

## **Z80 Accredited Standards Committee for Ophthalmic Optics**

**Westin Dallas Downtown, Dallas, Texas – Bluebonnet Ballroom**

### **ASC Z80 PARENT COMMITTEE MEETING MINUTES**

**Tuesday, November 14<sup>th</sup>, 2023: 8:30 am – 11:00 am**

- **Call to Order and Introductions.** Dr. Carl Tubbs, Chair of ASC Z80, called the meeting to order at 8:33 am, Tuesday, November 14<sup>th</sup>, 2023. A sign-in sheet was distributed for attendees to document their participation. Each person identified themselves to the group in turn around the meeting room.

A roll call of ASC Z80 member representatives in attendance was taken. Seventeen (17) voting representatives or their designees of the twenty (20) member organizations were present, thus constituting a quorum.

Attendee List:

Ari, Ramzi	Hilmantel, Gene	Torgerson, Neil*
Arnold, Kelly	Ing, Eliesa^	Tubbs, Carl*
Bancos, Simona	Janakiraman, Priya*	Van Arnam, Rick*
Bianchi, Lauren	Mattsson-Boze, Daniel	Vitale, Michael* <sup>(2)^(3)</sup>
Buckholt, Carl*	Pretzie, Robert	Wang, Zhenguo
Calogero, Donald*	Rice, Christopher	Weeber, Henk
Citek, Karl*	Saviola, Jim*	Whitney, Richard
Crary, Monica	Savoy, Richard	Williby, Greg^
Domm, William	Smith, Ron	Wilson, Carrie
Drum, Bruce	Stone, Ralph*	Wong, Elissa
George, Melanie	Suryakumar, Rajaraman^	

\*Voting representative; ^Proxy; <sup>(X)</sup>Number of votes, if more than 1

- **Acceptance of the Agenda.** The agenda was unanimously accepted without modification.
- **Acceptance of the Spring 2023 Meeting Minutes.** The minutes of the last meeting of the Parent Committee that had been distributed were unanimously accepted without modification.
- **Chair's Comments.** Dr. Tubbs welcomed everyone to the Z80 Meeting and thanked them for their support of the standards process, and to consider recruiting new colleagues. Dr. Tubbs reminded all representatives to vote on ballots as they are distributed, or at least to cast a vote to abstain.

- **Vice Chair's Comments.** Ms. Lauren Bianchi, Vice Chair, thanked everyone for their participation and recognized the time and commitment required of everyone to work on standards. (Dr. Tubbs, Chair, needed to depart from the meeting at 9:20 am, during the Subcommittee Reports, at which time Ms. Bianchi took over the meeting.)
- **Secretary's Comments.** Dr. Karl Citek, Secretary, reminded the subcommittee chairs and others presenting reports to this Parent Committee to submit final versions of their reports in a timely manner and as Word documents, rather than PDF or other files, so that they could be more easily included with the Parent Committee Meeting Minutes as a single document.
- **Legal Counsel's Report.** Mr. Rick Van Arnem, Legal Counsel for ASC Z80, reminded everyone to stay compliant with regard to anti-trust procedures, not only in official meetings but during all interactions. Mr. Van Arnem also provided an update of the on-going Zero Tech v. Brita/Clorox patent lawsuit, as well as the new ASTM v. PRO! copyright infringement lawsuit. The Z80 Committee is referred to the Legal Counsel's report included as a portion of these minutes.
- **Secretariat's Report.** Mr. Michael Vitale, representing the Secretariat, The Vision Council, reviewed the approvals and sales of standards year-to-date, the list of 27 standards administered by ASC Z80, and member voting information. The Z80 Committee is referred to the Secretariat's report included as a portion of these minutes.
- **Subcommittee (SC) Reports.**
  - SC1:** Mr. Richard Whitney, Chair of SC1, projected the written subcommittee report for view by the Z80 Committee. Key points were covered by Mr. Whitney. The Z80 Committee is referred to the SC1 report included as a portion of these minutes.
  - SC2:** Dr. Citek, Chair of SC2, 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 report included as a portion of these minutes. Dr. Citek proposed the following motions:
    - Motion:** Reaffirm ANSI Z80.3 without revision. Seconded. Motion passes.
    - Motion:** Request PINS to open ANSI Z80.3 for review. Seconded. Motion passes.
  - SC3:** Ms. Bianchi, Substitute Chair of SC3, projected the written subcommittee report for view by the Z80 Committee. The Z80 Committee is referred to the SC3 report included as a portion of these minutes.
  - SC4:** Dr. Raj Suryakumar, Chair of SC4, projected the written subcommittee report for view by the Z80 Committee. Key points were covered by Dr. Suryakumar. The Z80 Committee is referred to the SC4 report included as a portion of these minutes. Dr. Suryakumar proposed the following motions:

**Motion:** Reaffirm ANSI Z80.7 without revision. Seconded. Motion passes.

**Motion:** Request PINS to open ANSI Z80.7 for review. Seconded. Motion passes.

**Motion:** Request to change the title of ANSI Z80.7 to Monofocal Intraocular Lenses. Seconded. Motion passes.

**Motion:** Reaffirm ANSI Z80.30 without revision. Seconded. Motion passes.

**Motion:** Request PINS to open ANSI Z80.30 for review. Seconded. Motion passes.

**SC6:** Mr. Daniel Mattsson-Boze, Chair of SC6, projected the written subcommittee report for view by the Z80 Committee. Key points were covered by Mr. Mattsson-Boze. The Z80 Committee is referred to the SC6 report included as a portion of these minutes. Mr. Mattsson-Boze proposed the following motions:

**Motion:** Reaffirm ANSI Z80.10 without revision. Seconded. Motion passes.

**Motion:** Request PINS to open ANSI Z80.10 for review. Seconded. Motion passes.

**Motion:** Request PINS to open ANSI Z80.36 for review. Seconded. Motion passes.

**Motion:** Request PINS to work a new standard for Contrast Sensitivity Testing. Seconded. Motion passes.

**SC7:** Dr. Greg Williby, Chair of SC7, projected the written subcommittee report for view by the Z80 Committee. Key points were covered by Dr. Williby. The Z80 Committee is referred to the SC7 report included as a portion of these minutes. As in the subcommittee meeting, significant discussion occurred regarding public safety issues of multi-dose preservative-free eye drops. Future work could include incorporating requirements into an existing standard or create a new standard altogether.

**SC8:** Mr. Vitale, Chair of SC8, reported that SC8 did not meet and that there was nothing to report.

**Spectral Bands Task Force (SBTF):** Dr. Kelly Arnold, Chair of the Task Force, summarized the work of the Task Force. The Z80 Committee is referred to the SBTF report included as a portion of these minutes.

▪ **Information Reports.**

**ISEA Z87:** Mr. Vitale, Chair of the Z87 Committee, reported ANSI Z87.1 is under revision for 2025 and that ANSI Z87.62 for biohazard safety eyewear is under revision for 2026.

**U.S. Food & Drug Administration:** Dr. Don Calogero, FDA, summarized the involvement of the FDA in ASC Z80. The Z80 Committee is referred to the FDA report included as a portion of these minutes.

**US TAG for ISO/TC94/SC6:** Mr. Vitale reported that there is no update since April 2023.

▪ **Next Plenary Meetings:**

ASC Z80: April 21-23, 2024; Sheraton Sand Key, Clearwater Beach, Florida.

ASC Z80: October 6-8, 2024; Sheraton Sand Key, Clearwater Beach, Florida.

ISO/TC172/SC7: November 18-22, 2024; Tokyo, JP.

▪ **New Business:** None.

- **Closure of the Meeting:** Ms. Bianchi thanked everyone for their participation, wished them safe travels, and brought the meeting to a close at 10:41 am.

Respectfully submitted,  
Karl Citek



Legal Counsel's Report  
ASC Z-80  
Rick Van Arnam  
The Westin Dallas Downtown  
November 14, 2023

Legal Update

1 *Antitrust Reminder*

- a. Quick reminder of our antitrust position and the existence of our antitrust policy on the website. Need to be mindful of antitrust issues anytime you are acting as a perceived representative of ASC Z-80.

2 *Update on Zero Technologies v. Brita and Clorox*

- a. Discussed this case at past meetings. The claim is that Brita, while working on a task force for an ASC (NSF Int'l) responsible for adopting and then managing a standard for gravity-fed water filters, did not tell the other on the task force it was developing a patent that would be essential to the standard. Brita learned information from the task force and used that in developing its patent.
- b. After the patent was issued (which was after the standard was issued), Brita/Clorox sued its competitors for patent infringement.
- c. This case demonstrates two key issues for standard writing activity:
  - i. You can't use standards to undertake anticompetitive behavior. You must disclose intellectual property rights, such as a patent, that might be implicated by a proposed or adopted standard.
  - ii. Under ANSI patent policy, you can incorporate a patent in a standard if there is a technical reason for the inclusion. But you have to make it available free or at a reasonable price, or state that you won't enforce the patent.
- d. The case is still ongoing. Currently tied up with some procedural issues as to whether the case should proceed in district court in PA or be part of case ongoing in Del.

3     *American Society for Testing and Materials, et al. v. Public. Resource. Organization!*

- a. This case involves whether a 3<sup>rd</sup> party can disseminate free of charge a standard that has been incorporated by reference into federal or state laws and regulations. Or does this constitute copyright infringement because the standard developing organization owns the copyright of the standard?
- b. The “incorporation by reference” doctrine allows agencies, like the FDA, to reference privately developed standards in published rules and regulations without reproducing the entire standard itself.
  - i. 27,000 standards have been incorporated by reference into the federal code of regulations.
  - ii. Congress encourages incorporation by reference as it avoids making the agency duplicate industry efforts. Once incorporated into a regulation promulgated via the rule making process, that standard becomes part of the law.
- c. In this case, a fire extinguisher standard issued by one of the plaintiffs was incorporated by reference into a federal regulation that was promulgated by the rule making process. Then the defendant posted online a full copy of the standard.
- d. The defendant is a nonprofit that publishes and shares public domain materials in the US and internationally. This includes US laws and regulations. It has published 100s of incorporated by reference standards.
- e. The Court of Appeals for the DC Circuit held that the defendant’s use of the copyrighted materials to be allowed under the “fair use” doctrine.
  - i. The fair use doctrine is an affirmative defense to a claim of copyright infringement. It exempts the use of copyrighted materials for criticism, news reporting, teaching, research, and similar uses.

- f. There is a multipart test for determining fair use and the court was swayed that the defendant's use passed this test
  - i. It is a non-profit and it uses the standards for educational purposes, which it disseminates for free.
  - ii. The defendant's use of the standard is different from that of the plaintiffs -- it is simply providing access to the law, while the plaintiffs are creating industry and engineering best practices.
  - iii. Legal texts containing the law, such as the code of federal regulations, are never provided copyright protection. If the standard had been set out in full in the regulation, rather than being incorporated by reference, it would not have gotten copyright protection.
  - iv. Unclear what economic harm the plaintiffs experienced, as they make the standards available in public reading rules.
- g. ANSI is concerned about this decision and has stated its position on its website that the decision does not invalidate copyrights on incorporated by reference documents, and that the decision is limited to the facts before the court, and to the DC jurisdiction.
- h. Our concern is that this could impact our standards when they are incorporated by reference. We own our copyright and make money by selling standards. Don't want folks to have free access to them.

## **ASC Z80 Secretariat's Report**

### **November 2023**

#### **Member Status and Dues**

- 20 voting members, all dues are current.

<b><u>Year</u></b>	<b><u>ASC Z80 Standards Sales</u></b>	<b><u>National Standards Approved</u></b>
2023	185 (to-date)	3 Approved or Reaffirmed (to-date)
2022	258	5 Approved or Reaffirmed
2021	242	5 Approved or Reaffirmed
2020	211	4 Approved or Reaffirmed

#### **Standards Tracking - ASC Z80 Standards Status as of November 2023**

##### *27 Standards under the ASC Z80 umbrella:*

- Z80.1-2020 Prescription Ophthalmic Lenses – Recommendations – Approved by ANSI on December 22, 2020. Next revision due in 2025; PINS submitted in March 2022.
- Z80.3-2018 Nonprescription Sunglass and Fashion Eyewear Requirements – Approved by ANSI on February 14, 2018. Next revision due in 2023 – out for Public Review to Reaffirm while in Development; PINS submitted in March 2018.
- ANSI/ISO 7998 / 8624 / 12870 – Optics Set (replaced Z80.5) – Approved by ANSI on March 3, 2016. Next revision due when ISO revises these three items.
- Z80.7-2013 (R2018) Intraocular Lenses – PINS submitted in March 2018; Approved by ANSI on September 25, 2018 (reaffirmed while in development for revision). Next revision is due in 2023 - out for Public Review to Reaffirm while in Development.
- Z80.9-2020 Devices for Low Vision – Approved by ANSI on April 9, 2020. Next revision is due in 2025. 2023 Errata published (June 2023); PINS submitted in April 2023.
- Z80.10-2018 Tonometers – Approved by ANSI on September 27, 2018 – Next revision due in 2023 - out for Public Review to Reaffirm while in Development. PINS submitted in July 2023.
- Z80.11-2012 (R2022) Laser Systems for Corneal Reshaping – PINS submitted in June of 2014. The next revision is due in 2027 (reaffirmed while in development).
- Z80.12-2007 (R2022) Multifocal Intraocular Lenses – Approved by ANSI in April of 2012. The next revision is due in 2027.
- Z80.13-2007 (R2022) Phakic Intraocular Lenses – Approved by ANSI in April of 2012. The next revision is due in 2027.
- Z80.14 Ophthalmic Viscosurgical Devices – New item, will adopt when work in ISO is complete.
- Z80.17-2013 (R2023) Focimeters – Approved by ANSI on October 19, 2023. The next revision is due in 2028.
- Z80.18-2016 (R2021) Contact Lens Care Products – Vocabulary, Performance Specifications, and Test Methodology – Approved by ANSI on September 9, 2021. The next revision is due in 2026.
- Z80.20-2016 (R2021) Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties – Approved by ANSI on September 9, 2021. The next revision is due in 2026. PINS submitted in September 2019 (reaffirmed while in development).

- Z80.21-2020 Instruments - General-Purpose Clinical Visual Acuity Charts- approved by ANSI on January 24, 2020. The next revision is due in 2025.
- Z80.23-2018 (R2023) Corneal Topography and Tomography Systems – Standard Terminology, Requirements – Approved by ANSI on October 19, 2023. Next revision is due in 2028.
- Z80.27-2014 (R2019) Implantable Glaucoma Devices – Approved by ANSI on December 9, 2019 (reaffirmed while in development for revision). The next revision is due in 2024; PINS submitted November 2017.
- Z80.28-2022 Methods of Reporting Optical Aberrations of Eyes – approved by ANSI on July 11, 2022. The next revision is due in 2027.
- Z80.29-2015 (R2020) Accommodative Intraocular Lenses- approved by ANSI on September 28, 2020. The next revision is due in 2025; PINS submitted December 2020.
- Z80.30-2018 Toric Intraocular Lenses – Approved by ANSI on April 24, 2018. The next revision is due in 2023 - out for Public Review to Reaffirm.
- Z80.31-2022 Specifications for Ready-to-Wear Near-Vision Spectacles – approved by ANSI on October 28, 2022. The next revision is due in 2027.
- Z80.32 Methodology for Representation of Optically-Induced Phenomena – New item, PINS submitted in 2009.
- Z80.34 Information Interchange Billing and Billing Reimbursement – New item, PINS submitted in 2014. (Inactive)
- Z80.35-2018 (R2023) Extended Depth of Focus Intraocular Lenses – Approved by ANSI on September 25, 2023. Next revision is due in 2028; PINS submitted October 2023
- Z80.36-2021 Light Hazard Protection for Ophthalmic Instruments – Approved by ANSI on April 9, 2021. The next revision is due in 2026. Errata published (March 2022). PINS submitted June 2023.
- Z80.37-2017 (R2021) Ophthalmics – Slit-lamp Microscopes – Approved by ANSI on November 9, 2021. The next revision is due in 2026. PINS submitted June 2023.
- Z80.38-2017 (R2021) Ophthalmics – Light Hazard from Operation Microscopes Used in Ocular Surgery – Approved by ANSI on November 9, 2021. The next revision is due in 2026.
- Z80.39-xx Non-Accommodative Multi-Range Intraocular Lenses – New item; PINS updated in July 2023 (scope and title).

### **Member Voting Information**

- All experts and voting members are reminded to vote on every item that comes across their email, even if it is just to abstain.
- Thanks to Michele for all her efforts to keep us on track.

### **ISO / OEOSC TAG Update**

- TC172/SC7 Plenaries in 2023:
  - First Plenary, May 11<sup>th</sup> (virtual)
  - In person TC172/SC7 Meetings, May 22<sup>nd</sup> - 26<sup>th</sup>, Paris, France
    - All meetings took place as scheduled and were well received.
    - Experts seemed to agree that having in-person meetings allows for greater collaboration and networking.
    - Thanks to AFNOR / EssilorLuxottica for hosting the meetings.
- TC172/SC7 Virtual Plenary is scheduled for November 28<sup>th</sup>, 2023.

# SC1 - ASC Z80.1 Spectacle Lens Meeting Agenda

**Nov 13, 2023**  
**Dallas, Texas**  
**9AM – 11AM**

**Dick Whitney – Chair**  
**Rick Tinson – Vice Chair**

1. **Call to Order** – The meeting was called to order at 9:05AM

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

The following people participate in the Meeting. Each person introduced themselves and their company affiliation.

	<b>First Name</b>	<b>Last Name</b>	<b>Company</b>
1	Emmanuel	Alabi	ICS
2	Ramzi	Ari	Essilor of America, Inc.
3	Lauren	Bianchi	Marchon
4	Jeffrey	Brown	Vision Ease
5	Carl	Buckholt	Essilor/Luxottica
6	Karl	Citek	American Optometric Association
7	Koby	Curtis	Younger
8	Scott	Gabor	Colts Laboratories
9	Jacob	Gary	Colts Laboratories
10	Pete	Hanlin	Essilor/Luxottica
11	Tom	Hicks	Opticians Assoc. of America
12	Brent	McCardle	Carl Zeiss Vision
13	Robert	Pretzie	Hoya
14	Richard	Savoy	American Optometric Association
15	Rick	Tinson	Retired
16	Neil	Torgerson	Walman
17	Michael	Vitale	The Vision Council
18	Richard	Whitney	Consultant
19	Greg	Williams	Colts Laboratories
20	Carrie	Wilson	Optigal Consulting





# SC1 - ASC Z80.1 Spectacle Lens Meeting Agenda

**Nov 13, 2023**  
**Dallas, Texas**  
**9AM – 11AM**

**Dick Whitney – Chair**  
**Rick Tinson – Vice Chair**

## 3. Anti- Trust discussion

As required ASC operating procedures, the meeting began with a reminder of the importance of each member being aware of and following the Anti- trust compliance document for ANSI ASC Z80. Participants are encouraged to review Annex E of the operating procedures in ASC Z80 Operating procedures which can be found at ([www.z80asc.com](http://www.z80asc.com))

## 4. Approval of last meeting minutes (May 23)

The meeting minutes from the previous May 2023 were reviewed and approved. Rick Tinson motioned to approve, Carrie Wilson seconded.

## 5. ANSI Z80.1-2025 revision / Schedule for 2025 Publication

- **Overview of present agreed upon changes for 2025**

Karl Citek reviewed the entire document and tracked changes from the past meetings. The Chair appreciates his service in keeping an up to date document from each meeting and being about to show wording agreed upon as we move toward 2025. It is expected that the next two meetings should complete the process in time to process the 2025 revision by that time.

A good portion of the meeting included discussion on past changes, and included taking out tentative references to Myopia control lenses, a past topic of consideration.

It was agreed closely review the content of the summary table in Annex D, which is published by the Vision Council and is the only part of the Standard that is free. Added guidance to terms and instructional Sections (such as Annex F on Focimetry) will be considered.

American National Standard

Z80.1-2020 Draft ASC Z80 review –

Annex D Optical and Mechanical Tolerances Summary

(Informative)

Both uncut and edged finished lenses shall meet the following requirements. For let “as-worn” compensations, the tolerances in this annex apply to those values specific the spectacle component or completed spectacles and not to the prescribed power.

		MEASURE	POWER RANGE	TOLERANCE	SECT.	
Edged or uncut)	ive Power	Sphere Meridian Power (minus cylinder convention)	$\geq 0.00 \text{ D}, \leq \pm 6.50 \text{ D}$	$\pm 0.13 \text{ D}$	5.1.1.1	
		For SV, MF, Degressive, Assistive	$> \pm 6.50 \text{ D}$	$\pm 2\%$		2%
		Sphere Meridian Power (minus cylinder convention)	$\geq 0.00 \text{ D}, \leq \pm 8.00 \text{ D}$	$\pm 0.16 \text{ D}$	5.1.1.2	
		For Progressive	$> \pm 8.00 \text{ D}$	$\pm 2\%$		2%
		Cylinder	$\geq 0.00 \text{ D}, \leq -2.00 \text{ D}$	$\pm 0.13 \text{ D}$	5.1.1.1	

# SC1 - ASC Z80.1 Spectacle Lens Meeting Agenda

Nov 13, 2023  
Dallas, Texas  
9AM – 11AM

Dick Whitney – Chair  
Rick Tinson – Vice Chair

Also reviewed and discussed was section 7.2.2 of the 2020 ANSI Z80.1 Standard, where a claims requirement was implemented with the intent of also implementing identical wording in the Z80.3 Standard when revised. The present wording states:

## 7.2.2 Claims for Transmittance Attenuation for Wavelengths Longer than 380 nm

Manufacturers of lenses who claim transmittance cutoff at a nominated wavelength, the spectral transmittance shall be less than 2% at the nominated wavelength and at wavelengths below it to 380 nm.

Dick Whitney indicated that the ISO 8980-6 committee studied the cutoff issue of 2% and found that sample thickness and the sharp cutoff made holding 2% to be difficult. From extensive study, they propose the following:

## Wavelength cut: updated proposal (5<sup>th</sup> April)

In addition to complying with the requirements of ISO 8980-3 lenses claiming a specific wavelength cut shall comply with clauses X.X.

### Clause X.X. Wavelength cut

For lenses claimed to have a wavelength cut at a nominated wavelength, the spectral transmittance measured according to clause Y.Y. shall be less than 5% at the nominated wavelength. Spectral transmittance for all wavelengths, between the nominated wavelength minus 10nm and 280nm, shall be less than 1%.

### Y.Y. Measurement of spectral transmittance

The spectral transmittance shall be measured with a spectrophotometer or other equivalent measurement device, which is capable of making spectral transmittance measurements with relative uncertainty less than or equal to 10%, and spectral (wavelength) uncertainty within +/- 1nm. A calibrated holmium oxide glass or quartz filter shall be used for this verification.

The spectral resolution shall not be greater than 1nm.

Note to entry: spectrophotometers complying with ASTM xxxx

A plano lens of representative nominal thickness  $2.0^{+0.1}_{-0.3}$  mm shall be used to determine the transmittance.

The measurement shall be made at the position of the reference point and with the incident beam normal to the front surface of the lens.

The general methods of evaluating the components of uncertainty are set out in ISO/IEC Guide 98/3.

Appendix XX may provide informative background to the measurement methodology

ISO 8980-6 draft

The ANSI committee agree to revise this section using the above logic; since the ANSI Z80.3 standard is being re-affirmed and then revised, this change will occur when this section is included.

## 6. ISO TC172 Updates

- **Paris May meeting feedback** – Very successful meetings were reported, as this was the first face to face meeting since Covid. Mike indicated how important this was and commented that much is accomplished during coffee breaks!

# **SC1 - ASC Z80.1 Spectacle Lens Meeting Agenda**

**Nov 13, 2023  
Dallas, Texas  
9AM – 11AM**

**Dick Whitney – Chair  
Rick Tinson – Vice Chair**

- **ISO 10322 SF Blank revision overview – Diameter and Surface power proposal**  
Work continues on the revision of the Blank standard revision, which much be completed by May 2024. Two areas are being reviewed (Blank Diameter and curve tolerancing by Base. A Nov/Dec meeting of the ISO committee will be called and final resolution needed by early next year.

**7. New Business- Annex B.1 Inspection LED vs. Incandescent. Section 8.11 \*or comparable light source**

An additional revision topic was raised under new business regarding Annex B. The issue of how Inspection lighting, originally written for only incandescent should be specified. Ultimately it as agreed to drop reference to bulb type and only use Lux output and lighting geometry.

**8. Old Business- None**

**9. Next Meeting – ASC Z80: Apr 21-23, 2024; Sheraton Sand Key, Clearwater, FL**

**10. Adjournment – The meeting adjourned at 11:05**

**ASC Z80 SC2**  
**Non-Prescription Eyewear Subcommittee Meeting**  
**November 13, 2023, 11:00 - 2:00 PM CDT**  
**Buckeye Room**  
**Westin Dallas Downtown**  
**Dallas, TX**

**Minutes**

Attendees: Karl Citek (chair), Emmanuel Alabi, Ramzi Ari, Lauren Bianchi, Jeffrey Brown, Carl Buckholt, Koby Curtis, Scott Gabor, Jacob Gary, Pete Hanlin, Tom Hicks, Brent McCardle, Robert Pretzie, Rick Savoy, Rick Tinson, Neil Torgersen, Michael Vitale, Richard Whitney, Greg Williams, Carrie Wilson

- 1) Call to order: 11:30 AM CDT**
- 2) Introductions & introductory comments**

**Reminder about Antitrust Compliance, requirements can be reviewed at ANSI Z80 website, [www.z80asc.com](http://www.z80asc.com), under Operating Procedures Annex D.**
- 3) Acceptance of Agenda with modifications**
- 4) Acceptance of minutes from meeting on May 1, 2023 – No changes**
- 5) ANSI Z80.3 Non-Prescription Sunglasses & Fashion Eyewear**
  - a. Will seek reaffirmation of 2018 version for 2023.**
  - b. Discussed and completed revision of the document for the following items:**
    - i. Requirements and test procedures regarding resistance to radiation of lenses, aligning with ISO 12312-1:2022 and ISO 18526-3.**
    - ii. Incorporation of recommendations from Spectral Bands Task Force, introducing the term High Energy Visible (HEV) light divided into three bands: HEV3 (380-400 nm), HEV2 (400-455 nm), and HEV1 (455-500 nm).**
  - c. Will seek new PINS to reopen document to allow incorporation of these revisions.**
  - d. Future revisions will consider evaluation of haze / wide-angle scatter, aligning with ISO standards.**
- 6) Other business – none**

**7) New business – none**

**8) Next meetings:**

- a. ASC Z80: April 21-23, 2024, Sheraton Sand Key Resort, Clearwater Beach, FL**
- b. ASC Z80: October 6-8, 2024, Sheraton Sand Key Resort, Clearwater Beach, FL**
- c. ISO TC 172/SC 7 Plenary Meeting: November 2024, Tokyo, JP.**

**9) Adjourn: 2:14 PM CDT**

### SC3 Spectacle Frames Meeting Agenda

November 13, 2023; Start Time: 2:21PM - End Time: 2:38PM

The Westin Dallas Downtown – Buckeye Room

Attendees:

Emmanuel Alabi	Pete Hanlin	Michael Vitale
Ramzi Ari	Tom Hicks	Richard Whitney
Jeffrey Brown	Brent McCardle	Greg Williams
Carl Buckholt	Richard Savoy	Scott Gaber
Karl Citek	Rick Tinson	Robert Pretzie
Koby Curtis	Neil Torgersen	

#### 1. Call meeting to order

- Roll call/ sign in sheet
- Reminders: Anti-trust rules can be found at <https://www.z80asc.com/uploadedfiles/ASC-Z80-Operating-Procedures-2018-02- FINAL.pdf> (annex D)

#### 2. Acceptance May 2023 Meeting Minutes vote: Accepted with no changes

#### 3. Acceptance of agenda vote: Accepted with no changes

#### 4. Old Business

- ISO TC172/ SC7: May 22-26, 2023 Paris, France updates
  - Current Draft July 2023

#### 5. New Business

- ISO 12870 – Nickel Release EN16128 alignment
  - Current Draft July 2023

#### 6. Open forum for discussion

- Future of the industry: QR codes to inform materials or how to handle the frame (no heat, no alcohol, etc). This would be helpful for Labs, opticians, customers, etc.
  - on demo lens
  - on invoice
  - On Manufacturer website?
- Discuss with ISO to use QR codes instead of physical CE booklets?

