

American National Standard

*for Ophthalmics –
Prescription Ophthalmic Lenses –
Recommendations*



Currently in preview, click buy full version

ANSI®
Z80.1-2015
Revision of
ANSI Z80.1-2010

American National Standard
for Ophthalmics –
Prescription Ophthalmic Lenses –
Recommendations

Secretariat
The Vision Council

Approved August 20, 2015
Editorially Revised January 25, 2016

American National Standards Institute, Inc.

American National Standard

Approval of an American National Standard requires review by ANSI that the requirements for due process, consensus, and other criteria for approval have been met by the standards developer.

Consensus is established when, in the judgement of the ANSI Board of Standards Review, substantial agreement has been reached by directly and materially affected interests. Substantial agreement means much more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that a concerted effort be made towards their resolution.

The use of American National Standards is completely voluntary; their existence does not in any respect preclude anyone, whether he has approved the standards or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standards.

The American National Standards Institute does not develop standards and will in no circumstances give an interpretation of any American National Standard. Moreover, no person shall have the right or authority to issue an interpretation of an American National Standard in the name of the American National Standards Institute. Requests for interpretations should be addressed to the secretariat or sponsor whose name appears on the title page of this standard.

CAUTION NOTICE: This American National Standard may be revised or withdrawn at any time. The procedures of the American National Standards Institute require that action be taken periodically to reaffirm, revise, or withdraw this standard. Purchasers of American National Standards may receive current information on all standards by calling or writing the American National Standards Institute.

Developed by

The Accredited Committee Z80 for Ophthalmic Standards -

The Vision Council
Z80 Secretariat
225 Reinkers Lane
Alexandria, VA 22314

Published by

The Vision Council
Z80 Secretariat
225 Reinkers Lane
Alexandria, VA 22314

Copyright © 2015 by The Vision Council
All rights reserved.

No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without prior written permission of the publisher.

Printed in the United States of America

Contents

Foreword	ã
1 Scope and Purpose	1
2 Normative References	2
3 Definitions	3
4 Classification	11
5 Optical Requirements	11
6 Mechanical & Durability Requirements	11
7 Transmittance & Attenuation Requirements	16
8 Test Methods	16
9 Markings for Lenses	25
10 Identification	26
Annex A Technical Addendum to Impact Testing	28
Annex B Recommended System for Visually Inspecting Lens for Defects	32
Annex C The Boxing System of Measurement	33
Annex D Optical and Mechanical Tolerances Summary	34
Annex E Position of Wear ("As-worn") Definitions	36
Annex F Bibliography	37

Foreword (This foreword is not part of American National Standard ANSI Z80.1-2015.)

Summary of Changes to ANSI Z80.1 for 2015

This 2015 revision represents the most current consensus of experts in this field. The changes from the 2010 standard are the result of a thorough study by the ANSI Z80.1 committee of the relevance and applicability of its contents.

This publication includes modifications to several portions of the standard that had not been updated for some time:

- The Scope and Purpose sections were both reworded to better reflect how the committee believes the standard should be used in today's environment;
- The definitions area was reviewed with changes and modifications;
- "Position of Wear" definitions were added in a new annex E for informational purposes, in order to help instruct others on three terms commonly used in this area. These terms are becoming more commonplace with growing popularity of newer fabrication technologies and lens designs;
- A further clarification of how tolerances should be applied to compensated lenses was added in the optical requirements section;
- A voluntary permanent lens marking standardized character (^) was added as a recommendation, to be applied on lenses that contain such compensation;
- Other modifications to the marking guidelines were also made;
- Another new addition to the standard was included in the area of transmittance, where a recommendation for minimum transmittance when driving was added. The new section provides guidance and is intended to harmonize with ANSI Z80.3 requirements in this area;
- Reference to orientation of polarization axis was added;
- The "FDA Impact" guidelines were again included, with an additional sentence added to refer the reader to the specific authoritative source which should be referenced on this topic, the Federal Register;
- Following the recent publication of the revised Standard ANSI Z80.1-2015, a typographical error was identified in the formula for the calculation of UVB mean transmittance in subclause 3.13. The error has been corrected and the correct formula is now listed in subclause 8.13.

