ICNIRP TG STATEMENT

ADJUSTMENT OF GUIDELINES FOR EXPOSURE OF THE EYE TO OPTICAL RADIATION FROM OCULAR INSTRUMENTS

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Adjustment of guidelines for exposure of the eye to optical radiation from ocular instruments: statement from a task group of the International Commission on Non-Ionizing Radiation Protection (ICNIRP)

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A variety of optical and electro-optical instruments are used for both diagnostic and therapeutic applications to the human eye. These generally expose ocular structures to either coherent or incoherent optical radiation (ultraviolet, visible, or infrared radiation) under unique conditions. We convert both laser and incoherent exposure guidelines derived for normal exposure conditions to the application of ophthalmic sources. © 2005 Optical Society of America

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1. Introduction

During ophthalmic diagnostic examination and testing, the eyes' natural defense mechanisms against the potential hazards from viewing bright light, such as squinting, blinking, eye movements, pupillary constriction, and glare avoidance, may be compromised. The use of mydriatics and cycloplegics to dilate the pupil and fix accommodation inhibit the pupillary constriction to bright light.[1,2] Furthermore, the use of chin rests, patient instructions to fixate on a given target, or other measures may reduce the relative movement of the retina with respect to the light source. Key underlying assumptions in the derivation of current ocular exposure limits for exposure durations greater than 0.25 s considered that normal eye movements spread the distribution of incident energy over a larger retinal area and that pupillary constriction in response to bright light would limit the power incident on the retina.[3] Ophthalmic surgical procedures (retinal surgery, cataract extractions, etc.) conducted under a general anesthetic will further compromise these protective mechanisms.[4] Current guidelines, which were developed largely for healthy (i.e., "normal") members of the population, are not appropriate for this particular group, which may have disease-compromised eyes that could result in lower thresholds. Therefore, although current guidelines represent the best knowledge derived from healthy subjects, the safety factor takes into account that thresholds may be lower. Thus the optical safety of ophthalmic examinations requires careful review—particularly with regard to the use of continuous light sources. The International Commission on Non-Ionizing Radiation Protection (ICNIRP) has issued guidelines for limiting human exposure from optical radiation emitted by lasers[5] and intense light sources.[6–8] These guidelines currently do not address the special conditions that occur when the eye is exposed by some optical radiation [i.e., ultraviolet (UV), light and infrared (IR) radiant energy] emitted from ophthalmic instruments. The application of ICNIRP guidelines to ophthalmic light sources has been of interest to several standardization committees. The Technical Committee (TC) 172/SC7 of the International Standards Organization (ISO) has made

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progress in drafting safety standards for some ophthalmic light sources[8,9]; however, there has been uncertainty in the proper application of the guidelines to specific instruments and exposure conditions. Hence ICNIRP established a task group to provide specific guidance in the application of the current guidelines and basic limits for exposure to different ocular tissues, both of which are essential because of the underlying assumption of an awake, task-oriented eye when the current guidelines were derived. During ophthalmic examinations, the pupil may be dilated and eye movements may be restricted, thereby increasing the concentration of radiant energy at the retina.[10,11] Furthermore, unlike conventional ocular light exposure, a converging beam may enter the eye and create a localized zone of increased irradiance in the crystalline lens. Noninvasive instruments, such as ophthalmoscopes, slit-lamp biomicroscopes, keratinoscopes, retinoscopes, fundus cameras, indirect ophthalmoscopes, scanning laser ophthalmoscopes, optical coherence tomographic (OCT) systems, wave-front analyzers, and operating microscopes, are primary examples. This statement provides additional guidance to address these conditions.

Specialized diagnostic instruments are now under development, such as newer generations of OCT instruments, fluorescence monitors, noninvasive glucose monitors, retinal thickness analyzers, and Doppler flow meters. These instruments may employ a number of technologies, such as Raman spectroscopy, Fourier-transform infrared (FTIR) and far infrared (FIR) spectroscopy, fluorometry, scatter goniometry, and polarization spectroscopy. The radiant energy may be delivered as continuous wave (cw) or as single or repetitive pulses. Several types of illumination sources are used in ophthalmic diagnosis, personal identification, and retinal information projection. These include incandescent lamps, arc lamps, light-emitting diodes (LEDs), and lasers. Some instruments employ UV sources and short-wavelength light and IR radiation. As noted above, unusual ocular exposure conditions, such as Maxwellian view, in which most of the retina is illuminated by a beam focused in the lens (as shown in Fig. 1) exist only when the eye is exposed by some ophthalmic instruments.

The retinal image size d_r shown in Fig. 1 can be calculated based on the equal angular subtense of the projected source and the retinal image at the eye's nodal point. The angular subtense of the source is the angular subtense α projected to infinity as produced by the optics of the instrument. The projected radiance of the source cannot exceed the radiance of the bare source used in the instrument. The retinal image size d_r is calculated based on the particular device and the worst-case exposure conditions.

2. Adverse Effects of Intense Optical Radiation on the Eye

There are five principal types of hazards to the eye from optical sources—whether the sources are lasers or incoherent. These are listed below along with any

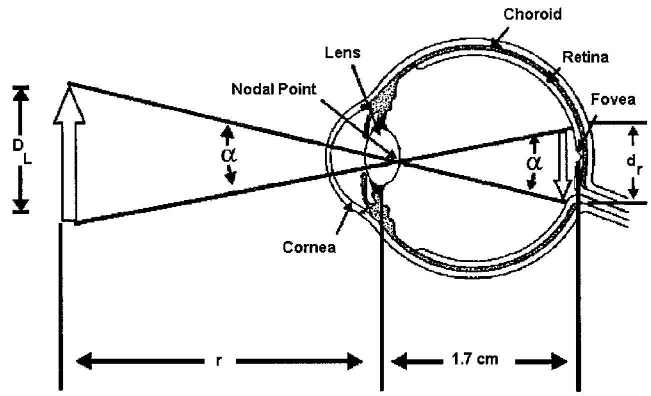

Fig. 1. Maxwellian view. A large retinal area can be illuminated by a converging beam focused at or near the eye's nodal point (approximately 17 mm in front of the retina).

special considerations relating to ophthalmic instrument use:

1. UV photochemical injury to the cornea (photokeratitis) and lens (cataract) of the eye (180 to 400 nm). In deriving the exposure limits (ELs), the underlying assumptions were (a) that exposures could be averaged over a 1-mm aperture at the corneal plane for pulsed exposures lasting less than approximately 0.3 s, whereas, for cw exposures for more than 10 s, the averaging aperture increases to 3.5 mm; and (b) that no unusual focusing of radiant energy within the lens (as could occur during Maxwellian view) was contemplated. Thermal damage to the cornea and lens is rarely of concern in the UV region except from a laser beam of high irradiance. However, the underlying assumption that relative eye movements during normal vision will exceed a 1-mm area is not valid for ophthalmic examination. Hence the 1-mm aperture should be applied for cw exposures to radiant energy from ophthalmic instruments during the use of which the head or eye may be restrained.
2. Blue-light photochemical injury to the retina of the eye (principally 400 to 550 nm; unless aphakic, 310 to 550 nm).[12] Retinal injuries have been reported to result from retinal exposures to the light from operating microscopes during cataract surgery.[13] The underlying assumptions in deriving the ELs for the normal eye were (a) a 3-mm pupil resulting from staring at a bright light and (b) an intact crystalline lens [for which the blue-light hazard function $B(\lambda)$ applies]. However, during cataract surgery, after the lens has been removed and before insertion of an artificial intraocular lens (IOL), the normal filtration of UV radiation (UVR) by the lens is not present, thus potentially exposing the retina to near-UVR (approximately 310–400 nm) from a light source, and the aphakic $A(\lambda)$ weighting function should apply. If the pupil is dilated by mydriatics, the retinal hazard will be increased. The retinal averaging area should be 30 μm for a stabilized image, which could occur during ocular surgery, or 180 μm for normal, awake (unstabilized-image-) viewing conditions, which cor-

responds to the 11-mrad angular averaging field of view for measuring blue-light effective radiance.

