

Contents

	Page
Foreword	iv
1 Scope and purpose	1
2 Normative references	1
3 Definitions	2
4 Physical requirements	2
4.1 Scope	2
4.2 Requirements	2
4.2.1 Tolerances and dimensions	3
5 Optical requirements	3
5.1 Scope	3
5.2 Requirements	3
5.2.1 Optical characterization	3
5.2.2 Dioptric power	3
5.2.3 Imaging quality	3
5.2.4 Spectral transmittance	4
6 Mechanical requirements	4
6.1 Scope	4
6.2 Requirements	4
6.2.1 Mechanical characterization	4
6.2.2 Mechanical Testing	4
7 Biocompatibility requirements	5
7.1 Scope	5
7.2 General Guidelines	5
7.3 Biological test requirements	5
7.4 Physicochemical test requirements	5
8 Sterility/package integrity requirements	6
8.1 Scope	6
8.2 Requirements	6
9 Shelf-life and transport stability requirements	6
9.1 Scope	6
9.2 Requirements	6
10 Clinical evaluation	6
10.1 Scope	6
10.2 Clinical investigation plan	6
10.3 Effectiveness requirements	7
11 Labeling	8

Annexes

A	Optical characterization	9
A.1	General	9
A.2	Optical characterization	9
A.2.1	Theoretical evaluation.....	9
A.2.2	Optical testing	9
B	Clinical investigation	10
B.1	General	10
B.1.1	Clinical measurements	11
B.2	Objectives of the clinical investigation	11
B.3	Design of the clinical investigation	11
B.3.1	Investigation duration.....	12
B.3.2	Enrollment of subjects	13
B.3.3	Inclusion and exclusion criteria for subject selection	13
B.3.3.1	Inclusion criteria	13
B.3.3.2	Exclusion criteria.....	13
B.3.4	Examination schedule.....	14
B.4	Clinical tests.....	17
B.4.1	Visual acuity and manifest refraction	17
B.4.1.1	Minimum near add procedure at 40 cm	18
B.4.1.2	Luminance	19
B.4.1.3	Data recording procedures	19
B.4.2	Specular Microscopy	19
B.4.3	Contrast sensitivity.....	19
B.4.4	Pupil size	20
B.4.5	Slit lamp exam	20
B.4.6	Measurement of intraocular pressure	21
B.4.7	Subject questionnaire	21
B.4.8	Accommodation measures	21
B.4.8.1	Objective accommodation measures.....	21
B.4.8.1.1	Objective optical/refractive methods.....	22
B.4.8.1.1.1	Autorefractors	22
B.4.8.1.1.2	Wavefront aberrometry	22
B.4.8.1.2	Objective biometric methods	22
B.4.8.2	Subjective accommodation measures	24
B.4.8.2.1	Defocus curves	24
B.4.8.2.2	Push-down test	25
B.4.9	Reading ability test	26
B.5	Investigation analyses	27

	Page
B.5.1	Safety analyses 27
B.5.2	Effectiveness analyses 27
B.5.3	Accountability analyses 29
B.5.4	Stability analyses 30
B.5.4.1	Objective accommodative stability 30
B.5.4.2	Manifest refraction spherical equivalent (MRSE) stability 31
B.6	Adverse events and adverse device effects 31
C	Labeling for AIOs 32
C.1	Scope 32
C.2	Information to be found on the outer container 32
C.3	Labeling for inner container and/or pouch 32
C.4	Physician package insert 32
C.5	Patient labeling 33
D	Determination of sample sizes for the clinical investigation 34
D.1	Statistical symbols and definitions 34
D.2	Calculation of necessary sample sizes 35
D.2.1	Sample size of the AIO arm, based on safety considerations 35
D.2.2	Sample size for the primary effectiveness endpoint 35
D.2.3	Sample size based on effectiveness estimates using noninferiority hypothesis testing 36
D.3	Substudies 36
D.3.1	Sample size for a contrast sensitivity substudy 36
E	Bibliography 37
Tables	
B.1	Minimum sample size (subjects) for evaluation 12
B.2	Recommended postoperative examination schedule 15
B.3	Accountability at each post-operative visit 29
D.1	Symbol definitions 34
D.2	Normal quantities to use in equations 35

Foreword (This foreword is not part of American National Standard ANSI Z80.29-2015 (R2020).)

This standard contains five annexes. Annex A is normative and is considered part of the standard. Annexes B through E are informative and are not considered part of the standard.

Suggestions for improvement of this standard are 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 Optics, Z80. Committee approval of this standard indicates general consensus but in no way implies that all committee members voted for approval. At the time it approved this standard, the Z80 Committee had the following members:

Thomas C. White, M.D., Chairman
Quido Cappelli, Vice-Chairman
William Benjamin, O.D., Secretary
Jeff Endres, Secretariat Z80

<i>Organization Represented</i>	<i>Name of Representative</i>
Abbott Medical Optics	Leonard Borrmann
Advance Medical Technologies Association	Michael Pflieger
American Academy of Ophthalmology	Dr. Thomas White
American Academy of Optometry.....	Dr. David Loshin
American Ceramic Society	Lyle Rubin
American Glaucoma Society	Dr. Steven Gedde
American Optometric Association	Dr. Karl Citek
American Society of Cataract and Refractive Surgery	Dr. Stephen Klyce
Contact Lens Institute.....	Stan Rogaski
Contact Lens Manufacturers Association	Quido Cappelli
Department of Veterans Affairs	Dr. John Townsend
Federated Cornea Societies/ASCRS	Dr. Michael Belin
Food & Drug Administration	Don Calogero
National Association of Optometrists & Opticians	Nick Mileti
Optical Laboratory Association.....	Michael Vitale
Opticians Association of America	Tom Hicks
Sunglass Association of America	Frederick Grethel
The Vision Council	Jeffrey Endres
U.S. TAG Leader to ISO TC 172/SC7	Jeffrey Endres

The working group for Accomodative Intraocular Lenses, which fall under the Medical Ophthalmic Devices Subcommittee, had the following members who worked on the writing of this standard:

Carl Tubbs, MD, Subcommittee Chair	Stan Bentow	Michael Pflieger
Sanjeev Kasthurirangan, WG Chair	Don Calogero	Kim Regis
	Bruce Drum	Michael Simpson
	Kristen Featherstone	Raj Surykumar
	Adrian Glasser	Nick Tarantino
	George Green	Steve VanNoy
	Gene Hilmantel	Tom White
	Ashley McGlone	Ari Zak

American National Standard for Ophthalmics –

Accommodative Intraocular Lenses

1 Scope and purpose

This standard applies to any ocular implant whose primary indication is the correction of aphakia and is designed to provide vision over a continuous range of distances by affecting a change in the vergence power of the eye resulting from the implant design that changes eye optical power or implant position in response to a stimulus. For the purposes of this standard, these implants are referred to as accommodative intraocular lenses (AIOLs).

This standard addresses specific requirements for AIOLs 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 11979-5, *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*