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Ophthalmic instruments — Background for light hazard specification in ophthalmic instrument standards

Instruments ophtalmiques — Contexte des spécifications du risque lumineux dans les normes relatives aux instruments ophtalmiques

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Foreword

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Introduction

Light tissue damage is mechanical, thermal or chemical. Mechanical injury such as that from a laser is a disruption, fragmentation or vaporization of tissue. Photothermal injury is the conversion of light energy into heat. In photochemical injury (actinic) a photosensitized molecule reacts directly with target tissue in a Type 1 (free radical) reaction, or with molecular oxygen to produce singlet oxygen or super oxide which in turn reacts with target tissue in Type 2 (photodynamic) reactions. Photochemical retinal injury without exogenous photosensitizers (phototoxicity) usually occurs with prolonged exposure to light levels that are tolerated with shorter exposure times. These mechanisms are not mutually exclusive but can occur simultaneously or sequentially.

There are at least two basic types of acute experimental retinal phototoxicity. The first is the acute blue-green phototoxicity that Noell discovered in 1966. Rhodopsin mediates this type of damage and also scotopic vision. Rhodopsin absorption peaks around 507 nm (blue-green), so scotopic sensitivity and Noell's phototoxicity are highest in the blue-green part of the spectrum. The second is the acute UV-blue phototoxicity that Ham et al discovered in 1976. Its severity increases with decreasing wavelength, so UV radiation is potentially more hazardous than violet light which in turn is potentially more hazardous than blue light. In 1978, Mainster showed that clear PMMA intraocular lenses transmitted potentially hazardous UV radiation to the retina between 330 nm and 400 nm. By 1986 most intraocular lenses had UV blocking chromophores to protect patients.

Staring at the sun can cause acute UV-blue phototoxicity. Operation microscopes and endoilluminators can cause acute macular injuries with brilliant illuminance of 20 000 lx or more. Epidemiological evidence linking age-related macular degeneration (AMD) to lifelong light exposure is currently inconclusive. Evidence showing a link between cataract surgery and progression of AMD is confounded by pseudophakes' intense operating microscope exposure during surgery and the fact that the risk of AMD is increased in cataract patients. Intraocular lenses that block violet and blue light in addition to UV radiation have recently been introduced. Their use is controversial because there is no clinical evidence that it decreases the risk of AMD and they partially block blue light that is useful for older adults' declining scotopic vision.

There are a wide variety of ophthalmic instruments that direct optical radiation into the eye for various applications. The term "optical radiation" includes ultraviolet, visible and infrared radiation. In its widest use, the term optical radiation covers the wavelength range of approximately 100 nm to 1 mm. While there are a number of product performance and user standards that are applicable to products that emit optical radiation, they cover only the region of interest from 250 nm to 2,5 µm.

Ophthalmic instruments can be used for diagnosis and treatment as well as for measurements, monitoring and observing the eye. New ophthalmic instruments using optical radiation are always being developed. Many ophthalmic instruments use intense optical radiation that is potentially hazardous. It is well known that optical radiation of sufficient intensity is capable of producing ocular damage. There have been numerous reports of ocular damage from the optical radiation emissions not only from the sun, but also from operation microscopes and endoilluminators used during ocular surgery as well as from lasers. See Bibliography [1] to [31]. While the majority of injuries from operation microscopes and endoilluminators produce minimal symptoms, scotoma and permanent central vision loss have occurred in some patients. See Bibliography [11].

In the case of photochemical damage, clinical changes are not immediately evident. Retinal edema or mild pigmentary changes are typically seen within one or two days of exposure and varying degrees of pigmentary modelling become more visible after one to three weeks. See Bibliography [18]. This is true with all photochemical damage. It should also be noted that it has been shown that photochemical damage follows a dose-response relationship with the risk of retinal damage increasing with increasing retinal exposure. In the case of operation microscopes, some studies have indicated that retinal injuries may occur with exposure times ranging from 20 min to 120 min, although a recent study suggests that retinal injuries can occur in exposure times of shorter duration. See Bibliography [49]. While the incidence of serious injury is unknown, it appears to be infrequent. There is yet more subtle damage that may occur that may not be noticeable or visible as a retinal lesion.

It should be noted that modern ophthalmic instruments use increasingly efficient light sources, such as tungsten, xenon and metal halide lamps. The emissions from such lamps have a higher colour temperature and emit significantly more blue light as well as ultraviolet radiation than those from traditional tungsten filament lamps. Unlike the older lamps, the light output from the new lamps does not diminish significantly in intensity throughout their longer life. See Bibliography [1]. Further, the optical radiation emissions from these new lamps can present a real hazard to the eye. As a result, ophthalmic instruments being used to examine or treat an eye can create the risk of physical damage to that eye. In this regard, studies show that the optical radiation emissions from some common ophthalmic instruments can exceed safety guidelines in relatively short exposure times. See Bibliography [19] and [36]. Those most at risk may be the elderly and infants, especially those with diseased eyes. The risk increases the longer the eye is exposed to the light. Ironically, it is generally the patient whose eye is not healthy that requires the longest examination. Since some ophthalmic instruments clearly present a risk of retinal damage and others present a potential risk for retinal damage, a number of safety performance standards have been developed.

Standards exist for the optical radiation safety of lamps and lamp systems (CIE S-009E:2002[53], IEC 62471:2006[56]) as well as a number of standards for the performance and safe use of lasers (e.g. IEC 60825-1[54] and IEC 60601-2-22[55]). Optical radiation safety limits for ophthalmic instruments are included in the performance standards for some of these instruments. Finally, there are standards for optical radiation safety in the work environment. However, there is no single comprehensive standard applicable to all ophthalmic instruments that direct optical radiation into or at the eye.

ISO 15004-2[52] has been developed to fill that void. It will be applicable to all ophthalmic instruments that are designed to direct optical radiation into or on to the eye for diagnostic or monitoring purposes. Its objective is to provide uniform requirements for such specific-use instruments. It is intended to establish minimal optical radiation safety specifications and requirements that will be useful to both manufacturers and users of the instruments.

The scope of ISO 15004-2[52] is intentionally broad. It covers ophthalmic instruments used for diagnosis of ocular disease, ocular monitoring instruments, lasers, continuous wave and pulsed light source instruments, and operation microscopes and endoilluminators. It is also intended to cover other medical diagnostic instruments such as ocular glucometers currently under development. It is not applicable to portions of instruments emitting radiation for treatment of the eye as these instruments are designed to produce damage and/or structural changes to the eye.

