

Z80 Accredited Standards Committee for Ophthalmic Optics
PALM ROOM, SHERATON SAND KEY, CLEARWATER BEACH, FLORIDA

ASC Z80 PARENT COMMITTEE MEETING MINUTES

Tuesday, May 2nd, 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 8:31 am, Tuesday, May 2, 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	Kasthurirangan, Sanjeev	Tubbs, Carl*^
Arnold, Kelly	Lahousse, Daniel	Van Arnam, Rick
Bianchi, Lauren	Lakkis, Carol	Vitale, Michael*^(7)
Buckholt, Carl*	Mancuso, Adam	Weeber, Henk
Calogero, Donald*	Mattsson-Boze, Daniel	Whitney, Richard
Citek, Karl*^	McCardle, Brent	Williams, Greg
Crary, Monica	Pfriem, Dale	Williby, Greg
Domm, William	Scott, Wesley	Wilson, Carrie
Drum, Bruce	Sliney, David	Yuhass, Phil
George, Melanie	Stone, Ralph*	Zheng, Ying
Hilmantel, Gene	Suryakumar, Rajaraman	
Ing, Eliesa^	Torgerson, Neil*	

*Voting representative; ^Proxy; (X)Number of proxy votes, if more than 1

- **Acceptance of the Agenda.** The agenda was unanimously accepted without modification.
- **Acceptance of the Fall 2022 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. Dr. Tubbs reminded all representatives to vote

on ballots as they are distributed, to request more information as necessary to reach a decision, or at least to cast a vote to abstain.

Dr. Tubbs also acknowledged the contributions of members who have recently retired, Dr. Michael Belin and Mr. Charlie Campbell, and encouraged current members to recruit new members.

- **Vice Chair's Comments.** Ms. Lauren Bianchi, Vice Chair, noted that, with the retirement of Committee members and throughout the industry in general, current members should engage in succession planning to get and keep new members involved in order to ensure the future of the standard writing process.
- **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, so that they could be 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 a brief update of the on-going Zero Tech v. Brita patent 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, reported that all 21 members voted to affirm the updated operating procedures last year and thanked Ms. Michele Stolberg for her work during the ANSI audit. Mr. Vitale reviewed the budget and other business items, and reminded all experts that opinions and comments can be submitted individually and that official member votes are submitted only by the nominated representatives of the members. 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. Karl 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.
 - SC3:** Mr. Daniel Lahousse, 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: Request to change the title of ANSI Z80.39 to Static Full Visual Range Intraocular Lenses. Seconded. Motion passes.

Motion: Reaffirm ANSI Z80.35 without revision. Seconded. Motion passes.

Motion: Request PINS to open ANSI Z80.35 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 Z80.17 without revision. Seconded. Motion passes.

Motion: Reaffirm ANSI Z80.23 without revision. Seconded. Motion passes.

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

Motion: Request PINS to open ANSI Z80.37 for review. Seconded. Motion passes.

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

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 to be published by 2025 and that ANSI Z87.62 for biohazard safety eyewear, approved in 2021, is open for revision. Mr. Vitale also reported that while OSHA references Z87.1, it does so for only the 2010 version; a letter has been drafted requesting OSHA to adopt the 2020 version.

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. Dale Pfriem, the US TAG Chair for ISO/TC94/SC6, summarized the activity of this TC94/SC6 Subcommittee:

- ISO 12311, test methods standard, just moved to FDIS status, publication expected in 2023.
 - ISO 16321-4, biosafety standard, mirrors ISEA Z87.62 and is up for DIS vote. Project group is led by Dr. Annette Hoskin.
 - ISO also oversees "creative lifestyle" sunglass standard; reminder that ISO considers sunglasses to be safety equipment.
 - Laser eyewear safety standard was finally published last year.
- **Next Meetings:**
ISO/TC172/SC7: May 22-26, 2023; Paris, FR.
ASC Z80: November 12-14, 2023; Sheraton Downtown Dallas, Dallas, Texas.
ASC Z80: April 21-23, 2024; Sheraton Sand Key, Clearwater Beach, Florida.
ASC Z80: October 6-8, 2024; Sheraton Sand Key, Clearwater Beach, Florida.
 - **New Business:** Mr. Vitale requested that any meeting room requests for the Fall 2023 meeting in Dallas be submitted as soon as possible.
 - **Closure of the Meeting:** Dr. Tubbs again thanked everyone for their participation, wished them safe travels, and brought the meeting to a close at 10:49 am.

Respectfully submitted,
Karl Citek

ASC Z80 Committee Secretariat's Report April/May 2023

Member Status and Dues

- 21 Voting members through EOY 2022, all dues are current
- As of April 1st, we have 20 voting members
- Financials for 2022 with Budget for 2023

<u>Income</u>	<u>2023 Proposed</u>	<u>2022 Actual</u>	<u>2022 Proposed</u>
Z80 Member Dues	\$40,000.00	\$36,000.00	\$36,000.00
Standard Sales Royalties	\$20,000.00	\$20,331.00	\$20,000.00
<u>Total Income</u>	<u>\$60,000.00</u>	<u>\$56,331.00</u>	<u>\$56,000.00</u>
<u>Expenses</u>			
ANSI Dues*	\$13,500.00	\$13,390.00	\$13,100.00
ISO/OEOSC Dues**	\$18,981.00	\$17,579.00	\$13,000.00
Z80 Mtg Expense	\$15,000.00	\$12,528.85	\$15,000.00
Z80 Travel Expense	\$1,500.00	\$1,300.00	\$1,100.00
Z80 Legal Counsel	\$2,450.00	\$2,450.00	\$2,450.00
Z80 Insurance Expense	\$1,500.00	\$1,451.00	\$1,300.00
Z80 Administration	\$14,000.00	\$12,579.00	\$14,375.00
<u>Total Expense</u>	<u>\$66,931.00</u>	<u>\$61,277.85</u>	<u>\$60,325.00</u>
<u>Net Income</u>	<u>(\$6,931.00)</u>	<u>(\$4,946.85)</u>	<u>(\$4,325.00)</u>

* Includes ANSI Membership & Support of 25 Standards

** Includes OEOSC Membership & ISO TC172/SC7 Support (2022 Billing, Invoiced & Paid in 2023)

Sales of ASC Z80 Standards

- 2022 = 258
- 2021 = 242
- 2020 = 211

National Standards Approved in 2020/2021/2022

- 5 National Standards approved or reaffirmed in 2022
- 5 National Standards approved or reaffirmed in 2021
- 4 National Standards approved or reaffirmed in 2020

Standards Tracking - ASC Z80 Standards Status as of March 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; 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.
- Z80.9-2020 Devices for Low Vision – Approved by ANSI on April 9, 2020. Next revision is due in 2025. 2023 Errata in process with ANSI Publishing; PINS submitted in April 2023.
- Z80.10-2018 Tonometers – Approved by ANSI on September 27, 2018 – Next revision due in 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 (R2018) Focimeters – Approved by ANSI in June 2018. The next revision is due in 2023.
- 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 Corneal Topography and Tomography Systems – Standard Terminology, Requirements – Approved by ANSI on November 9, 2018. Next revision is due in 2023.
- 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.
- 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 Extended Depth of Focus Intraocular Lenses – Approved by ANSI on September 25, 2018. Next revision is due in 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).
- Z80.37-2017 (R2021) Ophthalmics – Slit-lamp Microscopes – Approved by ANSI on November 9, 2021. The next revision is due in 2026.
- 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 submitted in May 2018.

ANSI 2022 Audit

- The audit went very well with only minor issues to be resolved or addressed.
 - *The auditor recommends that TVC/ASC Z80 cease using the designation “ANSI” and “American National Standards Institute” incorrectly, thus giving the incorrect impression that ANSI has a direct role in the development of the TVC/ASC Z80’s standards.*
 - *The auditor observed that TVC/ASC Z80 improperly referred to the ASC Z80 Committee as “ANSI Z80” and “American National Standards Institute Z80” in meeting minutes and on the ASC Z80 website.*
 - *Update ASC Z80 Patent Policy (Operating Procedures update)*
 - *Update Commercial Terms and Conditions Policy (Operating Procedures update)*
 - *Revise the Anti-Trust Policy (Operating Procedures update)*
 - *Update Appeals Policy (Operating Procedures update)*
 - *Announce public review periods “in suitable media” (or on the ASC Z80 website)*
 - *Issue an erratum for Z80.9-2020 to correct the publication errors.*
- Website and Operating Procedures have been updated accordingly
- Special thanks to Michele for all her work in organizing the required documentation for the audit

Member Voting Information

- ANSI and ISO voting – Even with Michele sending follow up emails, the voting for items is not proficient.
- All experts and voting members should vote on every item that comes across their email, even if it is just to abstain.

ISO / OEOSC TAG Update

- TC172/SC7 Plenaries in 2023:
 - First Plenary, May 11th (virtual)
 - In person TC172/SC7 Meetings, May 22nd - 26th, Paris, France
 - Frustrations from ANSI with the host country not allowing enough space for experts to attend the second plenary (in-person only)

LEGAL REPORT, ASC Z-80 COMMITTEE
May 2, 2022
CLEARWATER BEACH, FLORIDA

I. ASC Z-80 ANTITRUST COMPLIANCE POLICY

The ASC Z-80 committee has a policy of strict compliance with the federal antitrust laws. The antitrust laws prohibit certain combinations and agreements among competitors, and members of an standards writing committees can be considered competitors in the context of antitrust challenges even if their businesses are not in the same geographic areas or in the same product lines. Thus, a committee member's conduct at all ASC Z-80 meetings and events should comply with antitrust laws. The penalties for violations of the antitrust laws can be very severe—not only for ASC Z-80, but also for its individual members.

