ICNIRP STATEMENT

COMMENTS ON THE 2013 ICNIRP LASER GUIDELINES

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International Commission on Non-Ionizing Radiation Protection (ICNIRP)[1]

INTRODUCTION

In 2013, the International Commission on Non-Ionizing Radiation Protection (ICNIRP) published guidelines on exposure limits for laser radiation of wavelengths between 180 nm and 1,000 μm (ICNIRP 2013a). Since then, the application of the limits has shown that some additional guidance is needed for complex exposure cases. This statement refers primarily to extended laser sources as opposed to the more common point sources. Questions received about the application of exposure limits for retinal thermal hazards from extended sources subtending more than 5 mrad made it clear that clarifications were needed regarding the description of angular subtense and repetitive-pulse correction factors. It is also confirmed that the exposure limit to protect the cornea in the far infrared wavelength range is not based on aversion responses. Also, this statement provides clarification on symbols used in the tables.

SYMBOLS USED FOR ANGULAR SUBTENSE OF THE RETINAL IMAGE

In the 2013 laser guidelines, as in earlier guidelines, the symbol α denotes the angular subtense of the apparent source, which is equal to the angular subtense of the retinal image. However, the use and meaning of the symbol α is not entirely consistent throughout the guidelines. While the physical extent of the retinal image is not limited to the diameter associated with the angular subtense $\alpha_{\max}$, in some formulas the numerical value of α is limited to $\alpha_{\max}$. An example where the numerical value of α is not limited to $\alpha_{\max}$ is equation 5 in the 2013 ICNIRP laser guidelines. While the text above equation 5 correctly states the limitations, the discussion is short and therefore prone to misunderstandings (see, for instance, comment 4.5 and Fig. A8 of Berlien et al. [2017]; also, in the Artificial Optical Radiation Directive in Europe [EU 2006], the equivalent of equation 5 is given without stating the restrictions for its application).

It is emphasized here that equation 5 is applicable only for the case of homogenous and circular sources (and therefore retinal images) that extend beyond $\alpha_{\max}$ and where the measurement field of view (FOV) is open (i.e., the angle of acceptance that defines the measurement FOV is at least as large as the retinal image), as also noted in the text of the 2013 guidelines. For the case of a homogenous and circular retinal image profile and when the exposure level is determined with an open FOV, equation 5 of the guidelines is an alternative (i.e., is equivalent) to limiting the value of C_E to $\alpha_{\max}$; i.e., $C_E = \alpha_{\max}/\alpha_{\min}$ where the exposure level is determined with a circular FOV that is limited to the same angular subtense $\gamma_{th} = \alpha_{\max}$. The latter is generally applicable also for nonhomogenous and noncircular sources (Schulmeister 2015; Schulmeister et al. 2018). Equation 5 can be derived by simple radiometric principles from the general method of limiting both the value of α for $C_E(\alpha)$ and the angle of acceptance γ_{th} for the exposure level determination to $\alpha_{\max}$. In order to avoid misunderstandings, the symbol C_E^{open} could be used for the case that C_E is extended beyond $\alpha_{\max}$ and the measurement FOV is implied to be open (as was done in equation 5 of the 2013 guidelines), while the symbol C_E should be reserved for the generally applicable scheme (as defined in Table 2 of the 2013 guidelines), using a limited FOV.

Fig. 1a shows the dependence of the retinal thermal exposure limit (EL) on the angular subtense of a circular homogenous apparent source (i.e., a circular homogenous irradiance profile of the image) as described in equation 5 of the 2013 guidelines (implying that the exposure level is determined with an unrestricted field of view, i.e., a FOV that is at least as large as the apparent source). Fig. 1b shows the equivalent trend for the general definition of C_E; i.e., the value of α in C_E is restricted to the exposure-duration-dependent $\alpha_{\max}$, and the exposure level is determined