Ophthalmic instruments — Background for light hazard specification in ophthalmic instrument standards

1 Scope

The purpose of this Technical Report is to provide detailed information on the rationale behind the limit values and the requirements of ISO 15004-2[52]. The specifications in ISO 15004-2 are substantially revised from those in ISO 15004:1997[50].

2 Classification of instruments

Based upon experience in establishing conformance with current International Standards for ophthalmic instruments, it was deemed necessary to distinguish between ophthalmic instruments that do not emit potentially hazardous optical radiation from those that do. In the existing International Standards, i.e. those published before the introduction of ISO 15004-2, there is no distinction between such instruments. Consequently, the existing International Standards require that the optical radiation emissions from all instruments be characterized in the same way and measured with the same level of uncertainty. Manufacturers of **both** potentially hazardous **as well as** non-hazardous instruments are required to make spectral measurements with an uncertainty of less than $\pm$ 30 %, to determine the aphakic and blue-light radiance values for the instrument, and to report this information to the user. For non-hazardous instruments, these requirements are overly burdensome. There is no justifiable public health reason to require a manufacturer to report the radiance values for non-hazardous instruments. If anything, it would be sufficient for a manufacturer of an instrument that emitted non-hazardous optical radiation to simply inform the user that the optical radiation emitted from the ophthalmic instrument is not hazardous.

The new standard, ISO 15004-2, is based on the premise that it should not impose unnecessary requirements for instruments that emit non-hazardous optical radiation. With this in mind, ISO 15004-2 classifies instruments into two groups, Group 1 and Group 2, according to whether or not the instruments are potentially hazardous. Instruments in Group 1 are non-hazardous and are for unrestricted use. The only requirement for ophthalmic instruments in this group is to objectively demonstrate that they are non-hazardous. Instruments in Group 2 are potentially hazardous and are, therefore, subject to minimal requirements.

In addition, there are other ophthalmic instruments that by their design and function, emit such low levels of optical radiation that it can be readily documented without the need for any measurements that they are in Group 1. Examples of such instruments include ophthalmometers and perimeters. In some cases, the documentation can be obtained from the optical radiation emission specifications in the product-related International Standards for these instruments. In other cases, it may be shown that white light emitted from the instrument cannot exceed 10 000 cd/m^2 in order for the instrument to perform its intended function. The optical radiation emissions from such ophthalmic instruments would thus be below the emission limits for instruments in Group 1.

3 Time basis for limits for continuous wave instruments

There are separate emission limits for instruments in Group 1 and Group 2.

In Group 1, the limits are at a level such that the optical radiation emissions from instruments in Group 1 do not present any known potential optical radiation hazard. Consequently, there are no restrictions on the clinical use of such instruments.

The limits for most continuous wave instruments in Group 1 are based on a rationale of a 2 h exposure period. This rationale is based on the concept that a total exposure time, either from several different ophthalmic instruments with similar optical radiation emissions or from the same instrument during repeated examinations, could be as much as 1 h in a single day. This situation might occur in a teaching hospital when investigating an individual with interesting or unusual pathology. Unfortunately, patients with ocular pathology may have a higher risk of ocular damage from optical radiation than individuals whose eyes are healthy. While a 1 h cumulative examination is conceivable, it is believed that no examination would result in a total exposure time exceeding 2 h in a single day. The proposed limits, therefore, are based on a 2 h exposure period.

Instruments for which a 2 h exposure time is not appropriate include operation microscopes, endoilluminators, and patient monitoring instruments. In the case of operation microscopes and endoilluminators, it is conceivable that a total exposure time for complicated surgery might be in the order of several hours. An exposure from these instruments would rarely exceed 4 h in a single day. Therefore, the limits for these instruments are based on a 4 h exposure period. For instruments intended for continuous exposure in excess of 4 h, it is intended that the limit be based upon the longest maximum exposure time associated with the use of the instrument. Thus, for example, the limits, which are shown in Table 1 of ISO 15004-2:2007, shall be reduced by a factor equal to one half of the continuous exposure time, in hours, associated with the intended use of the instrument.

4 Emission limits

4.1 General

The limits specified in ISO 15004-2 are derived from the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines for human exposure to optical radiation. See Bibliography [48]. The limits are generally the same values provided by the American Conference of Governmental Industrial Hygienists[33] (ACGIH), upon which the previous International Standards were based. However, ACGIH has not provided specific guidance on how their limit values could be applied to ophthalmic instruments; whereas, ICNIRP has provided a document listed as [48] in the Bibliography. The ICNIRP and ACGIH limits are based on the same biological data. However, the ICNIRP document on ocular instruments has specified the limits for ophthalmic instruments and instruments that are designed to direct optical radiation into or at the eye. For ISO 15004-2, therefore, it is appropriate to use the ICNIRP limit/guideline.

In the ICNIRP Guidelines, it is noted that there are at least six separate types of optical radiation hazards to the eye from instruments that have a continuous wave output. They are:

1) UV injury to the cornea (photokeratitis) and lens (cataract) of the eye from optical radiation in the wavelength range 180 nm to 400 nm;

2) blue-light photochemical injury to the retina of the eye principally from optical radiation in the wavelength range 400 nm to 550 nm (305 nm to 550 nm for an aphakic eye);

3) thermal injury to the retina of the eye from optical radiation in the wavelength range 400 nm to 1 400 nm;

4) near-infrared thermal hazards to the lens, from optical radiation in the wavelength range from approximately 800 nm to 3 000 nm;

5) thermal hazards to the cornea and lens of the eye from focused beams and small beams with wavelengths over the wavelength range from 400 nm to 1 200 nm;

6) thermal injury (burns) to the cornea of the eye from optical radiation in the wavelength range from approximately 1 400 nm to 1 mm.

It is important to understand that some of the biological effects noted above are wavelength-dependent within the specified wavelength ranges. For example, UV radiation at 270 nm is 1 000 times more effective at producing photochemical injury to the cornea (photokeratitis) than is UV radiation at 320 nm. Retinal damage from blue light is yet another example. Blue light at 435 nm is ten times more effective at producing blue-light photochemical injury to the retina of the eye than is radiation at 500 nm. This wavelength dependence is described by a so-called action spectrum. An action spectrum is simply a functional description of the relative effectiveness of radiation as a function of wavelength for producing a biological endpoint. It is usually presented as a tabulation of the ratio of the dose at specific wavelengths to the dose at the most effective wavelength for producing the biological endpoint.