Committee members cannot come to understandings, make agreements, or otherwise concur on positions or activities that in any way tend to raise, lower, or stabilize prices or fees, divide up markets, or encourage boycotts. Specifically, members should not agree on:

- Current or future prices or fees, price or fee changes, discounting, regulation of production, and other terms and conditions of sale or of providing services. Committee members should be extremely careful about discussing prices or fees, as such agreements are clearly illegal.
- Allocating or monopolizing territories or customers (or patients, clients, etc.). Any agreement by competitors to “honor,” “protect,” or “avoid invading” one another's market areas or product lines would violate the law.
- Refusing to do business with those whose business practices they oppose. Competitors can discuss the policies or practices of suppliers, reimbursers, and other third parties, but they must never threaten directly or indirectly to act jointly to enforce changes to those policies or practices.

Discussions of pricing, fees, or boycotts as part of an ASC Z-80-scheduled programming or meetings could implicate and involve the committee in extensive and expensive antitrust challenges. Committee members should not make any representations, publicly or privately, which appear to represent an official policy or position of the committee without its express authorization.

The antitrust laws are complicated and often unclear. If any member is concerned that he or she may be in a “gray area,” that member should consult with ASC Z-80’s legal counsel or with the secretariate or subcommittee chairperson. If the conversation among competitors at an ASC Z-80’s meeting turns to antitrust-sensitive issues, participants should discontinue the conversation until legal advice is obtained, or else leave the meeting immediately.

II. Update on Zero Technologies v. Clorox/Brita

Clorox used its involvement in a national standards-setting organization to develop and file an early patent application for Brita water filters and created a monopoly.

Clorox/Brita participated on a task force that adopted a standard with a contaminant reduction claim for gravity fed water filters, but did not disclose that they already possessed patent applications that implicated the standard.

The case is still pending. I would expect that a decision will be made by the time we next meet for a summer meeting.

SC1 - ASC Z80.1 Spectacle Lens Meeting Minutes - Draft

May 1, 2023
Sheraton Sand Key, Clearwater FL
9AM – 11AM

Dick Whitney – Chair
Rick Tinson – Vice Chair

1. **Call to Order- Meeting started at 9:05 AM**
2. **Introductions & Introductory Comments / Roster**

The following people participated in the meeting.

ASC Z80.1 meeting attendees			1-May-23
	First Name	Last Name	Company
1	Emmanual	Alabit	ICS
2	Ramzi	Ari	Essilor of America, Inc.
3	Lauren	Bianchi	Marchon
4	Carl	Buckholt	Essilor/Luxottica
5	Karl	Citek	American Optometric Association
6	Jacob	Gary	Colts Laboratories
7	Tom	Hicks	Opticians Assoc. of America
8	Daniel	Lahouse	FGX International
9	Adam	Mancuso	Marchon
10	Michael	Rous	Colts Laboratories
11	Dave	Sliney	Consultant
12	Rick	Tinson	Retired
13	Neil	Torgerson	Walman
14	Michael	Vitale	The Vision Council
15	Scott	Wesley	US Army
16	Richard	Whitney	Carl Zeiss Vision
17	Greg	Williams	Colts Laboratories
18	Carrie	Wilson	Optigal Consulting

It was reported by Mike Vitale following an ANSI audit that future reference to this committee work should be ASC Z80.1 rather than an ANSI committee. The standard still will be referred to as ANSI Z80.1.

3. Anti- Trust discussion

It was reiterated that each meeting should include a discussion reminding its members to be sure to comply with the Anti- trust compliance document for ANSI ASC Z80. Members are encouraged to review Annex E of the operating procedures in ASC Z80 Operating procedures. (www.z80asc.com)

4. **Approval of last meeting minutes (Oct 22)** – The meeting minutes from the Oct 22 ASC SC1 meeting were reviewed. They were unanimously approved.

5. ANSI Z80.1-2025 revision work

Follow up discussion - Prism tolerances for high prism / low power

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At the last SC1 meeting, there was data presented by Zeiss (Brent McCardle) asking for review of low power/high prism tolerances. It has been pointed out the prism values higher than 6D are difficult to measure and asked that some added latitude be provided given this issue. Ultimately the committee agreed to propose the following addition to the 2025 Draft Standard:

5.1.4 Prescribed Prismatic Power

When measured by the method described in 8.X, the tolerance on the prescribed prismatic power of a lens shall be as specified in Table 5.

Table 54 – Tolerance on Prescribed Prismatic Power

Nominal Value of Prescribed Prismatic Power	$\leq 6 \Delta$	$> 6 \Delta$
Tolerance on Prescribed Prismatic Power	$\pm 0.33 \Delta$	$\pm 0.5 \Delta$

Vision Council Guide / Revision to Z80.1 summary table

A discussion of use of the Quick Reference Vision Council guide occurred, which is a free summary of the Summary table used in ANSI Z80.1. There was concern about the lack of understanding of how Compensated Rx's would be handled. Pete Hanlin suggested we add reference to this in the reference table, and it was also noted that the Vision Council Guide for the next revision should include the same guidance.

American National Standard

Z80.1-2020 Draft ASC Z80 review – XXX, 2023

Annex D Optical and Mechanical Tolerances Summary

(Informative)

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

	MEASURE	POWER RANGE	TOLERANCE	SECT.	COMMENTS
Individual Lenses (edged or uncut)	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% of meridian power
	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% of meridian power
	Cylinder	$\geq 0.00 \text{ D}, \leq -2.00 \text{ D}$	$\pm 0.13 \text{ D}$	5.1.1.1	
	For SV, MF, Degressive, Assistive	$> -2.00 \text{ D}, \leq -4.50 \text{ D}$ $> -4.50 \text{ D}$	$\pm 0.15 \text{ D}$ $\pm 4\%$		4% of cylinder power
Distance Refractive Power	Cylinder	$\geq 0.00 \text{ D}, \leq -2.00 \text{ D}$	$\pm 0.16 \text{ D}$	5.1.1.2	
	For Progressive	$> -2.00 \text{ D}, \leq -3.50 \text{ D}$	$\pm 0.18 \text{ D}$		

Myopia Control lenses

It was decided that further discussion/ revision work on the standard with regard to Myopia was not needed. The revision work on localized power errors was adequate as the wording agreed to

SC1 - ASC Z80.1 Spectacle Lens Meeting Minutes - Draft

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in Oct and in the draft specifies that designs which might be considered aberrations were exempt.

6. ISO TC172 Updates

- **Paris May meeting info**

ISO TC172/SC7 meetings will occur at the AFNOR headquarters in Paris the week of May 22. Prior to that, an on line Plenary meeting of SC7 will occur on May 11. Unfortunately, the second plenary will be held in person only. Since space is limited, many are excluded from the meeting. The Vision Council/ANSI sent a letter of objection to ISO, asking for a hybrid meeting but this was denied.

- **ISO 10322 SF Blank revision overview – Diameter and Surface power work (Dick Whitney chair)**

Dick Whitney reported that the ISO 10322 blank standard revision work is underway, with two areas of task group studies are progressing. Diameter and Surface power tolerances are being studied.

Diameter- Concerns have been raised about the complexity and over specifying diameter values by requiring 3 parameters to be met. After review of the issue, discussion by SC1 members led to the general observations that the Vision Council Lens description standard is what is being used when processing the lens, and it would be sensible to reference this for the Diameter requirements in the revised ISO document.

Curve tolerance proposed changes for Spherical Blanks

Dick Whitney reported that a second conference call is planned for the Task group examining a proposed power tolerance change will occur on May 4. Rodenstock/A&R have proposed a change to tightening curve tolerances. The top table shows the present standard requirements, while the bottom shows the proposed tightening. Also in the proposal is to require a control of curve to these tolerances for a 40mm diameter.

The ANSI committee was not clear on the need for such a change, and it was the groups unanimous input that it was **very important to conduct a ring test on product to determine capabilities**. There were also questions on data provided by Rodenstock where the A&R Lensmapper appeared to have been used. It is not clear that this would accurately collect data rather than a method that has a more limited (4-6mm) aperture.

Top table (Present Standard) / Bottom proposed:

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Values in dioptres (D)

Surface power	Tolerance on surface power ^a $\frac{F_1 + F_2}{2}$	Tolerance on surface cylindrical power ^b $ F_1 - F_2 $
$\geq 0,00$ and $\leq 2,00$	$\pm 0,09$	0,06
$> 2,00$ and $\leq 10,00$	$\pm 0,06$	0,06
$> 10,00$ and $\leq 15,00$	$\pm 0,09$	0,06
$> 15,00$ and $\leq 20,00$	$\pm 0,12$	0,08
$> 20,00$	$\pm 0,25$	0,08

Surface power	Tolerance for $(F_1 + F_2)/2$	Tolerance for $ F_1 - F_2 $
≥ 0 and ≤ 12	$\pm 0,06$	$\pm 0,04$
> 12 and ≤ 16	$\pm 0,09$	$\pm 0,04$
> 16 and ≤ 23	$\pm 0,12$	$\pm 0,06$
> 23	$\pm 0,18$	$\pm 0,06$

7. Old Business-

In discussions on the topic of identifying Compensated lenses, there were question as to whether the voluntary Caret Sign indicated in the standard to identify designs that had been adjusted could not be made mandatory. This is not possible. The best way to promote increased use of this valuable indicator is to encourage manufacturers and ECPs to adopt this practice.

