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Ophthalmic instruments — Fundamental requirements and test methods —

Part 2:
Light hazard protection

Instruments ophtalmiques — Exigences fondamentales et méthodes d'essai —

Partie 2: Protection contre les dangers de la lumière

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15004-2 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition, together with ISO 15004-1, cancels and replaces ISO 15004:1997. All reference to light hazard (definitions 3.4 to 3.9, subclause 6.3, subclause 7.5, Annexes A, C and D of ISO 15004:1997) has essentially been moved to the present part of ISO 15004 and has been technically revised.

ISO 15004 consists of the following parts, under the general title *Ophthalmic instruments — Fundamental requirements and test methods*:

— *Part 1: General requirements applicable to all ophthalmic instruments*

— *Part 2: Light hazard protection*

Ophthalmic instruments — Fundamental requirements and test methods —

Part 2: Light hazard protection

1 Scope

This part of ISO 15004 specifies fundamental requirements for optical radiation safety for ophthalmic instruments and is applicable to all ophthalmic instruments that direct optical radiation into or at the eye and for which there is a specific light hazards requirement section within their respective International Standards, i.e. all ophthalmic instruments listed in Annex B. It is also applicable to all new and emerging ophthalmic instruments that direct optical radiation into or at the eye. Where differences exist between this part of ISO 15004 and the light hazard requirements section of the respective vertical International Standard, then the vertical International Standard shall take precedence.

NOTE The emission limits are based on the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines for human exposure to optical radiation. See Bibliography [1].

This part of ISO 15004 does not apply to radiation that is in excess of limits specified in ISO 15004 and that is intended for treatment of the eye.

This part of ISO 15004 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.

2 Normative references

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

IEC 60825-1:2001, *Safety of laser products — Part 1: Equipment classification, requirements and user's guide*

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 For spectral irradiance measurements this opening is usually the entrance of a small sphere placed in front of the radiometer/spectroradiometer entrance slit.

3.1.2
continuous wave radiation source
CW radiation source
radiation source that is operated with a continuous output for a time greater than 0,25 s (i.e. a non-pulsed radiation source)

3.1.3
effective aperture
portion of the aperture that limits the amount of light delivered to the retina

NOTE For an obscured or noncircular aperture, it has an area equivalent to that of a non-obscured circular aperture.

3.1.4
emission limit
maximum value of optical radiation output allowed

3.1.5
endoilluminator
device consisting of a light source and an associated fibre optic light guide that is intended for insertion into the eye to illuminate any portion of the interior of the eye

3.1.6
field of view
conical solid angle as "seen" by the detector, such as the eye or the radiometer/spectroradiometer, out of which the detector receives radiation

NOTE The field of view denotes the angle over which radiance is averaged (sampled) and should not be confused with the angular subtense of the source α which denotes source size.

3.1.7
Group 1 instrument
ophthalmic instrument for which no potential light hazard exists and that can be shown to fulfil the requirements of 5.2

3.1.8
Group 2 instrument
ophthalmic instrument for which a potential light hazard exists and that does not fulfil the requirements of 5.2

3.1.9
irradiance
E
⟨at a point on a surface⟩ quotient of the radiant power dΦ incident on an element of a surface containing the point, by the area dA of that element, i.e.

$$E = \frac{\mathrm{d}\Phi}{\mathrm{d}A} \quad (1)$$

NOTE Irradiance is expressed in units of watts per square centimetre, W/cm^2.

3.1.10
manufacturer
natural or legal person who places the ophthalmic instrument on the market

3.1.11
maximum intensity
highest optical radiation emissions the instrument is capable of delivering under any and all conditions

3.1.12
operation microscope
stereo-microscope used for observation of surgical and other medical procedures, consisting of an illumination system and an observation system, including objective lens, variable or fixed power optical system, observation tube and eyepieces

3.1.13
optical radiation hazard
risk of damage to the eye by exposure to optical radiant energy

3.1.14
photoretinitis
retinal photochemically-induced injury resulting from a very intense retinal radiant exposure

NOTE The term photic maculopathy is also used to describe photoretinitis in the fovea-macular area of the retina.

3.1.15
pulsed light source
light source that delivers its energy in the form of a single pulse or a train of pulses where each pulse has a duration of less than 0,25 s

NOTE 1 A light source with a continuous train of pulses or modulated radiant energy where the peak radiated power is at least ten times the minimum radiated power is considered to be a pulsed light source.

NOTE 2 The pulse duration is the interval of time between the first and last instants at which the instantaneous value of a pulse reaches a specified fraction of its pulse magnitude or a specified threshold.

3.1.16
radiance
L
⟨in a given direction at a given point of a real or imaginary surface⟩ quantity defined by the formula

$$L = \frac{\mathrm{d}\Phi}{\mathrm{d}A \times \cos\theta \times \mathrm{d}\Omega} \quad (2)$$

where

$\mathrm{d}\Phi$ is the radiant power transmitted by an elementary beam passing through the given point and propagating in the solid angle $\mathrm{d}\Omega$ containing the given direction;

$\mathrm{d}A$ is the area of a section of that beam containing the given point;

θ is the angle between the normal to that section and the direction of the beam.

NOTE 1 The same definition holds for the time-integrated radiance L_i if, in the equation for L, the radiant power $\mathrm{d}\Phi$ is replaced by the radiant energy $\mathrm{d}Q$.

NOTE 2 Radiance is expressed in watts per steradian square centimetre, W/(sr·cm^2); time-integrated radiance is expressed in Joules per steradian square centimetre, J/(sr·cm^2).

3.1.17
radiant exposure
H
⟨at a point of a surface, for a given duration⟩ quotient of the radiant energy, $\mathrm{d}Q$, incident on an element of a surface containing the point over the given duration by unit area $\mathrm{d}A$ of that element

$$H = \frac{\mathrm{d}Q}{\mathrm{d}A} \quad (3)$$

Equivalently, the radiant exposure is defined as the integral of the irradiance, E, at a given point over a given duration, Δt

$$H = \int_{\Delta t} E \times \mathrm{d}t \tag{4}$$

NOTE Radiant exposure is expressed in Joules per square centimetre, J/cm^2.

3.1.18
scanning laser radiation
laser radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference

3.1.19
spectral irradiance
E_λ
quotient of the spectral radiant power $\mathrm{d}\Phi(\lambda)$ in a wavelength interval $\mathrm{d}\lambda$, incident on an element of a surface, by the area $\mathrm{d}A$ of that element and by the wavelength interval $\mathrm{d}\lambda$

$$E_\lambda = \frac{\mathrm{d}\Phi(\lambda)}{\mathrm{d}A \times \mathrm{d}\lambda} \tag{5}$$

NOTE Spectral irradiance is expressed in watts per square centimetre nanometre, W/(cm^2·nm).

3.1.20
spectral radiance
L_λ
⟨for a wavelength interval $\mathrm{d}\lambda$, in a given direction at a given point⟩ ratio of the spectral radiant power $\mathrm{d}\Phi(\lambda)$ passing through that point and propagating within the solid angle $\mathrm{d}\Omega$ in the given direction, to the product of the wavelength interval $\mathrm{d}\lambda$ and the areas of a section of that beam on a plane perpendicular to this direction ($\cos\theta\,\mathrm{d}A$) containing the given point and to the solid angle $\mathrm{d}\Omega$

$$L_\lambda = \frac{\mathrm{d}\Phi(\lambda)}{\mathrm{d}A \times \cos\theta \times \mathrm{d}\Omega \times \mathrm{d}\lambda} \tag{6}$$

NOTE Spectral radiance is expressed in watts per steradian square centimetre nanometre, W/(sr·cm^2·nm).

3.2 Symbols

Symbols, quantities and units are listed in Table 1.

Table 1 — Symbols, quantities and units

Symbol	Quantity	Unit
E	irradiance (at a point on a surface)	W/cm^2
E_λ	spectral irradiance	W/(cm^2·nm)
L	radiance (in a given direction at a given point of a real or imaginary surface)	W/(sr·cm^2)
L_λ	spectral radiance (for a wavelength interval dλ, in a given direction at a given point)	W/(sr·cm^2·nm)
L_i	time-integrated radiance	J/(sr·cm^2)
H	radiant exposure (at a point of a surface, for a given duration)	J/cm^2
H_λ	spectral radiant exposure	J/(cm^2·nm)
$E_\mathrm{S\text{-}CL}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation irradiance	W/cm^2
$E_\mathrm{UV\text{-}CL}$	unweighted corneal and lenticular ultraviolet radiation irradiance	W/cm^2
$E_\mathrm{A\text{-}R}$	$A(\lambda)$ weighted retinal irradiance	W/cm^2
$E_\mathrm{IR\text{-}CL}$	unweighted corneal and lenticular infrared radiation irradiance	W/cm^2
$E_\mathrm{VIR\text{-}AS}$	unweighted anterior segment visible and infrared radiation irradiance	W/cm^2
$E_\mathrm{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation thermal irradiance	W/cm^2
$L_\mathrm{A\text{-}R}$	$A(\lambda)$ weighted retinal radiance	W/(sr·cm^2)
$L_{i,\mathrm{A\text{-}R}}$	$A(\lambda)$ weighted retinal time-integrated radiance	J/(sr·cm^2)
$L_{i,\mathrm{VIR\text{-}R}}$	$R(\lambda)$ weighted, retinal visible and infrared radiation time-integrated radiance	J/(sr·cm^2)
$L_\mathrm{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiance	W/(sr·cm^2)
$H_\mathrm{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiant exposure	J/cm^2
$H_\mathrm{IR\text{-}CL}$	unweighted corneal and lenticular infrared radiation radiant exposure	J/cm^2
$H_\mathrm{VIR\text{-}AS}$	unweighted anterior segment visible and infrared radiation radiant exposure	J/cm^2
$H_\mathrm{S\text{-}CL}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm^2
$H_\mathrm{UV\text{-}CL}$	unweighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm^2
$H_\mathrm{A\text{-}R}$	$A(\lambda)$ weighted retinal radiant exposure	J/cm^2
$S(\lambda)$	ultraviolet radiation hazard weighting function (see Annex A)	—
$A(\lambda)$	aphakic photochemical hazard weighting function (see Annex A)	—
$R(\lambda)$	visible and infrared radiation thermal hazard weighting function (see Annex A)	—
$\Delta\lambda$	summation interval	nm
t	exposure time; for pulsed instruments: exposure time for a single pulse and for any group of pulses the instrument is capable of producing	s
Δt	pulse width up to a time of 0,25 s	s
$E_\lambda \cdot t$	spectral radiant exposure	J/(cm^2·nm)
$(E_\lambda \cdot \Delta t)$	spectral radiant exposure at time Δt	J/(cm^2·nm)

4 Classification

For the purposes of this part of ISO 15004, ophthalmic instruments are classified into two groups in order to separate those instruments that are capable of presenting a potential hazard from those which do not. The two groups are named Group 1 and Group 2. They are defined as follows:

a) Group 1 instruments: ophthalmic instruments for which no potential light hazard exists. Ophthalmic instruments that can be shown to fulfil the requirements of 5.2.

b) Group 2 instruments: ophthalmic instruments for which a potential light hazard exists. Those ophthalmic instruments that do not fulfil the requirements of 5.2.

NOTE The classification process is outlined in the Classification flowchart (see Annex F).

5 Requirements

5.1 General

Ophthalmic instruments shall be so designed that the energy in all wavelengths be attenuated as much as possible in keeping with the intended use of the instrument.

If another device is used in combination with an ophthalmic instrument, the connecting system shall not degrade the optical radiation safety of either instrument, nor shall the optical radiation hazards of the combined system exceed the levels that are given in this part of ISO 15004.

Scanning instruments shall be evaluated using the pulsed instrument criteria when the scan lengths are greater than the diameter of the measurement aperture. Where the scan length is less than or equal to the measurement aperture, they shall be evaluated using the continuous wave criteria.

5.2 Requirements for classification as a Group 1 instrument

An ophthalmic instrument shall be classified in Group 1 if any or all of the following criteria apply.

a) An International Standard exists for the instrument type but no light hazard requirements are included in that International Standard.

b) Its components, e.g. lamps, light-emitting diodes, non-removable filters, lenses, fibres, etc., prevent emissions in excess of the limits specified for instruments in the Group 1 and certification of this exists. Such instruments shall be classified as Group 1 by virtue of the test certification by the manufacturer of the components themselves without the need for further measurements. If such components prevent some, but not all emissions specified for Group 1, then measurements shall be required only for the unblocked wavelengths, but not for the blocked wavelengths.

c) Its only sources of radiation are Class 1 lasers as classified under IEC 60825-1:2001.

d) Its emission values are equal to or less than the limit values given in 5.4. The test methods used for determination of compliance shall be in accordance with 6.2.

Existing International Standards that contain light hazard requirements are listed in Annex B. The limit values to determine Group 1 classification are based upon an expected exposure time for the instrument type under consideration. The Group 1 limit values given in 5.4 are based upon a 2 h exposure. These limits apply to all instruments except operation microscopes, endoilluminators, and instruments designed for continuous exposure. For operation microscopes and endoilluminators, the limits for Group 1 shall be further reduced by a factor of 2. For instruments designed for continuous exposure, the limits should be reduced by a factor equal to one half of the continuous exposure time, in hours, associated with the intended use of the instrument.

5.3 Requirements for Group 2 instruments

5.3.1 Group 2 instruments shall comply with the emission limits and guideline values given in 5.5.

5.3.2 The test methods used for determination of compliance shall be in accordance with 6.3 and 6.4. However, if components that are being used in the instrument, e.g. lamps, light-emitting diodes, non-removable filters, lenses, fibres, etc., prevent some, but not all emissions specified for Group 2, then provided that documentation of test certification of the respective components is available, measurements shall be required only for the unblocked wavelengths, but not for the blocked wavelengths.

5.3.3 Where provision is made to vary the brightness of the Group 2 instrument, an indication of the maximum intensity and fractions of maximum intensity shall be provided on the instrument.

5.3.4 Information shall be supplied with Group 2 instruments as specified in Clause 7.

5.4 Emission limits for determination of Group 1 classification

5.4.1 Continuous wave instruments

The emission limits specified in Table 2 relate to maximum corneal and lenticular or retinal irradiance or instrument radiance as applied directly to the continuous wave instrument's criteria. To evaluate the respective radiation hazard criteria, the equations given for them in Table 2 shall be used. See Table 1 for an explanation of the quantities used in the equations and for associated units.

If wavelengths 250 nm to 400 nm are not emitted by the source or are blocked by filtration, the measurements of Table 2, 5.4.1.1 and 5.4.1.2 are not required.

Table 2 — Group 1 limit values for continuous wave instruments

	Parameter	Wavelength nm	Equation	Limit
5.4.1.1	Weighted corneal and lenticular ultraviolet radiation irradiance, $E_{\text{S-CL}}$	250 to 400	$E_{\text{S-CL}} = \sum_{250}^{400} E_\lambda \times S(\lambda) \times \Delta\lambda$	0,4 µW/cm^2
		The corneal and lenticular ultraviolet radiation irradiance shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the corneal plane with a diameter of 1 mm ($7,9 \times 10^{-3}$ cm^2).		
5.4.1.2	Unweighted corneal and lenticular ultraviolet radiation irradiance, $E_{\text{UV-CL}}$	360 to 400	$E_{\text{UV-CL}} = \sum_{360}^{400} E_\lambda \times \Delta\lambda$	1 mW/cm^2
		The corneal and lenticular ultraviolet radiation irradiance shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the corneal plane with a diameter of 1 mm ($7,9 \times 10^{-3}$ cm^2).		

Table 2 (*continued*)

	Parameter	Wavelength nm	Equation	Limit
5.4.1.3	Retinal photochemical aphakic light hazard The limit values given in a) and b) are equivalent. It is only necessary to evaluate the retinal photochemical aphakic light hazard with **either** a) **or** b) below.			
a)	Weighted retinal irradiance, $E_{\text{A-R}}$	305 to 700	$E_{\text{A-R}} = \sum_{305}^{700} E_\lambda \times A(\lambda) \times \Delta\lambda$	220 µW/cm²
		The retinal irradiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be evaluated by averaging the highest localized radiant power incident upon a circular area on the retina with a diameter of 0,18 mm ($2,54 \times 10^{-4}$ cm²). However, if the instrument is intended to be used with an eye that is immobilized, a 0,03 mm ($7,07 \times 10^{-6}$ cm²) diameter aperture shall be used instead of a 0,18 mm diameter aperture.		
b)	Weighted retinal radiance, $L_{\text{A-R}}$	305 to 700	$L_{\text{A-R}} = \sum_{305}^{700} L_\lambda \times A(\lambda) \times \Delta\lambda$	2 mW/(sr·cm²)
		Measurements of radiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be averaged over a right circular cone field-of-view of 0,011 rad. However, if the instrument is intended to be used with an eye that is immobilized, a field-of-view of 0,001 75 rad shall be used instead of the 0,011 rad field-of-view.		
5.4.1.4	Unweighted corneal and lenticular infrared radiation irradiance, $E_{\text{IR-CL}}$	770 to 2 500	$E_{\text{IR-CL}} = \sum_{770}^{2\,500} E_\lambda \times \Delta\lambda$	20 mW/cm²
		The corneal irradiance shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the corneal plane with a diameter of 1 mm ($7,9 \times 10^{-3}$ cm²).		
5.4.1.5	Unweighted anterior segment visible and infrared radiation irradiance, $E_{\text{VIR-AS}}$ **(for convergent beams only)**	380 to 1 200	$E_{\text{VIR-AS}} = \sum_{380}^{1\,200} E_\lambda \times \Delta\lambda$	4 W/cm²
		The anterior segment irradiance shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the beam waist with a diameter of 1 mm ($7,9 \times 10^{-3}$ cm²).		

Table 2 (*continued*)

	Parameter	Wavelength nm	Equation	Limit
5.4.1.6	Retinal visible and infrared radiation thermal hazard The limit values given in a) and b) are equivalent. It is only necessary to evaluate the retinal visible and infrared radiation thermal hazard with **either** a) **or** b) below.			
a)	Weighted retinal visible and infrared radiation thermal irradiance, $E_{\text{VIR-R}}$	380 to 1 400	$E_{\text{VIR-R}} = \sum_{380}^{1400} E_\lambda \times R(\lambda) \times \Delta\lambda$	0,7 W/cm^2
		The position of the highest irradiance found in the irradiated retinal area shall be found. The weighted retinal visible and infrared radiation irradiance value, $E_{\text{VIR-R}}$, shall then be calculated by dividing the spectral radiant power, $\Phi_{\text{VIR-R}}$, in watts, incident on the retina in a 0,03 mm circular disc centred on the position of highest irradiance by the area of this disc (7,07 × 10^{-6} cm^2). See Annex D for instructions on the way to make this calculation.		
b)	Weighted retinal visible and infrared radiation thermal radiance, $L_{\text{VIR-R}}$	380 to 1 400	$L_{\text{VIR-R}} = \sum_{380}^{1400} L_\lambda \times R(\lambda) \times \Delta\lambda$	6 W/(sr·cm^2)
		Measurements of radiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be averaged over a right circular cone field-of-view of 0,001 75 rad.		

5.4.2 Pulsed instruments

The ultraviolet radiation limits for Group 1 pulsed instruments that can be operated in a continuous mode are the same as those for Group 1 continuous wave instruments. In such cases, the criteria for continuous wave instruments shall be modified by incorporating the time averaged values of repetitively pulsed instruments. The time averaged value is given by the ratio of the maximum energy that can be produced in a specific period of time to the time involved.

EXAMPLE 1 The time averaged limit for the weighted corneal and lenticular ultraviolet radiation irradiance $E_{\text{S-CL}}$ effective irradiance for an instrument that emits ten pulses in 5 s with an energy of 1 µJ/cm^2 per pulse is 10 µJ/cm^2/5 s = 2 µW/cm^2. This, therefore, would exceed the limit of 0,4 µW/cm^2 for the Group 1.

EXAMPLE 2 The time averaged irradiance for an instrument that emits two pulses in 10 s with an energy of 1 µJ/cm^2 per pulse would be 2 µJ/cm^2/10 s = 0,2 µW/cm^2. This is below the Group 1 limit of 0,4 µW/cm^2.

The emission limits specified in Table 3 relate to corneal, lenticular, anterior segment or retinal infrared radiation radiant exposure as applied directly to the pulsed instruments criteria. These criteria shall apply both to a single pulse and to any group of pulses. To evaluate the respective radiation hazard criteria, the equations given for them in Table 3 shall be used. See Table 1 for an explanation of the quantities used in the equations and for associated units.

Pulsed instruments shall be evaluated at their highest intensity output.

The nominal pulse duration, Δt, for pulsed instrument evaluation is determined by the time interval equal to the full width at half maximum of the pulse. The energy integration time, t, is the full pulse width for an individual pulse, and for multiple pulses, it is the time that includes each individual pulse and combination of pulses.

Table 3 — Group 1 visible and infrared radiation limit values for pulsed instruments

	Parameter	Wavelength nm	Equation	Limit
5.4.2.1	Weighted retinal visible and infrared radiation radiant exposure The limit values given in a) and b) are equivalent. It is only necessary to evaluate the weighted retinal visible and infrared radiation radiant exposure with **either** a) **or** b) below.			
a)	Weighted retinal visible and infrared radiation radiant exposure, $H_{\text{VIR-R}}$	380 to 1 400	$H_{\text{VIR-R}} = \sum_{380}^{1\,400} \left(E_\lambda \times \Delta t\right) L_\lambda \times R(\lambda) \times \Delta\lambda$	6 $t^{3/4}$ J/cm^2 (see NOTE 1 and 2)
		The retinal radiant exposure shall be the radiant energy detectable through a 7 mm diameter aperture at the cornea and shall be evaluated by averaging the highest localized radiant energy incident upon a circular area on the retina with a diameter of 0,03 mm (7,07 × 10^{-6} cm^2). See Annex D for instructions on the way to make this calculation.		
b)	Weighted visible and infrared radiation time-integrated radiance, $L_{i,\text{VIR-R}}$	380 to 1 400	$L_{i,\text{VIR-R}} = \sum_{380}^{1\,400} \left(L_\lambda \times \Delta t\right) \times R(\lambda) \times \Delta\lambda$	50 $t^{3/4}$ J/(sr·cm^2)
		The retinal time-integrated radiance shall be the radiant energy detectable through a 7 mm diameter aperture at the cornea and shall be averaged over a right circular cone field-of-view of 0,001 75 rad.		
5.4.2.2	Unweighted corneal and lenticular infrared radiation radiant exposure, $H_{\text{IR-CL}}$	770 to 2 500	$H_{\text{IR-CL}} = \sum_{770}^{2\,500} H_\lambda \times \Delta\lambda$	1,8 $t^{1/4}$ J/cm^2
		The corneal and lenticular radiant exposure shall be evaluated by averaging the highest localized radiant energy incident upon a circular area at the corneal plane with a diameter of 1 mm (7,9 × 10^{-3} cm^2).		
5.4.2.3	Unweighted anterior segment visible and infrared radiation radiant exposure, $H_{\text{VIR-AS}}$ **(for convergent beams only)**	380 to 1 200	$H_{\text{VIR-AS}} = \sum_{380}^{1\,200} H_\lambda \times \Delta\lambda$	25 $t^{1/4}$ J/cm^2
		The anterior segment radiant exposure shall be evaluated by averaging the highest localized radiant exposure incident upon a circular area at the beam waist with a diameter of 1 mm (7,9 × 10^{-3} cm^2).		

NOTE 1 For pulsed instruments, the limits shall be evaluated for all times, t (in seconds), less than or equal to 20 s. For exposure times greater than 20 s, the limits are the same as those for Group 1 continuous wave instruments as specified in Table 2, subclauses 5.4.1.4, 5.4.1.5 and 5.4.1.6.

NOTE 2 For repetitively pulsed lasers, the retinal limits of 5.4.2.1 a) and b) are further reduced by a correction factor of $N^{-1/4}$, where N is the number of pulses. For example, the correction factor for an instrument that produces 20 pulses is 0,474. Therefore, in the case of 5.4.2.1 a), the limit becomes 2,8 $t^{3/4}$ J/cm^2 and for 5.4.2.1 b) it becomes 23,7 $t^{3/4}$ J/(sr·cm^2).

5.4.3 Limit for multiple source instruments

The optical radiation emissions from instruments that are designed to direct optical radiation on to the same point(s) in or on the eye from multiple light sources shall be below all applicable limits for each light source alone. For all intended consecutive and/or simultaneous use of the light sources, the limit that is applicable for each surface of the eye (cornea, lens, retina) is given by the expression:

$$\frac{(E,H,L)_1}{\text{Limit}_1}+\frac{(E,H,L)_2}{\text{Limit}_2}+\ldots+\frac{(E,H,L)_i}{\text{Limit}_i}\leq 1 \tag{7}$$

where

E is the quantity irradiance or effective irradiance;

H is the quantity radiant exposure or effective radiant exposure;

L is the quantity radiance or integrated radiance;

i is the ith source.

5.5 Emission limits and guideline values for Group 2 instruments

5.5.1 Continuous wave instruments

The emission limits specified in Table 4 relate to corneal and lenticular radiant exposure, retinal radiant exposure or integrated radiance, corneal and lenticular irradiance, anterior segment irradiance and retinal irradiance or radiance, as applied directly to the continuous wave instruments criteria. To evaluate the respective radiation hazard criteria, the equations given for them in Table 4 shall be used. See Table 1 for an explanation of the quantities used in the equations and for associated units.

If wavelengths 250 nm to 400 nm are not emitted by the source or are blocked by filtration, the measurements of Table 4, 5.5.1.1 and 5.5.1.2 are not required.

Table 4 — Group 2 limit values for continuous wave instruments

<table>
<tr><th></th><th>Parameter</th><th>Wavelength
nm</th><th>Equation</th><th>Limit</th></tr>
<tr><td rowspan="2">5.5.1.1</td><td rowspan="2">Weighted corneal and lenticular ultraviolet radiation radiant exposure, $H_{\text{S-CL}}$</td><td>250 to 400</td><td>$H_{\text{S-CL}}=\sum_{250}^{400}(E_\lambda\times t)\times S(\lambda)\times\Delta\lambda$</td><td>3 mJ/cm²</td></tr>
<tr><td colspan="3">The corneal radiant exposure shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the corneal plane with a diameter of 1 mm (7,9 × 10⁻³ cm²).</td></tr>
<tr><td rowspan="2">5.5.1.2</td><td rowspan="2">Unweighted corneal and lenticular ultra-violet radiation radiant exposure, $H_{\text{UV-CL}}$ or irradiance, $E_{\text{UV-CL}}$</td><td>360 to 400</td><td>$H_{\text{UV-CL}}=\sum_{360}^{400}(E_\lambda\times t)\times\Delta\lambda$
$E_{\text{UV-CL}}=\sum_{360}^{400}E_\lambda\times\Delta\lambda$</td><td>1 J/cm² for $t < 1\,000$ s
1 mW/cm² for $t \geqslant 1\,000$ s</td></tr>
<tr><td colspan="3">The corneal radiant exposure shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the corneal plane with a diameter of 1 mm (7,9 × 10⁻³ cm²).</td></tr>
</table>

Table 4 (*continued*)