Evaluating the potential hazards that may be associated with an instrument for a wavelength-dependent biological endpoint is usually accomplished by calculating a so-called effective irradiance or effective radiant exposure. The effective irradiance for ultraviolet radiation, for example, is given by the expression:

$$E_{\text{eff}} = \sum_{\lambda_1}^{\lambda_2} E_\lambda \times S(\lambda) \times \Delta\lambda$$

where

E_{eff} is the effective ultraviolet irradiance;

E_λ is the spectral irradiance;

$S(\lambda)$ is the biological weighting factor at wavelength λ for UV photochemical injury to the cornea (photokeratitis);

$\Delta\lambda$ is the wavelength summation interval;

where the summation is over the specified wavelength range from λ_1 to λ_2.

The other wavelength-dependent dose-related quantities including effective radiant exposure, effective radiance and effective integrated radiance all use similar expressions.

It is also important to note that the limit/guideline specified below are based on data for healthy eyes. It does not take into account persons with diseased eyes, infants, or individuals who are photosensitized. These individuals may be more susceptible to ocular damage than individuals with healthy eyes.

Finally, it is important to note that in evaluating limits for scanning optical radiation such as that from scanning lasers, the length of the scan will determine if the radiation is to be treated as continuous wave or pulsed optical radiation. If the scan length is greater than the specified measurement aperture, the radiation is considered to be pulsed radiation. If the length of the scan is completely contained within the specified measurement aperture, the radiation is considered to be continuous wave radiation. However, the scanning pattern may be of such a nature that when scanned across a circular measurement aperture, the scan length may be partly inside the aperture during a portion of the scan and partly outside of the aperture during other portions of the scan. In such a case, the optical radiation may need to be considered as pulsed radiation with varying pulse widths. Also, the limits are to be evaluated for each pulse and every combination of pulses as prescribed in this Technical Report.

4.2 Ultraviolet radiation limits for Group 1 and Group 2 instruments

As noted in 4.1, UV photochemical injury to the cornea (photokeratitis) is wavelength-dependent. The threshold for producing a transient but acute photokeratitis is an effective radiant exposure of 4 mJ/cm^2 in one day. See Bibliography [37]. In this case, the effect is dose-dependent and cumulative. The weighted corneal ultraviolet radiation radiant exposure limit recommended by ICNIRP is 3 mJ/cm^2 in one day for Group 2 instruments. This limit must be evaluated for all times, t, up to 7 200 s unless there is a vertical standard which specifies that the limit be evaluated up to a different time, t.

It should be noted that there is only a very limited safety factor for this limit. Such a small safety factor has been deemed to be acceptable because photokeratitis at an exposure level of 4 mJ/cm^2 in one day is probably a transient event and does not result in permanent damage. When taking exposure times into account, the limit recommended by ICNIRP for Group 1 instruments is 0,4 µW/cm^2. (See time basis for limits above.) An effective irradiance level of 0,4 µW/cm^2 would result in an effective radiant exposure of 3 mJ/cm^2 in 2 h.

The rationale for the differences between the Group 1 and Group 2 limits is based on several factors. They include the nature and mechanism of the tissue damage and safety factors between tissue damage and limits.

The Group 1 limit for weighted corneal and lenticular ultraviolet irradiance over the wavelength range 250 nm to 400 nm, other than operation microscopes, endoilluminators, and monitoring instruments, is 0,4 µW/cm^2. For the exposure time basis of 2 h for instruments in Group 1, the radiant exposure is allowed to be as high as the Group 2 limit of 3 mJ/cm^2.

However, as noted in selecting the time basis for instruments in Group 1, while it is believed that a one hour exposure time in one day is conceivable, it is believed that no examination would result in a total exposure time exceeding 2 h in a single day. Therefore, it is not likely that the radiant exposure from a Group 1 instrument would ever be equal to or exceed the Group 2 limit. The probable transient nature of the damage was considered in developing the Group 1 and Group 2 limits with minimal safety requirements in mind.

There is a second UV radiation criterion that must be taken into account; namely, to provide protection to the lens of the eye from both thermal and possible, but unknown, photochemical damage. The threshold for producing acute UV cataracts is on the order of 100 mJ/cm^2 at wavelengths in the range 300 nm to 305 nm, with an action spectrum extending from about 290 nm to 325 nm. See Bibliography [39] and [40]. Depending upon the wavelength, between 300 nm and 305 nm, the level that will produce an acute cataract is 2 to 10 times greater than the level that will produce photokeratitis at those wavelengths. However, because of the very narrow action spectrum for producing acute cataracts, ICNIRP recommended that UV radiation below 360 nm be eliminated to the extent that is reasonably possible. It is believed that the effective irradiance limit noted above would satisfy this criterion.

Further, the threshold for damage to the lens of the eye is 33 J/cm^2 at 359 nm. See Bibliography [41]. The ICNIRP Guidance document notes that irradiance levels of 1 mW/cm^2 for very lengthy periods (8 h) would be very acceptable for UV radiation in the wavelength range 360 nm to 400 nm. In support of this limit, it should be noted that the eye is routinely exposed to such levels outdoors. See Bibliography [38]. Finally, an irradiance of 1 mW/cm^2 is below the effective irradiance limits for all wavelengths greater than 320 nm. For these reasons, ICNIRP recommended a limit of 1 mW/cm^2 for the wavelength range 360 nm to 400 nm for Group 1 instruments. ICNIRP also recommends a limit of 1 J/cm^2 for times less than 1 000 s and a limit of 1 mW/cm^2 for times greater than or equal to 1 000 s for Group 2 instruments. It should be noted that the radiant exposure limit in this case need only be evaluated for all times up to 1 000 s for the radiant exposure limit of 1 J/cm^2. The fact that some common photosensitizers are activated by optical radiation in the UV-A wavelength range (320 nm to 400 nm) was taken into account in recommending this limit.

For the reasons noted above, it was deemed appropriate, keeping in mind the concept of minimal requirements, to set irradiance levels for the wavelength range 360 nm to 400 nm for both Group 1 and Group 2 at an irradiance of 1 mW/cm^2. In addition, a radiant exposure of 1 J/cm^2 for exposure durations less than 1 000 s was set for Group 2 instruments to allow for greater flexibility for instruments in this Group. This radiant exposure limit allows for higher irradiance levels for shorter periods of time.

4.3 Visible radiation limit for Group 1 instruments

As noted earlier, blue-light photochemical injury to the retina of the eye is also wavelength-dependent. The threshold for producing a visible retinal lesion is a retinal radiant exposure of 22 J/cm^2 at 440 nm and 3 J/cm^2 at 320 nm. See Bibliography [42]. For Group 1, ICNIRP recommends that the aphakic weighted radiance limit be 2 mW/(cm^2 sr) with an equivalent weighted aphakic retinal irradiance of 220 µW/cm^2. Such an exposure from Group 1 instruments would not exceed the threshold for producing a visible retinal lesion in a 2 h time

period. Bearing in mind that a visible retinal lesion will be produced by a retinal radiant exposure of 22 J/cm^2 at 440 nm, a retinal exposure limit of 220 μW/cm^2 provides a safety factor slightly greater than ten.