3. Retinal thermal injury of the eye (400 to 1400 nm). The underlying assumptions in deriving the ELs were (a) that a 7-mm aperture for averaging corneal irradiance and a smaller 3-mm pupil existing for exposure durations greater than ~1 s were necessary and (b) that eye movements compensate for any potential increased risk for exposure durations longer than 5–10 s. However, the pupil may be 8 mm during the use of mydriatics, and eye movements may be reduced or stabilized during an examination. The related near-IR thermal limit (770-1400 nm) was based on the underlying assumption that direct viewing could take place for periods of 10 s or longer without an aversion response (reduced visual stimulus) and that a 7-mm pupil was appropriate. This near-IR limit corresponds to a retinal irradiance of approximately 0.7 W/cm^2, and this was thought to be acceptable for large retinal-area irradiation for lengthy periods. In terms of retinal irradiance distribution, the image-size dependence of retinal hazard requires analysis of image-area "hot-spots" as small as 30 μm in diameter.

4. Near-IR thermal hazards to the lens (approximately 800 to 3000 nm). The underlying assumptions were (a) that the energy was absorbed in the cornea, aqueous, and lens, and (b) that a 3.5-mm aperture was adequate for irradiance averaging for periods of 10 s or greater because of heat conduction and eye movement. No considerations were made with regard to a beam waist within the lens, which would occur with Maxwellian-view illumination. For that reason, thermal model calculations were necessary to develop guidance for limiting apertures in the plane of the lens. This approach is also necessary to determine the thermal risks to the cornea and lens from pulsed, high-irradiance UV-A sources (generally lasers). A 1-mm averaging aperture is then appropriate for ophthalmic instruments.

5. Thermal injury (burns) of the cornea of the eye (approximately 1400 nm to 1 mm). The underlying assumptions were (a) that the energy was absorbed in the cornea with only slight absorption in the aqueous, although thermal diffusion will heat the aqueous, and (b) that a 3.5-mm aperture was adequate for irradiance averaging for periods of 10 s or greater because of heat conduction and eye movements. However, for a stabilized eye, a 1-mm limiting aperture is appropriate.

A. Damage Mechanisms

The photochemical hazards 1 and 2 discussed above require particular attention, since exposure durations may not be limited by the aversion response to bright light, and since exposures are additive in accordance with the Bunsen–Roscoe law of photochemistry (reciprocity of irradiance and exposure duration). The product of the dose rate and the exposure duration must always result in the same radiant exposure dose (in joules per square centimeter at the retina) to produce a threshold injury. For example, blue-light retinal injury (photoretinitis or photic maculopathy) can result from viewing either an extremely bright light for a short time or a less bright light for longer exposure periods. Guidelines for exposure to UVR and bright light are based on this knowledge. As with any photochemical injury mechanism, one must consider the *action spectrum*, which describes the relative effectiveness of radiation of different wavelengths in causing a photobiological effect. The action spectrum for UVR damage to the crystalline lens (cataract) for acute exposure peaks near 305 nm; for damage to the cornea (photokeratitis), at 270 nm. For clinical exposures, the action spectrum for short-term photic retinopathy (phototoxicity) peaks at ~445 nm in the phakic eye (the blue-light hazard).

Reciprocity also helps to distinguish photochemical injury mechanisms from thermal injury (e.g., retinal burns), in which, because of the protective role played by heat conduction, a very intense exposure causes a retinal coagulation within seconds; otherwise, the surrounding tissue conducts the heat away from the retinal image. Injury thresholds for acute injury in experimental animals for both corneal and retinal effects have been corroborated for the human eye from accident data.

B. Dosimetry

For ophthalmoscopes and those instruments designed to illuminate the retina, it is critical to determine the retinal irradiance. The optical parameters of the human eye and the radiometric parameters of the light source are required to calculate irradiances (dose rates) at the retina. Exposure of the anterior structures of the human eye to UV and IR is also of interest for some sources, and the relative position of the light source and the degree of lid closure can greatly affect the proper calculation of this exposure dose. For assessing the risk of photochemically induced injury, as with ultraviolet and short-wavelength light exposures, the spectral distribution of the light source is of far greater importance than that for thermal injury. The dose response and action spectra for photokeratitis,[14,15] for acute cataractogenesis,[16,17] and for short-term, acute photoretinitis for the primate[12] have been published and may be used as the basis for benefit-versus-risk analysis of exposures that exceed the guidelines.

C. Quantities and Units

The radiometric quantities, such as radiance, used to describe the "brightness" of a source [in $W/(cm^2\ sr)$], and irradiance, used to describe the irradiation level on a surface (in W/cm^2), are particularly useful for a description of the potential hazards. Radiance and luminance are particularly valuable because these quantities are conserved. Photometric quantities, such as luminance (brightness in cd/cm^2 as perceived by a human standard observer) and illuminance in lux (the

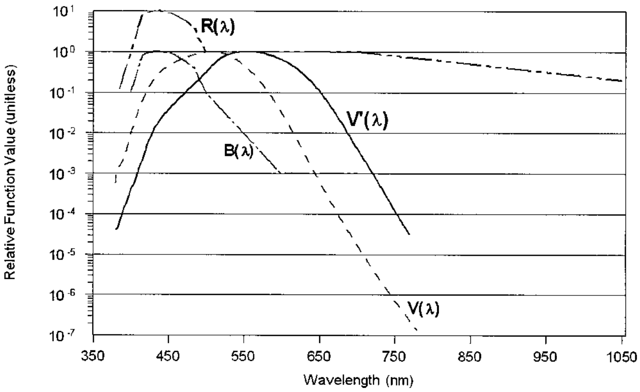

Fig. 2. CIE spectral sensitivity (standard observer) curves $V(\lambda)$, $V'(\lambda)$ for the human eye. For comparison, the ICNIRP blue-light hazard function $B(\lambda)$ and the current retinal thermal hazard function $R(\lambda)$ are also provided. At this time ICNIRP is considering revising the retinal thermal hazard action spectrum $R(\lambda)$ so that it has no numerical factors greater than 1.0, which has been the case for wavelengths between 400 and 500 nm. The current values between 380 and 440 nm should be divided by 10, and the values between 440 and 500 nm should all be lowered to a single value of 1.0.

light falling on a surface), indicate light levels spectrally weighted by the standard photometric (photopic) visibility curve, which peaks at 555 nm for the human eye (Fig. 2), and these quantities are important in the description of the performance of those instruments that illuminate the eye for visual observation; however, these units are generally not useful in determining the potential hazard. To quantify a photochemical effect it is not sufficient to specify the irradiance (W/cm^2) since the efficiency of the effect will be highly dependent on wavelength. Generally, shorter-wavelength, higher-energy photons are more efficient. Unfortunately, since the spectral distributions of different light sources vary widely, there is no simple conversion factor between photometric (either photopic or scotopic) and radiometric quantities. This conversion may vary from 15 to 50 lumens/Watt ($lm\ W^{-1}$) for an incandescent source, to $\sim$100 $lm\ W^{-1}$ for the Sun or a xenon arc, to perhaps 300 $-$400 $lm\ W^{-1}$ for a fluorescent source or some LEDs.[18]

Because of the varied possibilities of ocular illumination conditions, conservation of radiance can serve as a powerful tool for expressing fundamental limits for the evaluation of the potential risks of ophthalmic instrument exposure. This principle states that radiance is conserved regardless of the optics throughout a light beam path, but it may be attenuated by filtration. The radiance of the source cannot be increased; however, it may be decreased by apertures or by transmission loss in the optical delivery system. This principle is generally not easy to apply to collimated laser beams; however, for any conventional light source, it becomes a valuable tool for evaluating or limiting risks from ophthalmic exposure. For example, with respect to surface-emitting LEDs, ICNIRP has found that no realistic hazard exists from these devices based on radiance limitations.[19]

D. Retinal Irradiance Calculations

For a relaxed normal eye, the retinal irradiance (exposure rate) is directly related to source radiance (brightness). It is *not* readily related to corneal irradiance.[20] Eq. (1) gives the general relation, where E_r is the retinal irradiance (W/cm^2), L_s is the source radiance, [in $W/(cm^2\ sr)$], f is the effective focal length of the eye (in centimeters), d_e is the pupil diameter (in centimeters), and τ is the transmittance of the ocular media:

$$E_r = \pi L_s \tau d_e^{\,2}/4f^2. \tag{1}$$

This equation was derived by considering the equal angular subtense of the source and the retinal image at the eye's nodal point (see Fig. 1) and for the relaxed eye. The transmittance τ of the ocular media in the visible spectrum for young persons (and most animals) is as high as 0.9 (i.e., 90%).[21] If one uses the effective focal length f of the adult human eye (Gulstrand eye), where $f = 1.7$ cm, one has

$$E_r = 0.27 L_s \tau d_e^{\,2}. \tag{2}$$

Eqs. (1) and (2) assume that the iris is pigmented and that the pupil acts as a true aperture. In albino individuals the iris is not very effective, and some scattered light reaches the retina. Nevertheless, imaging of a light source still occurs, and Eq. (1) is still valid if the contribution of scattered light (that falls over the entire retina) is added.

