the proposed 2020 revision to ANSI Z87.1- 2015 is being circulated for comment within the committee at this time. Comments are due by Sept 25.

2. The full ANSI Z87.1 will meet on Wednesday, Oct 10 in Washington D.C. and review the comments received. The goal is to have a revision of this standard ready for 2020.

3. A biohazard eyewear subcommittee is actively working on a new standard ANSI Z87.62 and will be meeting face to face on Thursday Oct 11. This is being chaired by James R. Harris, PhD, PE from National Institute for Occupational Safety and Health. He has been holding frequent conference calls. They are working on test methods and requirements for splash and spurt of biohazardous materials.

FDA Report
ANSI August 2018 Z80 Meeting

- The most recent publication of FDA recognized standards (list number 049) from June 7, 2018, Federal Register (available at the following link) included all or part of the following ophthalmic standards:
    - Parts 1-4 of ISO 18369 – Ophthalmic optics – Contact lenses
    - Part 8 of ISO 11979 – Ophthalmic implants – Intraocular lenses

  The next list (number 050) will be published in the Federal Register in the next 1-2 months.

- Following is a list of recent FDA decisions of interest (see attached for Indications for Use for each device):
    - P170034: Hydrus® Microstent
    - P170039: CustomFlex™ Artificial Iris
    - P170043: iStent inject® Trabecular Micro-Bypass System (Model G2-M-IS)
    - P910056/S027: enVista® One-Piece Hydrophobic Acrylic Toric Intraocular Lens (Model MX60T)
    - K180299: ACUVUE (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive
    - P170035: Bausch + Lomb Ultra® (samfilcon A) Contact Lenses
    - DEN180001: IDx-DR

- CDRH Reorganization – Four offices within CDRH – Office of Device Evaluation (ODE), Office of Compliance (OC), Office of Surveillance and Biometrics (OSB), and Office of In Vitro Diagnostics and Radiological Health – are merging to form one new office – the Office of Product Evaluation and Quality (OPEQ) – to create one office to evaluate the total product life cycle for devices. Under the old structure, ODE is primarily concerned with the premarket review of devices and OC and OSB are primarily concerned with post-market review of devices (for recalls and post-market studies, respectively). Under the new structure, a reviewer can be involved in a particular device for the total product life cycle, from premarket to post-market. Within OPEQ, devices are reviewed within different Offices of Health Technology (OHTs). Ophthalmic devices are regulated within OHT1, and Dr. Malvina Eydelman is the office director.

Recent PMA Approvals/ 510(k) Clearances

P170034: Hydrus® Microstent - This device is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG).

P170039: CustomFlex™ Artificial Iris - This device is indicated for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia.

P170043: iStent *inject*® Trabecular Micro-Bypass System (Model G2-M-IS) - This device is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma.

P910056/S027: enVista® One-Piece Hydrophobic Acrylic Toric Intraocular Lens (Model MX60T) - This device is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia and corneal astigmatism following removal of a cataractous lens for improved uncorrected distance vision.

K180299: ACUVUE (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive - The ACUVUE (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive (spherical) is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.
The ACUVUE (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive TORIC is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with nondiseased eyes who may have 10.00D or less of astigmatism.
The ACUVUE (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive MULTIFOCAL is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may have 0.75D or less of astigmatism.
The ACUVUE (senofilcon A) Soft (hydrophilic) Contact Lens with photochromic additive MULTIFOCAL TORIC is indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) and presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and may have 10.00D or less of astigmatism.
These lenses are also indicated for the attenuation of bright light as they contain a photochromic additive which dynamically absorbs visible light.
These lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.
Eye Care Professionals may prescribe the lenses either for daily disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement. When prescribed for daily disposable wear, no cleaning or disinfection is required. Lenses should be discarded upon removal. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only and should be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When the lenses are worn in a frequent/planned replacement modality, they are intended to be worn for up to 2-weeks (14 days).

P170035: Bausch + Lomb Ultra® (samfilcon A) Contact Lenses - These devices are indicated for:
Single Vision Spherical (SVS) Vision Correction
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens is indicated for extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.
Presbyopia Vision Correction
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens for Presbyopia is indicated for extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia andastigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for add powers ranging from +0.75D to +5.00D.
Astigmatism Vision Correction
The BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens for Astigmatism is indicated for extended wear for up to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism up to 5.00 diopters.

DEN180001: IDx-DR – IDx-DR is indicated for use by health care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. IDx-DR is indicated for use with the Topcon NW400.

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

Sand Key, FL – 21 August 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. The next meeting of SC6 and it's working groups is planned for November 12 – 16, 2018 in Hangzhou, China.

Work Group Activity Summary / Highlights

WG1 – Definitions:
ISO 4007, the SC6 terminology / definitions has progressed a revision of its document to FDIS stage.

WG 2 – Test Methods:
Several (revised) test method documents have been revised currently in DIS stage ballot 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

One test method document is under systematic review:

- ISO 12311 Test Methods for Sunglasses and Related Eyewear is under systematic review until December 3 2018

WG 3 – Sunglasses:
ISO 12312-1: Eye and face protection – Sunglasses and Related Eyewear is currently under systematic review until September 3 2018

WG 4 – Occupational Eye and Face Protection:
Four document (revisions) have recently passed DIS stage balloting - 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

The U.S. voted to approve all (with comments) excepting Protectors for Welding.

Two document (revisions) are currently still in DIS ballot stage – these being:

- ISO/DTR 2263.2 Patient and client eye protectors for use during laser or intense light source (ILS) procedures – Guidance
- ISO/CD 12609.1 Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications -- Part 1: Specification for products

WG 5 – Eye and Face Protection for Sports:
Two documents are currently in DIS stage ballot:

- 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. obtained with respect to preexisting ASTM standards covering these protectors.

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. The joint working group plans to meet September 18 – 19 in Kista, Sweden.

Respectfully submitted,

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