It should be noted here that ISO 15004-2[51] does not contain a limit for visible radiation for Group 2 instruments as explained below. It should also be noted that there is a significant difference from previous International Standards in the presentation of the retinal hazard limits. In order to provide measurement flexibility, the limits for retinal hazards for instruments in both Group 1 and Group 2 are expressed as equivalent retinal irradiance or radiant exposure and radiance or integrated radiance.

It should be noted that the 2 h exposure time period used for classifying instruments in Group 1 results in a time-integrated radiance of 14,4 J/(cm^2 sr). This time-integrated radiance is a factor of seven times lower than the Group 2 guideline. Thus, it is highly unlikely that the integrated radiance from a Group 1 instrument would ever be equal to or exceed the Group 2 limit.

4.4 Infrared radiation limits for Group 1 and Group 2 instruments

Infrared radiation of sufficient intensity is absorbed by the lens and produces damage by degradation of the lens proteins. The unweighted corneal and lenticular infrared radiation irradiance limit is based upon an irradiance level that has been found to produce a cataract on the lens. For example, an irradiance of 1 W/cm^2 for 60 s at the cornea from a continuous wave ND-YAG laser at a wavelength of 1,06 μm was sufficient to elevate the temperature immediately behind the iris to form a cataract on the anterior surface of the lens. See Bibliography [43]. In addition, glass and steel industry workers exposed chronically for 10 y to 15 y to infrared radiation irradiance levels of 80 mW/cm^2 to 400 mW/cm^2 have developed cataracts. See Bibliography [44]. An unweighted corneal and lenticular infrared radiation irradiance limit of 100 mW/cm^2 is recommended by ICNIRP for Group 2 instruments since that irradiance level is well below the level required to produce an acute injury to the anterior ocular structures. ICNIRP also recommended an irradiance level of 10 mW/cm^2 for Group 1 instruments. This level is well below levels that are known to produce chronic injury.

Focused visible and near infrared radiation of sufficient intensity can produce damage to the lens of the eye. The unweighted anterior segment visible and infrared radiation irradiance will be applicable only to instruments that produce a convergent beam on the cornea and lens of the eye. The limits are based upon an injury threshold irradiance of 42 W/cm^2 for an exposure time of 5 s in a 1,4 mm spot size at a laser wavelength of 1,3 μm. See Bibliography [45]. Based upon this data, ICNIRP recommended an unweighted anterior segment visible and infrared radiation irradiance of 20 W/cm^2 for Group 2 instruments and 4 W/cm^2 for Group 1 instruments. The factor of 5 between the Group 1 and Group 2 limits for $E_{\text{IR-CL}}$ and $E_{\text{VIR-AS}}$ is deemed to provide an acceptable separation between Group 1 and Group 2 instruments given the nature of thermal damage to the cornea and lens and thermal damage thresholds.

Finally, optical radiation can cause thermal injury to the retina. When assessing the retinal hazard created due to light entering the eye, one of the critical factors is the irradiance value occurring in the area illuminated on the retina. If the light entering the eye is in a beam that is essentially collimated and coming from a small area source, the wavefront of the light entering the eye may be considered to be a plane wave and the area of the retina thus illuminated can approach the diffraction limit. In the case of a real eye that has been well corrected for sphero-cylindrical error, the residual, higher order aberrations will not allow a diffraction limited point spread to form if the pupil of the eye is greater than 2,5 mm to 3 mm in diameter. However, in the cases of collimated beams from small sources that have a cross section diameter larger than 3 mm as they enter the eye, a good approximation of the point spread on the retina may be found by assuming that its size is that of a diffraction limited point spread pattern for a 3 mm pupil. This image size will be taken here to represent the smallest and hence most hazardous condition for the retina for radiation damage.

The diffraction limited pattern for a circular aperture is an Airy disk, whose cross section takes the form of the square of a Bessel function of the first kind, order 1 divided by the radial distance from the centre of the pattern, i.e.

$$I(r) = I_0 \left[2 \frac{J_1(kar/f)}{(kar/f)} \right]^2$$

where

a is the radius of the pupil aperture;

f is the distance from the pupil aperture to the focal plane where the pattern forms and $k = 2\pi/\lambda$.

This pattern first takes the value 0 at a distance from the centre, r_0, equal to

$$r_0 = \frac{0{,}61\lambda f}{na}, \text{ or a diameter, } d_0 = \frac{1{,}22\lambda f}{na} \quad (1)$$

where

n is the refractive index of the material where the pattern forms;

λ is the wavelength of light;

f is the distance from the pupil aperture to the focal plane where the pattern forms.

It so happens that in this area the Airy pattern is very closely matched by a Gaussian pattern whose $1/e^2$ radius is equal to $r_0/\sqrt{2}$. To simplify calculations then, the Gaussian pattern shall be used instead of the Airy pattern so that the irradiance, $E(r)$, takes the form

$$E(r) = E(0)e^{-4\left(\frac{r}{r_0}\right)^2} \quad (2)$$

If the small illuminated area associated with diffraction limited imaging were to be stationary on the retina, the irradiance could be simply found by dividing the total energy entering the eye by that area, defined for these purposes as the area of a disc of diameter d_0. However, the eye is never stationary and so this small spot is continually scanned over the retinal surface as the eye executes small motions known as *saccades*. These motions consist of rapid movements interspersed with very brief stationary periods lasting from a millisecond up to about 100 ms. The effect on irradiance is that of creating an effective irradiated area that is larger than the diffraction pattern. To get an estimate of this effective area in a way that can be useful for hazard analysis, the position of fixation as the result of the saccades can be expressed as the statistical probability of the centre of the irradiation pattern or area being displaced from a mean position by assuming a probability function of position. It is reasonable to assume that this probability function, $P(r)$, takes the form of a standard distribution, i.e. a Gaussian form with a standard deviation σ, so that

$$P(r) = e^{-\frac{1}{2}\left(\frac{r}{\sigma}\right)_2} \quad (3)$$

Having assumed a Gaussian form for the irradiation pattern and a Gaussian probability function for the position of that pattern, the effective pattern will now be expressed as the convolution of these two patterns thereby representing the fact that energy is being delivered by a Gaussian irradiance pattern as that pattern moves in the statistical way given by the probability function and thus builds up a hazard condition in the retinal tissue.