8. Next Meeting Dates –

Nov 12-14, 2023 in Dallas Tx
April 21-23, 2024
Oct 6-8, 2024

9. Adjournment – The meeting was adjourned at 11:10AM

ASC Z80 SC2
Non-Prescription Eyewear Subcommittee Meeting
May 1, 2023, 11:00 - 2:00 PM EDT
Palm Room
Sheraton Sand Key Resort
Clearwater Beach, FL

Minutes

Attendees: Karl Citek (chair), Emanuel Alabi, Ramzi Ari, Kelly Arnold (for Item 5.a.ii), Lauren Bianchi, Carl Buckholt, Daniel Lahousse, Jacob Gary (for Item 5.a.i, via Zoom), Pete Hanlin, Tom Hicks, Adam Mancuso, Brent McCardle, Dale Pfriem, Mike Rous, Wesley Scott, David Sliney, Rick Tinson, Neil Torgersen, Michael Vitale, Dick Whitney, Greg Williams, Carrie Wilson

- 1) Call to order: 11:10 AM EDT
- 2) Introductions & introductory comments

Reminder about Antitrust Compliance, requirements can be reviewed at ANSI Z80 website, www.z80asc.com, under Operating Procedures Annex D.
- 3) Acceptance of Agenda with modifications
- 4) Acceptance of minutes from the October 27, 2022 – No changes
- 5) ANSI Z80.3 Non-Prescription Sunglasses & Fashion Eyewear
 - a. Discussed and revised 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. See attached presentation by Jacob Gary, Greg Williams, and Dale Pfriem; thanks to them for working on incorporating this updated information into the standard.
 - ii. Incorporation of recommendations from Spectral Bands Task Force, introducing the term High Energy Visible (HEV) divided into three bands: HEV3 (380-400 nm), HEV2 (400-455 nm), and HEV1 (455-500 nm). Thanks to Kelly Arnold for leading the Spectral Bands Task Force and providing this information for incorporation into the standard.
 - iii. Draft standard with all suggested revisions will be provided to SC2 members for review prior to the Fall 2023 meeting.
- 6) Other business – none
- 7) New business – none

8) Next meetings:

- a. ISO TC 172/SC 7 Plenary Meeting: May 22-26, 2023, Paris, FR.
- b. ASC Z80: November 12-14, 2023, Sheraton Downtown Dallas, Dallas, TX
- c. ASC Z80: April 21-23, 2024, Sheraton Sand Key Resort, Clearwater Beach, FL
- d. ASC Z80: October 6-8, 2024, Sheraton Sand Key Resort, Clearwater Beach, FL

9) Adjourn: 12:34 PM EDT



PROPOSED CHANGE TO ANSI Z80.3 RESISTANCE TO RADIATION



PURPOSE

The purpose of this proposal is to more closely align the requirements in **ANSI Z80.3: 2018** (*for Ophthalmics - Nonprescription Sunglass and Fashion Eyewear Requirements*) to **ISO 12312-1: 2022** (*Eye and face protection - Sunglasses and related eyewear - Part 1: Sunglasses for general use*) and improve the validity of the product testing after the irradiation conditioning.



APPARATUS DESCRIPTIONS

ANSI Z80.3

- 5.9 Resistance to radiation test
- Use a high-pressure xenon arc lamp of nominal 450 W electrical power, having an ozone-free fused silica envelope. Burn in a new lamp for at least 150 h; discontinue use after 2000 h of operation. Mount the lamp with its axis vertical. Operate it with the lamp current equal to $25\text{ A} \pm 0.2\text{ A}$.
- Place a polished clear white crown glass filter between the arc and the lens (e.g., Schott B270, 4 mm thick, or equivalent); the wavelength at which the transmittance of this filter is 46% should be $320\text{ nm} \pm 5\text{ nm}$.

ISO 18526-3

- ISO 18526-3:2020
- 6.8.2.1.1 Fused-silica envelope high-pressure xenon lamp.
 - The power of the lamp shall be between $(450 \pm 50)\text{ W}$.
 - The spectral transmittance of the lamp envelope shall be at least 30 % at 200 nm.
 - New lamps shall be burned in for at least 150 h.
 - The lamp shall not be used after 2000 h of operation.
 - NOTE A suitable lamp reference is XBO-450 OFR.
- 6.8.2.1.2 Long wavelength pass filter, with the spectral transmittance shall be as defined in Figure 2 and Annex B, placed between the lamp and the test sample. A shift of $\pm 5\text{ nm}$ is permitted.
- NOTE The cut-on $\lambda_c = 320\text{ nm}$ is defined as the wavelength at which $\tau_{\lambda,c} = 46\%$.



TESTING PROCEDURE DESCRIPTIONS

ANSI Z80.3

- Mount the lens under test on the horizontal axis of the arc, at a distance of $300 \text{ mm} \pm 10 \text{ mm}$ from the center of the arc, with the surface of the lens essentially perpendicular to the axis of
- the radiant beam from the arc.
- Expose the lens for $50 \text{ h} \pm 0.2 \text{ h}$.

ISO 18526-3

- The test shall be carried out as follows:
- Stabilize the lamp current at $(25,0 \pm 0,2) \text{ A}$.
- The air temperature in the immediate area of the test sample shall be $(28 \pm 5) ^\circ\text{C}$.
- Expose the front surface of the test sample to radiation from the lamp. The angle of incidence of the radiation on the test sample's front surface shall be essentially perpendicular. The distance from the axis of the lamp to the nearest point on the test sample shall be $(300 \pm 10) \text{ mm}$. The exposure time shall be $(80,0 \pm 0,2) \text{ h}$ at a lamp power of $(450 \pm 50) \text{ W}$ unless otherwise specified in the requirements.



SPECIFICATIONS

ANSI Z80.3

- The relative change of luminous transmittance shall not exceed:
- 1) 5% for Cosmetic lens category;
- 2) 8% for General Purpose category; or
- 3) 10% for Special Purpose category.

ISO 12312-1: 2022

- Following irradiation as specified in ISO 18526-3:2020, 6.8.2, the relative change in the luminous transmittance of the filters referred to the initial τ_v D65 (for photochromic filters and electro-optical filters, in the faded state) shall be less than or equal to the values shown in Table 5.
- In addition, the following shall be met:
 - a) the wide-angle scatter shall not exceed the value of 3 %;
 - b) for electro-optical filters, the reduced luminance coefficient (l^*) shall not exceed $3,0 \text{ (cd/m}^2\text{)}/\text{lx}$ in their faded and darkened states (narrow angle scatter).
 - c) for photochromic filters, $\tau_v 0/\tau_v 1$ shall be $\geq 1,25$;
 - d) the UV requirements for the initial filter category shall continue to be satisfied; and
 - e) all claimed transmittance requirements.



APPARATUS

Difference

- ISO 18526-3:2020 has the following differences
 - The spectral transmittance of the lamp envelope shall be at least 30 % at 200 nm.
 - Specifies permissible range of lamp power ($450\text{w} \pm 50 \text{ w}$)

Proposal

- Mimic ISO 18526-3:2020 clause 6.8.2



TESTING PROCEDURE

Difference

- ISO 18526-3:2020
 - Stabilize the lamp current at $(25,0 \pm 0,2)$ A.
 - The air temperature in the immediate area of the test sample shall be (28 ± 5) °C.

Proposal

- Mimic ISO 18526-3:2020 clause 6.8.2, as it is a clearer description.
- Considerations should be made whether to include or exclude the air temperature.

SPECIFICATIONS

Difference

ISO 12312-1: 2022 has the following differences:

- ❖ Classes are defined with different spectrum ranges than ANSI Z80.3's categories.
- ❖ In addition, the following shall be met:
 - ❖ a) the wide-angle scatter shall not exceed the value of 3 %;
 - ❖ b) for electro-optical filters, the reduced luminance coefficient (I^R) shall not exceed 3,0 (cd/m²)/lx in their faded and darkened states (narrow angle scatter).
 - ❖ c) for photochromic filters, $\tau_V 0/\tau_V 1$ shall be $\geq 1,25$;
 - ❖ d) the UV requirements for the initial filter category shall continue to be satisfied; and
 - ❖ e) all claimed transmittance requirements.

Proposal

- ❖ Continue with Z80.3 categories and post irradiation requirements for relative change to luminous transmittance.
- ❖ Mimic ISO 12312-1: 2022, with regards to the additional post exposure scan for wide angle scatter and all transmittance (excluding the luminous transmittance requirements already described in ANSI Z80.3)
- ❖ This would change the post exposure requirements from luminous transmittance only, to all applicable clauses (category dependent) in ANSI Z80.3: 2018 4.10 Transmittance Properties
- ❖ Luminous transmittance
- ❖ Transmittance properties related to traffic signal recognition
 - ❖ Color Limits
 - ❖ Traffic signal transmittance
 - ❖ Spectral transmittance
- ❖ Ultraviolet mean transmittance
- ❖ Near infrared transmittance
- ❖ Blue light transmittance
- ❖ Add in Wide-angle scatter (Plano only), to both pre and post irradiation.



