

# American National Standard

*for Ophthalmics –  
Extended Depth of Focus  
Intraocular Lenses*

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**ANSI<sup>®</sup>**  
**Z80.35-2018**

American National Standard  
for Ophthalmics –  
**Extended Depth of Focus  
Intraocular Lenses**

Sponsor

**The Vision Council**

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# American National Standard

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The Accredited Committee Z80 for Ophthalmic Standards -

The Vision Council  
Z80 Secretariat  
225 Reinekers Lane  
Suite 700  
Alexandria, VA 22314

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**Foreword** (This foreword is not part of American National Standard ANSI Z80.35-2018.)

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 Z80.35 standard deals with extended depth of focus (EDF) intraocular lenses used to correct aphakia and provided extended range of focus. The Z80.35 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 to just restore basic visual function but are expected to achieve improved visual function. The Z80.35 standard addresses the additional requirements for a new generation of intraocular lenses that provide extended range of focus.

This standard contains six annexes. Annexes A and D are normative and considered part of this standard. Annexes B, C, E and F 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, 225 Reinekers Lane, Suite 700, Alexandria, VA 22314

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:

Carl Tubbs, Chairman  
Neil Roché, Vice-Chairman  
William J. Benjamin, O.D., Secretary  
Michael Vitale, Secretariat

<i>Organization Represented</i>	<i>Name of Representative</i>
Advanced Medical Technology Association .....	Michael Pflieger
American Academy of Ophthalmology .....	Carl Tubbs
American Academy of Optometry.....	David Loshin
American Ceramic Society .....	Lyle Rubin
American Glaucoma Society .....	Steven Gedde
American Optometric Association .....	William Benjamin
American Society of Cataract and Refractive Surgery .....	Stephen Klyce
Contact Lens Institute .....	Stan Rogaski
Contact Lens Manufacturers Association .....	Martin Dalsing
Cornea Society .....	Michael Belin
Department of Veterans Affairs .....	John Townsend
Food & Drug Administration CDRH/Division.....	Don Calogero
Individual .....	Ralph Stone
Johnson & Johnson Vision .....	Priya Janakiraman
National Association of Optometrists & Opticians .....	Nick Mileti
Optical Laboratory Association.....	Steve Sutherlin
Opticians Association of America .....	Tom Hicks
Sunglass Association of America .....	Tibor Gross
The Vision Council.....	Michael Vitale
ISO TC 172/SC7 .....	Michael Vitale

Individual Member

Ralph Stone

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

Carl Tubbs, SC4 Chair  
Sanjeev Kasthurirangan, Z80.35 Chair  
Raj Suryakumar, Clinical Leader  
Charles Campbell, Optical Leader

Ophelia Biggs  
Don Calogero  
Carmen Canovas  
Bruce Drum  
Carrie Garufis  
George Green  
Gene Hilmantel  
Andrew Jones  
Michael Pflieger  
Michael Simpson  
Nicholas Tarantino  
Eugenia Thomas  
Steve Van Noy  
Srividhya Vilupuru  
Henk Weeber  
Xin Wei

# American National Standard for Ophthalmics –

## Extended Depth of Focus Intraocular Lenses

### 1 Scope and purpose

This standard applies to intraocular lenses (IOLs) whose function is the correction of aphakia, with extended range of focus above a defined functional visual acuity threshold to provide useful distance and intermediate vision with monotonically decreasing visual acuity from the best distance focal point.

This standard addresses specific requirements for Extended Depth of Focus Intraocular Lenses (EDF IOLs) that are not addressed in the normative references, and include 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 with 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, *Ophthalmics – Intraocular lenses*

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

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

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

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

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

ISO 11979-4, *Ophthalmic implants – Intraocular lenses – Part 4: Labelling and information*

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

ISO 11979-7, *Ophthalmic implants – Intraocular lenses – Part 7: Clinical investigations*

ISO/DIS 11979-8, *Ophthalmic implants – Intraocular lenses – Part 8: Fundamental requirements*

ISO/WD 11979-9, *Ophthalmic implants – Intraocular lenses – Part 9: Multifocal intraocular lenses*