As is well known, the Fourier transform of a convolution is equal to the product of the Fourier transforms of the two functions that form the convolution. Thus

$$Fo\ (E \times P) = Fo\ (E)\ Fo\ (P) \quad (4)$$

As is also well known, the Fourier transform of a Gaussian function is another Gaussian function given by

$$Fo\left(e^{-ar^2}\right) = \sqrt{\frac{\pi}{a}}e^{-\frac{w^2}{4a}} \quad (5)$$

Therefore, in light of Equations (4) and (5), the Fourier transform of the convolution of two Gaussian functions, e^{-ar^2} and, e^{-br^2} is found to be

$$Fo\left(e^{-ar^2}\times e^{-br^2}\right)=\sqrt{\frac{\pi}{a}}e^{-\frac{w^2}{4a}}\sqrt{\frac{\pi}{b}}e^{-\frac{w^2}{4b}}=\frac{\pi}{\sqrt{ab}}e^{-\frac{w^2}{4}\left(\frac{1}{a}+\frac{1}{b}\right)}=\frac{\pi}{\sqrt{ab}}e^{-\frac{w^2}{4}\left(\frac{a+b}{ab}\right)}$$

Now if the quantity $ab/(a+b)$ is defined as c, the above equation may be written as

$$Fo\left(e^{-ar^2}\times e^{-br^2}\right)=\left(\frac{\sqrt{\pi c}}{\sqrt{ab}}\right)\sqrt{\frac{\pi}{c}}e^{-\frac{w^2}{4c}}$$

But the expression on the right hand side of this equation is recognized as the Fourier transform of the Gaussian function

$$\left(\frac{\sqrt{\pi c}}{\sqrt{ab}}\right)e^{-cr^2}=\sqrt{\frac{\pi}{a+b}}e^{-\frac{abr^2}{a+b}}$$

where the definition of c has been used along with Equation (5). Thus it is seen that the function created by the convolution of two Gaussian is itself a Gaussian function with exponential constant given by $ab/(a+b)$.

This result is now used to directly write an expression for the effective retinal irradiance distribution created by the convolution of a Gaussian irradiation pattern and a position probability function of that irradiance pattern caused by saccadic eye movements. From Equations (2) and (3) for E and P the values of the exponential constants a and b are

$a = 4/r_0^2$

$b = 1/2\sigma^2$

so that the exponential constant for the convolution, c, is

$$c=\frac{ab}{a+b}=\frac{\left(4/r_0^2\right)\left(1/2\sigma^2\right)}{4/r_0^2+1/2\sigma^2}=\frac{4}{8\sigma^2+r_0^2} \tag{6}$$

Now this constant is expressed in terms of an effective image radius r_e, i.e. $c = 2/r_e^2$, so that it is found that $r_e = 4\sigma^2 + r_0^2/2$, or, $r_e=\sqrt{4\sigma^2+r_0^2/2}$.

Expressed as an effective diameter this result is $d_e=2\sqrt{4\sigma^2+r_0^2/2}$.

To assign representative values to the effective image size, let us take the case of light at a near infrared wavelength, λ = 0,785 µm, forming a diffraction limited pattern on the retina from a 3 mm diameter pupil and use for position data the smallest value for standard deviation (horizontal–fixed head) from Steinman[47] of 11 µm.

The value to use for r_0, found by using Equation (1) with values of 1,336 for n and 17 mm for f, is then

$$r_0=\frac{0{,}61\lambda f}{na}=\frac{0{,}61(0{,}785)17}{1{,}336(1{,}5)}=4{,}06\ \mu\text{m}$$

The effective diameter of irradiation area is then found to be

$$d_e = 2\sqrt{4\sigma^2 + r_0^2/2} = 2\sqrt{4(11)^2 + 4{,}06^2/2} = 44{,}4\ \mu m$$

If the wavelength is changed to be in the mid-visible, λ = 0,555 µm, r_0 = 2,87 µm and d_e is found to equal 44,2 µm. Thus it is the motion of the eye that dominates the value of the effective irradiation area for diffraction-limited or quite small retinal patterns.

If, on the other hand, only saccades of the type referred to as *nystagmus* – very small, high frequency motions – are considered as the source of spot movement on the retina during short exposures, then the value for motion is given as about 7 µm. See Bibliography [44]. These motions occur at frequencies of 50 Hz to 100 Hz and so, if they are discontinuous, occur every 10 ms to 20 ms. This value is in accord with the 22 ms duration value given by Steinman[47]. If this lower value for motion is taken as the standard deviation, then the calculated values for the effective diameter become 28,3 µm and 28,6 µm for the wavelengths of 555 nm and 785 nm respectively, showing that again it is the motion that sets the value for the effective diameter, and not the wavelength used.

The considerations given above indicate that a reasonable lower limit for the diameter of the retinal irradiated area to use to find retinal irradiance for use in hazard analysis is 0,030 mm.

Irradiance levels of 1 W/cm^2 to 1 000 W/cm^2, depending upon spot size, can produce retinal damage. See Bibliography [46]. Based on this injury data, ICNIRP recommended a retinal irradiance limit of 1,2/d_r W/cm^2 limit for the weighted retinal visible and infrared radiation thermal irradiance for Group 2 instruments. The symbol d_r is the retinal image size expressed in millimetres. The corresponding instrument radiance limit is 10/d_r W/(cm^2 sr). For Group 1 instruments, ICNIRP recommended a retinal irradiance limit of 0,7 W/cm^2 with a corresponding instrument radiance limit of 6 W/(cm^2 sr).

There are three additional types of optical radiation hazards to the eye from instruments that have a pulsed output. They are:

1) a thermal-weighted, retinal-visible and infrared radiation-radiant exposure from optical radiation over the wavelength range from 400 nm to 1 400 nm for emission durations from 10 µs to 0,25 s;

2) an unweighted-corneal and lenticular infrared radiation-radiant exposure from optical radiation over the wavelength range from 770 nm to 2 500 nm;

3) an unweighted corneal and lenticular infrared radiation-radiant exposure from instruments that produce a focused beam at the cornea and lens from with radiation over the wavelength range from 400 nm to 1 200 nm.

The exposure limits for pulsed instruments are based on the American Conference of Governmental Hygienists Threshold Limit Values[33] to provide protection to the cornea, lens and retina of the eye with pulsed optical radiation at wavelengths from 400 nm to 1 400 nm.

It should be noted that the Group 2 limit is the same as Group 1 limit at d_r = 1,7 for $L_{VIR\text{-}R}$ and $E_{VIR\text{-}R}$ for continuous wave instruments and for $H_{VIR\text{-}R}$ and $L_{VIR\text{-}R}$ for pulsed instruments. For these cases, the Group 1 limit was selected to represent the worst case scenario at the maximum diameter of 1,7 mm. However, the Group 2 limit is allowed to vary with decreasing spot size with the concept of minimal requirements in mind. This allows for higher limits for spot sizes on the retina smaller than the spot size with a maximum diameter of 1,7 mm.