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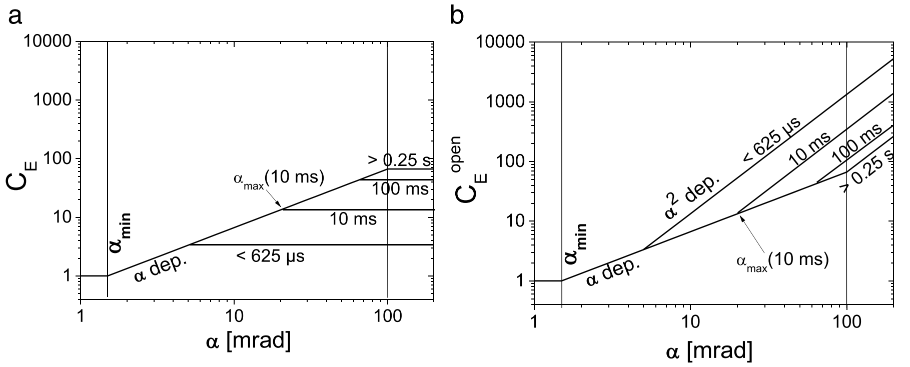

Fig. 1. Dependence of the correction factor C_E for retinal thermal exposure limits as a function of angular subtense of the image of the apparent source. In (a), the value of α in C_E is limited to $\alpha_{max}/\alpha_{min}$; in this case the measurement angle of acceptance is also limited to α_{max}. For circular homogenous image irradiance profiles, the effect of the angle of acceptance to reduce the exposure level can be accounted for by increasing the correction factor beyond α_{max}, shown in (b), but then the measurement needs to be performed with an open field of view.

with an angle of acceptance limited to an extent that is equal to α_{max}. The ratio of exposure level over EL is the same in both cases. As noted in the 2013 guidelines, the actual (physical) retinal image of the apparent source is *not* limited in its extent to α_{max}; it is the value of α in the determination of C_E which is limited.

The general definition is applicable to noncircular image profiles with homogeneous irradiance distribution (such as an ellipse), where each dimension α_x and α_y is limited to α_{max} prior to determining the average $\alpha_{lim} = (\alpha_x + \alpha_y)/2$ and where the exposure level is determined with a field of view limited to an angle equal to α_{max}. The limited FOV reduces the exposure level compared to the open FOV exposure level. Alternately, an open FOV can be used where the effect of the open FOV on the safety analysis can be accounted for by increasing C_E with the respective factor, here given by the symbol κ, eqn (1) (see also Marshall 2017; Schulmeister et al. 2018). For this concept, the limited C_E, where α_x and α_y are limited to α_{max}, is increased by the factor κ to result in a factor C_E^{open} which is used to determine the EL:

$$C_E^{open} = \kappa \times C_E = \kappa \times \frac{\alpha_{lim}}{\alpha_{min}} = \kappa \times \frac{\alpha_x + \alpha_y}{2} \times \frac{1}{\alpha_{min}}. \quad (1)$$

For a given image profile, the factor κ can be determined as the ratio of the total power within the image (i.e., the power that passes through the 7 mm measurement aperture) to the power that lies within a circular FOV with an angular subtense $\gamma_{th} = \alpha_{max}$. For a homogeneous circular profile larger than α_{max}, $\kappa = \alpha^2/\alpha_{max}^2$ and equation 5 of the 2013 ICNIRP guidelines follows. We note that for arrays or nonhomogenous irradiance profiles, the analysis implies the need to also consider fields of view smaller than the limitation given by α_{max} as well as to vary the extent of the field of view in each dimension independently, as described in the measurement section (under the heading "Thermal") of the 2013 guidelines; in practice this analysis is often performed with rectangular FOVs (see also Schulmeister 2015).

