

# American National Standard

*for Ophthalmics –  
Toric Intraocular Lenses*

---





**ANSI®**  
**Z80.30-2010**

American National Standard  
for Ophthalmics –  
**Toric Intraocular Lenses**

Secretariat  
**The Vision Council**

Approved March 24, 2010  
**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**CAUTION NOTICE:** This American National Standard may be revised or withdrawn at any time.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  
1700 Diagonal Road  
Suite 500  
Alexandria, VA 22033

## *Published by*

The Vision Council  
1700 Diagonal Road  
Suite 500  
Alexandria, VA 22033

Copyright © 2010 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

	Page
Foreword .....	iii
<b>1</b> Scope and purpose .....	1
<b>2</b> Normative references .....	1
<b>3</b> Definitions .....	2
<b>4</b> Physical requirements .....	2
4.1 Scope .....	2
4.2 Requirements .....	2
4.2.1 Tolerances and dimensions .....	2
<b>5</b> Optical requirements .....	3
5.1 Scope .....	3
5.2 Requirements .....	3
5.2.1 Dioptric power .....	3
5.2.2 Axis orientation mark(s) .....	3
5.2.3 Imaging quality .....	3
5.2.4 Spectral transmittance .....	4
<b>6</b> Mechanical requirements .....	4
6.1 Scope .....	4
6.2 Requirements .....	4
6.2.1 Toric IOLs for the correction of aphakia .....	4
6.2.2 Toric IOLs for the modification of the refractive power of the phakic eye .....	4
<b>7</b> Biocompatibility requirements .....	4
7.1 Scope .....	4
7.2 General guidelines .....	4
7.3 Biological test requirements .....	5
7.4 Physicochemical test requirements .....	5
<b>8</b> Sterility/package integrity requirements .....	5
8.1 Scope .....	5
8.2 Requirements .....	5
8.2.1 Toric IOLs for the correction of aphakia .....	6
8.2.2 Toric IOLs for the modification of the refractive power of the phakic eye .....	6
<b>9</b> Shelf-life and transport stability .....	6
9.1 Scope .....	6
9.2 Requirements .....	6
9.2.1 Toric IOLs for the correction of aphakia .....	6
9.2.2 Toric IOLs for the modification of the refractive power of the phakic eye .....	6

	Page
<b>10</b>	Clinical investigation plan ..... 6
10.1	Scope..... 6
10.2	Requirements ..... 6
10.2.1	Toric IOLs for the correction of aphakia..... 6
10.2.2	Toric IOLs for the modification of the refractive power of the phakic eye ..... 6
10.3	Safety and effectiveness requirements..... 7
<b>11</b>	Labeling ..... 7
11.1	Scope..... 7
11.2	Requirements ..... 7
11.2.1	Labeling of spherical power ..... 7
11.2.2	Labeling of cylindrical power..... 7
11.3	Additional requirements ..... 7
11.3.1	Additional requirements for toric IOLs for the corrections of aphakia ..... 7
11.3.2	Additional requirements for toric IOLs for the modification of the refractive power of the phakic eye..... 7
<b>Table 1</b>	Nominal and cylindrical dioptric power tolerances ..... 3
<b>Annexes</b>	
<b>A</b>	Dioptric power and image quality assessment ..... 8
<b>B</b>	Guidance on additional clinical requirements for toric IOLs..... 9
<b>C</b>	Wavefront sensor test methods for toric IOL dioptric power and image quality measurement ..... 17
<b>D</b>	Bibliography ..... 30

**Foreword** (This foreword is not part of American National Standard ANSI Z80.30-2010.)

In 1985, the Z80 committee became an ANSI accredited standards committee. The scope of the Z80 committee is the development of standards for the field of ophthalmic optics.

The Z80.30 standard deals with toric intraocular lenses used to correct for astigmatism in either phakic or aphakic eyes. The Z80.30 committee originated from the Z80.7 committee on intraocular lenses. Intraocular lenses have become the most common functional prosthetic implanted in the world today. Reproducibility is such that these lenses are no longer meant just restore basic visual function but are expected to achieve excellent visual function. The Z80.30 standard addresses the additional requirements for a new generation of intraocular lenses that correct for pre-existing and surgically induced astigmatism. Unlike the Z80.7 standard, the Z80.30 toric standard is for both aphakic and phakic lenses.

This standard contains four annexes. Annex A is normative and is considered part of this standard. Annexes B, C, and D are informative and are not considered part of this standard.