	Parameter	Wavelength nm	Equation	Limit
5.5.1.3	Unweighted corneal and lenticular infrared radiation irradiance, $E_{\text{IR-CL}}$	770 to 2 500	$E_{\text{IR-CL}} = \sum_{770}^{2500} E_\lambda \times \Delta\lambda$	100 mW/cm^2
		The corneal irradiance shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the corneal plane with a diameter of 1 mm ($7{,}9 \times 10^{-3}$ cm^2).		
5.5.1.4	Unweighted anterior segment visible and infrared radiation irradiance, $E_{\text{VIR-AS}}$ **(for convergent beams only)**	380 to 1 200	$E_{\text{VIR-AS}} = \sum_{380}^{1200} E_\lambda \times \Delta\lambda$	20 W/cm^2
		The unweighted anterior segment irradiance shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the corneal plane with a diameter of 0,5 mm ($2{,}0 \times 10^{-3}$ cm^2).		
5.5.1.5	Retinal visible and infrared radiation thermal hazard The limit values given in a) and b) are equivalent. It is only necessary to evaluate the retinal visible and infrared radiation thermal hazard with **either** a) **or** b) below.			
a)	Weighted retinal visible and infrared radiation thermal irradiance, $E_{\text{VIR-R}}$	380 to 1 400	$E_{\text{VIR-R}} = \sum_{380}^{1400} E_\lambda \times R(\lambda) \times \Delta\lambda$	$\left(\frac{1{,}2}{d_\text{r}}\right)\frac{\text{W}}{\text{cm}^2}$
		In the expression for the limit value, under normal intended conditions of use, d_r, expressed in millimetres, is the minimum retinal image diameter of the source based on the standard eye (see Annex D for instructions on the way to determine the value of d_r). If the calculated value of d_r is greater than 1,7 mm, the value of 1,7 mm shall be used for d_r. If the calculated value of d_r is less than 0,03 mm, the value of 0,03 mm shall be used for d_r. The retinal irradiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be evaluated by averaging the highest localized radiant power incident upon a circular area on the retina with a diameter of 0,03 mm ($7{,}07 \times 10^{-6}$ cm^2). See Annex D for instructions on the way to make this calculation. NOTE: If the value used for d_r is 0,03 mm, the irradiance is more simply given by dividing the spectral radiant power entering the eye, $\Phi_{\text{VIR-R}}$, in watts, by the area of a 0,03 mm circular diameter disc ($7{,}07 \times 10^{-6}$ cm^2).		
b)	Weighted retinal visible and infrared radiation thermal radiance, $L_{\text{VIR-R}}$	380 to 1 400	$L_{\text{VIR-R}} = \sum_{380}^{1400} L_\lambda \times R(\lambda) \times \Delta\lambda$	$\left(\frac{10}{d_\text{r}}\right)\frac{\text{W}}{\text{sr} \cdot \text{cm}^2}$
		In the expression for the limit value, under normal intended use conditions, d_r, expressed in millimetres, is the minimum retinal image diameter of the source based on the standard eye (see Annex D for instructions on the way to determine the value of d_r). If the calculated value of d_r is greater than 1,7 mm, the value 1,7 mm shall be used for d_r. If the calculated value of d_r is less than 0,03 mm, the value of 0,03 mm shall be used for d_r. Measurements of radiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be averaged over a right circular cone field-of-view of 0,001 75 rad.		
NOTE The limits specified in 5.5.1.1 and 5.5.1.2 shall be applicable for all times, t (in seconds), less than or equal to 7 200 s. These limits do not apply to operation microscopes, endoilluminators, and instruments designed for continuous exposures where the limits are further reduced as specified in 5.2.				

The values specified in Table 5 for weighted retinal radiant exposure (aphakic photochemical light hazard) are guideline values. No limit values are set for weighted retinal photochemical light hazards for Group 2 instruments.

Table 5 — Group 2 guideline values for continuous wave instruments

	Parameter	Wavelength nm	Equation	Guideline
5.5.1.6	Retinal radiant exposure guideline (aphakic photochemical light hazard) The guideline values given in a) and b) are equivalent. It is only necessary to evaluate the retinal photochemical light hazard with **either** a) **or** b) below.			
a)	Weighted retinal radiant exposure, $H_{\text{A-R}}$	305 to 700	$H_{\text{A–R}} = \sum_{305}^{700} \left(E_{\lambda} \times t\right) \times A(\lambda) \times \Delta\lambda$	10 J/cm^2
		The retinal irradiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be evaluated by averaging the highest localized radiant power incident upon a circular area on the retina with a diameter of 0,18 mm (2,54 × 10^{-4} cm^2). However, if the instrument is designed to be used with an eye that is immobilized, a 0,03 mm (7,07 × 10^{-6} cm^2) diameter aperture shall be used instead of a 0,18 mm diameter aperture.		
b)	Weighted retinal time-integrated radiance, $L_{\text{A-R}}$	305 to 700	$L_{i,\text{ A–R}} = \sum_{305}^{700} \left(L_{\lambda} \times t\right) \times A(\lambda) \times \Delta\lambda$	100 J/(sr·cm^2)
		Measurements of radiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be averaged over a right circular cone field-of-view of 0,011 rad. However, if the instrument is designed to be used with an eye that is immobilized, a field-of-view of 0,001 75 rad shall be used instead of the 0,011 rad field-of-view.		

NOTE Visible light is necessary for diagnosis of ocular pathology, and thus is commonly used in instruments such as direct and indirect ophthalmoscopes, slit-lamp microscopes, operation microscopes and endoilluminators. It is not reasonable to set limits on visible radiation that is needed for the diagnosis of disease or for visualization during ocular surgery. A surgeon may have to exceed an exposure level that is known to be hazardous during an extended complicated surgery or a clinician may have to exceed an exposure level that is known to be hazardous during an extended ocular examination for diagnosis of ocular pathology. With this in mind, a hazard exposure guideline for visible light, rather than a limit, is set so that clinicians are informed about potential optical radiation hazards that may be associated with the use of their instruments.

5.5.2 Pulsed instruments

The Group 2 ultraviolet radiation limits for pulsed instruments shall be evaluated by using the continuous wave instrument Group 2 criteria. In such cases, the criteria for continuous wave instruments shall be modified by incorporating the time averaged values of repetitively pulsed instruments. The time averaged value is given by the ratio of the maximum energy that can be produced in a specific period of time to the time involved.

EXAMPLE 1 The time averaged irradiance for an instrument that emits ten pulses in 5 s with an energy of 1 mJ/cm^2 per pulse is (10 mJ/cm^2)/5 s = 2 mW/cm^2. Thus, in 5 s, the radiant exposure would be (5 s)(2 mW/cm^2) = 10 mJ/cm^2. This therefore would exceed the limit of 3 mJ/cm^2 for Group 2.

EXAMPLE 2 The time averaged irradiance for an instrument that emits two pulses in 10 s with an energy of 1 mJ/cm^2 per pulse would be (2 mJ/cm^2)/10 s = 0,2 mW/cm^2. Thus, in 10 s, the radiant exposure would be (10 s)(0,2 mW/cm^2) = 2 mJ/cm^2 which is below the limit of 3 mJ/cm^2.

The emission limits specified in Table 6 relate to weighted retinal visible and infrared radiation radiant exposure or integrated radiance, unweighted corneal and lenticular infrared radiant exposure, and unweighted anterior segment visible and infrared radiation radiant exposure (for convergent beams only), as applied directly to the pulsed instruments criteria. To evaluate the respective radiation hazard criteria, the equations given for them in Table 6 shall be used. See Table 1 for an explanation of the quantities used in the equations and for associated units.

Pulsed instruments shall be evaluated at their highest intensity output.

The nominal pulse duration, Δt (in seconds), for pulsed instrument evaluation is determined by the time interval equal to the full width at half maximum of the pulse. The energy integration time, t (in seconds), is the full pulse width for an individual pulse, and for multiple pulses, it is the time that includes each individual pulse and combination of pulses.

Table 6 — Group 2 visible and infrared radiation limit values for pulsed instruments

<table>
<tr><th></th><th>Parameter</th><th>Wavelength
nm</th><th>Equation</th><th>Limit</th></tr>
<tr><td>5.5.2.1</td><td>Retinal visible and infrared radiation thermal hazard
The limit values given in a) and b) are equivalent. It is only necessary to evaluate the retinal visible and infrared radiation thermal hazard with either a) or b) below.</td><td colspan="3"></td></tr>
<tr><td rowspan="2">a)</td><td rowspan="2">Weighted retinal visible and infrared radiation radiant exposure, $H_{\text{VIR-R}}$</td><td>380 to 1 400</td><td>$H_{\text{VIR–R}} = \sum_{380}^{1\,400} \left(E_\lambda \times \Delta t\right) \times R(\lambda) \times \Delta\lambda$</td><td>$\left(\frac{10}{d_r} t^{3/4}\right) \frac{\text{J}}{\text{cm}^2}$</td></tr>
<tr><td colspan="3">In the expression for the limit value, under normal intended use conditions, d_{r}, expressed in millimetres, is the minimum retinal image diameter of the source based on the standard eye (see Annex D for instructions on the way to determine the value of d_{r}). If the calculated value of d_{r} is greater than 1,7 mm, the value 1,7 mm shall be used for d_{r}. If the calculated value of d_{r} is less than 0,03 mm, the value of 0,03 mm shall be used for d_{r}.
The retinal radiant exposure shall be the radiant energy detectable through a 7 mm diameter aperture at the cornea and shall be evaluated by averaging the highest localized radiant energy incident upon a circular area on the retina with a diameter of 0,03 mm (7,07 × 10^{-6} cm^2). See Annex D for instructions on the way to make this calculation.</td></tr>
</table>

Table 6 (*continued*)