PROPOSED CHANGES TO ANSI Z80.3: 2018 SECTION 4.14

Change the wording
in Section 4.14 to:

*Lenses subjected to the
test described in 5.9
shall meet all relevant
requirements in section
5.9, after irradiation.*

PROPOSED CHANGES TO ANSI Z80.3: 2018

SECTION 5.9 APPARATUS

- Change the section to:
 - Apparatus –
 - Fused-silica envelope high-pressure xenon lamp.
 - The power of the lamp shall be between (450 ± 50) W.
 - The spectral transmittance of the lamp envelope shall be at least 30 % at 200 nm.
 - New lamps shall be burned in for at least 150 h.
 - The lamp shall not be used after 2000 h of operation.
 - NOTE A suitable lamp reference is XBO-450 OFR.
 - Long wavelength pass filter, with the spectral transmittance shall be as defined in Figure 2 and Annex B, placed between the lamp and the test sample. A shift of ± 5 nm is permitted.
 - NOTE The cut-on $\lambda_c = 320$ nm is defined as the wavelength at which $\tau_{\lambda,c} = 46$ %.



PROPOSED CHANGES TO ANSI Z80.3: 2018

SECTION 5.9 TESTING PROCEDURE

- Change the section to:
 - **Testing Procedure** – The test shall be carried out as follows:
 - Stabilize the lamp current at $(25,0 \pm 0,2)$ A.
 - The air temperature in the immediate area of the test sample shall be (28 ± 5) °C.
 - Expose the front surface of the test sample to radiation from the lamp. The angle of incidence of the radiation on the test sample's front surface shall be essentially perpendicular. The distance from the axis of the lamp to the nearest point on the test sample shall be (300 ± 10) mm. The exposure time shall be $(50,0 \pm 0,2)$ h at a lamp power of (450 ± 50) W unless otherwise specified in the requirements.



PROPOSED CHANGES TO ANSI Z80.3: 2018

SECTION 5.9 REQUIREMENTS

- Change the section to:
 - **Requirements**
 - The relative change of luminous transmittance shall not exceed:
 - 1) 5% for Cosmetic lens category;
 - 2) 8% for General Purpose category; or
 - 3) 10% for Special Purpose category.
 - Transmittance properties related to traffic signal recognition shall comply with the appropriate requirements in Table 4.
 - Color Limits shall comply with the appropriate requirements in Table 4.
 - Traffic signal transmittance shall comply with the appropriate requirements in Table 4.
 - Spectral transmittance shall comply to section 4.10.2.3.
 - Ultraviolet mean transmittance shall comply with the appropriate requirements in Table 4.
 - Near infrared transmittance shall comply with the appropriate requirements in Table 4.
 - Blue light transmittance shall comply with the appropriate requirements in Table 4.



ASC Z80 - SC3 Spectacle Frames Meeting Minutes

May 1, 2023

Start Time: 2:00 pm

End Time: 3:30 pm

Sheraton Sand Key – Palm Room

- Meeting was called to order and the below were in attendance.

Name	Affiliation	Name	Affiliation
Alabi, Emmanuel	ICS Laboratories, Inc.	Ari, Ramzi	EssilorLuxottica
Bianchi, Lauren	Marchon Eyewear Inc.	Buckholt, Carl	EssilorLuxottica
Citek, Karl	AOA, Pacific University College of Optometry	Hicks, Tom	Optician Associates of America
Lahousse, Daniel	FGX International Inc.	Mancuso, Adam	Marchon Eyewear, Inc.
McCardle, Brent	Zeiss	Rous, Mike	Colts Laboratory
Scott, Wesley	US Army Medcom	Tinson, Rick	
Torgersen, Neil	Walman Optical	Vitale, Michael	The Vision Council
Whitney, Richard	Carl Zeiss Vision, Inc.	Williams, Greg	Colts Laboratory
Wilson, Carrie	Optical Consulting		

- Anti-trust rules were reviewed and can be found at [TVC-ASC-Z80-Operating-Procedures-REV2021-3-31-21-ANSI-approval-5-13-21.pdf](#) (annex D).
- A vote was passed with no objections and there was an acceptance of the October 2022 Meeting Minutes (page 19-20).
- The meeting agenda for this gathering was voted and passed with no objections.
- Old Business topics reviewed were as below.
 - Review of ISO WG2 Activities
 - Withdrawal without replacement of ISO/TS 24348, Ophthalmic optics – Spectacle frames – Method for the simulation of wear and detection of nickel release from metal and combination spectacle frames.
 - Quick question to the group: has anyone seen an increase in frame distortion on acetate frames recently? – Final review of the comments of the group were in regards to manufacturing deviation from raw materials supplier recommended processes and unrelated to standards work.
- New Business
 - Daniel Lahousse brought the ISO work group activities (CEN TC 170 WG8) to the attention of the committee as there is discussion to update EN 16128 to accommodate pre and post damage review to test standard and evaluation of test surface for consistent results. Below reports were made available for review as the inter-lab correlation study raised to light the variation in methods and results between labs.
 - CEN TC170 WG8 N439 – Inter-lab correlation study
 - CEN TC170 WG8 N440 – Comments on damage review
 - Next Meetings update
 - ISO TC172/ SC7: May 22-26, 2023 Paris, France
 - Fall 2023 ASC Z80 meeting to be held November 12-14 in Dallas, Texas
 - Spring 2024 ASC Z80 meeting to be held April 21-23 in Clearwater, Florida
 - Fall 2024 ASC Z80 meeting to be held October 6-8 in Clearwater, Florida
- Adjournment was agreed with thanks to those who participated.

SC4 Parent Committee Report

- SC4: Chair: Dr. Raj Suryakumar
- Meeting Room: Gulf Room
- Meeting Dates: 04/30/2023 (Z80.39/Z80.35 and Z80.11) and 05/01/2023 (Z80.29)
- Meeting Start 8:00 am, Meeting End: 5:00 pm – both days
- Reviewed and Accepted Agenda, Meeting was both Virtual + In-person
- *All meetings 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">• Reaffirmed 2022• Two meetings so far in 2023• 1st meeting 03/21, 2nd meeting 04/30• 20 attendees• 87 comments recd since Mar 2023• Reviewed comments up to #45 (at the Annexes)• Plan to continue virtually in June and in-person at the Fall Meeting (Nov 2023)
Z80.07	Intraocular Lenses	<ul style="list-style-type: none">• Date of last review 2018 (reaffirmed while in development)• SC4 will review the Word Document of the Standard and come back in Nov 2023 with motion to reaffirm
Z80.39	FVR IOL	<ul style="list-style-type: none">• 1st meeting in 2023 on 04/30• ~32 comments on Revision-2• Review of all comments were completed• Discussion also included harmonization of elements of ISO 11979-7 to the Z80.39 FVR standard• Next revision after ISO 11979-7 discussion in May• Motion: Requesting approval to change the title for Z80.39 to Static Full Visual Range Intraocular Lenses
Z80.29	Accommodating IOLs	<ul style="list-style-type: none">• 2 meetings so far Jan-18 and, Mar-10• ASC meeting yesterday (05/01) was meeting #3• 79 new comments since last meeting in Mar• 50 of 79 comments addressed.• Revisions will continue via virtual discussions in June/July and in-person Nov 2023

Z80.27	Glaucoma	<ul style="list-style-type: none"> • Key discussion point has been around definition for refractory glaucoma • Clinical definitions for Refractory Glaucoma in the draft standard were not aligned with the how the devices are currently regulated in US • Next step will be to create a draft version with clear definitions in Annexes on C and D • Revised document will be re-circulated to the group • Group to meet virtually by June/July 2023
Z80.30	Toric Intraocular Lenses	<ul style="list-style-type: none"> • Date of last review 2018 • SC4 will review the Word Doc and come back in Nov 2023 with motion to reaffirm
Z80.35	Extended Depth of Focus	<ul style="list-style-type: none"> • ISO Update from 11979-7 requirements on EDF presented was by FDA and contrasted against the current requirements in Z80.35 • Group discussed the differences between the two standards • Motion to re-affirm Z80.35 in 2023 • Motion to open up PINS for revision

Report on the activity of ASC Z80 SC6 – Instruments & Low Vision Devices – 2023

2023-05-01

Attendees: Charlie Campbell, Dr. Karl Citek, Dr. Bruce Drum, Dr. Stephen Klyce, Sanjeev Kasthurirangan, Dr. Michelle Sandrian, Dr. David Sliney, Daniel Mattsson-Boze, Philip Yuhas, Dr. Shulei Zhao, Dr. Eli Peli

Items of business discussed

1. Z80.17 Focimeter and Z80.23 Corneal Topography and Tomography Systems

We decided that we do not need to update these standards at this time and that they should be reaffirmed

2. Z80.10 Tonometers

We decided that due to the ongoing ask by FDA for each Tonometer submission for R&R testing, which is lacking from the standard, that we would open the standard for revision and address this lack.

There is some groundwork we need to accomplish before the November meeting including contacting some colleagues relative to this proposal, getting some tonometer manufactures on board, and figuring out the details of what we want to add to the standard.

We will discuss the details further in November

We ask the committee to approve a PINS for this standard.

3. ANSI Z80.37 Slit Lamp

We discussed the slit lamp standard particularly with respect to how the photochemical hazard should be the only/prominent hazard due to the photochemical hazard in Z80.36 being more restrictive than thermal hazard.

We decided that this standard needs to be revised.

We ask the committee to approve a PINS for this standard

4. ANSI Z80.36 Light Hazard Protection for Ophthalmic Instruments

We discussed Z80.36 which has recently been updated (2020), but, in our opinion, needs to be considered again relative to some of the limits. There was some work done on the thermal calculations and it seems that there is a problem with the current standard.

We would like to change this standard, but we must do some homework first.