#### 7. Next Meetings update

- Spring ASC Z80: April 21-23, 2024: Sheraton Sand Key, Clearwater FL
- Fall ASC Z80: Oct 6-8, 2024: Sheraton Sand Key, Clearwater, FL
- ISO TC172 SC7: Tokyo, Japan: Nov 2024

#### 8. Adjournment at 2:38



### SC4 Parent Committee Report

- SC4: Chair: Dr. Raj Suryakumar
- Meeting Room; Mulberry, Westin Hotel, Dallas, TX
- Meeting Dates: 11/12/2023 (Agenda: ISO Update, Z80.39, Z80.35 and Z80.11) and 11/13/2023 (Agenda Z80.29, Z80.30, Z80.7)
- Meeting Start 8:00 am, Meeting End: 5:00 pm – both days, 1 hr lunch break (12-1pm)
- Reviewed and Accepted Agenda, Meeting was both Virtual + In-person
- *All meetings on both days started with the Group reviewing the Operating procedures for Z80 including guidelines for discussions with competitors (Annex D)*

Updates as follows,

Std #	Name	Updates and Actions
Z80.11	Laser Systems for Corneal Reshaping	<ul style="list-style-type: none"><li>• Reaffirmed 2022</li><li>• 3 meetings so far in 2023</li><li>• 1<sup>st</sup> meeting 03/21, 2<sup>nd</sup> meeting 04/30, 3<sup>rd</sup> meeting 11/12</li><li>• 26 attendees on Sunday (11/12) - in person + virtual</li><li>• 121 comments received; 81 have been addressed so far</li><li>• WG created to align on definitions for FS, system calibration (Annex B), and Characterization of laser ablation beams and treatment patters (Annex C)</li><li>• Continue revisions at the next ASC Z80 Meeting (Apr 2024)</li></ul>
Z80.7	Intraocular Lenses	<ul style="list-style-type: none"><li>• Z80.7 already has a PINS in place from March 2018</li><li>• 1<sup>st</sup> Meeting 11/13</li><li>• 4 comments were received</li><li>• 27 Attendees (in person + virtual)</li><li>• All comments reviewed and addressed at the meeting Mon (11/13)</li><li>• BSR-8 filed for Public Review "Reaffirmation while in development", open thru 12/4/23;</li><li>• Group proposing a) Motion to re-affirm Z80.07 in 2023, and b) Second Motion to open up PINS for Z80.07 for revision, c) Motion to change title to Monofocal Intraocular Lenses</li></ul>

Z80.39	FVR IOL	<ul style="list-style-type: none"> <li>• 1<sup>st</sup> meeting in 2023 on 04/30, 2<sup>nd</sup> meeting 11/12</li> <li>• Draft#3 of the Standard circulated prior to meeting.</li> <li>• 80 comments received.</li> <li>• 26 attendees</li> <li>• Discussion included identification of the differences between requirements of ISO 11979-7 (from May 2023) to the Z80.39 FVR standard</li> <li>• Majority of the comments received were related to the recent changes to ISO 11979-7 (from May-2023)</li> <li>• Group discussed and aligned on revisions related to ISO 11979-7. Next steps will be to send the revised version of the standard to the group.</li> <li>• Next meeting Apr-2024</li> </ul>
Z80.29	Accommodating IOLs	<ul style="list-style-type: none"> <li>• 4 meetings so far in 2023 (Jan-18, Mar-10, May-01, Nov-13)</li> <li>• Several new comments since May-2023</li> <li>• 40 attendees (in person + virtual)</li> <li>• 103 total comments (31 revised/new comments since May)</li> <li>• Revisions will continue via virtual discussions in Jan-2024 and in-person Apr 2024</li> <li>• Group consensus that due to significantly different non-clinical and clinical requirements it may be best to, a) consider limiting scope to certain types of AIOLs (example, mechanisms that use capsular bag to drive dynamic optic /accommodation) based mechanisms), b) Define the requirements based on types of approaches/designs for MoA, c) Clarify how the “dynamic” aspect needs to be understood/interpreted for outlining clinical and non-clinical requirements for D-EDF and D-FVR IOLs.</li> <li>• Jan meeting to outline the line-of-sight for this approach</li> </ul>
Z80.30	Toric Intraocular Lenses	<ul style="list-style-type: none"> <li>• 28 attendees (in person + virtual)</li> <li>• Group identified many reasons for revising standard (FDA submitted rationale for revision of various sections of the current standard)</li> <li>• Proposal from ASCRS related to impact from low amounts of astigmatism was reviewed and discussed by the group</li> <li>• Group agreed it would be important to implement these edits in the Z80.30. To this end, group is proposing a) Motion to re-affirm Z80.30 in 2023, and b) Second Motion to open up PINS for revision</li> </ul>

Z80.35	Extended Depth of Focus	<ul style="list-style-type: none"> <li>• 26 attendees (in person + virtual)</li> <li>• Group discussed ISO Update from 11979-7 (Update from May-2023) requirements contrasted against the current requirements in Z80.35</li> <li>• Revised standard will be circulated to the group for comments</li> <li>• Next meeting to discuss revisions in Apr-2024</li> </ul>
Z80.27	Glaucoma	<ul style="list-style-type: none"> <li>• No new update since last meeting</li> <li>• Could not meet since Apr meeting due to prioritization of other standards and ISO activity (11979-7)</li> <li>• Previously, the key discussion point has been around definition for refractory glaucoma</li> <li>• Clinical definitions for Refractory Glaucoma in the draft standard were not aligned with the how the devices are currently regulated in US</li> <li>• Next step will be to create a draft version with clear definitions in Annexes on C and D – information will be sent out to all SC4 experts about recommendation to create a small WG (with industry, AGS, FDA) to review draft document prior to discussion/edits with the larger (entre) SC4 group.</li> </ul>

Other items,

- Many thanks to Michele for supporting with email communication to the SC4 experts
- Thanks to Michael Vitale (Secretariat, Z80) for support with meeting set up
- I would also like to acknowledge Don Calogero (FDA) for compiling the changes between ISO 11979-7 and ANSI Z80.39/35 that allowed an efficient discussion with the group covering various items/edits.

ASC Z80 SC6  
November 13, 2023  
Dallas, Texas

Meeting minutes

**Attendance:**

Bruce Drum  
Daniel Mattsson-Boze  
Stephan Klyce  
Ron Smith  
Zhenguo Wang

Oliver Flynn  
David Sliney  
Tyler Manning  
Shulei Zhao

Charlie Campbell did not attend but responded to an email enquiry and, as such, participated.

**Call to order: 10:12 AM**

**1) Discussion of Agenda: *Changed agenda due to additional topics. This was agreed to***

Updated agenda to include changes from spring  
Added Z80.37 standard to agenda  
Added OCT guidance discussion to agenda

**2) Three standards are up for review this year**

- a) Z80.10 Tonometers: *Incorporate recommended changes and send out for comment. Because it is due for renewal or update this year, we will reaffirm the standard but continue to edit it. 10 years in coming.***

**Discussion of Z80.10 Tonometer**

Bruce Drum gave a presentation of the edits he has made to the standard. There was general agreement to the proposed changes. Bruce indicated that he would incorporate these changes and send them out for review and comments.

- b) ANSI Z80.37: *This standard was tabled for now as it may be fixed by updates to the light hazard standard below***

**Discussion of Z80.37**

We Tabled Z80.37 since it is dependent on Z80.36 changes. Once the changes have been made to the Z80.36 standard we will address this standard and see if changes are needed.

- c) ANSI Z80.36: *Contacting Charlie Campbell to determine scope of work to be done. Will create Working group to assess and incorporate changes***

**Discussion of Z80.36**

There has been some discussion of the thermal limits in this standard. The weighting functions of the standard were changed but the limits were not changed. The limits and

the weighting function balance each other. Charlie (and others) have done some calculations that indicate there could still be a thermal hazard. Charlie was not present in the meeting so we will contact Charlie and socialize the changes to get agreement. Prior to this, however, we would like to see the ISO 15004-2 changes and then harmonize the two standards afterwards.

We will table this until after the January meeting of ISO.

**3) Review of ISO 15752-2010: Ron Smith to create redline and send to committee. Need to determine how to get the Word document version of this for editing**

Ron Smith presented some proposed changes to ISO 15752, Endo-illuminators. The discussion was around NNPA acceptance of Alcon's proposed changes. We would like to get with the working group for this standard and propose our changes.

Ron will work on redline and circulate to SC6 group and then propose this to ISO WG. Ron to get in touch with Frank Muller

**4) Discussion of Contrast Sensitivity Standard: request a PINS to begin the work of creating this standard. Create a WG to assist in creating this standard. Bruce will work on first draft with items discussed today.**

Bruce Drum proposed a new standard, Contrast Sensitivity standard. He used the visual acuity standard as a basis for this standard. Discussed the various aspects of this new standard and later discussions indicated that this is a needed standard.

**5) Discussion of OCT, how resolution is measured. Axial resolution.: Considered FDA "guidance" for OCT. Bruce to look at where we are with FDA guidance document.**

Zhenguo Wang initiated a discussion on OCT and resolution measurement. We discussed the FDA guidance document, which is still waiting for an official release, and how we could push this to be finalized. Bruce Drum will discuss this with Michelle. There was also discussion of ISO OCT standard and possibly creating an ANSI OCT standard.

**6) Other items for discussion: no further items were up for discussion.**

**Meeting adjourned: 2:30 PM**

<b>ASC Z80 SUBCOMMITTEE 7: CONTACT LENSES and CARE PRODUCTS</b>
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**Meeting:** Fall 2023 ASC Z80 SC7 Committee

**Location:** Westin Dallas Downtown, Dallas, Texas.

**Scheduled Time:** Monday, November 13, 2023. 8:30 am CST start.

**Final Agenda (10 NOV 2023)**

**Meeting Start:** 8:45 am

**Meeting Finish:** 4:46 pm

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**REPORT TO PARENT COMMITTEE**

ASC Z80 SC7 meeting occurred with 17 members in the room and another 15 members joining via Zoom. Opening items included roll call, review of antitrust compliance, committee leadership, review of ISO TC 172 business plan (N 412), and committee voting procedures.

ANSI Z80.18 and Z80.20 reaffirmed in 2021. Z80.18 will be impacted by changes to ISO 19045-2 that are underway concerning methods on disinfecting efficacy for contact lens care products. Z80.20 has an open PINS and will be impacted by changes to ISO 18369-1 associated with scleral lens terminology.

Committee reviewed several items related to the 13 resolutions passed at the last ISO TC 172/SC 7 meeting in Paris concerning standards within WG9. Highlights are included in this summary; all are mentioned in the full committee notes.