E. Spectral Weighting

The radiant exposure is a quantity used to describe a total exposure dose from a flash lamp (for thermal effects) or for a lengthier cw or repetitive exposure (for a photochemical effect). For example, light-induced retinal injury that occurs only after prolonged exposure (i.e., greater than 100 s) is generally agreed to result from a photochemical injury mechanism, rather than from thermal injury. Two key factors distinguish a photochemical process from a thermal process. Thermal injury is a *rate process* and is dependent on the absorption of energy across the spectrum in a volume of tissue. By contrast, any photochemical process will have a long-wavelength cutoff at which photon energies are insufficient to cause the molecular change of interest. A photochemical reaction will also exhibit reciprocity between irradiance (exposure dose rate) and exposure duration. Repair mechanisms, recombination over long periods, and photon saturation for extremely short periods lead to reciprocity failure. For the lengthy exposures characteristic of light damage studies, it is difficult to know what effective exposure time to use for an exposure calculation. The product of the irradiance E in mW/cm^2 and the exposure duration t is the radiant exposure H in mJ/cm^2, i.e.,

$$H = Et. \tag{3}$$

Although both E and H may be defined over the entire optical spectrum, it is necessary to employ an action spectrum for photobiological effects. The retinal thermal hazard function, $R(\lambda)$, the CIE (Commission Internationale de l'Eclairage) spectral luminous efficiency function for photopic vision, $V(\lambda)$, and the blue-light hazard function, $B(\lambda)$, curves of Fig. 2 are examples of action spectra that may be used to spectrally weight the incident light. With modern computer spreadsheet programs, one can readily develop a method for spectrally weighting a lamp's spectrum by using a large variety of photochemical action spectra. These computations are straightforward and take the form

$$E_{\text{eff}} = \Sigma E_\lambda F(\lambda)\Delta\lambda, \tag{4}$$

where $F(\lambda)$ may be any action spectra of interest. One then can compare different sources to determine the relative effectiveness of the same irradiance from several lamps for a given action spectrum.

As one example, a 1000-W tungsten–halogen bulb has a large radiance, but the percentage of blue light is far less. A typical blue-light radiance is 0.95 W/(cm^2 sr) compared with a total radiance of 58 W/(cm^2 sr). The luminance is 2600 cd/cm^2—a factor of 3000 times brighter than a cool-white fluorescent lamp tube. When viewing a typical halogen lamp in a lighting fixture, one notes that the retinal image is small and that eye movements spread the exposure over a retinal area far larger than the instantaneous image area in order to minimize the risk. This illustrates the importance of considering the size of a light source and the effect of eye movements in any calculation of retinal exposure dose. If a person were exposed to a focal beam of light (e.g., from a laser or LED) that was brought to focus in the anterior chamber (the aqueous humor) or the lens, the light beam would diverge past this focal point and could be incident on the retina as a relatively large image. This type of retinal illumination is frequently referred to as Maxwellian view and does not occur in nature. The retinal irradiance calculation in this case would be determined by the depth of the beam waist in the eye; the closer to the retina, the smaller the retinal image and the greater the irradiance.

F. Intraocular Endoilluminators

Specialized endoilluminators are used in retinal–vitreous surgery. In vitrectomy there are two commonly used endoscopic illuminators: a flat-end probe or a "bullet" probe, which emits a fan-shaped beam for wide-angle illumination, and a chandelier probe, which provides an annular beam of light around a surgical probe. Yet another endoilluminator is termed the "pick" illuminator. During precise retinal

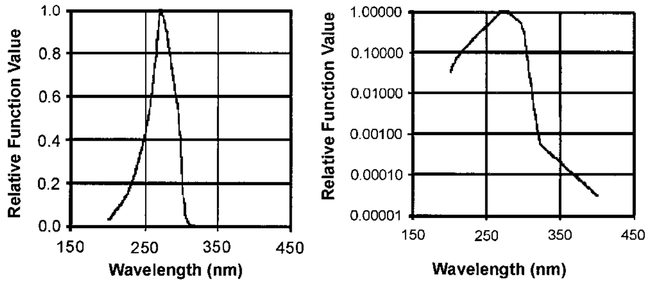

Fig. 3. ICNIRP UV hazard function $S(\lambda)$ describes approximately the relative spectral risk for photokeratitis and is also an envelope of the action spectra for cataract and erythema of the skin. The left panel shows $S(\lambda)$ as a linear plot, and the right panel shows $S(\lambda)$ as a semilogarithmic plot to illustrate the contribution of longer UV wavelengths.

surgery, the displacement of the light varies but typically may be ~5 mm from the retina. The 5-mm distance has therefore been recommended as a reference distance for standards concerning light toxicity.

3. Exposure Limits

A. Applying Ultraviolet Limits to Protect the Cornea and Lens

There are no serious mitigating factors relating to the direct application of UV guidelines to instrument exposures at the corneal plane. There is a very limited safety factor in the first UV criterion, which means that exceeding the spectrally weighted limit by a factor of 2 or more will probably result in a detectable, although probably transient, acute photokeratitis. Two factors must be considered: The averaging aperture should not increase with increasing exposure durations if the head is stabilized or eye movements are otherwise reduced, and the photosensitization by pharmaceuticals. Most instruments designed to illuminate ocular tissues are provided with filtration designed to eliminate needless UVR, and the UV limits are necessary to assess the leakage radiation. There are, however, instruments that require UVR to illuminate tissues for fluorescence diagnosis, etc. Two EL criteria apply: the total UV irradiance and the average spectrally weighted UV irradiance, E_{eff} at the location of exposure. The spectrally weighted irradiance is

$$E_{\text{eff}} = \Sigma E_\lambda S(\lambda)\Delta\lambda, \tag{5}$$

where the summation covers the full spectral range of $S(\lambda)$ to 400 nm (see Fig. 3). The maximum duration of exposure to stay within the limit, $t_{\max}$, is determined by dividing the EL by the measured effective irradiance to obtain the duration in seconds:

$$t_{\max} = (3\ \text{mJ/cm}^2)/(E_{\text{eff}}). \tag{6}$$

Critical to the derivation of any guidelines or standards for instrument emissions in UV is the consideration of multiple exposures within one day. If a patient were exposed repeatedly, as in a clinical teaching environment, the total exposure duration over one day should be compared with t_{max}.

In addition to the action-spectrum-based EL, an additional criterion[8] to protect the lens limits the dose rate to both lens (and the skin) from high irradiances. Initially, this was based only on the consideration to conservatively protect against thermal effects. For example, thermal injury was produced in the lens at 30 J/cm^2 (1 W for 1 s in a 2-mm beam diameter) from two lines of the argon laser at 351 and 364 nm.[22] This guideline was later thought essential not only to protect against thermal damage, but also to protect against possible—but unknown—photochemical damage to the lens from UVA. In the latter case, the potential problems of photosensitization must be addressed. The limit is 1 J/cm^2 in one day for wavelengths below 400 nm. This criterion is believed to have a significant safety factor—at least for wavelengths in the 360−400-nm band and for acute exposures. However, with regard to thermal effects in the lens, recent mathematical models of heat dissipation indicate that the risk of thermal damage from focal beams in the lens are of concern from 320 to 450 nm (Ref. 23):

$$H_{max} = \Sigma H_\lambda \Delta\lambda = 1\ \text{J/cm}^2. \tag{7}$$

The maximal exposure duration is then the limit of 1 J/cm^2 divided by the UV irradiance.

