

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

	Page
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.....	11
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 Autorefractors	22
B.4.8.1.2 Wavefront aberrometry	22
B.4.8.1.1 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 AIOLs 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 AIOL 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:

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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 as the 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*