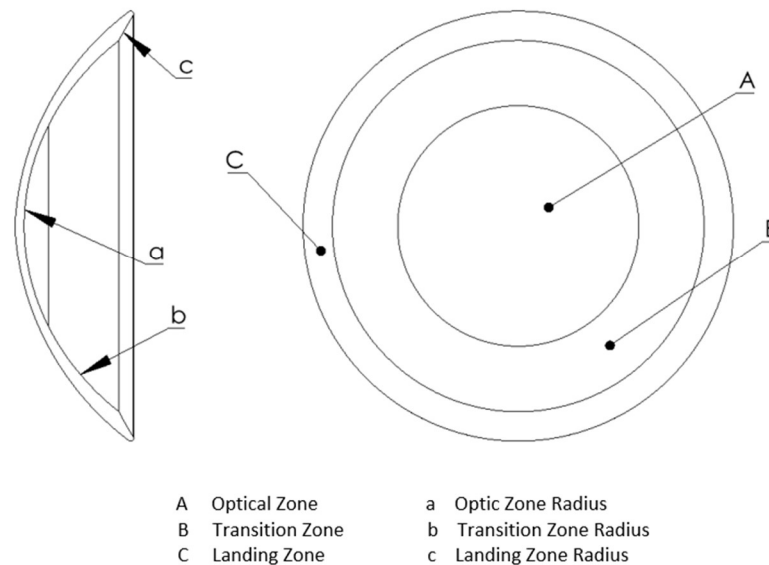
In preparation for the next ISO TC 172/SC 7/WG 9 meeting (March 2024, London), the committee reviewed three items:

- 1) ISO 18369-1: scleral lens terminology
- 2) ISO 11986: addition of Note 3 in scope
- 3) ISO 11987: amendment to scope

Regarding scleral lens terminology, committee experts presented terms and figures for review by ISO TC 172/SC 7/WG 9 to improve communications between prescribers and manufacturers. An example:



Cross Sectional and Bottom (posterior) View of a Scleral Lens Showing Distinct Zones



*Note to entry: assumes symmetrical design of the scleral lens.*

For ISO 11986, language to reemphasize the purpose of the standard, clarifying what is in-scope versus out-of-scope, was developed.

For ISO 11987, proposed language from BSI experts was reviewed. Committee supports modification but not the specific language provided.

Committee reviewed recommendation to reaffirm ISO 13212 (Ophthalmic optics — Contact lens care products — Guidelines for determination of shelf-life) and suggested changes should standard be opened.

A PWI was registered in the last ISO meeting for ISO 18369-3 to survey technologies and recommend applications to included test methods. Technologies under discussion include:

- Digital imagery.
- Low-coherence interferometry.
- OCT (Optical Coherence Tomography).

A PWI was registered in the last ISO meeting for ISO 18369-4 to continue work on mechanical testing, particularly modulus. Experts are working to discover sources of variability with known methods.

A NWIP on ISO 19045-3 was registered in the last ISO meeting. Experts are working to show cyst preparation method equivalency. Ring testing on care product disinfecting efficacy planned for 2024.

Ongoing work with CLCP symbols now includes a technical specification (TS). Intent is to raise further awareness to developed symbols while simultaneously to seek funding for validation work.

SC7 reviewed the results of the Spectral Band Task Force (SBTF). SC7 will hear proposals for inclusion of SBTF report in Z80.18 and Z80.20 in 2024.

Significant discussion occurred on public safety issues concerning multi-dose preservative-free (MDPF) eye drops. SC7 recognizes opportunities for standardization of microbiological safety of a multidose preservative free medical device during patient use. One challenge is that such devices may also have applicability to drug and OTC standards based on formulation. To respond swiftly to the known issues, SC7 is seeking guidance on potential paths forward as well as liaisons within other subcommittees in Z80 and other ANSI committees who may have products or standards that would be impacted by our response. Potential paths include seeking at a future date either a) a PINS for a new standard or b) a PINS to an existing standard.

At least 10 SC7 experts will participate in the next ISO TC 172/SC 7/WG 9 meeting to be held March 11-13, 2024, at the BSI offices in London. Meeting planned for Sunday proceeding meetings to confirm attendance and positions on topics.

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**Attendees: 32 in Total (R: In-room attendance, Z: Via Zoom)**

First Name	Last Name	Company / Group	Email	Attendance
Kelly	Arnold	J&J Vision Care Inc.	KArnold9@its.jnj.com	R
Jeremy	Barnes	Alcon	Jeremy.barnes@alcon.com	R
Allison	Campolo	Alcon Vision LLC	allison.campolo@alcon.com	R
Monica	Crary	Alcon Laboratories	monica.crary@alcon.com	R
William	Domm	Bausch & Lomb	William.Domm@bausch.com	R
Pamella	Gann	Alcon Vision LLC	pamellagann@alcon.com	R
Melanie	George	CooperVision	megeorge@coopervision.com	R
Angelo	Green	Food & Drug Administration	angelo.green@fda.hhs.gov	R
Yeming	Gu	Alcon Vision Care R&D, JCR-LL	yeming.gu@alcon.com	R
Heidi	McMinn	Bausch & Lomb	heidi.mcminn@bausch.com	R
Kimberly	Millard	Bausch & Lomb	Kimberly.Millard@bausch.com	R
Christopher	Rice	Purdue University	carice@purdue.edu	R
Ralph	Stone	Ralph Stone Consulting	ralphsuestone@prodigy.net	R
Michael	Vitale	The Vision Council	mvitale@thevisioncouncil.org	R
Rhonda	Walters	Alcon Vision LLC	rhondawalters@alcon.com	R
Greg	Williby	Johnson & Johnson Vision Care	gwilliby@its.jnj.com	R
Elissa	Wong	Food & Drug Administration	Elissa.Wong@fda.hhs.gov	R
Shawn	Conlon	Bausch & Lomb	(Shawn.Conlon@bausch.com	Z
Glenn	Davies	Bausch & Lomb	glenn.davies@bausch.com	Z
Tom	Karkkainen	Johnson & Johnson Vision Care	tkarkkai@its.jnj.com	Z
Sanjeev	Kasthurirangan	CooperVision	SKasthurirangan@coopervision.com	Z
Mark	Lada	Johnson & Johnson Vision Care	MLada@its.jnj.com	Z
Carol	Lakkis	Biomedical Consulting	clakkis22@gmail.com	Z
Brittany	McPherson	Bausch & Lomb	Brittany.McPherson@bausch.com	Z
Troy	Miller	Accu Lens Inc.	troy@acculens.com	Z
Samuel	Puig	CooperVision	spuig@coopervision.com	Z
Stanley	Rogaski	Contact Lens Institute	sjrogaski@comcast.net	Z
Paul	Shannon	Alcon Vision LLC	Stephen.shannon@alcon.com	Z
Chris	Steele	Bausch & Lomb	Chris.Steele@bausch.com	Z
Bonnie	Storm	Bausch & Lomb	Bonnie.Storm@bausch.com	Z
Paul	Trotto	Bausch & Lomb	paul.trotto@bausch.com	Z
Aaron	Zimmerman	American Optometric Assn	zimmerman.178@osu.edu	Z

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**Topic:** Opening Items

- Opening of the meeting
- Review of final agenda
- Roll call
- Introductory Items
  - Committee leadership, introductions.
  - Reminder on antitrust compliance guidelines for ANSI ASC Z80.
  - Overview of ISO TC 172/SC 7 Meeting held May 22-26, 2023, in Paris, France.
  - Needs for ISO TC 172/SC 7/WG 9 meeting on March 11-13, 2024, in London.
    - ISO 18369-1: scleral lens terminology
    - ISO 11986: addition of Note 3 in scope
    - ISO 11987: amendment to scope
    - Responses to J. Parker due end NOV
  - Reminder on obligations when calling meetings.

**Topic Leader:** Greg Williby

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**Topic:** ANSI Z80.18-2016 (R2021) - Ophthalmics - Contact Lens Care Products - Vocabulary, Performance Specifications, And Test Methodology

**Topic Leader:** Greg Williby

**Status:** Reaffirmed in 2021. Next review is due in 2026.

**Preliminary Notes:** Potential changes in time. Monitor ISO 19045-2 changes for impact on this standard. No recommended action at this time.

**Meeting Notes:** No further updates.

**Topic:** ANSI Z80.20-2016 (R2021) - Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements And Physicochemical Properties

**Topic Leader:** Greg Williby

**Status:** Reaffirmed in 2021. Next review is due in 2026.

**Preliminary Notes:** PINS opened in 2019 for revision with no change in scope. Request received from the Scleral Lens Society for addition/revision of the definitions relating to scleral lenses. Agenda item (Scleral lens terminology for ISO 18369-1 consideration) in this meeting to discuss further.

**Meeting Notes:** No further updates.

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**Topic:** ISO 11986:2017: Ophthalmic optics — Contact lenses and contact lens care products — Determination of preservative uptake and release.

**Topic Leader:** Ralph Stone, Mark Lada.

**Status:** Confirmed in 2023 (N 2389).

**Preliminary Notes:** In 2024 London meeting, agenda item to determine course of action on proposed note to Scope. Proposed note to be circulated to WG9 in December. Proposed note as developed in Paris ISO meeting:

Proposed Note 3: This standard is only intended to determine preservative uptake and release when developing new contact lens materials or contact lens care products. It is not intended in any way as a routine test of production contact lenses or contact lens care products. It should

only be necessary to consider using the test when there is a significant change in the formula or production of either the contact lens material or a contact lens care product.

**Meeting Notes:** Proposed note:

Preservative uptake/release results generated are intended for determining if additional testing is warranted. Preservative uptake and release testing is not intended as a routine test of production contact lenses or contact lens care products nor are testing results meant to establish finished goods specifications in any way.

**Topic** ISO 11987:2012: Ophthalmic optics — Contact lenses — Determination of shelf-life.

**Topic Leader:** Jeremy Barnes

**Status:** Confirmed in 2023 (N 2390).

**Preliminary Notes:** In 2024 London meeting, agenda item to determine course of action on amendment to scope. Proposed by UK. Proposed note to be circulated to WG9 in December.

**Meeting Notes:** After review of proposed language from BSI, we feel that pulling language from the introduction is appropriate. However, the proposed language in red (see slides) is not aligned to by SC7. We would enjoy participating in further discussions before or at the next ISO meeting. Experts to include are :

- Jeremy Barnes
- Angelo Green
- Greg Williby
- Sammy Puig
- Ying Zheng

**Topic:** ISO 11981:2017: Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses.

**Topic Leader:** Ralph Stone, Angelo Green, Mark Lada.

**Status:** Confirmed in 2023 (Resolution 811).

**Preliminary Notes:** No known issues.

**Meeting Notes:** No further updates.

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**Topic:** ISO 14729:2001: Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses.