In other sections of the ICNIRP 2013 laser guidelines, for instance in Table 5, the symbol α is used as a shorthand to mean "extent of the image of the apparent source." Strictly speaking, the usage of α in this sense is only applicable for the case of circular homogeneous retinal image profiles. For instance, in Table 5 for the retinal photochemical EL, there is a side note 2 given in the restriction column, "For $\alpha \leq \gamma_{ph}$, γ not restricted." This is intended to mean that when the image of the apparent source (as irradiance profile) is smaller than the defined measurement angle of acceptance γ_{ph}, any measurement angle of acceptance (symbol γ) can be used as long as it is larger than the image of the apparent source. For general applicability, instead of using a side note in the table, a footnote would have provided more space to avoid using the symbol α as shorthand for "extent of the retinal irradiance profile." The usage of the symbol α in this way can be misleading, since the symbol α has a very specific meaning related to the retinal thermal limits. For the determination of C_E as discussed above, as part of the retinal thermal EL, α is the average of α_x and α_y. Consequently, the numerical value of α can be smaller than a given value of γ_{ph} (i.e., the mathematical inequality $\alpha \leq \gamma_{ph}$ is fulfilled) while the image irradiance profile is, in one direction, larger than γ_{ph}. In this case, not restricting the FOV to γ_{ph} for corneal irradiance measurements results in a needlessly restrictive exposure level analysis.

The photochemical retinal EL as given in the 2013 and 2000 ICNIRP laser guidelines are derived directly from the radiance dose EL of 10^6 J m^{-2} sr^{-1} given in the ICNIRP incoherent radiation guidelines (ICNIRP 2013b) by multiplication by the solid angle equal to $\gamma_{ph}^2\pi/4$. Thus, it is evident from basic radiometric principles (Schulmeister 2001) that the radiance dose limit given in the incoherent optical radiation guidelines, together with the averaging angle of acceptance defined there, is identical to the laser EL, where the FOV is limited to γ_{ph}. In both cases γ_{ph} reflects the angular extent of very conservatively assumed eye movements. It is also pointed out that in both the 2013 laser guidelines as well as in the 2013 incoherent optical radiation guidelines, the retinal photochemical limits are expressed in terms of radiance dose (or radiance) as well as in terms of radiant exposure (or irradiance) at the cornea. The latter is convenient for retinal image profiles (apparent sources) that are smaller than the angle γ_{ph} and therefore are the default for laser radiation; the actual angle of acceptance for the measurement is then not relevant (as long as it is larger than the apparent source). The limits expressed as radiance dose (or radiance) are the default for incoherent optical radiation where γ_{ph} defines the averaging angle for the determination of the exposure level expressed as radiance.

MULTIPLE-PULSE CORRECTION FACTOR

A reduction factor C_P applies to the retinal thermal EL for repetitive exposures to pulses, lowering the per-pulse EL below the single-pulse EL. The 2013 laser guidelines, in the section "Repetitive pulse exposures" in item 3, define C_p with different trends that depend on exposure (pulse) duration and on the value of α. It needs to be clarified that the value of α in the criteria to determine C_P is *not* limited to the value of α_{max}. This is evident, since otherwise, the inequality in criterion b (if $\alpha > \alpha_{max}$) could never be fulfilled. The value of α used in these inequalities 3a and 3b is the same as that used for the assessment of the long-term exposure, i.e., comparing the average irradiance (or average power through the 7 mm aperture) against the EL for the respective exposure duration of typically 0.25 s or T_2. The value of α in this case is limited to α_{max} = 100 mrad. This is also consistent with the duration used to determine the number of pulses n, which is 0.25 s or T_2. With respect to the condition in b (if $\alpha \geq 100$ mrad, $C_P = 1$), α is not limited by α_{max} = 100 mrad but has to be understood as the angular subtense of the full image. In this case, it is required that *both* dimensions of the image of the apparent source are larger than or equal to 100 mrad in order to set C_P equal to unity. This criterion can be made consistent with using the parameter α limited to α_{max} = 100 mrad (as in the other criteria of item 3b) when it is changed to "if $\alpha = 100$ mrad, $C_P = 1$" noting that α in this case is then also determined as the average of the two dimensions. Only when *both* dimensions are greater than or equal to 100 mrad is the average equal to 100 mrad and then C_P can be set to unity.