	Parameter	Wavelength nm	Equation	Limit
b)	Weighted visible and infrared radiation time-integrated radiance, $L_{i,\text{VIR-R}}$	380 to 1 400	$L_{i,\text{VIR-R}} = \sum_{380}^{1\,400} (L_\lambda \times \Delta t) \times R(\lambda) \times \Delta\lambda$	$\left(\frac{85 t^{3/4}}{d_r}\right) \frac{\text{J}}{\text{sr} \cdot \text{cm}^2}$
		In the expression for the limit value, under normal intended use conditions, d_r, expressed in millimetres, is the minimum retinal image diameter of the source based on the standard eye (see Annex D for instructions on the way to determine the value of d_r). If the calculated value of d_r is greater than 1,7 mm, the value 1,7 mm shall be used for d_r. If the calculated value of d_r is less than 0,03 mm, the value of 0,03 mm shall be used for d_r. Measurements of radiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be averaged over a right circular cone field-of-view of 0,001 75 rad.		
5.5.2.2	Unweighted corneal and lenticular infrared radiation radiant exposure, $H_{\text{IR-CL}}$	770 to 2 500	$H_{\text{IR-CL}} = \sum_{770}^{2\,500} H_\lambda \times \Delta\lambda$	1,8 $t^{1/4}$ J/cm^2
		The corneal radiant exposure shall be evaluated by averaging the highest localized radiant energy incident upon a circular area at the corneal plane with a diameter of 1 mm (7,9 × 10^{-3} cm^2).		
5.5.2.3	Unweighted anterior segment visible and infrared radiation radiant exposure, $H_{\text{VIR-AS}}$ **(for convergent beams only)**	380 to 1 200	$H_{\text{VIR-AS}} = \sum_{380}^{1\,200} H_\lambda \times \Delta\lambda$	25 $t^{1/4}$ J/cm^2
		The anterior segment radiant exposure shall be evaluated by averaging the highest localized radiant energy incident upon a circular area at the beam waist with a diameter of 0,5 mm (2 × 10^{-3} cm^2).		
NOTE 1 For pulsed instruments, the limits shall be evaluated for all times, t (in seconds), less than or equal to 20 s. For exposure times greater than 20 s, the limits are the same as those for Group 2 continuous wave instruments as specified in Table 4, 5.5.1.3, 5.5.1.4, and 5.5.1.5. NOTE 2 For repetitively pulsed lasers, the retinal limits of 5.5.2.1 a) and b) are further reduced by a correction factor of $N^{-1/4}$, where N is the number of pulses. For example, the correction factor for an instrument that produces 20 pulses is 0,474. Therefore, in the case of repetitively pulsed lasers 10 in the limit for $H_{\text{VIR-R}}$ becomes 4,74 and the factor of 85 in the limit for $L_{\text{VIR-R}}$ becomes 40,5.				

5.5.3 Multiple source instruments

5.5.3.1 Limit for multiple source instruments

The optical radiation emissions from instruments that are designed to direct optical radiation on to the same point(s) in or on the eye from multiple light sources shall be below all applicable limits for each light source alone. And, for all intended simultaneous use and subsequent use for the ultraviolet radiation limits, the limit that is applicable for each surface of the eye (cornea, lens, retina) is given by the expression:

$$\frac{(E,H,L)_1}{\text{Limit}_1} + \frac{(E,H,L)_2}{\text{Limit}_2} + \ldots + \frac{(E,H,L)_i}{\text{Limit}_i} \leqslant 1 \qquad (8)$$

where

E is the quantity irradiance or effective irradiance;

H is the quantity radiant exposure or effective radiant exposure;

L is the quantity radiance or integrated radiance;

i is the ith source.

5.5.3.2 Guideline for multiple source instruments

The guideline for optical radiation emissions from instruments that are designed to direct optical radiation on to the same point(s) on the retina from multiple light sources for all intended consecutive and/or simultaneous use of the light sources in one day is given by the expression:

$$\left(\frac{n_1 H_1}{10\ \mathrm{J/cm^2}}, \frac{t_1 L_1}{100\ \mathrm{J/(sr\cdot cm^2)}}, \frac{t_1 E_1}{10\ \mathrm{J/cm^2}}\right)_1 + \left(\frac{n_2 H_2}{10\ \mathrm{J/cm^2}}, \frac{t_2 L_2}{100\ \mathrm{J/(sr\cdot cm^2)}}, \frac{t_2 E_2}{10\ \mathrm{J/cm^2}}\right)_2 + \dots + \left(\frac{n_n H_i}{10\ \mathrm{J/cm^2}}, \frac{t_n L_i}{100\ \mathrm{J/(sr\cdot cm^2)}}, \frac{t_n E_i}{10\ \mathrm{J/cm^2}}\right)_n < 1 \tag{9}$$

where

E is the quantity irradiance or effective irradiance;

H is the quantity radiant exposure or effective radiant exposure per pulse;

L is the quantity radiance or integrated radiance;

i is the ith source;

t_1, t_2 and t_n are the maximum expected exposure times in combination with the maximum number of pulses for sources 1, 2 and 3, respectively;

n_1, n_2 and n_i are the maximum expected number of pulses in combination with the maximum expected exposure times for sources 1, 2 and 3 respectively.

6 Test methods

6.1 General

All tests are type tests. All measurements shall be made at the instrument’s intended working distance.

6.2 Measurements made to classify instruments into Group 1 or Group 2

For measurements made to classify instruments in Group 1 or Group 2, the maximum uncertainty shall be less than the difference between the emission limits specified in 5.4 and the values measured (i.e. measured value $\leqslant$ emission limit − uncertainty). Broadband radiometers, such as blue-light-hazard, ultra-violet-hazard and retinal-thermal-hazard meters, may be used and may provide sufficient information. Luminance and illuminance meters may also be used if the spectral power distribution of the light source is known. If broadband meters are not used, the measurement means specified in Annex D and Annex E shall be used.

6.3 Group 2 instruments: Measurements

This subclause applies to the following radiometric quantities: spectral irradiance, spectral radiance, spectral radiant exposure, integrated spectral radiance, irradiance, radiant exposure, spectrally weighted irradiance, spectrally weighted radiance, spectrally weighted radiant exposure and spectrally weighted integrated radiance.

For measurements made to establish conformance with 5.5, the uncertainty in the values of spectral irradiance, spectral radiance, spectral radiant exposure and integrated spectral radiance determined shall be less than ± 30 %.

The intervals for spectral irradiance, spectral radiance, spectral radiant exposure and integrated spectral radiance measurements should be centred on the values used in Annex A with a recommended bandwidth of 5 nm or 10 nm as indicated. The recommended measurements unit is milliwatts per square centimetre per nanometre [mW/(cm^2·nm)] for spectral irradiance and Joules per square centimetre per nanometre [J/(cm^2·nm)] for spectral radiant exposure. These values should be recorded and, after being multiplied by the bandwidth, recorded as milliwatts per square centimetre (mW/cm^2) for that interval for spectral irradiance and as Joules per square centimetre (J/cm^2) for spectral radiant exposure. If lamps with narrow spectral lines are used, the bandwidth measurements may need to be less than 5 nm.

6.4 Determination of area

The measuring method used for determining the area shall be capable of an accuracy of ± 30 %.

NOTE 1 For irregular cross-section, it may be appropriate to measure the area by exposing a piece of photographic film and then measuring the exposed area on the negative.

NOTE 2 Uncertainty is an estimate of the difference between the measured and true values. See Bibliography [2] and [3].

6.5 Group 2 instruments: Determination of time and number of pulses to reach maximum exposure guidelines

6.5.1 Determination of time to reach the maximum exposure guideline for aphakic retinal exposure, t_{max} (for continuous wave instruments)

To determine the time to reach a potential optical radiation hazard for aphakic retinal exposure, either of the following formulae shall be used:

For irradiance: $$t_{max}\left(E_{A-R}\right) = \frac{10\ \left(\text{J/cm}^2\right)}{E_{A-R}\ \left(\text{W/cm}^2\right)} \tag{10}$$

For radiance: $$t_{max}\left(L_{A-R}\right) = \frac{100\ \left(\text{sr}\cdot\text{J/cm}^2\right)}{L_{A-R}\ \left(\text{sr}\cdot\text{W/cm}^2\right)} \tag{11}$$

6.5.2 Determination of the number of pulses necessary to reach the maximum exposure guideline for aphakic retinal exposure, n_{max} (for pulsed instruments)

To determine the number of pulses necessary to reach a potential optical radiation hazard for aphakic retinal exposure, either of the following formula shall be used:

For radiant exposure: $$n_{max}\left(H_{A-R}\right) = \frac{10\ (\text{J/cm}^2)}{H_{A-R}(\text{J/cm}^2)/\text{pulse}} \tag{12}$$

For integrated radiance: $$n_{max}\left(t \times L_{A-R}\right) = \frac{100\ \ (\text{J/cm}^2)}{t \times L_{A-R}(\text{J/cm}^2)/\text{pulse}} \tag{13}$$

7 Information supplied by the manufacturer

For Group 2 instruments the following particular information is required.

a) The manufacturer shall, on request, provide the user with a graph showing the relative spectral output of the instrument between 305 nm and 1 100 nm when the instrument is operating at maximum light intensity and maximum aperture. The spectral output shall be shown for the beam after it exits the instrument.

b) The manufacturer shall provide the user with the following information and cautionary statement in a prominent position in the user manual:

1) For continuous wave sources:

The manufacturer shall provide the user with information concerning the time to reach a potential optical radiation hazard as determined in 6.5.1.

CAUTIONARY STATEMENT:

"CAUTION – The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after ___ (e.g. xx min)."

2) For pulsed sources:

The manufacturer shall provide the user with information concerning the number of pulses to reach a potential optical radiation hazard as determined in 6.5.2.

CAUTIONARY STATEMENT:

"CAUTION – The light emitted from this instrument is potentially hazardous. The greater the number of pulses, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after ___ (xx pulses)."

3) For multiple source instruments with continuous wave output that can illuminate the same points on the retina:

The manufacturer shall provide the user with information on how to determine the time to reach the exposure guideline. This shall apply for the combination of light sources at various intensity settings.

CAUTIONARY STATEMENT:

"CAUTION – The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum output will exceed the safety guideline after ___ (e. g. xx min for source 1, yy min for source 2, …, and nn min for source n)."

NOTE 1 The exposure from all light sources is cumulative and additive.

NOTE 2 If the intensity of any of the light sources is reduced to 50 % of the maximum intensity, the exposure time for that light source to reach the exposure guideline is doubled. This linear relationship can be used to determine the time to reach the exposure guideline for the combination of light sources at various intensity settings.

NOTE 3 The weighted retinal radiant exposure guideline is 10 J/cm^2.