Background and Summary of Past revisions for ANSI Z80.1

The Z80 Standards Committee for Ophthalmic Lenses was organized in 1956. Three separate standards were drafted, two relating to the manufacture of lenses and one to the fabrication of ophthalmic lenses into prescription eyewear. A standard relating mainly to lenses, but containing additional tolerances for a mounted pair, was issued in 1954. The tolerances were based largely upon an analysis of measured parameters in typical single-vision, mass-produced lenses assembled into conservatively selected and sized mountings. The standard represented the state-of-the-art for such lenses and a set of quality goals for lenses surfaced in the ophthalmic laboratory on an individual basis.

At the beginning of 1970, the Standards Committee Z80 was reorganized with the Optical Society of America, its former sponsor, serving as Secretariat. In 1972, the committee's scope was broadened to include lenses other than prescription glass ophthalmic lenses in recognition of the importance of plastic ophthalmic materials

and the increased use of sunglasses and fashion eyewear. In the 1972 revision, certain tolerances for plastic and heat-treated lenses were relaxed in response to Federally mandated impact-resistant requirements for all ophthalmic lenses.

The 1979 revision reflected a shift in utilization from mass-produced lenses to a basic dependence upon custom-processed lenses at the laboratory level. It was an attempt to define the state-of-the-art in the manufacturing laboratory by recognizing the fact that, while individual tolerances may be reliably met, it is often not possible to achieve all requirements simultaneously. The Standard expressed desirable technical concepts that provide a framework for safety and effectiveness. The title was changed from a "requirement" to a "recommendation" to reflect the committee's intent.

In 1982, the Optical Laboratories Association assumed the responsibilities of the Secretariat. In 1985, the Z80 Committee became an Accredited Standards Committee.

The 1995 revision attempted to write the Z80.1 standard in a fashion consistent with ISO standards. This change included the practice of applying a tolerance to both meridional powers rather than sphere and cylinder as had been common practice. It was subsequently found that applying the ISO power tolerance method to custom fabricated eyewear resulted in unacceptably high rejection rates.

The 2005 revision recognized the need for change in the power tolerance methodology. This standard maintained the ISO approach to power tolerance, but used the highest meridian only rather than both meridians. For the first time since 1979, the mounted cylinder axis tolerance was adjusted based upon detailed scientific studies and a recognition of process capability and wear needs. The difference in refractive power tolerance between progressive addition lenses and single vision and multifocal lenses reflects the fact that the tolerance on allowable cylinder in the semi-finished blank curvature for progressive addition lenses in ISO standards is looser than the tolerance on single vision and standard multifocals. The tolerance for cylinder axis uses as its basis the amount of axis error that would be needed to result in an error of 0.13 D (the tolerance for cylinder refractive power). Additionally, the section on the lens measurement method has been rewritten to include automatic focimeters and better describe the method of measuring prism.

In January 2009 the Vision Council assumed responsibility for Secretariat.

The 2010 revision included several important areas of revision. The first change related to a transmission power tolerance, where the practice of using the sphere and cylinder (when expressed in minus notation) was again utilized. Two durability requirements for this revision were adapted from published ISO standards: Specifications and test methods for anti-reflective coatings and Minimum requirements for spectacle lens surfaces claimed to be abrasion resistant.

The standard remains a recommendation. Therefore, it is the specific intent of the Z80 Committee that this standard not be used as a regulatory instrument.

This standard contains six informative annexes, which are not considered part of the standard.

Suggestions for improvement of this standard will be welcome. Suggestions should be sent to The Vision Council, 225 Reinekers Lane, Suite 700, Alexandria, VA 22314.

