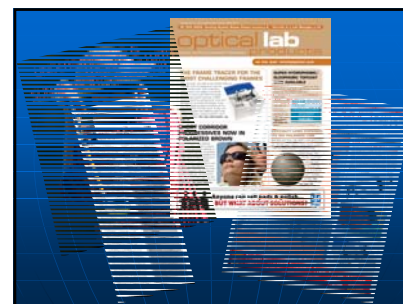


An Overview of the ANSI Standards

Ed De Gennaro
Richmond, Virginia

Ed De Gennaro
Director of Professional Content
First Vision Media Group



ANSI In Perspective

- Essentially a consulting firm
- Z80 Standards Committee formed in 1956
- It is a private, nongovernmental agency
- Unlike FTC, FDA, OSHA
- It issues standards not regulations
- Strictly voluntary - but!

How many ANSI standards are there today?

22!

What basic categories do the standards fall into?

Standards Categories

- Eyeglasses (Rx, safety & plano sun; RX frames)
- Contact lenses and care solutions
- Ophthalmic instruments
- Computerized equipment
- Medical devices (IOL's, shunts)

Current ANSI Standards

- Z80.1 Prescription Ophthalmic Lenses - Recommendations 2009
- Z80.3 Nonprescription Sunglasses and Fashion Eyewear - 2010
- Z80.5 Requirements for Ophthalmic Frames - 2010
- Z80.7 Intraocular Lenses - 2002
- Z80.9 Low Vision Aids - Requirements - 2010

Standards Con't

- Z80.10 Tonometers - 2009
- Z80.11 Laser Systems for Corneal Reshaping - 2007
- Z80.12 Multifocal Intraocular Lenses - 2007
- Z80.13 Phakic Intraocular Lenses - 2007
- Z80.17 Focimeters - 2008
- Z80.18 Contact Lens Care Products - 2010
- Z80.20 C.L. - Standard Terminology, Tolerances, Measurements and Physiochemical Properties (Combines Z80.2, 6 & 8) - 2010
- Z80.21 Instruments - General Purpose Clinical Visual Acuity Charts - 2010
- Z80.23 Corneal Topography Systems - 2008

Standards Con't

- Z80.24 Information Interchange for Ophthalmic Optical Equipment - 2007
- Z80.25 Instruments - Fundamental Requirements & Test Methods - 1996
- Z80.26 Data Processing & Interchange for Ophthalmic Instruments - 1996
- Z80.27 Aqueous Shunts for Glaucoma Application - 2001
- Z80.28 Methods for Reporting Optical Aberrations of Eyes - 2010
- Z80.30 Toric Intraocular Lenses - 2010
- Z80.31 Specs for SV Ready-To-Wear Near Vision Specs - 2012
- Z87.1 Occupational and Educational Eye and Face Protection Devices- 2010

Most Standards Will Have.....

- ANSI policy statement
- Forward
- Scope
- References
- Definitions
- Classification
- General requirements

Most Standards Will Have.....

- Test methods
- Identification
- Identification of the standard
- Tables
- Annexes
- Figures

ANSI Policies Statement

- Provide for due process
- Consensus = substantial agreement
 - More than a majority but not unanimity
- Completely voluntary
 - Can manuf., market, etc. outside the standard
- ANSI does not develop & will not interpret
 - Secretariat or sponsor may interpret
- Must reaffirm, revise or withdraw within 5 years

When was the last revision of the dress wear Standard (Z80.1)?

2009

Overview of Z80.1

- Covers prescription eyewear and custom made plano sunglasses
- 1995 put ISO power tolerance into the Standard
- Reverted back to the power tolerances of the 1987 Standard
- Includes automatic focimeters and better describes the method for measuring prism

Z80.1 History

- 1956: Z80 committee formed
 - Developed 3 drafts, 2 for manufactured lenses, 1 for fabricated glasses
- 1964: Issued combined standard for manufacturers & fabrication
- 1970: Committee reorganized
 - OSA as secretariat

Z80.1 History

- 1972: Broadened scope to include:
 - Lenses other than glass
 - Sunglasses and fashion eyewear
 - FDA impact requirements
- 1979: A shift from mass-produced lenses to lab.
 - Attempt to define state-of-the-art
 - Not all parameters would be met
 - "Requirements" became "Recommendations"

Z80.1 History

- 1982: OLA becomes secretariat
- 1985: Z80 committee becomes accredited
- 1987: Defines range of UV absorbing lenses
 - Expands appendices
 - Expands multifocals
 - Still a "Recommendation"
- 1995: Applies ISO power standards
- 1999: Shifts back to 1987 tolerances after finding 1995 tolerances too restrictive
- 2005: Corrects the change in power tolerance methodology

Scope

Who the standard is designed for

- Applies to the processing of lenses
 - in edged or assembled form
- A guide for labs and dispensers
- Should apply to uncuts from labs too
- Does not apply to nonRX sunglasses

Purpose

- Shift from mass-produced to lab.
- Does not represent the "state-of-the-art"
 - sets quality goals instead
- Difficult to meet all requirements simultaneously
 - 25% do not on average
- Expresses desirable technical concepts
- Not designed as a regulatory instrument

Tolerance on Distance Refractive Power

Single Vision & Multifocals

Absolute Power of Highest Power Meridian	Tolerance on Meridian of Highest Power	Cylinder = 0.00 D, = 2.00 D	Cylinder > 2.00 D, = 4.50	Cylinder > 4.50 D
From 0.00 up to 6.50	± 0.13 D	± 0.13 D	± 0.15 D	± 4%
Above 6.50	± 2%	± 0.13 D	± 0.15 D	± 4%

Tolerance on Distance Refractive Power

Progressive Addition Lenses

Absolute Power of Highest Power Meridian	Tolerance on Meridian of Highest Power	Cylinder = 0.00 D, = 2.00 D	Cylinder > 2.00 D, = 3.50	Cylinder > 3.50 D
From 0.00 up to 8.00	± 0.16 D	± 0.16 D	± 0.18 D	± 5%
Above 8.00	± 2%	± 0.16 D	± 0.18 D	± 5%

Cylinder Axis Tolerance

Cylinder Power	>0.00 up to 0.25	>0.25 up to 0.50	>0.50 up to 0.75	>0.75 up to 1.50	>1.50
Axis Tolerance	(+/-) 14	(+/-) 7	(+/-) 5	(+/-) 3	(+/-) 2

What is the tolerance for the sphere power meridian?