There is a discontinuity of C_p at $\alpha = 5$ mrad and at $\alpha = \alpha_{max}$ when the number of pulses n is larger than 40. This discontinuity is not based on discontinuities of biological effects but is due to recommending simplified rules. The discontinuity can be avoided in an assessment by assuming a smaller source not only for the determination of C_P, but generally for the safety assessment. This approach is justified because for a given power level (or energy per pulse) entering the eye, a larger retinal image cannot be more hazardous than a smaller one.

A similar situation in terms of a discontinuity of C_P is present at $t = T_i$. For instance, for $\alpha < 5$ mrad, the factor $C_P = 1$ for pulse durations of longer than T_i but $C_P < 1$ for pulse durations less than T_i, so that a shorter pulse could exceed the maximum permissible exposure (MPE), while the longer pulse with the same peak power is below the MPE, which is against biophysical principles. This discontinuity can be resolved by assuming a longer pulse duration for the determination of the correction factor.

While the text for the application of C_P to reduce the EL referred to the "single pulse limit," groups of pulses need to be interpreted as effective pulses, and C_P is applied to these effective pulses. This means that the total exposure level for a given group of pulses needs to be below the EL determined for the duration of that group of pulses, reduced by C_P based on the number of these groupings within the overall assumed exposure duration such as 0.25 s or T_2. Note that the value of α_{max} is determined for the duration of the group of pulses.

For assessment durations less than or equal to T_i a reduction factor applies as described in 3c of the 2013 laser guidelines (p. 287). Since the EL in this time domain is given as constant radiant exposure or constant energy, the cumulative radiant exposure or energy of pulses within T_i is compared to the EL. These added pulses are then counted as one when the value of n is determined.

BEAM DIAMETER DEFINITION

There sometimes is a concern that a criterion for a beam diameter for arbitrary irradiance profiles incident on the eye or the skin should be given in ICNIRP guidelines. However, from the point of view of recommending EL for the protection of the cornea and skin, this is not necessary. It is sufficient to recommend the use of apertures over which the irradiance is averaged, a dosimetric concept which is applicable independently of the beam diameter. While the injury threshold of the skin and the cornea in a certain range depend on the beam diameter of the incident laser beam (see, for instance, McCally et al. 2003), the respective ELs are simplifications and are recommended independently of the incident beam diameter. The parameter *beam diameter* as a value is only needed when the irradiance is to be calculated for a given total power in the beam, but this is an issue which is not in the scope of ICNIRP guidelines, as it is a question of basic radiometry and performing calculations rather than direct measurements. The quantity needed for the application of the ICNIRP EL is the irradiance or radiant exposure averaged over defined apertures, and it is not in the scope of the ICNIRP guidelines to specify how this exposure quantity is determined. For arbitrary irradiance distributions, which is two-dimensional information, it is not possible to define a beam diameter criterion that will in all cases result in the correct average irradiance when the total power in the beam is divided by the area defined by the beam diameter.

For the retinal thermal limits, which do depend on the parameter α, a method *is* described in the ICNIRP 2013 laser guidelines to determine the value of that parameter for irregular profiles (see section "Thermal" on p. 288 of the 2013 guidelines and notes above in this statement).