All of the above limits[5–7,24] are intended to protect both the cornea and lens, and it was recognized that the thresholds for acute UV cataractogenesis (of the order of 0.1 J/cm^2 at 300−305 nm) was above the threshold for photokeratitis. However, for instruments emitting a converging beam (as in Maxwellian view), the corneal exposure limits certainly should apply to the plane of the lens as well. The action spectrum for acute cataract is quite narrow—extending only from approximately 290 to 325 nm.[17] Therefore it would be prudent in any instrument design to avoid emission of any radiant energy below 330 nm. If UVR below 360 nm were blocked, as in almost all instruments, an irradiance of 1 mW/cm^2 for lengthy (e.g., 30 ks) exposure would be acceptable. The eye is routinely exposed to such levels outdoors.[18] An irradiance of 1 mW/cm^2 for 30 ks = 30 J/cm^2 is below $S(\lambda)$-based limits for all wavelengths greater than 320 nm. The thermal limit for a focused beam developed for IR-A would also limit thermal hazards to the lens from intense UV-A sources (generally lasers).

B. Applying Visible and Infrared Limits to Protect the Retina

The ocular exposure limits for intense visible and IR radiation exposure of the eye (from incoherent radiation) are several, since they protect against either photochemical or thermal effects to the lens or retina. There are parallel dual limits for protection of the retina from laser radiation. As a result of difficulties in retinal dosimetry in experimental studies and of other uncertainties, there are substantial safety factors in these limits.

There are two primary hazards that must be assessed in an evaluation of an intense visible-light source: the photoretinitis (blue-light) hazard and the retinal thermal hazard. These hazards are treated by dual limits in the guidelines for both the incoherent and the laser exposure. Additionally, lenticular exposure in the near-IR may be of concern, which is adequately treated in the guidelines for incoherent sources but is not really addressed for laser limits.

1. *Photometric Guideline*

Generally, white-light sources with a luminance less than 1 cd/cm^2 (10^4 cd/m^2) will not exceed the retinal blue-light or retinal thermal exposure limits, and this value is generally a maximal luminance for comfortable viewing. Although this value is not considered a limit, it is frequently provided as a quick check to determine the need for further hazard assessment.

2. *Retinal Thermal Guidelines*

The retinal thermal criteria, based on the action spectrum $R(\lambda)$, applies to pulsed-light sources and to intense sources in which the longest viewing duration of potential concern is 10 s. The retinal thermal hazard EL is not specified for longer durations because the pupil will certainly be tightly constricted within less than 0.5 s. The lids will be closed within 0.2 s owing to an aversion response. Eye movements and other factors would all limit the exposure to preclude thermal injury even if individuals forced themselves to overcome their natural aversion response. The retinal thermal limit is

$$\Sigma L_\lambda R(\lambda)\Delta\lambda \le 5/(\alpha t^{0.25})$$
$$\text{for } t > 10\ \mu\text{s and } 1.7\ \text{mrad} < \alpha < 0.1\ \text{rad}. \tag{8}$$

The basic retinal exposure limit from which this was derived was

$$H_{therm} = \Sigma E_\lambda R(\lambda)\Delta\lambda \le 50/(\alpha t^{0.25})\ [\text{J/cm}^2], \tag{9}$$

where $\alpha = d_r/17$ if d_r is expressed in millimeters and α is in radians.

Note 1: Based on recent research studies, ICNIRP recommends that consideration be given to revision of the retinal thermal hazard action spectrum $R(\lambda)$ to have no numerical factors greater than 1.0, as has been the case for wavelengths between 400 and 500 nm. The current values between 380 and 440 nm should be divided by 10 and the values between 440 and 500 nm should all be lowered to a single value of 1.0.

Note 2: Expression (8) and Eq. (9) above and Eqs. (10) and (11) presented in Subsection 3.C are empirical and may not all be dimensionally correct. To make them correct, one must insert a dimensional correction factor into the equations.

3. Applying Infrared Limits to Protect the Retina from Infrared Illuminators

An IR EL is used to protect against retinal thermal injury from low-luminance IR-illumination sources. This EL was developed only for special applications in which near-IR illuminators are used for night surveillance applications. These illuminators have a low visual stimulus and therefore permit lengthy ocular exposure with a dilated pupil. With regard to ophthalmic instruments, any near-IR source used for retinal examination or photography in order to take advantage of a dilated pupil would have comparable sources. Although the retinal thermal limit [based upon the $R(\lambda)$ function] for intense, visible, broadband sources is not provided for times greater than 10 s because of pupillary constriction, etc., the retinal thermal hazard—for other than momentary viewing—will only realistically occur when the source can be comfortably viewed, and this is the intended application of this special-purpose EL. The special-purpose EL was originally derived for IR illuminators used for area illumination for nighttime security to limit light trespass to adjacent housing. If directly viewed, the typical illuminator source may be totally invisible, or it may appear as a deep cherry red source that can be comfortably viewed. The EL is proportional to $1/\alpha$ and is simply limited to

$$\Sigma L_\lambda R(\lambda)\Delta\lambda \leq (0.6)/(\alpha)\ [\mathrm{W/(cm^2\ sr)}], \tag{10}$$

where $\alpha < 0.1$ rad.

It must be emphasized that expression (10) is not used for white light sources and was derived for unlimited viewing. The corresponding retinal irradiance would be $6/\alpha$ W/cm^2 or $1.2/d_r$ W/cm^2, where d_r is the retinal image size in millimeters (limited to 1.7 mm). This limit would directly apply to IR wave-front analyzers or OCT systems, in which the patients can stare into a collimated near-IR beam for prolonged periods of more than a few seconds. This criterion can also be covered in the retinal thermal hazard limit [expression (8)] for ophthalmic instruments used with a dilated pupil for the entire wavelength range 380–1400 nm:

$$\begin{aligned} E &= \frac{0.27(0.6)}{\alpha}(0.9)(0.49) = \frac{0.0714}{\alpha} = 0.071\frac{17}{d_r} \\ &= \Sigma E_\lambda R(\lambda)\Delta\lambda = \frac{1.21}{d_r}\ [\mathrm{W/cm^2}] \\ &= 1.2\ \mathrm{W/cm^2}\ \text{at}\ 1000\ \mu\mathrm{m},\ \ 12\ \mathrm{W/cm^2}\ \text{at}\ 100\ \mu\mathrm{m}, \\ &\quad 50\ \mathrm{W/cm^2}\ \text{at}\ 26\ \mu\mathrm{m}. \end{aligned} \tag{11}$$

In the limiting case of $\alpha = 0.1$ rad, the limiting radiance is $6\ \mathrm{W/(cm^2\ sr)}$ or an irradiance of $0.7\ \mathrm{W/cm^2}$ at the retina.

4. Photoretinitis Guidelines

The blue-light photoretinitis hazard criteria were based on the work of Ham *et al.*[25] and Hochheimer *et al.*[26] The limit for time t is expressed as a $B(\lambda)$ spectrally weighted radiance:

$$\Sigma L_\lambda B(\lambda) t\Delta\lambda \leq 100\ \mathrm{J/(cm^2\ sr)} \quad \text{for } t > 10\ \text{s and } \gamma = 0.011\ \text{rad}, \tag{12}$$

where γ is the cone-angle, field of acceptance of the measuring instrument. However, for the awake, task-oriented eye, this limit has a substantial safety factor, and values as much as 5–10 times this limit would be necessary to produce a visible lesion. The radiance limits were derived for a 3-mm pupil (constricted by the patient's staring at a bright light source) for a $B(\lambda)$ spectrally weighted retinal radiant exposure of $2.2\ \mathrm{J/cm^2}$, which was based on the thresholds of $20-30\ \mathrm{J/cm^2}$ reported by Ham.[12] Therefore the guideline exposure is $2.2\ \mathrm{J/cm^2}$ determined at the retina, but clearly levels of $5-10\ \mathrm{J/cm^2}$ would not be expected to result in a visible lesion unless the retinal threshold was reduced by a photosensitizer. Fluorescein has been reported to photosensitize the retina and to lower the threshold by almost 1 log unit (from 1.6 to 0.2 W/cm^2) in rabbit models.[26]