4) For multiple source instruments with pulsed light output that can illuminate the same points on the retina:

The manufacturer shall provide the user with information on how to determine the number of pulses to reach the exposure guideline. This shall apply for the combination of light sources at various intensity settings.

CAUTIONARY STATEMENT:

"CAUTION – The light emitted from this instrument is potentially hazardous. The greater the number of pulses, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum output will exceed the safety guideline after ___ (e.g. xx pulses for source 1, yy pulses for source 2, …, and nn pulses for source n)."

NOTE 1 The exposure from all light sources is cumulative and additive.

NOTE 2 If the intensity of any of the light sources is reduced to 50 % of the maximum intensity, the number of pulses for that light source to reach the exposure guideline is doubled. This linear relationship can be used to determine the time to reach the exposure guideline for the combination of light sources at various intensity settings.

NOTE 3 The weighted retinal radiant exposure guideline is 10 J/cm^2.

5) For multiple source instruments with continuous wave and pulsed light output that can illuminate the same points on the retina:

The manufacturer shall provide information on how to determine the combination of the time and number of pulses to reach the exposure guideline. This shall also apply for the combination of light sources at various intensity settings.

CAUTIONARY STATEMENT:

"CAUTION – The light emitted from this instrument is potentially hazardous. The longer the duration of exposure and the greater the number of pulses, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum output will exceed the safety guideline after ___ (e.g. xx min for source 1, yy pulses for source 2, …, and nn min <u>or</u> pulses for source n)."

NOTE 1 The exposure time and number of pulses from all light sources is cumulative and additive.

NOTE 2 If the intensity of any of the light sources is reduced to 50 % of the maximum intensity, the exposure time or number of pulses for that light source to reach the exposure guideline is doubled. This linear relationship can be used to determine the time to reach the exposure guideline for the combination of light sources at various intensity settings.

NOTE 3 The weighted retinal radiant exposure guideline is 10 J/cm^2.

c) Where provision is made to vary brightness, the manufacturer shall provide the user with information concerning the indication of the maximum intensity and fractions of maximum intensity.

Annex A
(normative)

Spectral weighting functions

Table A.1 — Spectral weighting functions for retinal hazard analysis

Wavelength (nm)	**Thermal hazard weighting function** $R(\lambda)$	**Aphakic photochemical hazard weighting function** $A(\lambda)$
305 to 335	—	6
340	—	5,88
345	—	5,71
350	—	5,46
355	—	5,22
360	—	4,62
365	—	4,29
370	—	3,75
375	—	3,56
380	0,006 25	3,19
385	0,012 5	2,31
390	0,025	1,88
395	0,05	1,58
400	0,1	1,43
405	0,2	1,3
410	0,4	1,25
415	0,8	1,2
420	0,9	1,15
425	0,95	1,11
430	0,98	1,07
435	1	1,03
440	1	1
445	1	0,97
450	1	0,94
455	1	0,9
460	1	0,8
465	1	0,7
470	1	0,62
475	1	0,55
480	1	0,45

Table A.1 (*continued*)

Wavelength (nm)	**Thermal hazard weighting function** $R(\lambda)$	**Aphakic photochemical hazard weighting function** $A(\lambda)$
485	1	0,4
490	1	0,22
495	1	0,16
500	1	0,1
505	1	0,079
510	1	0,06
515	1	0,05
520	1	0,039 8
525	1	0,031
530	1	0,025
535	1	0,019 9
540	1	0,015 8
545	1	0,012 6
550	1	0,01
555	1	0,007 9
560	1	0,006 3
565	1	0,005
570	1	0,004
575	1	0,003 1
580	1	0,002 5
585	1	0,002
590	1	0,001 6
595	1	0,001 3
600 to 700	1	0,001
705	0,98	—
710	0,95	—
715	0,93	—
720	0,91	—
725	0,89	—
730	0,87	—
735	0,85	—
740	0,83	—
745	0,81	—
750	0,79	—
755	0,78	—
760	0,76	—
765	0,74	—
770	0,72	—

Table A.1 (*continued*)

Wavelength (nm)	**Thermal hazard weighting function** $R(\lambda)$	**Aphakic photochemical hazard weighting function** $A(\lambda)$
775	0,71	—
780	0,69	—
785	0,68	—
790	0,66	—
795	0,65	—
800	0,63	—
805	0,62	—
810	0,6	—
815	0,59	—
820	0,58	—
825	0,56	—
830	0,55	—
835	0,54	—
840	0,52	—
845	0,51	—
850	0,5	—
855	0,49	—
860	0,48	—
865	0,47	—
870	0,46	—
875	0,45	—
880	0,44	—
885	0,43	—
890	0,42	—
895	0,41	—
900	0,4	—
905	0,39	—
910	0,38	—
915	0,37	—
920	0,36	—
925	0,35	—
930	0,35	—
935	0,34	—
940	0,33	—
945	0,32	—
950	0,32	—
955	0,31	—
960	0,3	—

Table A.1 (*continued*)

Wavelength (nm)	**Thermal hazard weighting function** $R(\lambda)$	**Aphakic photochemical hazard weighting function** $A(\lambda)$
965	0,3	—
970	0,29	—
975	0,28	—
980	0,28	—
985	0,27	—
990	0,26	—
995	0,26	—
1 000	0,25	—
1 005	0,25	—
1 010	0,24	—
1 015	0,23	—
1 020	0,23	—
1 025	0,22	—
1 030	0,22	—
1 035	0,21	—
1 040	0,21	—
1 045	0,2	—
1 050 to 1 400	0,2	—

Table A.2 — Spectral weighting function for ultraviolet radiation hazard analysis

Wavelength nm	**UV radiation hazard weighting function** $S(\lambda)$
200	0,03
205	0,051
210	0,075
215	0,095
220	0,12
225	0,15
230	0,19
235	0,24
240	0,3
245	0,36
250	0,43
254	0,5
255	0,52
260	0,65
265	0,81
270	1
275	0,96
280	0,88
285	0,77
290	0,64
295	0,54
297	0,46
300	0,3
303	0,12
305	0,06
308	0,03
310	0,02
313	$6,00 \times 10^{-3}$
315	$3,00 \times 10^{-3}$
316	$2,40 \times 10^{-3}$
317	$2,00 \times 10^{-3}$
318	$1,60 \times 10^{-3}$
319	$1,20 \times 10^{-3}$
320	$1,00 \times 10^{-3}$
322	$6,70 \times 10^{-4}$
323	$5,40 \times 10^{-4}$

Table A.2 (*continued*)

Wavelength nm	**UV radiation hazard weighting function** $S(\lambda)$
325	$5{,}00 \times 10^{-4}$
328	$4{,}40 \times 10^{-4}$
330	$4{,}10 \times 10^{-4}$
333	$3{,}70 \times 10^{-4}$
335	$3{,}40 \times 10^{-4}$
340	$2{,}80 \times 10^{-4}$
345	$2{,}40 \times 10^{-4}$
350	$2{,}00 \times 10^{-4}$
355	$1{,}60 \times 10^{-4}$
360	$1{,}30 \times 10^{-4}$
365	$1{,}10 \times 10^{-4}$
370	$9{,}30 \times 10^{-5}$
375	$7{,}70 \times 10^{-5}$
380	$6{,}40 \times 10^{-5}$
385	$5{,}30 \times 10^{-5}$
390	$4{,}40 \times 10^{-5}$
395	$3{,}60 \times 10^{-5}$
400	$3{,}00 \times 10^{-5}$

Annex B
(informative)

Product-related International Standards for ophthalmic instruments to which ISO 15004-2 applies and which contain a specific light hazard section

ISO 10936-2:2001, *Optics and optical instruments — Operation microscopes — Part 2: Light hazard from operation microscopes used in ocular surgery*

ISO 10939:2007, *Ophthalmic instruments — Slit-lamp microscopes*

ISO 10940:1998, *Ophthalmic instruments — Fundus cameras*

ISO 10942:2006, *Ophthalmic instruments — Direct ophthalmoscopes*

ISO 10943:2006, *Ophthalmic instruments — Indirect ophthalmoscopes*

ISO 15752:2000, *Ophthalmic instruments — Endoilluminators — Fundamental requirements and test methods for optical radiation safety*

NOTE This Annex provides information on the situation at the time of publication of this part of ISO 15004. Revised editions of the International Standards listed or additional new International Standards for ophthalmic instruments to which ISO 15004-2 applies and which contain a specific light hazard section might have become available since that time.

Annex C
(informative)

Measurement instruments

If the optical radiation emissions are sufficiently low, relatively simple and inexpensive optical radiation measurement instruments may be used to determine if an ophthalmic instrument is below the emission limits specified in 5.4 (Group 1). Broadband, direct reading "safety" meters which measure one of the spectrally weighted or non-weighted quantities are commercially available and may be used to directly measure potential optical radiation ocular and skin hazards. Spot luminance meters are also available to measure the quantity luminance. In general, if the luminance for a white light source is less than one candela per centimetre squared (1 cd/cm^2), spectral data would not be needed. Once the illuminance from an illuminance meter is measured, the spectral irradiance can be readily determined if the relative spectral power distribution is known. However, it is important to remember while performing these measurements that the measurements are to be averaged over a field-of-view of 0,011 rad (11 mrad or 0,63°). This means that at a distance of 50 cm from a light source, the field-of-view of the instrument must be emission-limited to a circular area with a diameter of 5,5 mm.

Annex D
(normative)

Measurement methods for radiance/irradiance

D.1 Measurements to determine Group 1 status and to determine radiance/irradiance parameter values for Group 2 instruments

In order to determine if an ophthalmic instrument has Group 1 status it shall not exceed any of the limits set forth in either Table 2 (continuous wave instruments) or in Table 3 (pulsed instruments). To determine the spectral irradiance values or spectral radiant power values needed to calculate the limit parameter values of an ophthalmic instrument, either the methods given in this annex or equivalent methods shall be used.