DUAL LIMIT TO PROTECT THE CORNEA FOR WAVELENGTHS LESS THAN 1400 NM

The 2013 laser guidelines increased the retinal thermal limit correction factor C_C to consider the finding that for wavelengths approaching 1,400 nm, preretinal ocular media absorb a significant portion of the radiation that is incident on the eye. This increase of the retinal limit made it necessary to recommend an additional limit to protect the cornea. In Table 5 of the 2013 laser guidelines, footnote d refers to the skin exposure limits, and for exposure in the infrared wavelength range (i.e., 780 nm to 1,400 nm), recommends cornea limits of 2 times the skin exposure limit. The averaging aperture used to determine the exposure level is not defined in the 2013 guidelines. This statement makes it clear that the eye averaging aperture defined for the wavelength range above 1,400 nm is to be used (1 mm diameter for exposure durations up to 0.35 s and 3.5 mm for exposure durations equal to and greater than 10 s, with a $t^{0.375}$ dependence in between). Also it should be noted that for beam diameters less than about 3 mm and wavelengths between about 1,330 nm and 1,400 nm, the exposure should not exceed the skin exposure limit because the recommendation of using 2 times the skin limit as dual limit might not be associated with a large enough reduction factor. For this discussion it should be considered that for the general application of exposure limits, the skin exposure limit applies for the eyelid, so that for a typical exposure analysis, there is no practical value in an exposure limit of the eye that is above the exposure limit of the skin. For wavelengths below about 1,300 nm, the reduction factor between the corneal injury threshold and the skin EL is at least of the order of 5 for small beams and 20 for beams larger than 3.5 mm, even for an immobilized eye (Schulmeister et al. 2019). For wavelengths approaching 1,400 nm, the reduction factor for assumed exposure durations of 10 s and longer is smaller because of the strongly increasing water absorption. However, as long as there are normal eye movements, protection is afforded when the skin EL is applied. However, for medical procedures with stationary eyes, beams of the order of 1 mm and wavelengths approaching 1,400 nm, averaging over a 3.5-mm-diameter aperture is not justified.

AVERSION RESPONSE IN RELATION TO THE CORNEAL EXPOSURE LIMITS

The section "Effects of mid and far infrared radiation" in the 2013 laser guidelines discusses potential aversion responses and notes that for exposures that approach 1,000 W m^{-2} for a second or two, there would be an "immediate sense of heating of the cornea leading to blinking and rotation of the eye." As a literature review by a German expert working group (Berlien et al. 2017) shows, a level of 1,000 W m^{-2} might not be sufficient to induce a blinking reflex. However, in discussions about the level of the EL, it is important that the current EL of 1,000 W m^{-2} is clearly not based on assumptions of aversion responses. The 2013 guidelines also states: "The infrared corneal aversion response requires further study before user safety requirements are relaxed." That the EL of 1,000 W m^{-2} is not based on the assumption of an aversion response is also evident from comparisons with corneal injury thresholds that were obtained with anesthetized animals and stationary laser beams. The corneal injury threshold for a 10 s exposure for a strongly absorbed wavelength (such as 10.6 μm) for a stationary eye and large beam diameters (which is associated with worst-case threshold levels) is equal to about 20,000 W m^{-2} (Farrell et al. 1985). Thus, the reduction factor is 20.

For longer exposure durations, the exposure limit remains constant at 1,000 W m^{-2} and the injury threshold, for a stationary eye, decreases somewhat, resulting in a reduction factor somewhat smaller than 20. Injury thresholds of the cornea can be modeled well with a computer model (Schulmeister and Jean 2011; Jean et al.[1]); the model predicts that the injury threshold is above 10,000 W m^{-2} even for 100 s exposure duration for a 6 mm beam at the cornea, without any eye movements and with a stationary laser beam. Due to the large reduction factor at 10 s, the EL is still well below the injury threshold for unrealistically long exposure durations of a stationary eye. For most exposure conditions, 10 s without any eye movements is unrealistically long. Therefore, it is irrelevant whether an aversion response is induced at the exposure limit level of 1,000 W m^{-2} or not. The safety of the cornea is assured by the conservatively low EL, even for intentional long-term exposure of an immobilized eye and a stationary beam, i.e., even for a person under anesthesia with no blinking and no eye movements (Fine et al. 1968).

In fact, based on well-characterized injury thresholds, the EL could be increased to 3,000 W m^{-2} for exposure

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[1] Jean M, Schulmeister K, Lund DJ, Stuck BE. Computer model to predict laser induced corneal injury. Submitted to JBO; 2020.

durations of 10 s and would still provide adequate protection even for the case of no aversion response or eye movements for several minutes; at these exposure levels, it probably *can* be assumed that aversion responses would be induced, reducing the effective exposure duration. Future updates of the laser guidelines might consider increases in the skin and eye ELs in the infrared wavelength range above 1,400 nm, particularly for exposure durations of 10 s, as they are currently conservative.