- We need to have a thermal study done to validate the calculations done by Charlie Campbell that showed the issue. Dr. Sliney will search for someone to do this study.
- We also want to see what happens with ISO 15004-2 in Paris as this may/will have some bearing on this standard.

We anticipate bring this standard up for revision in November. No PINS needed at this time.

5. ANSI Z80.9 Devices for Low Vision

An error was made in the publishing of this standard. A wrong figure was put into the standard and therefore, this standard needs to be updated. There may also be some other minor changes that we will address in the standard as well, especially relative to video delay/lag, as well as some definitions that may not be complete.

We have a PINS for this revision already.

6. Presentation by Eli Peli

Dr. Eli Peli made a fascinating presentation of, essentially, the history of Low Vision devices of the IOL and contact lens type, including some unique spectacles. It is a history fraught with reinventing the square wheel. Dr. Peli was interested in creating a standard that would help avoid such square wheels in the future, saving many people, at least 1250 British citizens, from further suffering.

We don't know if such a standard as this can be created. The title would be, how to avoid the reinvention of malfunctioning devices, or how to prevent stupidity from recurring.

We should ponder this some more.

7. Contrast sensitivity standard

Dr. Bruce Drum presented an idea of creating a new standard that addresses Contrast sensitivity. This is particularly needed in acuity charts but also has application in Perimetry.

We had a good discussion on this topic and decided that we need to do our homework.

- We want to include John Robson in the process
- Dr. Drum will write up a proposal for this

Dr. Citek recommended that we start with a relatively simple standard that we can build from

No further action at this time other than the homework.

ASC Z80 SUBCOMMITTEE 7: CONTACT LENSES and CARE PRODUCTS

Meeting: Spring 2023 ASC Z80 SC7 Committee

Location: Sheraton Sand Key, Clearwater, Florida. Skyview Room.

Scheduled Time: Monday, May 1, 2023. 8:30 am EDT start.

Final Agenda (1 MAY 2023)

Meeting Start: 8:34 am

Meeting Finish: 3:43 pm

REPORT TO PARENT COMMITTEE

ASC Z80 SC7 meeting occurred with 13 members in the room and another 16 members joining via Zoom. Opening items included roll call, review of antitrust compliance, committee leadership, the new OEOSC website, voting options, the new ISO code of conduct, and agendas associated with the upcoming ISO TC 172/SC 7 meetings later this month in Paris.

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.

Subcommittee reviewed the 11 standards that are up for systematic review. All 11 were voted for re-confirmation. All 11 will be discussed at the upcoming ISO meeting in Paris. Specific actions proposed:

- ISO 18369-1: open a preliminary work item (PWI) on scleral lens terminology.
- ISO 18369-4: editorial revision on the custodian of the oxygen permeability reference materials.
- ISO 11986: editorial revision on scope of standard.
- ISO 19045 Series
 - Organize a Part 3 to ISO 19045 on *Acanthamoeba* cysts.
 - Revision to methods on organism counts and staining within Part 1.

Subcommittee discussed need for international perspective on what strains are appropriate for use – and potentially other areas of improvements – within ISO 14729 and ISO 18259.

PWI on ISO 18369-3 concerning multifocal contact lens testing proceeding towards final technical specification (TS 6838). TS will be published for a two-year public review on topics raised.

PWI on ISO 18369-4 focusing on modulus – other parameters exhibited too much variability to warrant further work. Additional testing materials identified. Next round of testing needs additional international involvement.

PWI on ISO 19045-2 progressing; draft international standard (DIS) circulated and approved. Comments under review.

Discussion on validation of symbols for CLCP labelling under ISO 11978 focused on ability to resource project. Proposal with budget estimates to be developed ahead of Paris meeting. Proposal will be socialized at ISO meeting to identify funding sources.

10 SC7 experts will attend the Paris meeting in person, with additional members supporting online. Meeting planned for Sunday proceeding meetings to confirm attendance and positions on topics.

Attendees: (R: In-room attendance, Z: Via Zoom)

First Name	Last Name	Company / Group	Email	Attendance
Emmanuel	Alabi	ICS Laboratories, Inc.	ealabi@icslabs.com	
Kelly	Arnold	J&J Vision Care Inc.	KArnold9@its.jnj.com	R
Charles	Campbell		charles.e.campbell@mac.com	
Allison	Campolo	Alcon Vision LLC	allison.campolo@alcon.com	R
James	Cook		jnc31@sbcglobal.net	
Marcus	Cooke	Veterans Health Care System of the Ozarks (VHSO)	Marcus.Cooke@va.gov	
Monica	Crary	Alcon Laboratories	monica.crary@alcon.com	R
Glenn	Davies	Bausch & Lomb	glenn.davies@bausch.com	Z
William	Domm	Bausch & Lomb	William.Domm@bausch.com	R
Manal	Gabriel	Alcon Vision LLC	manalmg@yahoo.com	
Jobany	Garces	Davis Vision - Plainview	Jobany.Garces@versanthealth.com	
Melanie	George	CooperVision	megeorge@coopervision.com	R
Chandramallika	Ghosh	Food & Drug Administration	Molly.Ghosh@fda.hhs.gov	
Angelo	Green	Food & Drug Administration	angelo.green@fda.hhs.gov	Z
Yeming	Gu	Alcon Vision Care R&D, JCR-LL	yeming.gu@alcon.com	
Joseph	Hutter	Food & Drug Administration	joseph.hutter@fda.hhs.gov	
Tom	Karkkainen	Johnson & Johnson Vision Care	tkarkkai@its.jnj.com	Z
Sanjeev	Kasthurirangan	CooperVision	SKasthurirangan@coopervision.com	R
Mark	Lada	Johnson & Johnson Vision Care	MLada@its.jnj.com	Z
Carol	Lakkis	Biomedical Consulting	clakkis22@gmail.com	R
Shinwook	Lee	Alcon Vision LLC	shinwook.lee@alcon.com	
Brian	Loudermilk	Alcon Vision LLC	brian.loudermilk@alcon.com	
Kylie	Marflack	CooperVision	KMarflack@coopervision.com	
Heather	Michaels	CooperVision	hmichaels@coopervision.com	
Kimberly	Millard	Bausch & Lomb	Kimberly.Millard@bausch.com	R
Troy	Miller	Accu Lens Inc.	troy@acculens.com	
Randall	Mitchell	Alcon Vision LLC	randy.mitchell@alcon.com	
Mary	Mowrey-McKee	RP Stone Consulting	marymckee@aol.com	Z
Michelle	Mundorf	Johnson & Johnson Vision Care	mmundorf@its.jnj.com	Z
Michael	Pfleger	Alcon Vision LLC	michael.pfleger@alcon.com	
Samuel	Puig	CooperVision	spuig@coopervision.com	
Martine	Robie	CooperVision	MRobie@coopervision.com	
Stanley	Rogaski	Contact Lens Institute	sjrogaski@comcast.net	
Karen	Sentell		kbsentell@gmail.com	
Paul	Shannon	Alcon Vision LLC	Stephen.shannon@alcon.com	R
Joshua	Slane	Bausch & Lomb	Joshua.slane@bausch.com	
Scott	Steffen	Food & Drug Administration	scott.steffen@fda.hhs.gov	
Michele	Stolberg		ascz80@thevisioncouncil.org	
Ralph	Stone	Ralph Stone Consulting	ralphsuestone@prodigy.net	R
Paul	Trotto	Bausch & Lomb	paul.trotto@bausch.com	Z
Elmer	Tu	University of Illinois At Chicago	etu@uic.edu	
Michael	Vitale	The Vision Council	mvitale@thevisioncouncil.org	
Greg	Williby	Johnson & Johnson Vision Care	gwilliby@its.jnj.com	R
Elissa	Wong	Food & Drug Administration	Elissa.Wong@fda.hhs.gov	Z
James	Wu	Alcon Vision LLC	james.wu@alcon.com	Z
Ying	Zheng	Alcon Vision LLC	Ying.zheng@alcon.com	R
Aaron	Zimmerman	American Optometric Assn	zimmerman.178@osu.edu	Z
Heidi	McMinn	Bausch & Lomb		Z
Troy	Miller			Z
Michelle	Komal	Food & Drug Administration		Z
Jeremy	Barnes	Alcon	Jeremy.barnes@alcon.com	R
Otgonchimeg	Rentsendorj	Food & Drug Administration		Z
Barb	Klube			Z
Bailin	Liang			Z

Topic: Opening Items

- Opening of the meeting
- Roll call
- Review of final agenda
- Introductory Items
 - Committee leadership, introductions
 - Reminder on antitrust compliance guidelines for ANSI ASC Z80
 - ANSI & ISO Updates – Part 1

Topic Leader: Greg Williby

Starting Notes: Review of ANSI and ISO structure, notes on voting and meeting conduct.

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.

Starting Notes: Potential changes in time. Need to monitor as ISO standards are reviewed. No recommended action at this time.

Meeting Notes: Monitor ISO 19045-2, changes in ISO 19045-2 will impact this standard.

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

Topic Leader: Greg Williby

Status: Reaffirmed in 2021.

Starting 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. Definition work ongoing as part of ISO 18369-1; potential topic for introduction at upcoming ISO/TC 172/SC 7/WG 9 meeting.

Meeting Notes: Continue to monitor ISO 18369-1.

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

Topic Leader: Glenn Davies

Status: Result of systematic review is confirmation (N 2360). Will be discussed and final decision made in WG9 meeting.