**Topic Leader:** Monica Cary, Kim Millard

**Status:** Confirmed in 2023 (Resolution 807).

**Preliminary Notes:** Relationship to ISO 19045-2. Once changes are made to this standard, Annex D should be edited. Annex D would no longer be accurate. Fusarium name update required. Along with ISO 18259, discussions needed on strains and methodologies.

**Meeting Notes:** No further updates.

**Topic:** ISO 18259:2014: Ophthalmic optics — Contact lens care products — Method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms

**Topic Leader:** Monica Cary, Kim Millard

**Status:** Confirmed in 2019. Next systematic review in 2024.

**Preliminary Notes:** Along with ISO 14729, discussions needed on strains and methodologies.

**Meeting Notes:** Monitoring discussions for new, relevant microorganisms. Updating names of strains already in use.

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**Topic:** ISO 13212:2014: Ophthalmic optics — Contact lens care products — Guidelines for determination of shelf-life.

**Topic Leader:** Melanie George, Mark Lada, Ralph Stone, Jeremy Barnes.

**Status:** Reviewed and confirmed in 2019. Next systematic review in 2024.

**Preliminary Notes:** Recommendation is to re-confirm during 2024 review.

**Meeting Notes:** Recommendation is to reconfirm in 2024. If opened, suggest changes:

- Reference for the acceleration factor mentioned in Section 5.7, paragraph 9 (Arrhenius equation) to be obtained and could be considered for addition if future changes warrant revising the Standard but such a minor addition was not viewed as significant enough to open the Standard for revision for its inclusion alone.
- Section 5.1, Objective: *“The relevant assay methods shall be determined prior to the start of the stability testing”*. There is no mention of Risk Assessment in determination – an important aspect often mentioned in establishment of testing plans.
- Annex A (informative) Testing Plan: No 9-month interval listed.
- No mention of Low Temperature Testing, Freeze/Thaw Conditions – impact of temp. excursions (transit testing)
- Scope is limited to contact lens care products only but may have overlap/applicability to eye drop formulations (OTC and prescription). Separate Standard need or existing?

Discussion on scope – what is a medical device vs. combo product. Artificial tears, drops that aid comfort, dry eye products are examples. Position is to keep scope to lens care solutions. Discussion on 9-month data as additional condition, needs further discussion.

**ACTION:** Topic Leaders – organize meeting ahead of Spring 2024 ANSI meeting for further discussions.

**Topic:** ISO 14730:2014: Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date.

**Topic Leader:** Monica Cary, William Domm, Angelo Green, Kim Millard.

**Status:** Reviewed and Confirmed in 2019. 100% approved. Next systematic review in 2024.

**Preliminary Notes:** Need for discussion on preservative free solution challenges in the marketplace.

Potential item for new business discussion at next ISO meeting.

**Meeting Notes:** Preservative-free solutions (MDPF: multi dose, preservative free) posing opportunities for standardization of efficacy testing. Specific issues:

- 1) Preservative free solutions should be a new standard.
- 2) Testing should include both the product and the bottle. Product, bottles, and interactions should be in scope.
- 3) Goal of new work would be to align testing requirements with FDA guidance.
- 4) Shelf life testing complicated with acceleration and viability of organisms.
- 5) Applicability is complicated – may span both device and drug reviews.
- 6) Desire to better know the properties and characteristics of solutions that impact efficacy.
- 7) Additional issues likely exist.

Actions for Parent Committee Meeting

- 1) Problem statement
  - a. include applicability to drug products and OTC products.
  - b. Reminder on timing.
- 2) Course of action
  - a. New standard within Z80
  - b. Awareness to standards on drug side
  - c. Other avenues? CLI?
- 3) Clarify action of
  - a. New PINS now
  - b. New PINS in 2024

Results will be shared with WG9. No further call to action at ISO level.

**Topic:** ISO 18189:2016: Ophthalmic optics — Contact lenses and contact lens care products — Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/solution interactions.

**Topic Leader:** Elissa Wong, Pamella Gann, Paul Shannon, Mary Mowery-McKee.

**Status:** Reviewed and Confirmed in 2022.

**Preliminary Notes:** No known issues.

**Meeting Notes:** New topic leaders added.

**Topic:** ISO 14534:2011: Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements.

**Topic Leader:** Kelly Arnold.

**Status:** Reviewed and Confirmed in 2021.

**Preliminary Notes:** In 2021, a few countries did want to revise; comments could be starting point for revisions. Unclear how EU MDR topic impacts this standard. One possibility is Annex ZA in the standard.

**Meeting Notes:** Reminder that this is a pointer document to other standards. Starting next year, more may be found about EU MDR's impact.

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**Topic:** ISO 18369-1:2017: (Ed 2): Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications.

**Topic Leader:** Glenn Davies, Yeming Gu, Ralph Stone.

**Status:** Confirmed in 2023 (Resolution 809).

**Preliminary Notes:** Monitor topics on scleral lens terminology, classification of coated materials for future inclusion.

**Meeting Notes:** No further updates – see next agenda item.

**Topic:** Scleral lens terminology for ISO 18369-1 consideration

**Topic Leader:** Ralph Stone. Co-lead desired.

**Preliminary Notes:** *See proposal.*

**Meeting Notes:** Committee reviewed proposal in slides.

**ACTION:** Circulate current version (Greg). Provide revised version to Greg by 28 NOV (Ralph).

**Topic:** Classification of coated materials for ISO 18369-1 consideration



**Topic Leader:** Ralph Stone, Paul Trotto.

**Preliminary Notes:** *See proposal/slides.*

**Meeting Notes:** More work to be done. Products on the market that are coated. No further action at ISO level at this time. Three parts:

- 1) Surface coating
- 2) Interface
- 3) Base material

Use of classifications includes care products developers. Classifications used in ISO 11980. Possible IP use.

**ACTION:** Ralph to circulate proposal ahead of next ANSI meeting.

**Topic:** ISO 18369-2:2017 (Ed 3): Ophthalmic optics — Contact lenses — Part 2: Tolerances.

**Topic Leader:** Glenn Davies, Greg Williby.

**Status:** Confirmed in 2023 (Resolution 810).

**Preliminary Notes:** No known discussion topics.

**Meeting Notes:** No further updates.

**Topic:** ISO 18369-3:2017 (Ed 2): Ophthalmic optics — Contact lenses — Part 3: Measurement methods.

**Topic Leader:** Greg Williby.

**Status:** Confirmed in 2023 (Resolution 801) with PWI registered.

**Preliminary Notes:** *Separate agenda item on PWI.*

**Meeting Notes:** No further updates – see next agenda item.

**Topic:** Project Group on PWI ISO 18369-2017 (Ed 2): Ophthalmic optics — Contact lenses — Part 3: Measurement methods.

**Topic Leader:** Greg Williby, Heidi McMinn.

**Status:** Opened with Resolution 801 on May 26, 2023.

#### **RESOLUTION 801**

##### **Confirmation of ISO 18369-3:2017 and register the PWI**

On the recommendation of WG 9, the subcommittee decided to confirm ISO 18369-3:2017, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*, and at the same time, based on the recommendation of WG 9, to register a Preliminary Work item (PWI) for the revision of ISO 18369-3.

Project leader: Gregory Williby

**Preliminary Notes:** First report on progress due at next ISO meeting. Topics and illustrations in slides. Identified areas:

- Digital imagery (for lens diameters, other dimensions).
- Low-coherence interferometry (discussed at ISO concerning refractive index).
- OCT (Optical Coherence Tomography).

Two meetings at ISO level proposed ahead of March meeting.

**Meeting Notes:** Members to include:

- 1) Heidi McMinn
- 2) Yeming Gu
- 3) Sammy Puig

**Topic:** ISO/AWI TS (Technical Specification) 6838 Ophthalmic optics — Contact lenses — Tolerances and methods for measurement of multifocal contact lens addition power.

**Topic Leader:** Greg Williby

**Status:** Final dates provided in Resolution 800 from last ISO meeting:

**RESOLUTION 800**

**Circulation of ISO/DTS 6838**

On the recommendation of WG 9, the subcommittee decided to release ISO/DTS 6838, *Ophthalmic optics — Contact lenses — Tolerances and methods for measurement of multifocal contact lens addition power*, as revised, based on the discussions during the project group meetings, for circulation as a Draft Technical Specification by end of June 2023.

Project leader: Gregory Williby

Updated target dates are given below.

Target dates:

- Manuscript for DIS to subcommittee secretariat no later than	2023-07-15
- DTS submission to ISO CS no later than	2023-08-30
- Publication	2024-02-13

**Preliminary Notes:** Manuscript provided to subcommittee secretariat on 28 JUL 2023.

**Meeting Notes:** Update from Jalini is that DTS is under formatting with ISO. Tracking to above publication date.

**Topic:** ISO 18369-4:2017 (Ed 2): Ophthalmic optics — Contact lenses — Part 4: Physicochemical properties of contact lens materials.

**Topic Leader:** Ying Zheng

**Status:** Confirmed in 2023 (Resolution 802) with PWI registered. Comment approved as part of resolution:

**RESOLUTION 802**

**Correction of ISO 18369-4:2017, Confirmation of the systematic review and register the PWI**

On the recommendation of WG 9, the subcommittee decided to replace in ISO 18369-4:2017, *Ophthalmic optics — Contact lenses — Part 4: Physicochemical properties of contact lens materials*, 4.4.4, Note: "Dr. William J. Benjamin, 937 Tulip Poplar Lane, Hoover, Alabama, USA, 35244" by "Createch Rehder, 141 Traction St., Greenville, South Carolina, USA, 29611" on account of the death of Dr Benjamin.

In addition, on the recommendation of WG 9, the subcommittee decided to confirm ISO 18369-4:2017, and at the same time, based on the recommendation of WG 9, to register a Preliminary Work item (PWI) for the revision of ISO 18369-4.

Project leader: Ying Zheng

**Preliminary Notes:** *Separate agenda item on PWI.*

**Meeting Notes:** No further updates – see next agenda item.

**Topic:** Project Group on PWI 18369-4:2017 (Ed 2): Ophthalmic optics — Contact lenses — Part 4: Physicochemical properties of contact lens materials.

