

ANSI Z80.36-2016

# American National Standard

*for Ophthalmics –  
Light Hazard Protection  
for Ophthalmic Instruments*

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**ANSI®**  
**Z80.36-2016**

American National Standard  
for Ophthalmics –  
Light Hazard Protection  
for Ophthalmic Instruments

Secretariat  
**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  
1700 Diagonal Road  
Suite 500  
Alexandria, VA 22314

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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

<i>Organization Represented</i>	<i>Name of Representative</i>
Abbott Medical Optics.....	Leonard Borrmann Mark Gordon (Alt.)
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American Academy of Ophthalmology .....	Thomas White Carl Tubbs (Alt.) Pradeep Ramulu (Alt.) Scott Haber (Alt.)
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Contact Lens Institute.....	Stan Rogaski Peter Mathers (Alt.)
Contact Lens Manufacturers Association .....	Quido Cappelli Troy Miller (Alt.)
Department of Veterans Affairs .....	John Townsend Michael White (Alt.)

<i>Organization Represented</i>	<i>Name of Representative</i>
Federated Cornea Societies.....	Michael Belin David Glasser (Alt.) Kathy Colby (Alt.) Elmer Tu (Alt.)
Food & Drug Administration .....	Don Calogero Dexiu Shi (Alt.)
National Association of Optometrists & Opticians .....	Nick Mileti Doug Pelkey (Alt.) Joseph Neville (Alt.)
Optical Laboratories Association .....	Steve Sutherland
Opticians Association of America .....	Tom Hicks Chris Allen (Alt.)
Sunglass Association of America .....	Tibor Gross Nick Brown (Alt.) Rick Van Arnam (Alt.)
The Vision Council.....	Michael Vitale Neil Roche (Alt.) Dick Whitney (Alt.)
U.S. ISO TC 172/SC7.....	Michael Vitale

The Subcommittee on Instruments and Low Vision Devices, which developed this American National Standard, had the following members who contributed to this document:

William L. Brown, O.D., Ph.D, Chair  
Charles Campbell  
Bruce Drum  
Sharon Miller  
Robert Rosenberg  
David Sliney  
Thomas White



## American National Standard for Ophthalmics –

# Light Hazard Protection for Ophthalmic Instruments

## 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 test 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.