Suggestions for improvement of this standard will be welcome. They should be sent to: The Vision Council, 1700 Diagonal Road, Suite 500, Alexandria, VA 22033

This standard was processed and approved for submittal to ANSI by the Accredited Standards Committee on Ophthalmic Standards, 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, the Z80 Committee had the following members:

Thomas C. White, Chairperson  
Quido Cappelli, Vice-Chairperson  
Robert Rosenberg, Secretary  
Ken Wood, Secretariat

<i>Organization Represented</i>	<i>Name of Representative</i>
Advance Medical Technologies Association .....	Douglas J. Fortunato Richard Courtney (Alt.) Glenn Davies (Alt.) Bernie Liebler (Alt.)
American Academy of Optometry.....	David S. Loshin
American Academy of Ophthalmology .....	Thomas C. White Carl Tubbs (Alt.) Pradeep Ramulu (Alt.) Rebecca Hyder (Alt.)
American Ceramic Society .....	Lyle Rubin Herbert Hoover (Alt.)
American Glaucoma Society .....	Steven Gedde Douglas Rhee (Alt.)
American Optometric Association .....	Jeffrey Weaver Robert Rosenberg (Alt.) William Benjamin (Alt.) William Brown (Alt.)
American Society of Cataract and Refractive Surgery .....	Stephen Klyce Jack T. Holladay (Alt.)
Contact Lens Institute.....	Stan Rogaski Peter Mathers (Alt.)
Contact Lens Manufacturer's Association .....	Quido Cappelli Jan Svochack (Alt.) John Walfoort (Alt.)

<i>Organization Represented</i>	<i>Name of Representative</i>
Federated Cornea Societies/ASCRS .....	Michael Belin David Glasser (Alt.)
Food & Drug Administration .....	Don Calogero Robert James
National Association of Optometrists & Opticians .....	Nick Mileti Joe Dezenzo (Alt.) Franklin Rozak (Alt.)
Optical Laboratories Association .....	Daniel Torgersen Virginia (Susie) Leshner (Alt.) Richard Tinson (Alt.) Robert Dziuban (Alt.)
Opticians Association of America .....	Tom Hicks Chris Allen (Alt.)
Sunglass Association of America .....	Kenneth Frederick Scott MacGuffie (Alt.) Rick Van Arnam (Alt.)
US Leader to ISO TC 172/SC7 .....	Charles E. Campbell
US Department of Veterans Affairs .....	John Townsend Sharon R. Atkin (Alt.)
The Vision Council.....	Jeff Endres Steve Drake (Alt.) Neil Roche (Alt.) Dick Whitney (Alt.) Kenneth Wood (Alt.)

The subcommittee on Intraocular Lenses, which developed this standard, had the following members:

Carl Tubbs, SC4 Chair  
George Green, AIOL Leader

Timothy Adkins	Richard DeRisio	Rick McCarley
Undraa Altangerel	David Evans	Barbara Niksch
Sheryl Berman	Barbara Fant	Donald Sanders
Michael Breen	Adrian Glasser	Robert Sheehan
Don Calogero	Emily Graham	Nicholas Tarantino
Jeannie Cecka	Gene Hilmantel	Bruce Weber
Jimmy Chacko	Rebecca Hyder	Ari Zak
Shiao Chang	Yasushi Kato	Steven Ziemba

# American National Standard for Ophthalmics –

## Toric Intraocular Lenses

### 1 Scope and purpose

This standard applies to any monofocal intraocular lens (IOL) whose primary indication is the reduction of astigmatism either with the correction of aphakia or the modification of the refractive power of a phakic eye. It does not include IOLs used to correct presbyopia.

This standard addresses the vocabulary, optical properties and test methods, mechanical properties and test methods, labeling, biocompatibility, sterility, shelf-life and transport stability, and clinical investigations necessary for this type of device. As applies to any standard, alternative validated test methods may be used.

### 2 Normative references

The following standards contain provisions that, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this American National Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of the IEC and ISO maintain registers of currently valid International Standards.

ANSI Z80.7-2002, *Ophthalmics – Intraocular lenses*

ANSI Z80.13-2007, *Ophthalmics – Phakic intraocular lenses*

ISO 10993-2:2006, *Biological evaluation of medical devices – Part 2: Animal welfare requirements*

ISO 10993-6:1994, *Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*

ISO 14155-1:2003, *Clinical investigation of medical devices – Part 1: General requirements*

ISO 14155-2:2003, *Clinical investigation of medical devices – Part 2: Clinical investigation plans*

ISO 11979-1:2006, *Ophthalmic implants – Intraocular lenses – Part 1: Vocabulary*

ISO 11979-2:1999, *Ophthalmic implants – Intraocular lenses – Part 2: Optical properties and test methods*

ISO 11979-3:2006, *Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods*

ISO 11979-5:2006, *Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility*