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Comparison of laser induced corneal injury thresholds with safety limits for the wavelength range of 1200 nm to 1500 nm

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ABSTRACT
A computer model predicting thresholds for laser induced corneal injury was used to systematically analyze wavelength, pulse duration and beam diameter dependencies for wavelengths between 1200 nm and 1500 nm, for the exposure duration regime of 10 µs to 100 s. The thresholds were compared with maximum permissible exposure (MPE) values to protect the cornea as specified in ANSI Z136.1-2022, ICNIRP 2013 and IEC 60825-1:2014. In the wavelength range between 1200 nm and 1400 nm, the dominant hazard transitions from the retina to the cornea. Consequently, limits are needed to protect both the cornea and the retina. In the lower wavelength range, the retinal limits are more conservative, while in the higher wavelength range, the corneal limits are lower. Comparison with injury thresholds shows that the ANSI MPEs include a large safety margin for all wavelengths. Due to the 7 mm aperture stop defined in IEC 60825-1, levels permitted by the Class 3B limit exceed predicted injury thresholds for small beam diameters and wavelengths between approximately 1350 nm and 1400 nm. The Class 3B limit does not appear to be sufficiently protective for these conditions. For the skin MPEs, the margin between corneal injury thresholds and MPEs decreases steadily for wavelengths approaching 1400 nm. However, normal eye movements can be expected to reduce the effective exposure so that skin MPEs may serve as adequate limits to protect the cornea for wavelengths less than 1400 nm until a specific limit to protect the cornea is promulgated by ICNIRP.

Keywords: laser safety, corneal injury, damage threshold, computer model, ANSI Z136.1, IEC 60825-1.

I. EXPOSURE AND CLASSIFICATION LIMITS

A. Introduction

Exposure limits to protect the eye are defined in the laser safety standards IEC 60825-1[1], ANSI Z136.1[2] and the ICNIRP[3] guidelines. In the following, these documents are sometimes referred to simply as "IEC", "ANSI" and "ICNIRP", respectively. The European[4] standard EN 60825-1:2014 was identical with IEC 60825-1 at the time of publication. In 2021, amendment A11 was published[5], which featured an additional emission limit to protect the cornea. The term exposure limits (abbreviated to EL) is used by ICNIRP and the term maximum permissible exposure (abbreviated to MPE) is used in the ANSI and IEC standards, but the numerical values are in most cases the same; the differences are discussed below. IEC 60825-1 lists the MPEs, copied from the ICNIRP ELs, in an informative annex. Consequently, the discussion on IEC MPEs also applies to the ICNIRP ELs. The IEC standard lists MPEs for the purpose of determining hazard distances for Class 3B and Class 4 laser products. The primary purpose of the IEC standard is product safety classification, based on accessible emission limits (AELs). Class 1 AELs are derived directly from the MPEs by multiplication by the area of the measurement aperture.

The ANSI Z136 committee and ICNIRP review injury thresholds, mostly from animal studies, and derive MPE values set some factor below known injury thresholds. This factor is called reduction factor by ICNIRP but can also be called safety margin. It is known from animal studies (see Jean *et al.*[6] for a list), that the corneal injury thresholds are strongly dependent on wavelength and pulse duration, and to a lesser extent on the diameter of the laser beam incident on the cornea. A computer model for predicting corneal laser induced injury thresholds was developed at the Seibersdorf Laboratories and is described elsewhere[6,7]. The model is based on calculating the temperature as function of time in the cornea with a finite element software package and applying the Arrhenius integral to determine the threshold for a minimum lesion. The model was validated against all relevant experimental injury thresholds for exposure durations from 1.7 ns to 100 s and wavelengths from 1064 nm to 10.6 µm. The ratio of computer prediction to experimental injury threshold was used as a figure of merit to evaluate the model. The largest ratio found was 1.8, where 169 experimental injury thresholds were considered. The maximum factor of the model prediction being lower than an experimental threshold was 2.0. The threshold data computed for different wavelengths, pulse durations and beam diameters provide the basis for a systematic comparison with exposure limits, that was previously not available.

The wavelength range from approximately 1200 nm to 1400 nm is a transition zone where the anterior parts of the eye are relatively transparent at 1200 nm and highly absorptive at 1400 nm. As a result, the location of threshold level eye injury is the retina for wavelengths at 1200 nm and transitions to the cornea for wavelengths approaching 1400 nm. The wavelength dependence of the currently promulgated retinal MPEs reflects the sharp increase in absorption in the anterior parts of the eye within the transition zone. Since the MPEs to protect the retina are expressed as permitted irradiance at the surface of the eye, for wavelengths approaching 1400 nm, the retinal MPEs permit very high levels of exposure for the anterior parts of the eye. Also, retinal MPEs for large apparent sources are associated to high levels of permitted corneal irradiance, even for wavelengths towards the lower end of the wavelength transition range. Consequently, an additional limit is needed to protect the cornea. This paper only discusses potential corneal injury and limits to protect the cornea. In a hazard assessment or product classification, also the retinal limit needs to be considered. For small apparent sources, the retinal limit is the more conservative one and limits the ocular exposure: for instance, for 10 s exposure duration the retinal limit is lower than the ANSI corneal limit for wavelengths up to almost 1300 nm. However, for apparent sources of 100 mrad angular subtense, the ANSI corneal limit for 1200 nm is equal to the retinal limit.