Starting Notes: Minor comments from systematic review:

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Observations of the secretariat
CH- 001				ge	Adapt wording to the actual terminology e.g. "intended purpose" vs "intended use"	Needed clarification.	
DE- 002				ge	Clarification of new terminology e.g. "intended purpose" vs "intended use", e.g. afocal lenses without medical purpose		

See slides.

Meeting Notes: Relationship to EU MDR documents.

ACTION: Sanjeev to email relevant documents/links.

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

Status: Result of systematic review is confirmation (N 2361). Will be discussed and final decision made in WG9 meeting.

Starting Notes: Comments from systematic review: - *see slides*:

Comments	
Canada (SCC) Kubba, Dalia Ms	Since its publication, international guidelines were published for scleral lenses and for soft and rigid lenses. Many terms are now in conflict between these guidelines- which make consensus among experts in the field- and the actual document. I strongly recommend a complete revision to get concordance with modern published peer-reviewed literature.
France (AFNOR) Pierret, Irina Mme	Add some definition like the spectral factor of blue light filtration for example. Add a definition on the different type of stabilization and ballast of toric lenses (ballast, peri-ballast...), not really coherent today. Systematically use a common name for the name of materials. Make the labeling evolve to mention more important information such as the nature of the buffer solution, the presence of a surfactant and which one.
United States (ANSI) Team, ANSI ISO	If opened for revision, scleral lens terminology should be reviewed.

Regarding scleral lens terminology, see slides.

DECISION NEEDED: Alignment on a recommendation for a New Work Item (PWI).

Regarding classification for coated materials, see slides.

DECISION NEEDED: Alignment as a topic for Any Other Business (AOB).

Meeting Notes:

Decision on scleral lenses: support the opening of a PWI. Scope should be narrow – not intending to open full standard. Differences noted in terms used between clinicians and manufacturers.

Discussion on classification for coated materials occurred. Coatings are thin – how thick does a coating need to be to be consequential? Perhaps thick enough to override the properties of the bulk material. Can additional/different modification codes be used to convey properties of the coating. Modification code “c” currently used if the surface has been chemically modified. Information to convey: 1) ionicity, 2) thickness, 3) other?

Decision on classification for coated materials: informal discussions only at ISO.

ACTION: Ralph, Ying, Angelo, Joe Hutter to discuss nomenclature using the current modification codes. Report out at next ASC Z80 meeting.

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

Topic Leader: Glenn Davies

Status: Result of systematic review is confirmation (N 2362). Will be discussed and final decision made in WG9 meeting.

Starting Notes: Comments from systematic review:

Comments	
Canada (SCC) Kubba, Dalia Ms	Please see attached commenting document
France (AFNOR) Pierret, Irina Mme	Add the tolerances and spectral range of blue light filtration and specify more clearly the filtration tolerance of UVA and UVB
Ireland (NSAI) Nevin, Sharon Ms	Update might be required to align with updates required to other parts of the series.
Switzerland (SNV) ebchief, ebchief Mr	see commenting template

Template for comments and secretariat observations

Date:2022-12-03

Document:

Project:

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Observations of the secretariat
CH-001				ge	The terms contained in ISO/TS 6838 should be added in ISO 18369-1.		
CH-002		3.1.11.25			Clarification of the classification	Extend the definitions in relation to the common medical device wording.	
CH-003		3.1.2.1.8			Clarification of plus or minus power axis	Definition for clarification needed.	
CA-004		4.52			This section, as applied to rigid lenses, is not in the public interest. There should be a measurable standard established. As a practitioner, quality control of this element was routine for every lens.	The revision should establish a standard that can be evaluated by eyecare professional consumers of these product to ascertain quality standards are met.	
CA-005		4.53			This section, as applied to rigid lenses, is not in the public interest. There should be a measurable standard established. As a practitioner, quality control of this element was routine for every lens.	The revision should establish a standard that can be evaluated by eyecare professional consumers of these product to ascertain quality standards are met.	

Meeting Notes: Maintain position of confirming.

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

Topic Leader: Greg Williby

Status: Result of systematic review is confirmation (N 2363). Will be discussed and final decision made in WG9 meeting.

Starting Notes: Comments from systematic review:

Comments	
China (SAC) Wang, Likun Ms	with comments 4.3 Label back vertex power The definition of this term involves a new quantity value for contact lenses, whose formulation lacks reference sources and scientific basis. 4.3.3 Calibration Even with the new terminology "label back vertex power". The instrument calibration shall be carried out to assure measuring accuracy to known standards using spherical test lenses as specified in ISO 9342-2.
France (AFNOR) Pierret, Irina Mme	Following the evolution and the appearance of certain properties it would be good to add some adjustment as the recognition of certain device such as IS830 from Optimec to make a very large number of optical measurement. But also to evolve the range of spectral length by integrating the UVA, UVB, even blue light. because the ISO 18369-2 mentions the tolerances but the 18369-3 does not give specific conditions on the measurement methods. The spectral width of 10nm also seems to me too large.
Switzerland (SNV) ebchief, ebchief Mr	New measurement methods are in use

For additional comments, see slides. Four countries (France, Germany, Ireland, Switzerland) voted to revise.

Meeting Notes: Maintain position.

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

Topic Leader: Ying Zheng

Status: Result of systematic review is confirmation (N 2364). Will be discussed and final decision made in WG9 meeting.

Starting Notes: Comments from systematic review:

Comments	
France (AFNOR) Pierret, Irina Mme	With the appearance of new parameters and commercial terms, I think it would be interesting to establish new rules, definitions and or protocols on certain measurements such as: the measurement of Young's modulus (no protocol even though it is an important measurement), surface wettability, water retention (very much used to improve dry eye problems but everyone uses internal protocols that are not necessarily comparable)..

Template for comments and secretariat observations

Date:2022-12-03	Document:	Project:
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MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Observations of the secretariat
IE- 001				ge	Further update might be required to align with updates required to other parts of the series		
IE- 002		§4.05.4.2.2 & §4.5.4.2.2		te	For the measurement of refractive index the prism temperature (which will set the temperature of the contact lens) "shall be 20.0°C ±0.5°C" In ISO 18369-3: Where a lens is required to be maintained at a temperature this temperature is 20.0°C ±1.0°C except for Ultrasonic measurement which requires a temperature range of 20.0°C ±0.5°C (§4.2.3.4). The Chinese standards series for Ophthalmic Contact lenses GB11417 Parts 1-9, was written based on a historical version of ISO 18369 series, requires a wet cell temperature of 20°C also but with a tolerance of ±0.5°C.	Would there be a benefit to align all the temperatures the lens must be maintained at for measurements across the ISO 18369 family and with GB11417 1-9 e.g. choose the lower tolerance of ±0.5°C rather than ± 1.0°C for global alignment.	

From J Parker, agreement to a minor Editorial revision of 18369-4, which we could put in progress at the Paris meeting by agreement of the WG.

DECISION NEEDED: Alignment on a recommendation for a minor editorial revision.

ASC Z80 SC7 Contact Lenses

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/ Table/	Type of comment ²	Comments	Proposed change	Observations of the secretariat
	-	4.4.4	Note	Te	Update the custodian of the oxygen permeability reference material repository	Change: Dr. William Benjamin, 937 Tulip Poplar Lane, Hoover, Alabama, USA, 35244 To: Createch Rehder, 141 Traction St., Greenville, South Carolina, USA, 29611	

Meeting Notes:

Decision on minor editorial revision: continue with above proposed change.

On French comments, seek to better understand “water retention” and surface wettability concerns.

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

Topic Leader: Mary Mowery-McKee. Co-lead desired.

Status: Result of systematic review is confirmation (N 2392). Will be discussed and final decision made in WG9 meeting.

Starting Notes: Comments from systematic review:

Comments	
Australia (SA) Darne, Gauri Ms	Comment File attached
Ireland (NSAI) Nevin, Sharon Ms	See attached file
Portugal (IPQ) Isidoro, Alexandra Mrs	To be align with the new HTA reference documents

Template for comments and secretariat observations

Date:2023-03-05

Document:

Project:

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/ Table/	Type of comment ²	Comments	Proposed change	Observations of the secretariat
IE-001		5.6		te	Recommend including additional context for clarity.	Add the following section (i.e., rabbits may be kept in stockade restraints during lens wear, but it is not required)	
IE-002		9.2.2		ge	Taping the lids near the outer canthus to prevent expulsion has limited success. Are other strategies available to improve lens retention?		
AU-003	N/A	9.5.3	N/A	TE	Laboratory techniques for histology include frozen sections, which are now used more routinely.	Add a note that frozen samples sectioned with a cryostat may be used instead of/in addition to paraffin embedded samples.	
AU-004	N/A	11	N/A	GE	In the Test report, mention should be made of the Animal Ethics approving authority and the approval number.	Add to the end of point c) statement of compliance to appropriate good laboratory practices; “and animal ethics approving authority and approval number”	
IE-005		Throughout		ed	Where ISO 10993-10 is identified update needed to remove reference to irritation & add ISO 10993-23 wherever ISO 10993-10 is referenced for irritation	N/A	

Meeting Notes: For co-leads, Paul, Melanie suggested. Maintain position to confirm.

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.

Starting Notes: US comments collected. OUS comments collected. Discussion on the idea of acceptance criteria.

Meeting Notes: Multiple meetings to align US comments. OUS comments out for review; will align US positions on OUS comments ahead of Paris meeting. CD need by Q3 this year. Multiple new experts involved at ISO level. Vote for AWI based on prior draft provided. New comments recommended to be held over to next revision.