C. Applying Infrared Limits to Protect the Cornea and Lens

There are two criteria in the near-IR region to protect the lens and retina. To protect the lens against IR cataract, the EL applicable to IR-A and IR-B radiant energy, i.e., 780 to 3000 nm, specifies a maximal irradiance for continued exposure of 10 mW/cm^2 (average) over any 1000-s period, but not to exceed an irradiance of $1.8\, t^{-0.75}$ W/cm^2 (for times less than 1000 s); this corresponds to 1.8 W/cm^2 at 1 s, 320 mW/cm^2 at 10 s, 100 mW/cm^2 at 45 s, and 57 mW/cm^2 at 100 s. This is a conservative limit developed to control chronic exposure in hot industrial environments where the entire face is heated up, and it is based on the observation that IR cataract in workers appears only after a working lifetime exposure at irradiances of $80-400$ mW/cm^2 and estimates of heat buildup and dissipation during brief exposures. Levels well above 10 mW/cm^2 are experienced when standing near-IR radiant warmers or in front of a fire (e.g., $40-100$ mW/cm^2) in cold environments. Exposure of the lens to irradiances well above this conservative chronic-exposure guideline for periods of 1000 s or greater for examinations should not be hazardous, since the entire eye and adnexa are not illuminated by an ophthalmic instrument. Normally, IR exposure of the eye is self-limited by thermal discomfort of the face and would not occur for a patient under anesthesia. On the other hand, tissue temperature may be lowered during anesthesia. Taking all of these factors into account, the task group agreed on higher levels of 20 mW/cm^2 for indefinite exposure periods in any one day and up to 80 mW/cm^2 for controlled periods of several minutes, from at least 100 to 1000 s.

Ocular exposure to nonophthalmic optical sources will not produce a focal beam waist in the crystalline lens, and no consideration of this condition was made in the determination of the measurement conditions for the ocular exposure limits. The focal zone over which the radiant energy can be averaged in the lens interior necessitates a separate study. It is probable that the averaging zone should be less than 1 mm. Mathematical models of heat dissipation in tissue supported by experimental studies of corneal thermal injury from 10.6-μm CO_2 laser radiation show a strong spot-size dependence for irradiated spot sizes less than 1 mm as a result of heat flow.[27] This was the basis for our applying a 1-mm limiting aperture for corneal IR-B and IR-C laser exposure limits and the 3.5-mm limiting aperture of the cw limit of 0.1 W/cm^2, based on both thermal diffusion and eye movement. Thermal damage thresholds for CO_2 laser radiation exceed 1 W/cm^2 for a 10-s exposure for a fixed or stabilized eye in which absorption in the cornea is much greater than for visible and near-IR radiation from a Maxwellian-view illuminator. Lenticular injury thresholds for single exposures of a few hours or less are difficult to obtain. Wolbarsht[28] and Pits and Cullen[14] reported thresholds of the order of kJ/cm^2 for exposures of minutes or hours. Studies using a small-diameter laser beam of the order of 1-mm vary with wavelength, but as an example, 42 W/cm^2 for 5 s in a 1.4-mm spot size at a wavelength of approximately 1.3 μm, in which the lens absorbs significantly. Therefore, for a broadband source operating in the 450−1150-nm spectral region, an exposure up to 20 W/cm^2 under controlled conditions for limited periods would not pose a problem. However, for general purposes, an exposure limit of 4 W/cm^2 for a Maxwellian-view illuminator is recommended for wavelengths less than 450 nm and greater than 1150 nm. This irradiance should be averaged over a 1-mm aperture. For pulsed sources and brief periods of exposure of the order of 1 s or less, movement of the beam is no longer important. Thresholds for thermal damage to the lens from laser beams provide an indication of the levels required to protect the lens from thermal injury. The 30 J/cm^2 threshold for UV-A laser radiation in a 2-mm-diameter beam for 1-s (see Ref. 22), and the 42 W/cm^2 threshold for IR-A laser radiation at 1.3 μm in a 1.4-mm-diameter beam mentioned above for 5 s show that 30−40 W/cm^2 produce an adverse thermal load on the lens.[23]

4. Discussion

A. Exceeding the Exposure Limits—Benefit Versus Risk and Margins of Uncertainty

In deriving the ELs for all optical radiations, the ICNIRP generally applied a safety factor to account for uncertainties in the scientific data for known biological thresholds of injury to the relevant biological tissue and the consequences of exposure above the threshold, i.e., the shape of the dose-response curve. This factor was greatest for retinal thermal injury, in which the difficulties of exactly determining the retinal image size, the clarity of the ocular media, and the difficulties in histology led to uncertainties that were relatively large compared with the uncertainties in determining the exact dose to the skin, cornea, and lens. For this reason, the choice of a factor as great as 10 to reduce the 50% probability of retinal injury was not unusual in the derivation of limits from pulsed lasers. This factor of 10 is not a true safety factor because there is a statistical distribution of damage and because this factor was based on several considerations.[29] These considerations included the difficulties in performing accurate measurements of source radiance or corneal irradiance, the measurement of the source angular subtense, and the histological studies showing retinal changes at the microscopic level at levels of approximately 2 below the ED-50 value.[18] In practice, this means that an exposure at 2–3 times the EL would not be expected to actually cause a physical retinal injury. At 5 times the EL, one would expect to find some injuries in a population of exposed subjects.

The consequences of exceeding the just-detectable change in corneal epithelial status by exposure to IR or UVR was not as significant as exceeding this threshold in retinal tissue. However, safety factors of the order of 10 are typical at IR wavelengths greater than 1400 nm, not because of uncertainties in known thresholds, but to account for strong variations of thresholds with wavelength.[3,29]

The ELs are guidelines for controlling human exposure and should not be considered as fine lines between safe and hazardous exposures. With benefit-versus-risk considerations, it should therefore be considered appropriate to have some relaxed guidelines; however, to date, no standards group has seen the need to do this.

B. Photosensitivity

The ICNIRP task group agreed that transient inflammatory reaction of the cornea was not a serious problem; however, exposure of the lens could be of concern under very unusual photosensitization conditions, such as with orally administered psoralens. An irradiance limit of 1 mW/cm^2 was deemed adequate for ophthalmic instruments even though, for durations greater than 1000 s, a limit of 1 J/cm^2 in the UVA is recommended by ICNIRP for chronic exposure conditions. This approach was deemed possible for the exempt unrestricted-use category of ophthalmic instruments, since the further restriction that this limit be applied only to wavelengths greater than 370 nm could be added. Exposure to wavelengths less than 370 nm was limited to the $S(\lambda)$-weighted irradiance of 0.1 $\mu W/cm^2$.

C. Photoretinitis Hazard

With regard to the blue-light photochemical hazards, the task group agreed that owing to the larger pupillary aperture possible for a patient undergoing ophthalmic examination, the blue-light hazard limit should be reduced from $10\ \mathrm{mW/(cm^2\ sr)}$ to $2\ \mathrm{mW/(cm^2\ sr)}$ for any condition in which the pupil is dilated. The latter value conservatively corresponds approximately to a white-light source with a luminance of $1\ \mathrm{cd/cm^2}$. This luminance value is provided only for use as a quick and conservative check-test of the validity of the radiance measurement. It should be noted that the blue-light hazard function does extend into the UV spectrum to include the wavelength band between 305 and 400 nm, and this would apply for the phakic eye. For any instruments that would be used for the aphakic eye, $A(\lambda)$ weighting would apply. There are many locales in developing countries where aphakia still exists and where pseudoaphakic intraocular lens (IOL) implants may still be manufactured without a UVR absorber. Hence the blue-light radiance limit of $2\ \mathrm{mW/(cm^2\ sr)}$ should be determined with the aphakic hazard function, $A(\lambda)$. If only brief exposures were possible, as with a number of repetitive-pulse exposures in a dilated eye, a reduced integrated radiance limit of $20\ \mathrm{J/(cm^2\ sr)}$ would apply to the cumulative daily exposure.