+4.50 -1.25 175

- a. (+/-) 0.13D
- b. (+/-) 0.15D
- c. (+/-) 0.18D
- d. (+/-) 0.25D

■ Answer
● 0.13D

How much prism error can this one lens have?

- a. 0.25^
- b. 0.33^
- c. 0.50^
- d. 0.66^

Prismatic Power Tolerance
For a single lens


- 0.33Δ
- Note: A placement error of 1mm is allowed in any direction

Vertical Prism Tolerance
For a Mounted Pair

- 0.00D to 3.375D = 0.33Δ
- 1/3 for the right, 1/3 for the left, 1/3 for the mounted pair
- For powers above 3.375D, a 1mm error between the two PRPs.

Vertical Prism Imbalance Tolerance

Ordered:	Received:
OD -1.00	OD -1.00 1/3^ BU OK
OS -1.00	OS -1.00
	OD -1.00 1/3^ BU OK
	OS -1.00 1/3^ BU
	OD -1.00 1/3^ BU NG
	OS -1.00 1/3^ BD

 * A 1mm vertical placement error is allowable for a mounted pair

Horizontal Prism Tolerance
For a Mounted Pair

- 0.00D to 2.75D = 0.67Δ
- 2/3 for the right, 2/3 for the left, 2/3 for the mounted pair
- For powers higher than 2.75D, a 2.5mm placement error is allowed

Horizontal Prism Imbalance Tolerance

Ordered:	Received:
OD -3.00	OD -3.00 2/3^ BO OK
OS -3.00	OS -3.00
	OD -3.00 2/3^ BO OK
	OS -3.00 2/3^ BI
	OD -3.00 1/3^ BO OK
	OS -3.00 1/3^ BO
	OD -3.00 1/3^ BI OK
	OS -3.00 1/3^ BI
	OD -3.00 2/3^ BO NG
	OS -3.00 2/3^ BO

Prism Tolerance
For a Mounted Pair of Progressives

- Vertical:
 - Up to 3.375 = 0.33Δ
 - For higher powers, a 1mm placement error
- Horizontal
 - Up to 3.375 = 0.67Δ
 - For higher powers, a 1mm PD error is allowed

What is the maximum allowable horizontal error for this mounted pair of lenses?

-8.00 -1.75 x 20
-7.50 -1.00 x 165

- a. 1/3^
- b. 1/2^
- c. 2/3^
- d. none of the above

Answer

d. A 2.5mm PD placement error is allowable for a mounted pair

How much can a specified base curve be off?

Example: Ordered B.C. = +4.50

- a. 0.25D
- b. 0.50D
- c. 0.75D
- d. 1.00D

Answer: c. 0.75D

- For spherical base curves
 - use a lens clock or spherometer
 - must be for index 1.530
- For lenses using 546.07nm
 - instrument must be calibrated for this
- For aspherics
 - measure concave spherical curve
 - measure lens thickness
 - measure back vertex power
 - calculate the front nominal curve

How much warpage is permissible?

- a. 0.25D cylinder
- b. 0.50D cylinder
- c. 0.75D cylinder
- d. 1.00D cylinder

1.00 diopters!

"This recommendation need not apply within 6mm of the mounting eyewire."

What's the segment height tolerance for a mounted pair?

- a. 0.5mm
- b. 1.0mm
- c. 1.5mm
- d. 2.0mm

(+/-) 1mm for each lens and 1mm for the pair

- This rule also holds true for progressive lenses using the fitting cross as the reference point.
- For horizontal placement, 2.5mm is allowed. Inset should be symmetrical unless a monocular NPD was ordered.
- For progressives, the near reference point is set by the manufacturer, so the horizontal placement tolerance is exempted from this standard.

What is the segment size tolerance (from the ordered size)?

- a. 0.10mm
- b. 0.25mm
- c. 0.33mm
- d. 0.50mm

Answer: 0.5mm

- Measure at the widest point
- For measuring, you can use...
 - a shadowgraph
 - an optical comparator
 - a precision millimetric measuring instrument

P.D. ruler!!!

When you specify center thickness, how much can the lens be off?

- a. 0.1mm
- b. 0.2mm
- c. 0.3mm
- d. 0.4mm

(+/-) 0.3mm!

"The center thickness shall be measured at the prism reference point of the convex surface and normal to this surface."

What's The Add Power Tolerance?

- a. 0.06D
- b. 0.12D
- c. 0.18D
- d. 0.25D

b. 0.12D

Add Power	Up to 4.00D	>4.00D
Add Tolerance	(+/-) 0.12D	(+/-) 0.18D

*Adds above +4.00 are usually considered low vision aids

Where Can I Get The Standards?

American National Standards Institute
 11 West 42nd Street
 New York, NY 11036
 (212) 642-4900
<http://www.ansi.org/>

Thanks for Attending!

Ed De Gennaro
 Midlothian, Virginia

infocus@comcast.net
 (804) 739-0522

