American National Standard

for Ophthalmics –
Light Hazard Protection
for Ophthalmic Instruments

ANSI Z80.36-2016

Approved American National Standard
ANSI

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Z80.36-2016

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for Ophthalmics –

Light Hazard Protection for Ophthalmic Instruments

Secretariat

The Vision Council

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American National Standard

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Foreword (This foreword is not part of American National Standard ANSI Z80.36-2016.)

This American National Standard specifies fundamental requirements for optical radiation safety for ophthalmic instruments. It applies to all ophthalmic instruments (including current, new and emerging instruments) that direct optical radiation into or at the eye. It also applies to those parts of therapeutic or surgical systems that direct optical radiation into or at the eye for diagnostic, illumination, measurement, imaging, or alignment purposes. It does not apply to radiation that is intended for treatment of ocular tissues.

ANSI Z80.36-2016 was adapted by a group of experts within the ANSI ASC Z80 Instruments and Low Vision Devices Subcommittee under the chair of William L Brown, O.D., Ph.D. It is a performance standard.

This document was developed in 2016 when changes were made to ISO 15004-2 Light hazard protection that resulted in recommendations for levels of radiant exposure for retinal photochemical hazard that were unacceptable to the US delegation to the ISO.

Suggestions for improvement of this standard are welcome. They should be sent to the Vision Council, 1700 Diagonal Road, Suite 500, 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 does not necessarily imply that all committee members voted for its approval. At the time of approval of this standard, the Z80 Committee consisted of the following members:

Thomas C. White, M.D., Chair
Quido Cappelli, Vice-Chair
William Benjamin, O.D., Secretary
Michael Vitale, Secretariat

Organization Represented	*Name of Representative*
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Advance Medical Technologies	Michael Pfleger
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Organization Represented	*Name of Representative*
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William L. Brown, O.D., Ph.D, Chair
Charles Campbell
Bruce Drum
Sharon Miller
Robert Rosenberg
David Sliney
Thomas White

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1 Scope

ANSI Z80.36 specifies fundamental requirements for optical radiation safety for ophthalmic instruments and is applicable to all current ophthalmic instruments that direct optical radiation into or at the eye. It is also applicable to all new and emerging ophthalmic instruments that direct optical radiation into or at the eye, as well as to those portions of therapeutic or surgical systems that direct optical radiation into or at the eye for diagnostic, illumination, measurement, imaging, or alignment purposes.

ANSI Z80.36 does not apply to radiation that is intended for treatment of ocular tissues.

NOTE 1 to entry: Concerning the treatment beams of therapeutic devices, when risk assessments for non-target tissues are conducted, the limits given in this Standard can be applied to the treatment beam.

ANSI Z80.36 classifies ophthalmic instruments into either Group 1 or Group 2 in order to distinguish instruments that are non-hazardous from those that are potentially hazardous.

NOTE 1 to entry: The emission limits are based on the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines for human exposure to optical radiation. The limits and guidelines in this standard also account for the likelihood that eyes may be dilated and that eyes and head may be stabilized during ophthalmic examinations. See Bibliography [1].

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15004-1, *Ophthalmic instruments – Fundamental requirements and text method – Part 1: General requirements applicable to all ophthalmic instruments*

3 Terms, definitions and symbols

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1.1
aperture
aperture stop
opening that defines the area over which average optical emission is measured

Note 1 to entry: For spectral irradiance measurements, this opening is usually the entrance of a small sphere placed in front of the radiometer/spectroradiometer entrance slit.