These limits, when expressed as retinal radiant exposures and retinal irradiances, are based on the basic restriction of $2.2\ \mathrm{J/cm^2}$ (normalized at 440 nm where $B(\lambda) = 1.0$) for all durations less than 10,000 s and $0.22\ \mathrm{mW/cm^2}$ for longer durations. In the aphakic eye, the basic restriction (at the shortest-wavelength range) drops to $3.7\ \mathrm{J/cm^2}$ for 305−330 nm. These basic restrictions correspond to the above radiances, where a 7-mm dilated pupil was assumed. For durations less than 1000 s, the energy can be averaged over a 180-μm image area (corresponding to an angular field of view for radiance averaging of 11 mrad) for the unstabilized retinal image; however, as during some surgical procedures, the eye may be stabilized and, under these conditions, a 30-μm averaging area for retinal irradiance should apply. For pulsed sources, the retinal thermal hazard must also be evaluated for a single exposure and the entire spectral range from 400 to 1400 nm must be considered (see Subsection 3.B.2).

D. Large Retinal-Area Illumination

To protect against retinal thermal hazards that would only occur for pulsed illumination of large retinal areas, the limit of $5/(\alpha t^{-1/4})$ was adjusted to apply only to the worst-case, large source size, corresponding to $\alpha > 0.1$ rad, i.e., $d > 1.7$ mm. In this way, one radiance value would be protective for all larger source sizes, although overly conservative for smaller source sizes. Hence a single, conservative limit would be $50/(t^{-1/4})\ \mathrm{W/(cm^2\ sr)} = 50\ t^{3/4}\ \mathrm{J/(cm^2\ sr)}$. If the transmittance of the ocular media is taken as 0.9, the retinal corresponding irradiance is $E_r = 6\ t^{-1/4}\mathrm{W/cm^2}$ for exposure durations of less than 10 s.

E. Infrared Hazard to the Cornea and Lens

The radiant exposure for wavelengths in the IR-A and IR-B (780−3000 nm) if averaged over a 1-mm aperture, as recommended by ICNIRP for incoherent sources, is less restrictive than some IR corneal laser limits. However, the energy is dissipated over a larger volume in the IR-A and IR-B and is adjusted to a cw limit of $100\ \mathrm{mW/cm^2}$, as limited in both the corneal and lenticular planes. For pulsed sources, this value would be $1.8\ t^{-3/4}\ \mathrm{W/cm^2}$ for durations less than 45 s (i.e., $1.8\ t^{1/4}\ \mathrm{J/cm^2}$). It should be noted that the IR-C laser limit (i.e., $0.56\ t^{1/4}\ \mathrm{J/cm^2}$) applies to corneal exposure only at wavelengths greater than 1400 nm and is more conservative than the incoherent limit for durations less than approximately 45 s, but it is more lenient for lengthy exposures.

This finding is consistent with the fact that the thermal equilibrium time for the laser limit is shorter, leading to a more conservative limit for pulsed-laser sources. On the other hand, a patient undergoing an ophthalmic procedure has a cooler lens if under anesthesia, and the exposure is only acute. The 10 $-40\text{-}\mathrm{mW/cm^2}$ ICNIRP guideline is designed to protect against cumulative thermal injury that would occur over a lifetime of exposure. Therefore the laser criteria applied to the cornea and lens with a small averaging aperture to take into account Maxwellian-view optics should provide adequate protection. The averaging aperture should be a maximum of 1 mm.

F. Risk Assessment

One approach to assess the potential hazards of any ophthalmic instrument is to separately consider the effects at each key ocular plane: the cornea, lens, and retina. It is considered essential to evaluate the risks for both thermal and photochemical effects at both the corneal and lenticular planes even if the original exposure limits specify only corneal exposure levels. Concentration of energy in the crystalline lens normally does not take place in nature as it does in Maxwellian view. This risk assessment is necessary because, unlike conventional exposure to UVR from industrial and natural sources, exposure from ophthalmic instruments may produce a converging beam of radiation. The threshold for damage of the lens in the 300−310-nm band is actually just somewhat higher than the threshold for damage of the cornea. The effects of pupil dilation, eye movements, photosensitization, etc., should be considered for each ocular plane. Table 1 summarizes the recommendations for corneal, lenticular, and retinal exposure planes. Table 2 lists typical exposure conditions.

G. Product Safety Standards

There has been a general need for a basic international standard with risk criteria and exposure limits upon which the vertical standards could be based. The ISO and other international and national bodies are now concerned with the potential optical radiation hazards of ophthalmic sources. In the United States, the American National Standards Institute (ANSI) Z80.7 has been considering standards[30] and working also in conjunction with the ISO TC172/SC7. Furthermore, the Illuminating Engineering Society of North America

Table 1. Current General Exposure Guidance and Hazard Thresholds at Each Relevant Ocular Plane

Ocular Plane and Guideline	Exposure Guideline	Damage	Pupil Dilation	Eye Movement Relative to Source	Measurement Aperture-to-Average Irradiance	Photosensitivity
Cornea						
UV	3 mJ/cm^2 effective for $S(\lambda)$	4 mJ/cm^2 at 270 nm	N/A	Yes, moderate	1 mm (250 nm $\leq \lambda \leq$ 400 nm)	UV only
Lens						
UV-B	3 mJ/cm^2 effective for $S(\lambda)$	600 mJ/cm^2 at 300 nm	Possible increase in risk	Yes, moderate	1 mm (315 nm $\geq \lambda \leq$ 400 nm)	UV only
UV-A	1.0 J/cm^2	Photochem >2 J/cm^2 at >315 nm. Thermal at 351–364 nm: 33 J/cm^2, 1s	Possible	Yes, moderate	1 mm	UV only
IR	0.1 W cm^2	4 W/cm^2	Possible	Yes, moderate	1 mm	No
Retina						
Photochemistry	100 J/cm^2 sr effective for $B(\lambda)$ or $A(\lambda)$	3 J/cm^2 at the retina at 320 nm and 22 J/cm^2 at 442 nm	Constricted, 3-mm pupil	Yes, very important	7 mm at cornea, but derived for 3-mm pupil and 11-mrad acceptance angle, corresponding to 180 μm at the retina	Possible
Thermal	$5/\alpha t^{0.25}$ W/cm^2 sr effective for $R(\lambda)$	1−1000 W/cm^2 with retinal spot size	7 mm for pulsed, but transition to 3 mm by 10 s	Yes, very important	7 mm at cornea, but variable with t and for image diameters greater than 25 μm	N/A
Cornea and Lens						
IR-A and IR-B	1.8 $t^{-0.75}$ W/cm^2 for $t < 1000$ s	>4 W/cm^2	N/A	Small	1 mm	N/A
Cornea						
IR-C	0.1 W/cm^2	1 W/cm^2	N/A	Small	1 mm	N/A