**Topic Leader:** Ying Zheng

**Status:** Opened with Resolution 802 on May 26, 2023.

**Preliminary Notes:** Ring test on mechanical testing to be reviewed at next ISO meeting.

**Meeting Notes:** Discussed next round of ring testing. Multiple groups of results – both standard methods and lab-based methods. One goal is identification of key parameters or sources of variability in conducting method. Modulus is primary metric.

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**Topic:** Project Group on PWI ISO 19045-2. ISO/FDIS 19045-2, Ophthalmic optics —Contact lens care and *Acanthamoeba* trophozoites – Part 2: Method for evaluation of disinfection efficacy.

**Topic Leader:** Monica Crary, William Domm, Kim Millard.

**Status:** Determination to circulate as FDIS in Resolution 803.

**RESOLUTION 803**

**Circulation of ISO/FDIS 19045-2**

On the recommendation of WG 9, the subcommittee decided to release ISO/DIS 19045-2, *Ophthalmic optics — Contact lens care and Acanthamoeba trophozoites – Part 2: Method for evaluation of disinfection efficacy*, as revised, based on the discussions during the project group meetings, for circulation as a Final Draft International Standard by end of July 2023.

New Project leader: Dr. Wayne Heaselgrave

Updated target dates are given below.

Target dates:

- |   |            |
|---|------------|
| - Manuscript for FDIS to subcommittee secretariat no later than | 2023-07-15 |
| - FDIS submission to ISO CS no later than                       | 2023-07-31 |
| - Publication   | 2024-11-30 |

**Preliminary Notes:** FDIS in preparation for circulation.

**Meeting Notes:** No further updates.

**Topic:** NWIP on ISO 19045-3, Ophthalmic optics —Contact lens care and *Acanthamoeba* cysts – Part 3: Method for evaluation of disinfection efficacy.

**Topic Leader:** Monica Cary, Kim Millard, William Domm.

**Status** Opened with Resolution 804 on May 26, 2023.

**RESOLUTION 804**

**Registration of a NWIP of ISO 19045-3**

On the recommendation of WG 9, the subcommittee decided to register a new work item proposal for a future third part of the ISO 19045 series.

New title: ISO 19045-3, *Ophthalmic optics — Contact lens care products — Part 3: Method for evaluating disinfecting efficacy by contact lens care products using cysts of Acanthamoeba species as the challenge organisms*.

**Scope of the NWIP:** To describe a method for evaluating disinfecting efficacy by contact lens care products using cysts of *Acanthamoeba* species as the challenge organisms.

A new Form 04 will be filled out and an outline of the future project will be prepared at the end of October and submitted via CIB.

Timeframe: SDT 36 months

Project leader: Dr. Wayne Heaselgrave

**Preliminary Notes:** Meeting held between W. Heaselgrave, M. Crary, and W. Domm post ISO Paris meeting to begin outlining testing plans. Currently planning to begin testing on Acanthamoeba Cyst preparation methods between three groups. Plan to have preliminary data going into March ISO meeting in London. Official start of PWI is unclear as well as deadline dates at this time.

**Meeting Notes:**

NWIP Milestones (clarify deadline dates for PWI, reference N 2451)

- 1) First working draft, 8 NOV 2023
- 2) 31 JUL 2024 – end of consulting period
- 3) DIS target – 8 NOV 2025
- 4) 8 NOV 2026 – publication date

Working on cyst preparation now with goal of showing equivalency (biocidal resistance) between cyst preparation methods. No reason why a ring test cannot be completed in 2024.

**Topic:** ISO 19045:2015: Ophthalmic optics — Contact lens care products — Method for evaluating Acanthamoeba encystment by contact lens care products.

**Topic Leader:** Monica Crary, Kim Millard, William Domm.

**Status:** See PWI on ISO 19045-1.

**Preliminary Notes:** See PWI on ISO 19045-1.

**Meeting Notes:** No further updates.

**Topic:** PWI on ISO 19045-1:2015: Ophthalmic optics — Contact lens care products — Method for evaluating Acanthamoeba encystment by contact lens care products.

**Topic Leader:** Monica Crary, Kim Millard, William Domm

**Status:** PWI registered as per Resolution 805.

**RESOLUTION 805**

**Change of the document number of ISO 19045 to ISO 19045-1 and register the PWI**

On the recommendation of WG 9, the subcommittee decided to register a PWI for the revision of ISO 19045, *Ophthalmic optics — Contact lens care products — Method for evaluating Acanthamoeba encystment by contact lens care products*.

Additionally, based on the changes made in ISO/DIS 19045-2 and the registration of a NWIP regarding ISO 19045-3, the subcommittee decided to change the number of the current ISO 19045 to ISO 19045-1, *Ophthalmic optics — Contact lens care products — Part 1: Method for evaluating Acanthamoeba encystment by contact lens care product*.

Project leader: Dr. Wayne Heaselgrave

**Preliminary Notes:** Meeting held between W. Heaselgrave, M. Crary, and W. Domm post ISO Paris meeting to begin outlining testing plans. Current proposal is for consideration of an alternative method to be added into a revision draft in an Annex. Official start of PWI is unclear as well as deadline dates at this time.

**Meeting Notes:**

**Deliverables and Next Steps**

- Need to align on a revision plan and Working Draft (WD) for submission to ISO to gain PWI status and expected dates.
- Scope of WD will determine the need and scope of additional testing plans and potential RING tests:



- Difficulty in selecting a control solution (Disinfecting Solution) for such equivalency testing, can rely on already published control solutions (risk)?
- WD goal for discussion at ISO-interim in March 2024.

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**Topic:** ISO 11980:2012: Ophthalmic optics — Contact lenses and contact lens care products — Guidance for clinical investigations.

**Topic Leader:** Carol Lakkis.

**Status:** AWI (Active Work Item) registration (per Resolution 762) approved June 2022. DIS registration deadline 9 JUN 2024. Publication deadline 9 JUN 2025.

**Preliminary Notes:** Comments and working draft v8 circulated in August. CD circulated on 30 OCT in N2450. Further discussions on acceptance criteria expected in meeting.

**Meeting Notes:** Table A1 is area of discussion – sample sizes for extended wear up to seven days. Advice is that all other areas have been reviewed and aligned.

Acceptance criteria – further discussions suggest now is not time to include criteria in with other changes.

**ACTION NEEDED:** Review and provide comments to OEOSC (Michele) by 18 DEC.

**Topic:** ISO/WD TS 24891 CLCP Symbols.

**Topic Leader:** Carol Lakkis.

**Status:** Resolution 806 initiated a Technical Specification (TS) for proposed symbols regarding contact lenses and care products.

**RESOLUTION 806**

**Initiation of an ISO/TS for proposed symbols regarding contact lenses and contact lens care products**

On the recommendation of WG 9, the subcommittee decided to initiate a Technical Specification for proposed symbols regarding contact lenses and contact lens care products.

Title: *Ophthalmic optics — Contact lenses and contact lens care products — Proposed symbols.*

Project leader: Carol Lakkis

Timeframe: SDT 36 months

Call for experts no later than 2023-06-30

**Preliminary Notes:** PG finalized symbol candidates and has estimated costs, discussed sources of funding. TS drafted. NWIP for TS ballot – closing date 31 Jan 2024. Goal of TS is to widen the feedback on the proposed symbols and encourage additional validation work. Publication deadline 30 May 2026.

**Meeting Notes:** Document circulated (N 2452) as of this meeting. Feedback due 10 JAN 2024. Funding proposal under development. Once finalized, proposal will be circulated to seek funding. Estimate is eight funding sources for \$10,000 over two years.

**ACTION:** Carol to share proposal with Mike Vitale and Greg Williby once complete.

**ACTION NEEDED:** Review and provide comments to OEOSC (Michele) by 10 JAN 2024.

**Topic:** ISO 11978:2017 (Ed 3): Ophthalmic optics — Contact lenses and contact lens care products — Labelling (with AMD1).

**Topic Leader:** Glenn Davies. Carol Lakkis.

**Status:** Confirmed in 2023 (Resolution 808).

**Preliminary Notes:** Discussion on relationship to EU MDR documents expected in meeting.

**Meeting Notes:** No action pending.

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**Topic:** ISO 19979:2018: Ophthalmic optics — Contact lenses — Hygienic management of multipatient use trial contact lenses

**Topic Leader:** Carol Lakkis.

**Status:** Systematic review voting complete (N 2426). Standard confirmed.

**Preliminary Notes:** 3 countries wanted to revise (CA, CH, AU) – minor comments. Possible corrigendum to correct handwashing link.

**Meeting Notes:** No further actions. Will monitor next ISO meeting for corrigendum on handwashing.

**Topic:** ISO 9394:2012: Ophthalmic optics — Contact lenses and contact lens care products — Determination of biocompatibility by ocular study with rabbit eyes

**Topic Leader:** Elissa Wong, Brittany McPherson, Pamella Gann.

**Status:** Confirmed in 2023 (Resolution 812).

**Preliminary Notes:** No known issues.

**Meeting Notes:** No further action.

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**Topic:** ISO 15223 Input. ISO 15223-1:2021: Medical devices — Symbols to be used with information to be supplied by the manufacturer.

**Topic Leader:** Carol Lakkis.

**Status:** AWI Amendment 1.

**Preliminary Notes:** This is a medical device standard – outside ISO TC 172. Amendment focused on symbol 5.1.2 Authorized Representative only. No impact on ISO/WD TS 24891 CLCP Symbols.

**Meeting Notes:** Iris (WG9 member from DIN) on team. Nothing relevant to our committee.

**Topic:** ANSI – Spectral Band Task Force (SBTF).

**Topic Leader:** Kelly Arnold.

**Status:** Draft of publication to be provided to ASC Z80 Parent Committee in 2023.

**Preliminary Notes:** Publication route not yet determined.

**Meeting Notes:** Technical paper written – targeting availability by end DEC on ANSI webstore. Next step is to disseminate scheme in 2024.