This standard was processed and approved for submittal to ANSI by the Accredited Standards Committee Z80 (ASC Z80). Committee approval of this standard does not necessarily imply that all committee members voted for its approval. At the time it approved this standard, ASC Z80 had the following members:

Thomas C. White, M.D., Chair
 Guido Cappelli, Vice-Chair
 William J. Benjamin, O.D., Secretary

<i>Organization Represented</i>	<i>Name of Representative</i>
Abbott Medical Optics (AMO)	Leonard Borrmann Mark Gordon (Alt.)
Advance Medical Technologies Association.....	Michael Pfleger Dr. Richard Courtney (Alt.)
American Academy of Ophthalmology	Dr. Thomas White Dr. Carl Tubbs (Alt.) Dr. Pradeep Ramulu (Alt.) Scott Haber (Alt.)
American Academy of Optometry.....	Dr. David Loshin
American Ceramic Society	Lyle Rubin
American Glaucoma Society	Dr. Steven Gedde Douglas Rhee (Alt.)
American Optometric Association.....	Karl Citek Dr. Robert Rosenbaum (Alt.) Dr. William Benjamin (Alt.)
American Society of Cataract and Refractive Surgery (ASCRS)	Dr. Stephen ... Dr. Jack ... (Alt.)
Contact Lens Institute	Stan ... Peter ... (Alt.)
Contact Lens Manufacturers Association	Guido Cappelli Tony Miller (Alt.)
Department of Veterans Affairs	Dr. John Townsend Michael White (Alt.)
Federated Cornea Societies	Dr. Michael Belin Dr. David Glasser (Alt.) Kathy Colby (Alt.) Elmer Tu (Alt.)
Food & Drug Administration CDRH/ Division of Federal Agencies	Don Calogero Dr. Dexiu Shi (Alt.)
National Association of Optometrists & Opticians	Nick Mileti Doug Pelkey (Alt.) Franklin Rozak (Alt.)
Optical Laboratories Association	Steve Sutherlin Rick Tinson (Alt.)
Opticians Association of America	Tom Hicks Chris Allen (Alt.)
Sunglass Association of America	Tibor Gross Nick Brown (Alt.) Rick Van Arnam (Alt.)
The Vision Council	Michael Vitale Neil Roche (Alt.) Dick Whitney (Alt.)
U.S. ISO TC 172/SC7	Jeff Endres

The Subcommittee on Prescription Ophthalmic Lenses, which developed this standard, had the following members at the time of approval:

Richard Whitney, Chair
Rick Tinson, Vice-Chair

Rick Albright
William Brown
Karl Citek
Keith Cross
Jeff Endres
Ken Frederick
Pete Hanlin
Tom Hicks
David Hilber
Herbert Hoover
Darryl Meister
Nick Mileti
Doug Pelkey
Neil Roché
Robert Rosenberg
Lyle Rubin
Jonathan Schwarz
Daniel Simonetta
Michael Vitta
Greg Williams

Currently in preview, click buy full version

American National Standard for Ophthalmics –

Prescription Ophthalmic Lenses – Recommendations

1 Scope and Purpose

1.1 Scope

This standard applies to all prescription dress ophthalmic spectacle lenses in edged or assembled form. It is a guideline for entities that fabricate, assemble or process dress eyewear or lens components. Relevant optical and physical specifications and tolerances of this standard also apply to uncut lenses.

This standard does not apply to products covered by

- ANSI Z80.3, *American National Standard for Ophthalmics – Nonprescription sunglass and fashion eyewear requirements*
- ANSI Z80.31, *American National Standard for Ophthalmics – Specifications for single vision ready to wear near vision spectacles*
- ANSI Z87.1, *American National Standard for Occupational and educational personal eye and face protection devices*
- ASTM F803, *Eye protectors for selected sports*

1.2 Purpose

This standard reflects the shift in utilization from mass-produced lenses to a basic dependence upon custom-processed lenses. It provides minimum acceptable tolerances for new lenses prepared to an individual prescription.

The power, prism, and axis tolerances established in this standard are subject to measurement limitations associated with the accuracy and repeatability of the current state-of-the-art focimetry and other measurements commonly in use by laboratory technicians and eyecare professionals. Users should therefore take into account the measurement capability of the devices (and methodology) when applying tolerances to the spectacle lens. As such, this voluntary standard expresses technical concepts that provide a frame of reference for safety and effectiveness.