If an ophthalmic instrument is determined to have Group 2 status, the limits of 5.5 apply. To assess compliance with these limits, emission levels of the ophthalmic instrument shall be determined, which requires measurement of spectral irradiance values and spectral radiant power values. This shall be done using either the methods given in this annex or equivalent methods.

D.2 Method to determine $E_{\text{S-CL}}$, $E_{\text{UV-CL}}$, $E_{\text{IR-CL}}$ and $E_{\text{VIR-AS}}$

Corneal spectral irradiance values, E_λ, used to calculate $E_{\text{S-CL}}$, $E_{\text{UV-CL}}$, $E_{\text{IR-CL}}$ and $E_{\text{VIR-AS}}$ shall be determined with a measuring instrument capable of measuring spectral irradiance or spectral radiant power over the specified wavelength band. The measuring instrument shall be able to collect all radiant power that the tested ophthalmic instrument radiates into the plane where the cornea is placed during normal operation.

The radiation measurement shall be taken by placing the measuring instrument so that its sensor collects all the radiation emitted by the tested ophthalmic instrument that falls in the plane where the cornea is placed during normal operation.

If the measuring instrument's output is in spectral radiant power, the spectral irradiance values assigned to the ophthalmic instrument shall be taken to be the spectral radiant powers measured divided by the area that the ophthalmic instrument irradiates in the corneal plane.

If the measuring instrument's output is radiant power or irradiance, an additional measurement of the spectrum needs to be made. Then spectral radiant power or spectral irradiance is found by weighting the radiant power or irradiance by the spectrum measured.

D.3 Method to determine $E_{\text{A-R}}$

The retinal spectral irradiance values, E_λ, needed to calculate $E_{\text{A-R}}$ shall be determined by first finding the spectral radiance of the ophthalmic instrument using one of the two following methods.

1) If, from knowledge of the ophthalmic instrument design, the area of the instrument exit pupil, A_{exit}, and the distance of the exit pupil from the corneal plane, D_{p}, is available, the effective illumination solid angle, Ω_{e}, is found to be

$$\Omega_{\text{e}} = A_{\text{exit}} / D_{\text{p}}^2 \qquad \text{(D.1)}$$

The spectral radiance, L_λ, is then found from the spectral irradiance in the corneal plane, $E_{\lambda\text{-c}}$, as found using the method of D.2 by

$$L_\lambda = E_{\lambda\text{-c}} / \Omega_e = E_{\lambda\text{-c}} D_p^2 / A_{exit} \quad (D.2)$$

2) If Ω_e is unknown, the measurement of spectral irradiance is made under the following controlled conditions. An aperture whose area, A, is small with respect to the beam cross sectional area where it is placed is inserted into the beam between the ophthalmic instrument and the measuring plane. The spectral irradiance is measured using the method of D.2. The spectral radiance, L_λ, is then found from the spectral irradiance, E_λ, by

$$L_\lambda = E_\lambda D^2 / A, \quad (D.3)$$

where D is the distance from the aperture, whose area is A, to the measurement plane.

These spectral radiance values shall then be used to calculate the spectral irradiance values at the retina in the following way. The area of the pupil of the eye through which light passes in normal use of the ophthalmic instrument, A_p, shall be determined. Its value may either be determined by knowledge of ophthalmic instrument design and usage or by measurement. If it is necessary to determine its value by measurement, the measurement shall be made by placing a light-sensitive device such as a piece of photographic film or a CCD camera sensor in the plane where the pupil of the eye would be placed in normal instrument use and illuminating it to record the area illuminated. Then this illuminated area is measured and its value is taken to be A_p.

Calculation of retinal spectral irradiance shall then be made by first assuming that the pupil lies at an optical distance, D_o, of 17 mm from the retina. The retinal spectral irradiance, E_λ, is then given by

$$E_\lambda = L_\lambda A_p / D_o^2 = L_\lambda A_p / 289 \quad (D.4)$$

A third alternative method may be used for instruments, such as fundus cameras that produce a homogenous beam on the retina. The radiant power from the instrument is measured as in D.2. By knowing the instrument's optical properties, the area into which this radiation falls is calculated. The retinal irradiance is then found by dividing the radiant power entering the eye by the area irradiated on the retina. Specific information on making the relevant calculations is found in Annex E.

D.4 Method to determine $H_{S\text{-}CL}$, $H_{UV\text{-}CL}$, $H_{IR\text{-}CL}$ and $H_{VIR\text{-}AS}$

Corneal spectral radiant exposure values, H_λ, used to calculate $H_{S\text{-}CL}$, $H_{UV\text{-}CL}$, $H_{IR\text{-}CL}$ and $H_{VIR\text{-}AS}$ shall be determined using a measuring instrument capable of measuring all the spectral radiant power that the tested ophthalmic instrument radiates during a single pulse.

The measurement shall be taken by placing the measuring instrument so that its sensor collects all the radiation emitted by the tested ophthalmic instrument that falls in the plane where the cornea is placed during normal operation.

The spectral radiant exposure values are the measured spectral radiant power values divided by the measured irradiated area.

If the measuring instrument's output is radiant power or irradiance, an additional measurement of the spectrum needs to be made. Then spectral radiant power or spectral irradiance is found by weighting the radiant power or irradiance by the spectrum measured.

D.5 Method to determine H_{VIR-R} and H_{A-R}

Retinal spectral radiant exposure values, H_λ, used to calculate H_{VIR-R} and H_{A-R} shall be determined by first finding the spectral radiance of the ophthalmic instrument using one of the two following methods.

1) If, from knowledge of the ophthalmic instrument design, the area of the instrument exit pupil, A_{exit}, and the distance of the exit pupil from the corneal plane, D_p, are available, the effective illumination solid angle, Ω_e, is found to be

$$\Omega_e = \frac{A_{exit}}{D_p{}^2} \quad (D.5)$$

The spectral radiance, L_λ, is then found from the spectral radiant exposure in the corneal plane, $H_{\lambda-c}$, as found using the method of D.4 by

$$L_\lambda = \frac{H_{\lambda\text{-c}}}{\Omega_e \times t} = \frac{H_{\lambda\text{-c}}\ D_p{}^2}{A_{exit} \times t} \quad (D.6)$$

2) If Ω_e is unknown, the measurement of spectral radiant exposure is made under the following controlled conditions. An aperture whose area, A, is small with respect to the beam cross sectional area where it is placed is inserted into the beam between the ophthalmic instrument and the measuring plane. The spectral radiant exposure is measured using the method of D.4. The spectral radiance, L_λ, is then found from the spectral radiant exposure, H_λ, by

$$L_\lambda = \frac{H_\lambda\ D^2}{A \times t} \quad (D.7)$$

These spectral radiance values shall then be used to calculate the spectral radiant exposure values at the retina in the following way. The area of the pupil of the eye through which light passes in normal use of the instrument, A_p, shall be determined. Its value may either be determined by knowledge of ophthalmic instrument design and usage or by measurement. If it is necessary to determine its value by measurement, the measurement shall be made by placing a light-sensitive device such as a piece of photographic film or a CCD camera sensor in the plane where the pupil of the eye would be placed in normal instrument use and illuminating it to record the area illuminated. Then this illuminated area is measured and its value is taken to be A_p.

Calculation of retinal spectral radiant exposure shall then be made by first assuming that the pupil lies at an optical distance, D_o, of 17 mm from the retina. The retinal spectral radiant exposure, H_λ, is then given by

$$H_\lambda = \frac{L_\lambda A_p}{D_o{}^2 \times t} = \frac{L_\lambda\ A_p}{289 \times t} \quad (D.8)$$

A third alternative method may be used for instruments, such as fundus cameras that produce a homogenous beam on the retina. The radiant power from the instrument is measured as in D.2. By knowing the instrument's optical properties, the area into which this radiation falls is calculated. The retinal irradiance is then found by dividing the radiant power entering the eye by the area irradiated on the retina. Specific information on making the relevant calculations is found in Annex E.

D.6 Method to calculate d_r

To calculate the limit values E_{VIR-R} and L_{VIR-R} for continuous wave instruments and H_{VIR-R} and L_{VIR-R} for pulsed instruments, the diameter (in millimetres) of the source on the retinal surface, d_r, must be given a value. If the angular subtense of the source, α, as viewed by the eye with the ophthalmic instrument positioned at its normal intended use distance from the eye, is known or has been measured, d_r is found using

$d_r = 17 \tan\alpha$

where 17 mm is the distance from the nodal point of the standard eye to the retina.

Alternatively, d_r is found experimentally by forming an image of the source using a 17 mm focal length lens held at a distance from the ophthalmic instrument equal to the normal intended use position of the eye. The measured width of the image so formed in a plane 17 mm from the secondary principal plane of the lens is the value to use as d_r.

D.7 Example for determination of radiance from a measurement of irradiance

Diffuse light source, 15 mm in diameter, with a central hot spot with a diameter of 3 mm.

For this application, the eye is located a distance of 20 cm from the diffuse light source.

a) Determination of radiance

Radiance may be determined by measuring the radiant power that is transmitted through 2 apertures spaced at a known distance, z, apart using the relationship

$$L = \frac{\Phi \times z^2}{A \times a} \qquad \text{(D.9)}$$

where

L is the radiance;

Φ is the radiant power;

a is the area of the first aperture;

A is the area of the second aperture.

See Figure D.1.

Only the radiation that is within a field-of-view of 11 mrad needs to be considered.

b) Determination of aperture size for field-of-view of 11 mrad

In this application, the field of view of 11 mrad defines the diameter of the first aperture, d, that can be placed directly over the diffuse source at a distance z = 20 cm from the nodal point of the eye, since the pupil of the eye is the field stop.