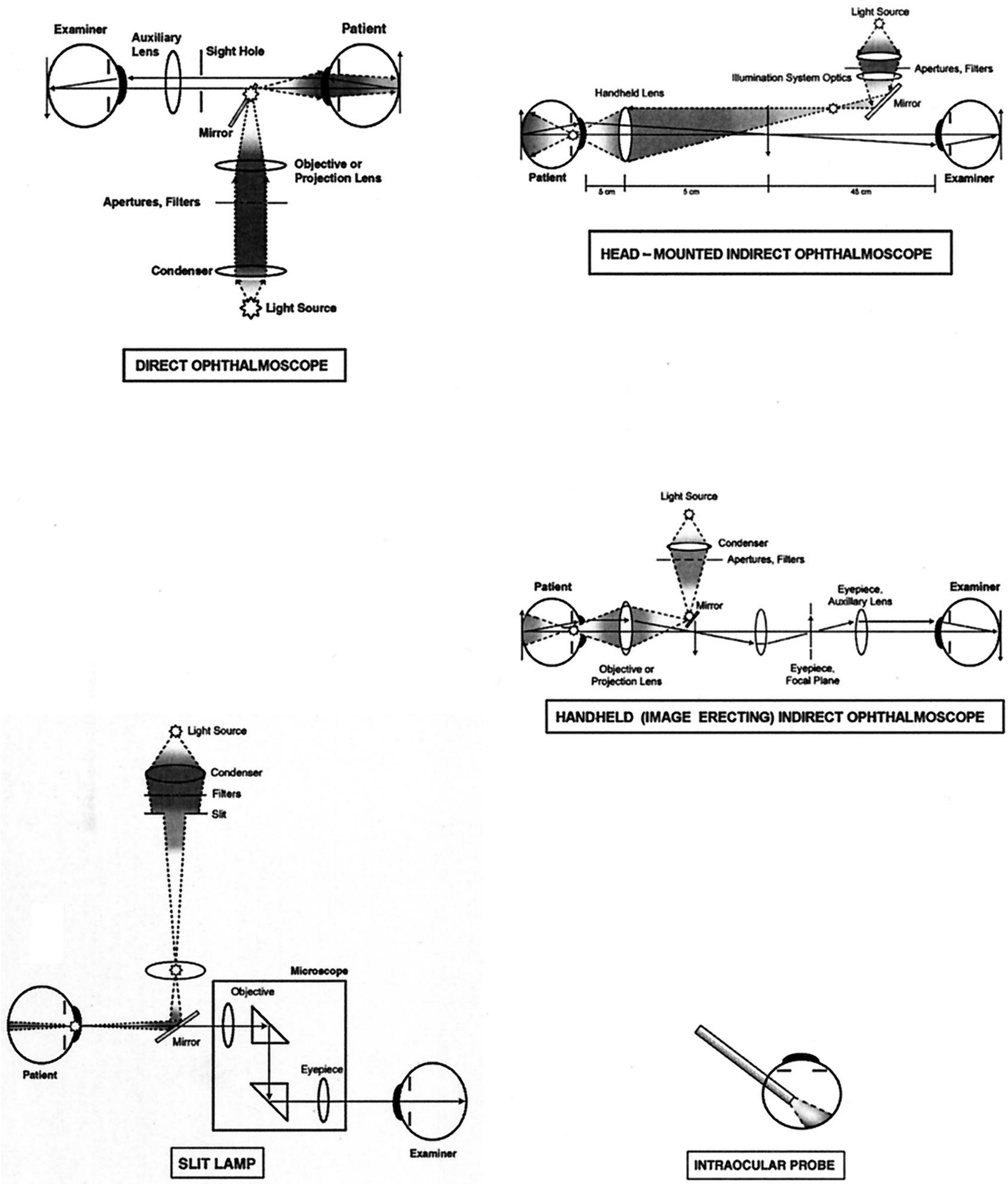

Fig. 4. Several representative retinal illumination patterns from a variety of different instruments. The upper-left panel shows the direct ophthalmoscope (type A), the upper-right panel shows the Maxwellian-view optics of the indirect ophthalmoscope (type B), and the central-right panel shows another type of indirect ophthalmoscope. A slit lamp (type A) is shown at the lower left. The lower-right panel shows an intraocular probe (neither type A nor type B). Some optical paths are shortened and are not to scale.

was planning a standard, such as RP27.6, on ophthalmic sources, and the CIE TC6-42 on photobiological safety of lamps also developed a generic standard with liaison from the International Electrotechnical Commission (IEC) TC34A. Medical electrical equipment is also treated by the IEC.[31] Laser product safety standards are covered by IEC TC76.[32]

H. Measurement Schemes

There has been a range of opinion on the need for standardized radiometric measurements and even standardized instruments for testing instruments. The range of emission values for the same lamp can vary, and this has led to some concern about the accuracy of any specific measurement.

To measure radiance, a common measurement method could employ a relay lens to image the source at an aperture. Alternatively, a "model eye" could be designed to perform easier measurements of retinal irradiance, e.g., a 7–8-mm pupillary aperture with a simple lens with a focal length of 170 mm; thus the retinal image was magnified by a factor of 10. However, the numerical aperture and geometry are not the same; hence a relay lens with a long focal length

Table 2. Ophthalmic Instruments[a]

Ophthalmic Instrument	Typical Exposure Time (s)[b]	Plane of System Stop	Plane of Focus	Head and Eye Stability	Typical Optical Source[c]
Direct ophthalmoscope	50–150 [500]	Pupil	Mirror	Low	Incandescent (including TH)
Retinoscope	30–150 [500]	Pupil	Aqueous	Low	Incandescent (including TH)
Binocular indirect ophthalmoscope	50–200 [500]	Pupil and nodal plane	Nodal (lens)	Low	Incandescent (including TH)
Slit lamp					
Anterior segment examination	10–150 [500]	Pupil	Examined surface	High	Incandescent (including TH)
Retinal examination with convex lens	50–150 [500]	Pupil and nodal plane	Nodal (lens)	High	Incandescent (including TH)
Retinal examination with concave lens	30–150 [500]	Pupil	Retina	High	Incandescent (including TH)
Lens probe	10–100 [500]	Lens	Lens	Varies	Incandescent (including TH)
Keratometer	10–100 [500]	Pupil	Cornea	High	Incandescent (including TH)
Corneal topograph	10–100 [500]	Pupil	Cornea	High	Incandescent (including TH)
Operating microscope	1000–10,000 [10,000]	Pupil	Variable	High	Incandescent (including TH)
Endoilluminator	1000–10,000	Retina	N/A	High	Incandescent (including TH, Xenon)
Fundus camera	100 μs−4 ms [150 ms]	Pupil, nodal plane	Pupil, nodal plane	High	Incandescent (including TH), Xenon flash
Laser SLO[d]	100–1000 [2000]	Lens and retina[d]	Retina with lens	High	Laser
Specular microscope	10–100 [500]	Pupil	Cornea	High	Incandescent (including TH)
Perimeter	200–1000 [2000]	Source	N/A	High	LED or incandescent
Synoptophore	300–2000 [4000]	Pupil	Retina	High	Incandescent
Tonometer	60–120 [300]	Pupil	Retina	High	LED or incandescent (including TH)
Tear scope	30–300 [2000]	Pupil	Retina	Low	Incandescent (including TH)
Corneal optical coherence tomography	10–100 [500]	Pupil	Cornea	High	Superluminescent diode or laser
Retinal thickness	10–100 [500]	Pupil	Cornea	High	Incandescent (including TH)
Retinal blood-flow meter	50–100 [200][e]	Pupil	Retina	High	Incandescent (including TH)
Retinal optical coherence tomography	10–100 [500]	Pupil	Retina	High	Superluminescent diode or laser

[a]Table 2 is a chart that covers representative instruments and key characteristics that would influence the potential hazard and the exposure at each of the three planes of concern.
[b]The maximum cumulative time is given in square brackets.
[c]TH, tungsten–halogen lamp.
[d]SLO, scanning laser ophthalmoscope. The SLO beam focal spot is the retina but the highest averaged irradiance at the nodal point.
[e]Exposure durations apply to the time of exposure on the same tissue location.

Table 3. Exposure Limits for Unrestricted Instrument Use: Photochemical Limits[a]

Hazard and Wavelength Range	Exposure Guideline Limit	Comments
UV cornea and lens		
$\lambda = 315–400$ nm	$H_{UV\text{-}A} = 1$ J/cm^2 for $t < 1000$ s and $E_{UV\text{-}A} = 1$ mW/cm^2 for $t \geq 1000$ s	Total UV irradiance limit to protect cornea and lens tissues; no spectral weighting; 1-mm aperture for irradiance averaging.
$\lambda = 180–400$ nm	$E_{UV} = 0.1$ μW/cm^2 (8 h). $E_{UV} = 0.4$ μW/cm^2 (2 h)	$S(\lambda)$ spectrally weighted irradiance for cw sources used for lengthy or repeated exposures based on a maximal 2-h or 8-h exposure; 1-mm aperture for irradiance averaging.
UV cornea pulsed hazard		
(single or multiple pulses) $\lambda < 400$ nm	$H_{UV} = 3$ mJ/cm^2	For pulsed sources in which the total integrated $S(\lambda)$-weighted radiant exposure should remain below the limit for the maximal number of daily exposures; 1-mm aperture.
Retinal photochemical hazard		
$\lambda = 305–700$ nm	$L_B = 2$ mW/(cm^2 sr) for $t > 10{,}000$ s, or $L_V = 1$ cd/cm^2 external	Radiance of light source spectrally weighted against the aphakic $A(\lambda)$ or phakic $B(\lambda)$ function based on $t > 10{,}000$-s exposure.
Expressed alternatively as a luminance limit for a white-light source	$H_r = 2.2$ J/cm^2 or $E_r = 0.22$ mW/cm^2 for $t > 10{,}000$ s; or 0.3 mW/cm^2 for $t = 2h$ $A(\lambda)$ or $B(\lambda)$ weighted	Retinal radiant exposure or irradiance for light source spectrally weighted against the aphakic $A(\lambda)$ or phakic $B(\lambda)$ function. Basic limit assumes 0.9 maximum transmittance of the ocular media and $t > 10{,}000$-s exposure. Averaged over 1.75 mrad or 30 μm.