Finally, the Group 1 limit was set to be the same as the Group 2 limit for $H_{IR\text{-}CL}$ and $H_{VIR\text{-}AS}$ for pulsed instruments because of the nature of infrared thermal damage associated with pulsed radiation on the cornea and lens while keeping the concept of minimal requirements in mind. It is important to note that limits that contain time, t, for pulsed sources need to be evaluated for all times up to 20 s unless there is a vertical standard which specifies that the limit be evaluated up to a different time, t.

4.5 Limit for multiple source instruments

It should be noted here that this Technical Report requires that for multiple source instruments which are designed to direct optical radiation on to the same point(s) of the eye, the optical radiation emissions shall be below all applicable limits for each light source alone. In addition, this Technical Report requires that for all intended consecutive and/or simultaneous use of the light sources within an 8 h period, the sum of the ratios of the optical radiation emitted over a specified wavelength range to the applicable limit for the optical radiation for the specified wavelength range shall be less than one. This requirement is especially important for new instruments which use multiple light sources and for other instruments such as fundus cameras which use both an illumination and a pulsed flash light source. This requirement is intended to take into account the combined potential risks from consecutive or simultaneous exposure of the same ocular tissues from multiple sources within a single instrument.

4.6 Visible light exposure guideline for Group 2 instruments

Visible light is necessary for diagnosis of ocular pathology. It is commonly used in instruments such as direct and indirect ophthalmoscopes, slit lamps, 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 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 radiation, rather than a limit, has been set, so that clinicians are informed about potential optical radiation hazards that may be associated with the use of their instruments. This requirement, of course, is only applicable for instruments in Group 2 since instruments in Group 1 are non-hazardous.

As noted earlier, blue-light photochemical injury to the retina of the eye is wavelength-dependent. Based on the threshold data for producing a visible retinal lesion of a retinal radiant exposure of 22 J/cm^2 at 440 nm and 3 J/cm^2 at 320 nm, the aphakic weighted retinal radiant exposure hazard level recommended by ICNIRP is 10 J/cm^2 for instruments in Group 2. The corresponding integrated radiance is 100 J/(cm^2 sr).

5 Averaging apertures

The limits for retinal radiant exposure are evaluated by averaging the highest localized radiant energy incident upon a circular area at the retinal plane with a diameter of 0,180 mm (or 0,030 mm for an immobilized eye). As with all similar apertures, it is intended that these apertures be viewed as sampling apertures. They are used to scan the retina to identify the maximum radiant energy that can be collected in a 0,180 mm diameter circle (or 0,030 mm for an immobilized eye). It should be noted that an averaging aperture of 0,180 mm is equivalent to a measurement instrument field-of-view of 11 mrad. This takes into account the movement associated with an eye that is not immobilized. A 0,030 mm aperture is equivalent to a measurement instrument field-of-view of 0,017 5 mrad; this takes into account an eye that is immobilized. ISO 15004-2 does not require that a measurement actually be made of the radiant energy collectible through the aperture. For a homogeneous spatial beam profile on the retina, for example, dividing the radiant energy that can be collected in an area of a 0,180 mm diameter circle (or 0,030 mm for an immobilized eye) is equivalent to the total radiant energy divided by the area of the retina irradiated. It is intended that the 0,030 mm sampling aperture be used for instruments that may produce a hot spot on the retina. However, these apertures require that the spatial beam profile on the retina be sufficiently well characterized so that the radiant energy in hot spots as small as 0,030 mm can be identified.

It should be noted here that the 0,030 mm averaging aperture for evaluating retinal exposures need only be used in special cases where a small spot is intentionally focused on the retina such as might occur when light from a highly collimated laser beam or a point source is directed on to the eye or when an eye is immobilized so that all saccadic movements are suppressed. Another example of where the 0,030 mm averaging aperture needs to be used is when a small spot can be focused on a single point for an instrument that uses an eye tracker. In the case of an instrument that uses an eye tracker, eye movements are tracked such that the spot is maintained on a single point on the eye.

The averaging aperture to evaluate the potential hazards to the cornea and lens is 1 mm. This averaging aperture is deemed to be sufficient to evaluate the thermal and photochemical risks for small spots on the cornea and lens based on considerations of heat flow and scattering within the layers of tissue. Similarly,

based on heat flow and scattering considerations, the averaging aperture for thermal retinal irradiance limits is 0,03 mm.

Finally, it should be noted that an instrument field of view is specified for measurement of radiance instead of a measurement aperture. The fields of view specified for the determination of source radiance are equivalent to the averaging apertures specified to determine the retinal radiant exposure.

6 Requirements

6.1 Measurement requirements and test certifications of components

There are measurement requirements for instruments in both Group 1 and Group 2. However, in regard to the measurement requirements, ISO 15004-2 allows test certifications of components to be used in place of measurements. Test certifications of the optical characteristics of components in the device such as the transmittance of filters or spectral emission curves of light sources, may be used to document that the emissions from the instrument are below the limits specified. It is intended that such test certifications would make it unnecessary to make certain measurements, and in some cases, any measurements at all. The use of test certifications in this way is consistent with the philosophy of minimal requirements for ISO performance standards.

An example where no measurements would be needed is the case in which a test certification that the luminance of a single white light source in an instrument is less than 10 000 0 cd/m^2. Such a test certification would be sufficient to document that the optical radiation emissions are below all Group 1 limits, and no measurements are required if this is the only light source used in the instrument.

As another example, consider the case of an instrument with a fixation light that uses a white light LED with a 2 mm diameter diffuse emitting surface and that has a certified radiant intensity of 2,0 mW/sr. The exit aperture to eye distance in normal use is 100 mm. The LED is located behind neutral density filters that are certified to provide two orders of magnitude of attenuation resulting in a radiant intensity of 0,02 mW/sr emitted from the light source. The white light LED is certified to not emit radiation at wavelengths below 400 nm and above 700 nm.

In this case, the radiance is given by dividing the attenuated radiant intensity by the area of the 2 mm diameter diffuse radiating surface. Thus, the radiance is 0,64 mW/(cm^2 sr) since the area of the 2 mm diameter surface is 0,031 4 cm^2. This value is a factor of three times below the 2 mW/(cm^2 sr) limit for instruments in Group 1. In this example, no measurements would be required since based on the certified components that are used; the levels are well below the limits for instruments in Group 1.

