American National Standard

for Ophthalmic Optics –
Intraocular Lenses

ANSI Z80.7-2013 (R2018)

ANSI®
Z80.7-2013 (R2018)
Reaffirmation of
ANSI Z80.7-2013

American National Standard
for Ophthalmic Optics –

Intraocular Lenses

Secretariat

The Vision Council

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American National Standard

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The Accredited Committee Z80 for Ophthalmic Standards -

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Foreword (This foreword is not part of American National Standard ANSI Z80.7-2013 (R2018).)

The Z80 Standards Committee for Ophthalmic Lenses was organized in 1956, and the committee's initial standard was issued in 1964. At the beginning of 1970, the Z80 Standards Committee was reorganized, with the Optical Society of America serving as secretariat. In 1972, the committee was authorized to broaden its scope from "prescription glass ophthalmic lenses" to "prescription ophthalmic lenses." Subsequently, the scope of the committee was further broadened to "ophthalmic standards."

The first Z80.7 subcommittee on intraocular lenses was established in 1976 to provide intraocular lens standards that could be used by both manufacturers and physicians. Intraocular lenses are lenses that have optical and haptic components and that are surgically implanted in the anterior or posterior chamber of the eye to correct vision.

In 1982, the Optical Laboratories Association (OLA) assumed the responsibility of the Secretariat; and in 1985, the Z80 committee became an accredited standards committee. The scope of the Z80 committee is for the establishment of standards that shall apply to ophthalmic lenses and to equipment, instruments and processes used in the final fabrication level which affect their performance; to ophthalmic frames, sunglasses and fashion eyewear; to contact lenses and accessories for their use; to low-vision aids and ophthalmic contact devices in addition to contact lenses; to optical instrumentation used in ophthalmic procedures and vision evaluation; to intraocular implant lenses; to viscoelastic devices; to aid ophthalmic endotamponades, ophthalmic irrigating solutions, glaucoma shunts, surgical microscopes used in ophthalmic surgery and endoilluminators. Further additions were made concerning not only intraocular implants used in cataract surgery, but also in refractive surgery in phakic eyes, laser reshaping of the cornea and corneal implants to alter the refractive power of the eye.

The Z80.7 subcommittee deals with intraocular aphakic implants to correct the condition of aphakia.

The current ophthalmic standards are drafted by subcommittees of the Z80 committee. These subcommittees may, in turn, establish working groups, as needed, to address detailed areas in the assigned project.

This standard contains five annexes. Annexes A through C are normative and are considered part of this standard. Annexes D and E 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 submission to ANSI by the Accredited Standards Committee on Ophthalmics, 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
Jeffrey Endres, Secretariat

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	Bernie Liebler (Alt.)
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	Jonathan Schwartz (Alt.)
Opticians Association of Amerca	Tom Hicks
	Chris Allen (Alt.)
Sunglass Association of America	Frederic Grethel
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Organization Represented	*Name of Representative*
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The Vision Council	Michael Vitale
ISO TC 172/SC7	Michael Vitale

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Ralph Stone

American National Standard for Ophthalmic Optics –

Intraocular Lenses

1 Scope and Purpose

This standard applies to monofocal intraocular lenses (IOLs) whose primary indication is the correction of aphakia.

This standard addresses the vocabulary, optical properties and test methods, mechanical properties and test methods, biocompatibility, sterility, shelf-life and transport stability, and clinical investigations necessary for this type of device.

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/AAMI/ISO 10993-2: 1993 (R2001), *Biological evaluation of medical devices – Part 2: Animal welfare requirements*

ANSI/AAMI/ISO 10993-3: 1993, *Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity*

ANSI/AAMI/ISO 10993-5:1999, *Biological Evaluation of Medical Devices – Part 5: Tests for Cytotoxicity: In vitro methods*

ANSI/AAMI/ISO 11134-1993, *Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization*

ANSI/AAMI/ISO 11135-1994, *Medical devices-validation and routine control of ethylene oxide sterilization*

ANSI/AAMI/ISO 11137-1994, *Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization*

ANSI/AAMI/ISO 14155:1996, *Clinical Investigation of Medical Devices*

AAMI TIR No. 19: 1998, *Technical Information Report (TIR) to ANSI/AAMI/ISO 10993-7*

Good Laboratory Practices (GLP), U.S. Code of Federal Regulations 21, Part 58

ISO 10993-7:1995 (R2001), *Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals*

ISO 10993-10:1995, *Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization*

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 11979-6.2, *Ophthalmic implants – Intraocular lenses – Part 6: Shelf-life and transport stability*

U.S. Animal Welfare Act 1966, as amended 1985