REVIEW OF EXPOSURE LIMITS AND NEED FOR ADDITIONAL DATA

The present statement provides additional information and guidance on the application of the 2013 laser guidelines but does not amend the exposure limits. ICNIRP intends to prepare and issue an update of the laser guideline at a later date. Currently, the committee is reviewing existing data and hopes to encourage additional experimental studies where there is a perceived need for additional data.

One of the updates of the EL under consideration relates to the long-term EL in the far ultraviolet (UV) wavelength range below 280 nm. The current EL, which shows no wavelength dependence, is applicable and necessary for pulse durations in the nanosecond regime in order to protect from photoablation of the cornea by ArF excimer laser radiation. The current ELs are unnecessarily low for exposure to continuous wave radiation or for the average irradiance assessment of pulsed exposure and can be increased to a level equivalent to the broadband EL as reflected by $S(\lambda)$ (Sliney 2019).

Lund (2019) reviewed the data relating the effective dose—expressed as energy per pulse—that produces an ophthalmoscopically visible lesion with a probability of 50% (the ED_{50}; see, for instance, Sliney et al. 2002) for small-spot laser exposures in the non-human primate retina to the duration of the exposure and showed that the currently defined EL provides a relatively small safety margin relative to the ED_{50} for exposure at 10 ps. It is incumbent on the committee to reconsider the definitions of the EL for small-spot exposures of duration less than 1 ns.

The correction factor C_C, which determines the wavelength dependence of the retinal EL in the wavelength regime above 1,200 nm, might not, as currently defined, provide a sufficient safety margin at 1,320 nm for larger beam diameters at the cornea in the exposure duration regime of roughly 100 μs to 100 ms. It might be necessary to adjust the definition of C_C leading to a decrease of the EL. Further analysis of the existing data and experimental studies to determine the impact of chromatic aberration on the ED_{50} for laser-induced retinal injury in rhesus monkey eyes at wavelengths near 1,320 nm would be valuable in the effort to determine whether a limitation to or adjustment of C_C is needed.

The EL for multiple pulses in the exposure duration regime of microseconds and less continues to be debated by the committee. Lund and Sliney (2014) recommended setting $C_P = 1$ for $\alpha \leq 5$ mrad in the microcavitation regime. At the time of the development of the 2013 laser guidelines, the experimental threshold data was insufficient to justify limiting the reduction factor C_P in this regime. Subsequent scientific studies by Lund et al. (2014) confirm that the additivity of multiple pulses is weak, i.e., the reduction of the injury threshold expressed as energy per pulse is small. Consequently, it is justified to limit C_P in this time domain to a minimum value of $C_P = 0.4$. When additional threshold data becomes available, it might be possible to set $C_P = 1$, thus greatly simplifying the calculation of the EL. ICNIRP thus recognizes the need for a non-human primate (rhesus monkey) retinal injury threshold study program for laser radiation in the nanosecond (1-100 ns) and microsecond (1-100 μs) pulse duration regime for multiple pulses, with a priority for the nanosecond regime.

Acquisition of data for these exposure conditions will assist in evaluation of the multiple-pulse reduction factor to assure adequate protection and to prevent overly conservative exposure limits that inhibit prudent use of laser devices for these exposure conditions. While there is a reliable collection of thresholds for single pulses in the nanosecond and lower microsecond pulse duration regime, there is no injury threshold data for multiple-pulse macular exposures assessed 24 h after exposure. Data both for minimum retinal image diameters as well as extended sources (retinal irradiance diameter of 100 μm or larger) are needed as a basis to review the multiple-pulse reduction factor C_P. Ideally, the pulse repetition rate is varied within the regime where permitted exposures are not limited by the average irradiance criterion. It would be a great benefit if a research laboratory with suitable expertise could perform such studies.

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