[a]In cases in which spectral weighting is noted in the Comments column, more complex spectroradiometric measurements are needed for a rigorous measurement.

might be adequate only for determining radiance. It should be noted that when auxiliary lenses such as contact lenses or condensing lenses are used by the practitioner, then the effect upon irradiance in each plane of interest would vary. Figure 4 illustrates the four general categories of ophthalmic illumination for a variety of different instruments.

To measure irradiance, the most biologically relevant plane should be chosen. In the case of Maxwellian-view instruments type B of Fig. 4, in which the highest irradiance occurs at or near the nodal point during proper use, the measurement should be averaged over a maximum aperture of 1 mm to capture the effect of localized zones of high irradiance (i.e., hotspots). For Maxwellian-view instruments, the potential hazard may actually be of concern at two different planes: in the lens and the retina. The radiance measurement relates to the potential hazard to the retina, and the irradiance measurement relates to the potential hazard to the lens. Therefore the choice of the irradiance measurement plane should be at the location of the greatest irradiance external to the instrument. However, for type A instruments that have a diverging beam, the closest useful instrument-to-cornea distance should apply. Measurements at the retinal plane require high resolution, corresponding to a 30-μm retinal image diameter. Diode-array beam sampling may be useful in this regard. If concerns exist for retinal irradiance distributions that are not uniform disc distributions (i.e., top-hat or Gaussian), one should check that the retinal irradiance limit in Tables 3 and 4 for each spot sized d_r is not exceeded for an aperture of that diameter.

5. Conclusions

The current guidelines for laser and incoherent optical sources incorporate certain inherent assumptions related to an awake, unstabilized eye. From this review, it is concluded that no corrections are relevant to exposure guidelines for exposure durations less than approximately 1 s. Tables 3 and 4 summarize the limits that could apply to unrestricted instrument use based on the assumption that very lengthy or extensive exposure could take place. Many instruments (e.g., perimeters and tear scopes) will clearly fall into the unrestricted category, whereas those instruments that emit levels exceeding those listed in Tables 3 and 4 would require a risk assessment. The appropriate technical standards committees[9] (e.g., ISO TC172/SC7/WG6), which would conduct a risk assessment for each specific application to develop instrument requirements based on a detailed assessment of actual use, etc., can be initially bypassed for a simple radiometric measurement of irradiance, radiant exposure, or radiance (as applicable) to determine if the unweighted value were to be exceeded. If the unweighted value were below the limit, then spectroradiometric measurements would not be required unless the spectral output were less than 400 nm, where $A(\lambda)$ values exceeded 1.4. For irregu-

Table 4. Exposure Limits for Unrestricted Instrument Use: Thermal Limits[a]

Hazard and Wavelength Range	Exposure Guideline Limit	Comments
Retinal thermal hazard for Pulsed sources	$L = (5/\alpha)\, t^{-0.25}$ W/(cm^2 sr) or 50 $t^{-0.25}$ W/(cm^2 sr) for sources where $\alpha > 0.1$ rad and for $t < 10$ s.	Applied to pulsed-light sources to protect against retinal thermal injury; $R(\lambda)$ spectrally weighted radiance per pulse, or $L = 50\, t^{-0.25}$ W/(cm^2 sr) when $\alpha > 0.1$ rad. Assumes that pupil diameter constricts from 7 to 3 mm between 0.25 and 1.0 s.
$\lambda = 380$–1400 nm	At the retinal plane, $E_{\text{therm}} = \Sigma E_\lambda R(\lambda)\Delta\lambda \leq (0.6/\alpha)\, t^{-0.25}$ W/cm^2 or $E_{\text{therm}} = (10/d_r)t^{-0.25}$ W/cm^2.	Applied to pulsed-light sources or very brief exposures expressed as a retinal irradiance. The angular subtense is expressed in radians. The retinal image diameter d_r is in millimeters.
Continuous sources	$L_{\text{therm}} = 6$ W/(cm^2 sr) for $d_r > 1.7$ mm. Therefore, for smaller d_r,	Retinal radiant exposure or irradiance, $R(\lambda)$ spectrally weighted, basic limit assumes 0.9 maximum transmittance of the ocular media.
$\lambda = 380$–1400 nm	$E_{\text{therm}} = 0.7$ W/cm^2 for $t \gg 10$ s and $d_r > 1.7$ mm. $E_{\text{therm}} = 1.2/d_r$ W/cm^2 for $t \gg 10$ s and $d_r < 1.7$mm	Lengthy exposure limit was based on near-IR limit for large retinal image areas. Retinal image diameter d_r is expressed in millimeters.
IR cornea–lens thermal hazard		
$\lambda = 770$–3000 nm	$E_c = 1.8\, t^{-0.75}$ W/cm^2 for $t < 20$ s. $E_c = 0.1$ W/cm^2 for $t > 20$ s.	cw exposure based on corneal heating of small, local areas of the cornea and lens for periods greater than 45 s and at least to 1000 s; 1-mm aperture for averaging irradiance.
$\lambda = 770$–3000 nm	$H = 1.8\, t^{0.25}$ J/cm^2	Total radiant exposure for pulsed source or from any exposure up to 45 s.
Convergent-beam anterior-segment ($\lambda = 380-1400$ nm)	$E = 25\, t^{-0.75}$ W/cm^2 for pulsed sources $t \leq 10$ s. $E = 4$ W/cm^2 (i.e., 32 mW in a 1-mm-diameter zone) for cw sources.	New limit with no spectral weighting and 0.5-mm aperture for irradiance averaging for pulsed sources; and 1.0-mm aperture for irradiance averaging for cw sources. Higher irradiances up to 20 W/cm^2 could be used under controlled conditions for $t < 1000$ s.

[a]In cases in which spectral weighting is noted in the Comments column, more complex spectroradiometric measurements are needed for a rigorous measurement.

lar source geometries, the 1.75-mrad field of view needs to be applied.

A. Risk Analysis

Exceeding the guidelines shown in Tables 3 and 4 would not be expected to cause injury unless the limits were exceeded by a substantial factor of 2–10. With regard to the safety factors incorporated into the guidelines, it should be noted that the smallest safety factors exist for the $S(\lambda)$-weighted limits in the UV spectral region for a very subtle endpoint (i.e., transient, barely detectable changes in corneal epithelial wing cells). This safety factor is small since these cells die in a normal physiological process and are sloughed off and replaced within 24–48 h. Nevertheless, because of this limited safety factor, it is recommended that the UV corneal protection guidelines be followed in product standards. This is of particular importance when photosensitizers may be present in the tissue. The greatest challenge relates to operating microscope illuminators, in which the 2.2-J/cm^2 retinal exposure guideline is frequently exceeded. In this case, the technical standards committee will need to perform a risk analysis. For example, a cautionary range of exposures between 2.2 and ~10 J/cm^2 could be considered a "cautionary zone" of exposures, where the clinician should exercise particular caution with potentially photosensitive individuals. Above 10 J/cm^2, the user of an ocular instrument must understand that the risk of injury in most patients increases significantly.

B. Laser Products

Although the guidelines developed here can be directly applied to laser sources, it is recommended that pulsed-laser products be restricted to IEC class 1 or class 1M products. For cw laser sources, the guidelines developed here should be applied to ophthalmic sources, since the laser guidelines for cw lasers are also based on the presumptions of a constricted pupil, an aversion response, and eye movements.

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