However, it is possible in this case, to make luminance measurements to document that the white light emitted is below the limit for instruments in Group 1. For measurements of the white light emissions, this Technical Report requires that they be made with an instrument with a field of view of 11 mrad. This means that the field of view of the luminance meter would be limited to a diameter of 1,1 mm on the radiating surface of the source since the exit aperture to patient distance is 100 mm. However, since the light emitted is homogeneous over the emitting surface, it is not critical in this case that an 11 mrad field of view be used. In this case, it is only necessary that the field of view be limited to the diameter of the emitting surface.

For the purpose of simplicity for explaining the concepts involved, consider the case of a green fixation light instead of a white fixation light. A measurement of luminance for this green fixation light yields a value of 0,44 cd/cm^2 or 0,44 lm/(cm^2 sr). For a worst case analysis, it may be assumed that all of the light is emitted at the peak wavelength of the visual response function at 553 nm. Using the relationship that 1 W at 553 nm results in 683 lm, a worst case radiance value of 0,64 mW/(cm^2 sr) is determined. Thus, if a luminance measurement is made, it is possible to show that the radiance would be well below the radiance limit of 2 mW/(cm^2 sr).

Finally, one could also determine that the green fixation light emissions are below the Group 1 limit by taking a measurement of illuminance. In this example, luminance may be determined by measuring the luminous flux that is transmitted through two apertures spaced a well known distance, z, apart using the relationship

$$L_{\mathrm{v}} = \frac{\Phi_{\mathrm{v}} \times z^2}{A \times a}$$

where

L_{v} is the luminance;

Φ_{v} is the luminous flux;

a is the area of the first aperture;

A is the area of the second aperture.

The illuminance meter would be located at a distance of 100 mm from the fixation light. In this case, the 11 mrad field of view requires that an aperture with a 1,1 mm diameter be placed over the emitting surface of the fixation light.

The illuminance at a distance z = 100 cm from the light source is given by

$$E_{\mathrm{v}} = \frac{\Phi_{\mathrm{v}}}{A}$$

so that the formula for luminance becomes,

$$L_{\mathrm{v}} = \frac{E_{\mathrm{v}} \times z^2}{a} = E_{\mathrm{v}} \frac{(10)^2}{\pi(0{,}055)^2}$$

$$L_{\mathrm{v}} = E_{\mathrm{v}} \frac{(10)^2}{\pi(0{,}055)^2}$$

All that needs to be done then is to measure the illuminance at distance z = 10 cm for the determination of the source luminance using an aperture of 1,1 mm over the diffuse source. This method takes into account the 11 mrad field of view.

For this example, the illuminance measured, E_{v} is $0{,}42 \times 10^{-4}$ lm/cm^2 or 0,42 lx. Using the above equation, this illuminance yields a luminance of 0,44 lm/(cm^2 sr). It should be noted here that the illuminance measured in this case is a factor of 3,3 times lower than the total illuminance of the LED because a portion of the radiating area is masked by the 1,1 mm aperture. The illuminance for this homogeneous source is reduced by the ratio of the area of the 1,1 mm diameter aperture over the source to the area of the 2 mm diameter radiating area of the LED. For this green light LED, the radiance of the LED is given, as in the calculation above, by the ratio of the luminance of 0,44 lm/(cm^2 sr) to 683 lm/W at 553 nm yielding 0,64 mW/(cm^2 sr).

If the luminance of a broadband source is measured and the relative spectral power distribution is known, the spectral radiance and the total radiance of the source can be determined using the following relationships.

$$L_{\mathrm{v}} = 683 \int_{380}^{770} L_{\lambda} \times V(\lambda)\, \mathrm{d}\lambda = 683 \sum_{380}^{770} L_{\lambda\mathrm{peak}} \times f(\lambda) \times V(\lambda) \times \Delta\lambda$$

where

L_{v} is the luminance of the source;

L_{λ} is the spectral irradiance at wavelength λ of the source at distance z;

$V(\lambda)$ is the visual response function;

$d\lambda$ is the infinitesimally small wavelength interval;

$\Delta\lambda$ is the summation interval;

$L_{\lambda peak}$ is the spectral irradiance at the peak of the spectral irradiance curve and is a constant;

$f(\lambda)$ is the relative spectral power distribution with f_λ being 1 at λ_{peak}.

$$L_\lambda = L_{\lambda peak} \times f_\lambda .$$

From these equations, and when L_v can be measured and f_λ is known, $L_{\lambda peak}$ can be determined and is used to determine L_λ. Once L_λ is known, L and L_A can be determined using the equations

$$L = \sum_{380}^{700} L_\lambda \times \Delta\lambda$$

and

$$L_A = \sum_{380}^{700} L_\lambda \times A(\lambda) \times \Delta\lambda$$

It is important to emphasize that measurements of visible light emissions are only needed when a test certification sheet for a light emitting diode (LED), for example, shows that light is only emitted in the visible wavelength range. Such a test certification sheet would be sufficient to document that there are no ultraviolet or infrared radiation emissions. No measurements of ultraviolet and infrared radiation emissions are required in this case if this is the only light source used in the instrument.

6.2 Measurement requirements for Group 1 instruments

The only requirement for Group 1 instruments in ISO 15004-2 is to objectively demonstrate that the emissions from the instrument are below limits specified for continuous wave instruments (Table 1 of ISO 15004-2:2007) and for pulsed instruments (Table 2 of ISO 15004-2:2007). In some cases involving pulsed instruments that can be operated for extended periods of time, it will be necessary to demonstrate that the emissions are below the limits specified for both continuous wave and pulsed instruments. In addition, it is also intended that the manufacturer should have flexibility in documenting that the emissions are below the limits. This is achieved with a flexible uncertainty specification for measurements to determine if an instrument is in Group 1. In this case, the proposed requirement specifies that the uncertainty in the measurements must be less than the difference between the limit and the measured value. Thus, very large uncertainties, even uncertainties of orders of magnitude, are allowed. The specification simply requires that the sum of the measured value and the uncertainty be less than the limit.

As noted above, the only requirement for Group 1 instruments is to objectively establish that emissions are below **all** the limits in this group. Simple radiometric measurements and/or calculations and test certifications of components as described above are recommended where possible. Instruments in Group 1 are exempt from all other requirements specified in ISO 15004-2.

Finally, careful measurements to determine if an instrument is in Group 1 will only be needed for instruments whose emissions are close to the limits specified for this group. In this regard, it is expected that manufacturers of instruments with emissions well below the limits may be able to use broadband instruments to demonstrate that their instruments are below the limits and, therefore, in Group 1. In some cases, a measurement of illuminance with a light meter may be the only measurement needed to demonstrate that an instrument is in Group 1. In the case of an instrument that uses a low wattage tungsten bulb operating at a low colour temperature around 2 300 K, for example, calculations based on the illuminance data may be sufficient to document that the emissions are below all the limits specified for Group 1.