Acceptance criteria discussed. Reasons for discussions include identifying the implicit criteria already in place. Also, EU MDR bringing new scrutiny to standards. SPE (Safety & Performance Endpoints) rates may be harder to define on CL side as incidence rates are typically lower than for IOLs. Current language speaks to ability to detect one adverse event. *Contact Lens Safety & Performance Guidance* – FDA document relevant to this space.

ACTION: Carol and Sanjeev to send email to ASC Z80 SC7. Gauge interest. Topic to be discussed at next ASC Z80 meeting.

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

Status: Result of systematic review is confirmation (N 2388). Will be discussed and final decision made in WG9 meeting.

Starting Notes: Comments from systematic review:

Comments	
France (AFNOR) Pierret, Irina Mme	today certain surface treatments are very effective but fragile with certain solutions such as peroxide and sodium hyaluronate. it could be interesting to check the compatibility between the solutions and the new contact lenses with innovative treatment
Italy (UNI) Novali, Cristina Ms	"5.2 Contact lenses from at least groups 1 through 4 should be tested if the care product(s) are used with non-hydrogel contact lenses" is no more applicable and should be changed.
Portugal (IPQ) Isidoro, Alexandra Mrs	To be align with new HTA reference documents.

Meeting Notes: Maintain position.

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

Topic Leader: Ralph Stone

Status: Result of systematic review is confirmation (N 2389). Will be discussed and final decision made in WG9 meeting.

Starting Notes: Comments from systematic review:

Comments	
Portugal (IPQ) Isidoro, Alexandra Mrs	no comment
United States (ANSI) Team, ANSI ISO	Proposed Note 3: Preservative uptake/release results generated using this guidance document are intended for informational purposes only and not meant for use in finished goods specifications in any way.

DECISION NEEDED: Alignment on a recommendation for a minor editorial revision.

PROPOSED NOTE 3: Preservative uptake/release results generated using this guidance document are intended for informational purposes only and not meant for use in finished goods specifications in any way.

Discussion on preventing usage on daily disposable lenses.

Meeting Notes:

Discussion on use of information. Note language revised.

PROPOSED NOTE 3: Preservative uptake/release results generated using this guidance document are intended for informational purposes to determine if additional testing is warranted and not meant for use in finished goods specifications in any way.

Decision on note: continue to advocate for minor editorial revision. See above new language.

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

Topic Leader: Jeremy Barnes (formerly Brian Loudermilk)

Status: Result of systematic review is confirmation (N 2390). Will be discussed and final decision made in WG9 meeting.

Starting Notes: Comments from systematic review:

Comments	
Portugal (IPQ) Isidoro, Alexandra Mrs	no comment

Meeting Notes: Maintain position.

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 Crary, Kim Millard

Status: Result of systematic review is confirmation (N 2393). Will be discussed and final decision made in WG9 meeting.

Starting Notes: Comments from systematic review:

Comments	
Australia (SA) Darne, Gauri Ms	Comments attached
China (SAC) Wang, Likun Ms	Recommended to merge with the ISO 14729-2001/Amd 1-2010
Portugal (IPQ) Isidoro, Alexandra Mrs	To be align with the new HTA reference documents

Template for comments and secretariat observations

Date:2023-03-05

Document:

Project:

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Observations of the secretariat
AU-001	N/A	3	N/A	GE	As in 2006 ISO 8320-1: and ISO 8320-1 were withdrawn and merged into ISO18369-1, these normative references should be updated	Update normative references ISO 8320-1: and ISO 8320-1 to ISO18369-1.	
AU-002	N/A	4	N/A	GE	As per normative reference change (ISO 8320 to ISO 18369)	Replace ISO 8320 with ISO 18369	
AU-003	N/A	6.4.1	N/A	GE	As silicone hydrogels are the majority of materials prescribed in most markets, and ISO 18369 was updated in 2017 to include them as Group 5, this section on lens materials should reference them.	Include " and enhanced oxygen permeability hydrogel lenses (Group 5) in the following statement: "Qualification of a lens care product regimen with all hydrophilic and all non-hydrophilic lenses requires testing with Group 1 and 4 hydrophilic lens types and silicone acrylate and fluorosilicone acrylate non-hydrophilic lenses.	
AU-004	N/A	Informative annex C	N/A	TE	In light of COVID19 pandemic and isolation of SARSCov2 in tears, this informative annex should be updated.	Include consideration of SARSCov2 in informative annex C	
AU-005	N/A	Informative annex D	N/A	TE	As the need for Acanthamoeba testing standards have been ascertained (due to outbreaks with lens solutions that pass this standard), the technical arguments in informative annex D are not aligned with current thinking and should be updated.	Include the need to have additional Acanthamoeba testing standards in informative annex D	

Discussion to align on ANSI positioning for informal discussions at the international level. Topics to include strains and methodologies.

Meeting Notes: Relationship to ISO 19045-2. Once changes made in this standard, Annex D should be edited. Annex D would no longer be accurate. Fusarium name update required.

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: Reviewed and Confirmed in 2019.

Starting Notes: Discussion to align on ANSI positioning for informal discussions at the international level. Topics to include strains and methodologies. Experiences testing according to ISO 18259 desired.

Meeting Notes: Informal discussions aimed at understanding what strains are appropriate for use. Determine if other experts see areas that can/should be improved.

Topic: Project Group on PWI 18369-3. 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: TS 6838 publication target modified since last meeting. FDIS due 1 SEP 2023 with publication target 13 JAN 2024 (per Resolution 772 in N2387).

Starting Notes: Meetings 24 FEB and 30 MAR to review international comments. Will review in Paris. Outcome of Paris meeting is either schedule for final review of items outstanding at end of Paris meeting or submit FDIS. *See slides.*

Meeting Notes: Two methods included in TS. Plan for Paris meeting is to a) discuss final draft and b) present final draft in plenary on Wednesday.

Topic: Project Group on PWI 18369-4.

Topic Leader: Ying Zheng

Status: Ongoing evaluation of test methods.

Starting Notes: Focus on modulus. The initial results show promising alignment among three labs. We are working on manual calculations on more data sets to have statistical comparison. Expanding OUS, looking for CooperVision and Menicon to participate. Strategy is to start with sheets to focus on lab-lab differences, then progress onto contact lens samples. *See slides.*

Meeting Notes: Sample preparation underway. Seeking non-US participation in further testing.

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

Topic Leader: Monica Crary, William Domm, Mary Mowery-McKee, Kim Millard

Status: DIS circulated, approved (N 2399). Comments received in N 2399, issued 20 APR.

Starting Notes: Comments reviewed, consistent with proposals for ISO 19045 series.

Meeting Notes: 100% approval. FDIS submission targeted ahead of Paris meeting.

Topic: ISO 19045-3 (proposed). WD ISO 19045-2. ISO/CD 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: Proposal for future PWI.

Starting Notes: Proposal for New Work Item (PWI-2):

PWI-2

Form a Project Group (PG) to begin standardizing the third part to the 19045 *Acanthamoeba* series of standards. Tentatively titled: 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.

Technical issues and support:

1. A small group of SMEs have been performing preliminary testing and equivalency work to gain alignment and streamline standard protocol development.
2. Protocol variables and concerns are being identified and tested including two encystment methods, excystment kinetics, and recovery procedures.

*Additional technical support can be provided if requested.

DECISION NEEDED: Alignment on a recommendation for a PWI.

Meeting Notes: Don't want the clock to start – advocate for a PWI. Otherwise aligned. (Updated NWI to PWI after meeting).

Decision is to support the PWI. Get guidance ahead of Paris meeting.

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: Reviewed and Confirmed in 2020. Proposal for future PWI.

Starting Notes: Proposal for New Work Item (PWI-1):

PWI-1

ISO 19045: Ophthalmic optics – Contact lens care products – Method for evaluating Acanthamoeba encystment by contact lens care products

1. Propose edit to title based on 19045-2 development to be:
ISO 19045-1: Ophthalmic optics – Contact lens care products – Part 1: Method for evaluating Acanthamoeba encystment by contact lens care products
2. Multiple technical issues have been identified and ANSI is proposing formation of a Project Group (PG) to further understand issues and make recommendations for revision of this standard (likely before next systematic review).

Technical issues and support:

1. Acanthamoeba organism counts being outside the limit of quantification of a hemocytometer that limit the specificity of the standard protocol.
2. Limitations in the lysis and staining steps that may lead to non-specific lysis and staining of trophozoites and cysts prior to analysis

*Additional technical support can be provided if requested.

DECISION NEEDED: Alignment on a recommendation for a PWI.

Meeting Notes: Alignment on the proposal based on prior meetings with US experts. Priority across ISO 19045 family is Part 3. This might be an issue should only one new work item proposal be accepted or allowed.

Decision is to support the PWI. Get guidance ahead of Paris meeting. Done.

Topic: Project Group on CLCP Labelling – Symbols (ISO 11978).

Topic Leader: Carol Lakkis

Status: Ongoing meetings.

Starting Notes: Ongoing discussions on funding for ring test conduct. Team of experts may be expanded to include China, others. *See slides.*

Meeting Notes: Symbols are for users; complicated validation. CLI open to supporting testing. CLI wants to see other countries support as well. Carol working on a proposal that can be shared with other countries and other stakeholders. Discussion on population; inclusion of children. This type of user validation was done by a central ISO committee in the past. High-risk (to safety) symbols require more rigorous validation than low-risk symbols.

ACTION – Carol to develop proposal as part of PG update in Paris meeting.