Thus $0{,}011 = \frac{d}{z}$ and $d = 0{,}011 \times z = 2{,}2$ mm

c) Determination of irradiance

Irradiance is determined by measuring the radiant power that is transmitted through the second aperture with a diameter of 7 mm, at a distance z = 20 cm from the light source. The irradiance is then equal to the radiant power divided by the area of a 7 mm aperture.

NOTE A 7 mm diameter aperture is used as specified for the measurement of the optical radiation incident on the eye.

Since $E = \frac{\Phi}{A}$,

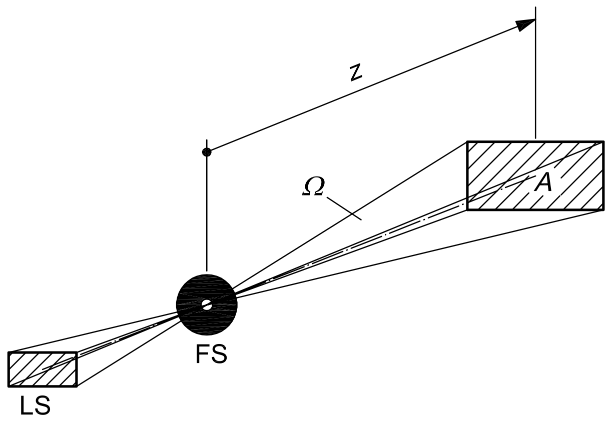
$$E = \frac{\Phi}{0{,}384\ \text{cm}^2} \quad \text{(D.10)}$$

the formula for radiance becomes

$$L = \frac{E \times z^2}{a}, \quad \text{(D.11)}$$

$$L = E \frac{(200)^2}{\pi(1{,}1)^2}$$

It is only necessary to measure the irradiance at distance z = 20 cm, for the determination of the source radiance using an aperture of 2,2 mm over the hot spot of the diffuse source. This method takes the 11 mrad field of view into account.



Key

- Ω solid angle subtended by light source LS
- A area of the second aperture
- z distance between the first aperture (FS) and the second aperture (with area A)

Figure D.1 — Solid angle Ω subtended by a light source

Annex E
(informative)

Guidance on the direct measurement of irradiance

E.1 Measurements of irradiance in corneal or pupillary plane

To determine the spectral irradiance in the plane of the cornea or the pupil of the eye, the ophthalmic instrument is located in the intended position of use. The spectral irradiance is then determined by dividing the maximum spectral radiant power or radiant exposure that can be collected in a 1 mm diameter circular area in the applicable measurement plane by the area of the 1 mm aperture used.

E.2 Measurements of retinal irradiance

To determine the spectral irradiance in the plane of the retina, the ophthalmic instrument is located in the intended position of use. The retinal irradiance for photochemical retinal hazard shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be evaluated by averaging the highest localized radiant power incident upon a circular area on the retina with a diameter of 0,18 mm ($2{,}54 \times 10^{-4}$ cm^2). However, for both photochemical and thermal retinal hazards, if the instrument is intended to be used with an eye that is immobilized, a 0,03 mm ($7{,}07 \times 10^{-6}$ cm^2) diameter aperture shall be used instead of a 0,18 mm diameter aperture.

Once spectral radiant power has been determined, it is then necessary to determine the spatial beam profile on the retina. The spatial beam profile of the radiation on the retina may be determined by direct measurements or by a combination of measurements and calculations using geometrical optics.

The area of the retina illuminated may be determined by geometrical optics for an ophthalmic instrument that produces a Maxwellian view with a circular beam waist at the pupillary plane of the eye. This is applicable for instruments that produce a homogenous beam on the retina. In this case, the cone angle is determined by measurements of the beam diameter, 2 x (where x is the radius), at a known distance, l, beyond the pupillary plane. The cone half angle, Θ, in this case is given by the expression:

$$\Theta = \tan^{-1}\left(x / l\right) \quad \text{(E.1)}$$

The radius, r, of the beam on the retina in centimetres, is given by the product, $r = 1{,}7 \tan \Theta = 1{,}7\ (x / l)$. In this case, the area on the retina is given by the product of πr^2.

In the case of a collimated beam incident on the cornea of the eye, the area to be used is either 0,03 mm, if the eye is immobilized, or 0,18 mm if the eye is not immobilized.

In the case of a divergent beam on the eye such as that from a direct ophthalmoscope, the area on the retina illuminated is given by the expression:

$$a_{\mathrm{r}} = \Omega\ \left(1{,}7\right)^2 \quad \text{(E.2)}$$

where Ω is the source solid angle of emission in steradians.

Ω may be determined by measurements of the beam area at two distances from the exit aperture of the ophthalmic instrument. The beam areas at the two different distances can be used to determine the cone angle(s) from which the solid angle may be derived.

In this case, the solid angle Ω is given by the expression:

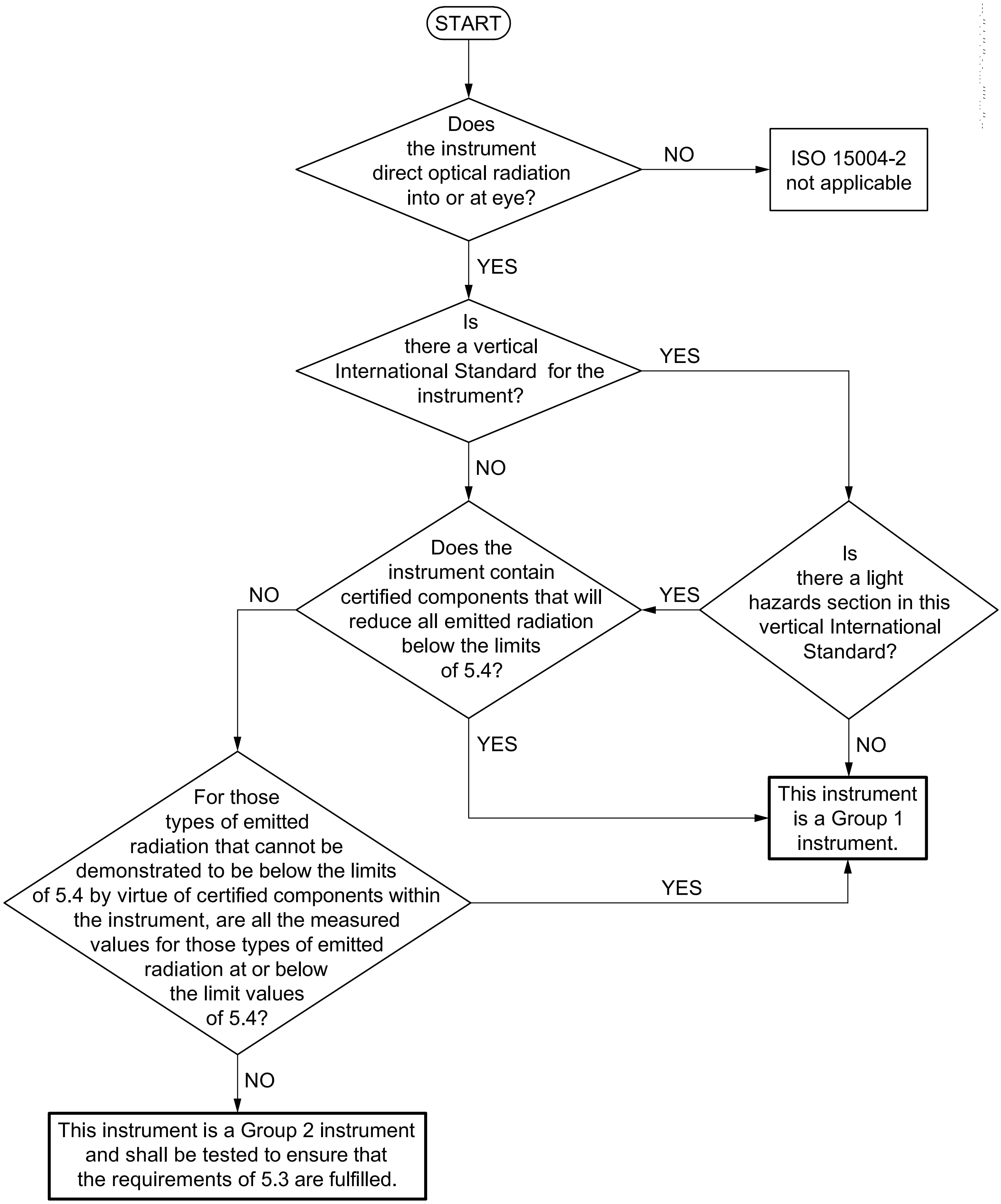
$$\Omega = 2\pi\left(1 - \cos\alpha\right) \quad \text{(E.3)}$$

where α is the cone angle.

For evaluating photochemical hazards for divergent beams, the following procedures for a non-immobilized eye shall be used. The spectral irradiance on the retina is determined by dividing the maximum spectral radiant power or radiant exposure that can be collected in a 0,18 mm diameter circular retinal area by the area of the aperture used. For an immobilized eye, or for retinal thermal hazards, a 0,03 mm aperture shall be used.

Annex F
(informative)

Classification flowchart



NOTE It is unlikely that instruments such as operation microscopes, slit-lamp microscopes, indirect ophthalmoscopes, or endoilluminators will be in Group 1. This can be confirmed by demonstrating that the emission from the instruments exceeds any one of the emission limits specified for instruments in Group 1. Alternatively, measurements made in accordance with requirements for instruments in Group 2 can confirm that an instrument is not in Group 1.

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