At first glance, it may seem like a difficult task to determine if an instrument is in Group 1 or Group 2. A first step in evaluating if an instrument is in Group 1 would be to evaluate the radiometric quantity where the highest emission is expected. If the measured value is below the limit for that quantity, the procedure would then be to systematically evaluate the radiometric quantities for the remaining emissions. If the measured or calculated values are below **all** the limits specified, the instrument is in Group 1. To determine that an instrument is in Group 2, it is only necessary to demonstrate that the optical radiation emissions exceed one of Group 1 limits. If so, then ISO 15004-2 requires the manufacturer to objectively establish that emissions from the instrument are below all applicable emission limits specified.

6.3 Requirements for Group 2 instruments

6.3.1 Measurement requirements

The manufacturer of Group 2 instruments must objectively establish that all the emissions from the instrument are below all specified applicable emission limits. As noted in 6.1, ISO 15004-2 allows test certifications for components to be used in place of measurements. Test certifications of the optical characteristics of components in the device such as the transmittance of filters or spectral emission curves may be used to document that the emissions from the ophthalmic instrument are below the limits specified for Group 2 instruments. Such test certifications would make certain measurements unnecessary.

It should be noted that ISO 15004-2 specifies that when measurements are needed, the uncertainty in the measurements shall be less than ± 30 %.

6.3.2 Time and/or number of pulses to reach a potential optical radiation hazard

ISO 15004-2 requires manufacturers to determine the time or number of pulses to reach a potential hazard for effective aphakic retinal radiant exposure for Group 2 instruments. The requirement is based upon the belief that the user should have information about the potential hazards that may be associated with a potentially hazardous instrument. This information will allow the user to take appropriate action to minimize the risk associated with the use of the instrument if he chooses to do so.

6.3.3 Variable intensity requirement

Where provision is made to vary intensity, in order that the user know what proportion of the total light is being used, an indication shall be provided both of the maximum intensity and fractions thereof. This will allow the user to determine safe exposure times for reduced settings.

7 Particular information

ISO 15004-2 incorporates informational requirements that are applicable to instruments in Group 2. Spectral information should be provided by the manufacturer, on request, to users who believe that spectral information is needed for safe use of the instrument for specific patients. With this information, a user may wish to modify the optical radiation emissions to further reduce the potential risks that may be associated with the use of the device.

Alternatively, a user may wish to select an instrument with a specific spectral power distribution for use in a particular situation. This may be especially important both in the management of medical conditions and complications, and in medical research. At the same time, it is also believed that manufacturers should **not** be required to provide technical information to the user that may not be needed or useful. Unlike ISO 15004[50] the new standard ISO 15004-2[52], therefore, does not require the manufacturers to provide all users with this information. It does, however, require that a graph of relative spectral output between 305 nm and 1 100 nm at maximum intensity and aperture be provided upon request from the user.

ISO 15004-2 requires the manufacturer to provide the user with information on the time to reach a potential optical radiation hazard dose for instruments with continuous visible light output and the number of pulses for instruments with visible pulsed light output. It also requires that this safety information be provided in the safety information section of the user manual.

8 Test methods

The uncertainty associated with measurements to determine if instruments are in Group 1 is not a fixed value. In this case, the uncertainty in the measurements must be less than the difference between the emission limit and the measured value. As noted earlier, the measurement uncertainty can be very high. This requirement is designed to provide relief from complex and expensive measurements for evaluating instruments, such as ophthalmometers and perimeters, whose optical radiation emissions are very low and not potentially hazardous. This requirement is consistent with the concept of minimal requirements.

For instruments in Group 2, the uncertainty requirement for measurement of optical radiation is $\pm$ 30 %. It is believed that potentially hazardous optical radiation emissions from instruments designed to direct their optical radiation in or on the eye should be characterized with the greatest possible accuracy. The values specified in this Technical Report are technologically feasible and take into account the uncertainty and the variability in the biological data from which the limits were derived. As in the first edition of ISO 15004, the measurement uncertainty for determination of area shall be $\pm$ 30 % or better. Methods described in a recent IEC standard[56] published in 2006 should be used for estimating uncertainty in optical radiation data.

9 Annexes of ISO 15004-2

9.1 Annex A is a normative annex and contains the spectral weighting functions used for evaluating optical radiation hazards. This includes the weighting functions for thermal hazard function, the aphakic retinal hazard function and the ultraviolet radiation hazard function. These weighting functions are the same as those in the present ophthalmic instrument standards.

9.2 Annex B is an informative annex which contains references to product-related International Standards for ophthalmic instruments covered by ISO 15004-2.

9.3 Annex C is an informative annex which recommends the use of simple radiometric broad-band instruments to determine the radiometric quantities. It is believed that such measurement instruments may be used when the optical radiation emissions are sufficiently low. It is important to note that it is not intended to require manufacturers to measure very low levels of optical radiation. In cases of low levels of optical radiation, it is intended that it would be possible to demonstrate conformance with a limit by showing that the optical radiation emissions are below the sensitivity of the instrument and that the sensitivity of the instrument is below the limit being evaluated. Thus, it may be sufficient to demonstrate conformance with a limit by simply specifying that the emissions are below the sensitivity of the instrument being used for measurements and the accuracy associated with the instrument.

Annex C is also intended to make the user of ISO 15004-2 aware that broad-band, 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.

9.4 Annex D is a normative annex which contains a detailed discussion of measurement methods for the determination of radiance/irradiance based on instrument radiance. Separate methods are described to determine corneal/anterior segment irradiance, retinal irradiance, corneal spectral radiant exposure/anterior segment radiant exposure and retinal radiant exposure. With regard to retinal irradiance/radiant exposure, two methods are described based upon the initial information available. A simplified method is described for the case in which the beam characteristics of the instrument are known from the design of the instrument. It is believed that manufacturers of the instruments will have this information and will be able to use this simplified method. However, if the beam characteristics of the instrument are unknown, then the other measurement methods described may be used.

9.5 Annex E is an informative annex which contains a discussion of measurement methods for the direct determination of irradiance. The determination of irradiance is described for three conditions. They are: a collimated parallel beam on the cornea; a diverging beam on the cornea; a converging beam on the anterior segment of the eye. The procedures described in Annex E do not require the determination of source radiance or integrated radiance as described in Annex D.

9.6 Annex F provides a chart intended to facilitate the use of ISO 15004-2.

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