**ACTION:** Kelly – provide proposal on location for inclusion in Z80.18 and Z80.20 at next ASC Z80 meeting.

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**Topic:** Closing Items

- Review list of 2024 systematic reviews
- Next Meeting - ISO TC 172/SC 7

## ASC Z80 SC7 Contact Lenses

- November 28, 2023. Virtual.
  - Agenda review (N 2447) and attendees.
- Next Meeting - ISO TC 172/SC 7/WG 9
  - March 11-13, 2024. BSI, London.
  - Agenda review and attendees.
- Call for New Work Items
  - New members to ASC Z80 SC7
    - Christopher Rice
    - Heidi McMinn
    - Pamella Gann
    - Rhonda Walters
    - Brittany McPherson
    - Chris Steele
    - Shawn Conlon
    - Bonnie Storm
- Next Meeting - ASC Z80 SC7
  - April 21-23, 2024. Clearwater Beach, Florida.
- Closure of the meeting

**Topic Leader:** Greg Williby

# **SBTF Fall Meeting Update**

## **Dallas, TX**

### **14 November 2023**

#### **SBTF Spring meeting recap**

- Reviewed 3-band scheme consensus
- Worked with SC1-3 to outline inclusion of scheme in Z80.3 revision
- Aligned to write Technical Report that would serve as reference for Z80.3.

#### **Review of Nomenclature, Band Scheme, and Usage Recommendations**

- Radiation in the range of 380 – 500 nm is to be referred to as High Energy Visible light with the acronym HEV
- HEV is split into sub-bands of:
  - **HEV3: 380 – 400 nm**
  - **HEV2: 400 – 455 nm**
  - **HEV1: 455 – 500 nm**
- SBTF recommends that claims of blocking/filtering HEV provide:
  - **Full HEV transmission spectrum** for the device
  - **HEV sub-band transmission percentages** of radiation blocked/filtered by the device

#### **Technical Report**

- First draft circulated to team in August
- Second draft circulated to team in October; incorporation of comments
- Final draft circulated to team in November; no comments on draft2, final figures completed
- Awaiting review of Parent Committee – deadline 17-Nov-2023
- Publication of technical report under an ASC Z80 cover
- Purchase of report will be available at ANSI webstore once formatting is complete

#### **Socialization of band scheme**

- Next steps of SBTF will be to socialize the band scheme
- The Vision Council, leveraging working relationships with trade associations and WebMD
- Academic infiltration, e.g., National Federation of Opticianry Schools (NFOS)
- Certification bodies, such as TUV, OSHA, BSI etc.
- Continuing Education course credits
- Society Newsletters
- Trade Journal editorials

#### **Branching out to ISO**

- 2024 focus on including Band Scheme in Z80 Standards, where appropriate
- 2025 consider generating discussion at ISO in preparation for systematic review of ISO 20473
  - Need to bring SC7 into alignment
  - Need to reach out to other SCs in TC172
- 2026 systematic review of ISO 20473



# SBTF Update

ASC Z80 Fall Meeting  
November 12 – 14, 2023  
Dallas, TX

## SBTF Spring Meeting Recap



Reviewed 3-band scheme consensus



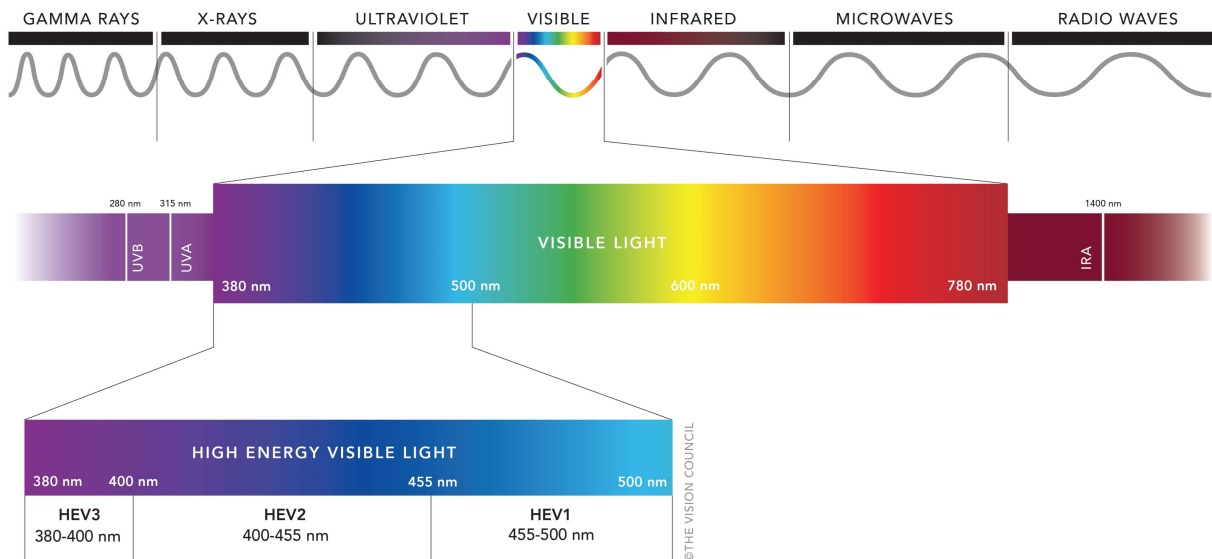
Worked with SC1-3 to outline inclusion of scheme in Z80.3 revision



Aligned to write Technical Report to serve as reference for Z80.3

## HEV Nomenclature, Band Scheme, and Recommendation for Claims

- Radiation in the range of 380 – 500 nm is to be referred to as **High Energy Visible** light with the acronym **HEV**
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Graphic illustration provided by Eyesafe Inc.

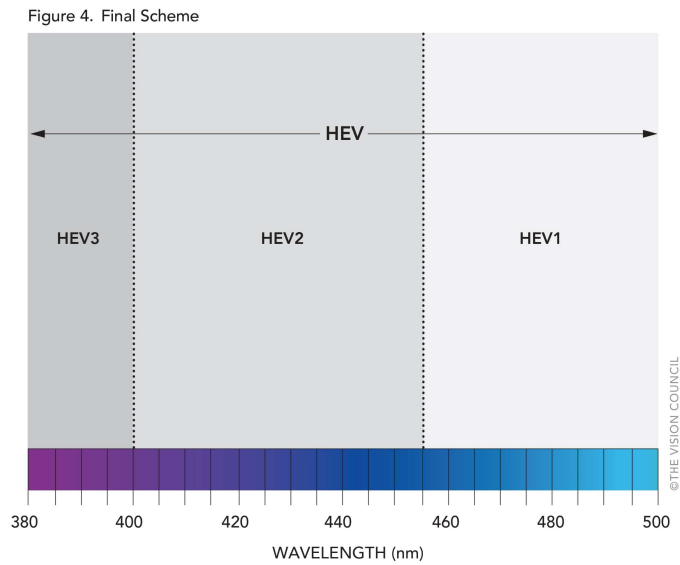


Figure 4. HEV band scheme developed by the ANSI Z80 Spectral Bands Task Force. This figure shows high energy visible (HEV) light to comprise the wavelengths of 380 – 500 nm with sub-bands of HEV3 (380 – 400 nm), HEV2 (400 – 455 nm) and HEV1 (455 – 500 nm).

Graphic illustration provided by Eyesafe Inc.

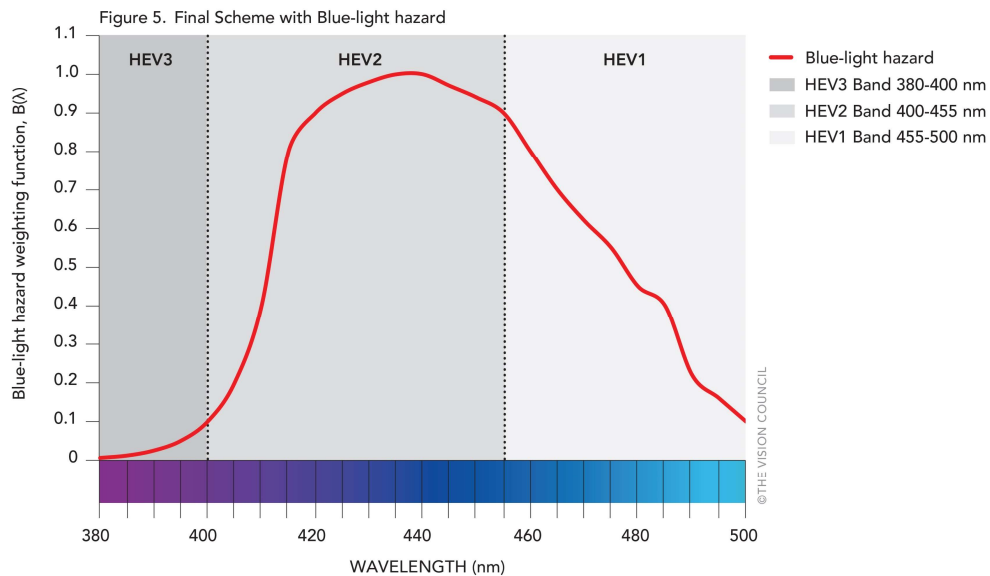


Figure 5. HEV band scheme developed by the ANSI Z80 Spectral Bands Task Force. This figure shows high energy visible (HEV) light to comprise the wavelengths of 380 – 500 nm with sub-bands of HEV3 (380 – 400 nm), HEV2 (400 – 455 nm) and HEV1 (455 – 500 nm).

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  - Final figures completed
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  - Deadline 17-Nov-2023
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## SBTF Next Steps

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### **Branching out to ISO**

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- 2026 systematic review of ISO 20473

## **ASC Z80 Parent Committee Meeting**

**Tuesday November 14, 2023**

### **US FDA Report**

1. We have published one ophthalmic guidance since the last ASC Z80 parent committee meeting:

- FINAL: Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations - Premarket Notification (510(k)) Submissions: Guidance for Industry and Food and Drug Administration Staff 7/27/2023

This guidance provides labeling recommendations for hydrogen peroxide-based contact lens care products (HPCPs) submitted in premarket notification (510(k)) submissions. It contains specific consumer labeling recommendations and suggested format and content for the package insert labeling, carton labeling and bottle labeling.

2. FDA has recognized no new Ophthalmic standards in the past 6 months.