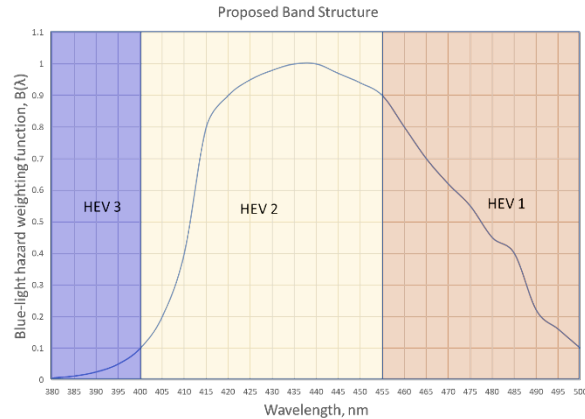
Topic: ANSI – Spectral Band Task Force (SBTF).

Topic Leader: Kelly Arnold

Status: Ongoing meetings.

Starting Notes: Outcomes reached on banding, to be reviewed in SBTF meeting 1 MAY (in Clearwater) – *see slides.*

Meeting Notes: Outcome is alignment to the following scheme:



ISO/TR 20772 is a document covering spectrum information and will be referenced in future SBTF work. Debut of HEV terminology will be in ANSI ASC Z80.3. ASC Z80 SC7 will monitor other sub-committees for PINS and inclusion of this work.

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

Topic Leader: Carol Lakkis

Status: Edition 1 published in 2018. Next systematic review in 2023.

Starting Notes: Noted poster on topic (courtesy Monica Crary) – *see slides*.

Meeting Notes: Standard open now – votes due 12 MAY. Recommendation is to confirm. Comments heard about other methods – those beyond peroxide or heat.

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

Topic Leader: Melanie George, Mark Lada, Ralph Stone.

Status: Reviewed and Confirmed in 2019. Next systematic review in 2024.

Starting Notes: *See slides*.

Meeting Notes: Recommendation is to re-confirm during 2024 review. Add Jeremy to list ASC Z80 experts.

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

Topic Leader: Mary Mowery-McKee. Co-lead desired.

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

Starting Notes: No known issues. ISO 14730 used as model for USP<51> test.

Meeting Notes: Recommendation is to re-confirm. Add Kim, Monica, Melanie to list of ASC Z80 experts to support topic.

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: Paul Shannon, Mary Mowery-McKee

Status: Reviewed and Confirmed in 2022.

Starting Notes: Confirmed 7 Apr 2022. 79% approval; 21% approval with comments. 3 countries provided comments. Conclusion was no changes.

Meeting Notes: Maintain position.

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.

Starting Notes: Confirmation in 2021 influenced by EU MDR. Carol – a few countries did want to revise. Mary – developed in conjunction with the EN standard in the 1990s. Value is providing a starting point for development and review.

Meeting Notes: No news. Unclear how the broad topic of EU MDR impacts this standard. One possibility is Annex ZA in the standard.

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: Next systematic review in 2026.

Starting Notes: No current activities. Not adding contact lens symbols. Carol to monitor, provide updates.

Meeting Notes: This is a medical device standard – outside ISO TC 172. Carol to follow up with AAMI.

Topic: Closing Items

- ISO Meeting Prep
 - ISO virtual opening meeting will be May 11, 1 pm CEST (7 am EDT).
 - US Expert Meeting – Sunday, May 21. Paris.
 - Time – TBD (afternoon)
 - Location - TBD
- Call for New Work Items
- Next Meeting – ANSI – ASC Z80 SC7 - Contact Lenses – November 12-14, 2023. Dallas, Texas.
- Miscellaneous Business
 - SBTf Meeting – 5 pm
- Closure of the meeting

Topic Leader: Greg Williby

ASC Z80 Spectral Bands Task Force

Meeting: Spring 2023 ASC Z80 Spring Meeting

Location: Sheraton Sand Key, Clearwater, Florida. Skyview Room.

Scheduled Time: Monday, May 1, 2023. 5:00 – 6:00 pm ET

Agenda:

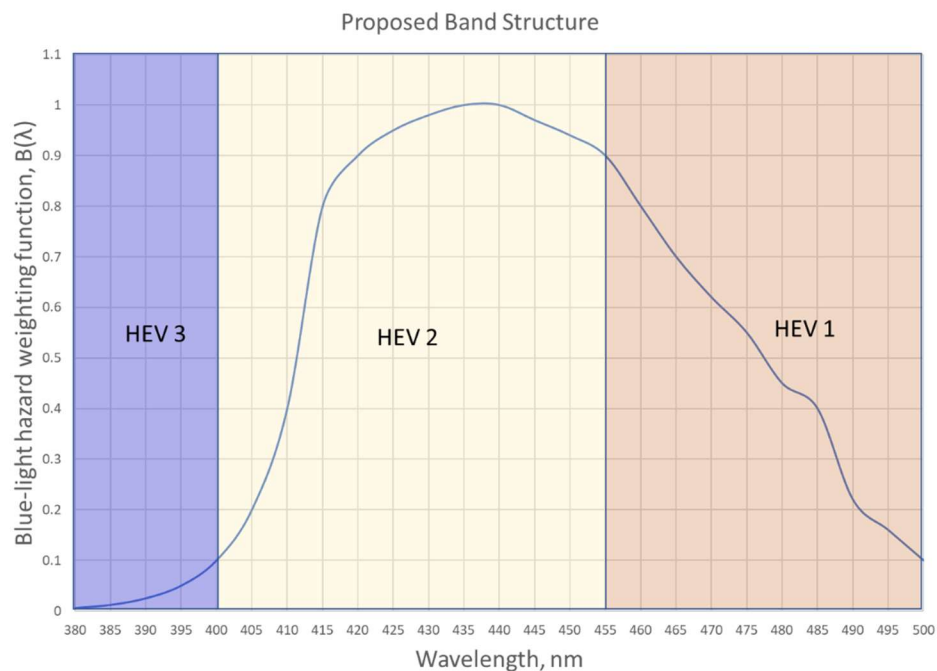
- Review of consensus at end of Meeting 8
- Disclosure of impact on Z80.3
- Discussion of closure Technical Report
- Discussion of socialization of band scheme
- Mention of US work at ISO

Consensus:

- HEV Range 380-500 nm
- Lesser band structure
 - HEV3: 380 – 400 nm
 - HEV2: 400-455 nm
 - HEV1: 455-500 nm

ANSI Nominative Report for ASC Z80 SBTF:

- Discussion of scope for technical report yielded more appropriate term of nommative report as it is an effort to define and standardize new terms
- Build on ISO TR 20772 (2017)
- Discussion of energy calculations of the bands in order to bolster rationale
- M. Vitale checking with ANSI for guidance with regard to structure, scope, process
- K. Arnold to start drafting succinct description of work done by task force



Work with SC2 and Revision of Z80.3:

- K. Arnold met with members of SC2 to describe scope and status of SBTF
- Appealed to SC2 to incorporate SBTF consensus in revision of Z80.3
- Scope of edits to complement edits previously suggested by SC2
- Notes to introduce the term High Energy Visible light; note to introduce band scheme available for optional reporting
- SC2 comfortable with SBTF reviewing draft of revision, regarding comments added by SBTF.
- Need to reference SBTF nominative report (NR); NR will need to be written and approved by end of summer 2023 to dovetail with revision timeline of Z80.3

Socialization of band scheme

- After Nominative Report is written, and after Z80.3 is revised, socialization of the scheme will be driven
- R. Tinson conversation with Aarlan Aceto – President of National Federation of Opticianry Schools (NFOS); A. Aceto enthusiastic for NFOS to be a route to reach established and rising opticians
- Discussion of different routes for socialization and wider-spread communication of scheme through work with
 - The Vision Council, leveraging working relationships with trade associations and WebMD
 - Certification bodies, such as TUV, OSHA, BSI etc.
 - Continuing Education course credits
 - OAA Newsletter
 - Trade Journal editorials

Discussion of US Work at ISO

- Some comments in CL space (From France) regarding blue light, the recommendation for definition of spectral range of blue light filtration and energy calculations in this space.
- Gauging comfort of Task Force mentioning “US is also interested in this area and to this end, we have a task force that is developing nomenclature in this region. We are in the process of writing up our conclusions in a nominative report; we would be happy to share that with you.”
- Task force comfortable with sharing the band scheme with folks at ISO if discussion lends itself

ASC Z80 Parent Committee Meeting

Tuesday May 2, 2023

US FDA Report

1. Things are returning to normal in terms of FDA standards travel.
2. We have published two guidances related to digital health that affect ophthalmic devices:
 - a. Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions <https://www.fda.gov/media/166704/download>

This draft guidance discusses a regulatory framework to allow machine learning/artificial intelligence changes to device software without the need for prior approval.
 - b. Clinical Decision Support Software [Clinical Decision Support Software](#)

This final guidance impacts many reviews of ophthalmic devices. This guidance clarifies the scope of FDA's oversight of clinical decision support software. Since not all software used in health care settings is considered a medical device, it clarifies the criteria for non-device clinical decision support software and provides examples.
3. FDA has recognized 3 Ophthalmic standards in the past 6 months:

Standard	Title of Standard
ISO 10942 - 2022	Ophthalmic instruments – Direct Ophthalmoscope
ISO 11979-10 - 2018	Ophthalmic Implants – Intraocular Lenses – Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes
NEMA PS 3.1 – 3.20 (2022d)	Digital Imaging and Communications in Medicine (DICOM) Set