The model predictions for single pulses are used in this paper for the comparison with the MPEs to protect the cornea in the wavelength range of 1200 nm to 1500 nm. The comparison can serve as a basis for laser safety committees to consider possible improvements of the MPEs and product safety limits. A comparison of multiple pulse thresholds against the respective MPE values is beyond the scope of the paper but has been discussed in an ILSC 2019 proceedings paper[8].

B. Maximum permissible exposure values

In the 2013 to 2014 time - frame, some of the exposure limits promulgated by IEC, ANSI[9] and ICNIRP were updated. In 2020, ICNIRP[10] provided additional information to the 2013 update. Compared to previous editions, the limits to protect the cornea for exposure to laser radiation with wavelengths above 1500 nm were not changed. Of relevance to this paper is the significant increase in MPEs to protect the retina in the 1250 nm to 1400 nm wavelength range. Prior to the 2013/2014 revision, the retinal limit, defined in the retinal hazard wavelength range of 400 nm to 1400 nm, was low enough so that the cornea was not at risk as long as the exposure of the eye was below the retinal limit[*]. In previous editions, there was a "clean cut" at 1400 nm between the limit to protect against injury of the retina for shorter wavelengths and injury to the cornea at longer wavelengths. The increase of the retinal limit in the wavelength range from 1250 nm to 1400 nm made it necessary to define additional limits to protect the cornea. Due to the strong absorption of the pre-retinal media in this wavelength range, the cornea can be damaged at levels below the retinal exposure limits. The additional limits to protect the cornea in the wavelength range below 1400 nm have been defined differently by ICNIRP, IEC and ANSI. The MPEs to protect the cornea are summarized in Table I and are discussed in detail in the following subsections.

[*] For exposure to highly divergent beams at very close distances, for large retinal image sizes and relatively deeply penetrating wavelengths, the iris and lens can be at risk even though the exposure is below earlier retinal thermal limits; IEC and ANSI introduced corresponding guidance already in the pre-2013/2014 editions, and this issue is not in the scope of this paper.

Table I. MPEs to protect the cornea for infrared wavelengths between 1200 nm and 1500 nm and exposure durations greater than 1 ns, expressed in terms of the incident radiant exposure in J cm^{-2}. IEC and ICNIRP specify the MPEs in J m^{-2}.

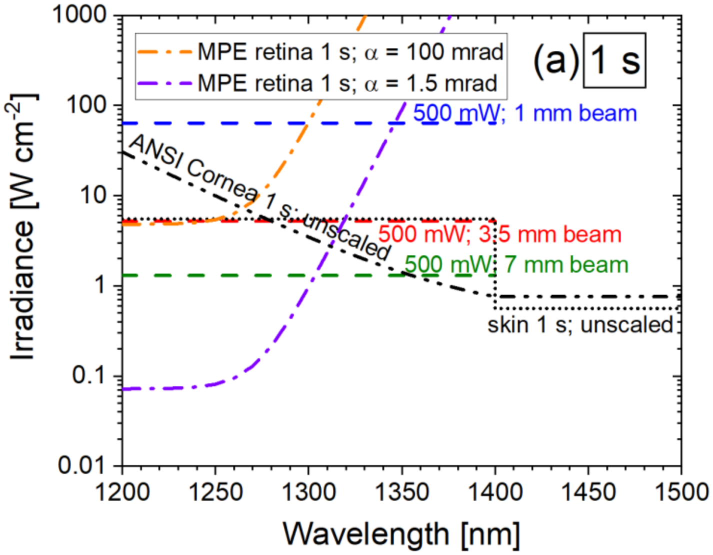
<table>
<tr><th>Wavelength</th><th>Exposure Duration</th><th>ANSI: dedicated “corneal” MPEs for λ < 1400 nm</th><th>IEC/ICNIRP: for λ < 1400 nm skin MPEs used to protect the cornea</th></tr>
<tr><td rowspan="5">1200 - 1400 nm</td><td>1 ns - 100 ns</td><td rowspan="2">0.3 K_λ J cm^{-2}</td><td>0.02 C_4 J cm^{-2} #</td></tr>
<tr><td>100 ns - 1 ms</td><td rowspan="3">1.1 C_4 $t^{0.25}$ J cm^{-2} #</td></tr>
<tr><td>1 ms - 4 s</td><td>0.3 K_λ + 0.56 $t^{0.25}$ - 0.1 J cm^{-2}</td></tr>
<tr><td>4 s - 10 s</td><td>0.3 K_λ + 0.7 J cm^{-2}</td></tr>
<tr><td>>10 s</td><td>0.03 K_λ + 0.07 W cm^{-2}</td><td>0.2 C_4 W cm^{-2} #</td></tr>
<tr><td rowspan="4">1400 - 1500 nm</td><td>1 ns - 1 ms</td><td>0.3 J cm^{-2} §</td><td>0.1 J cm^{-2} $</td></tr>
<tr><td>1 ms - 4 s</td><td>0.56 $t^{0.25}$ + 0.2 J cm^{-2} §</td><td rowspan="2">0.56 $t^{0.25}$ J cm^{-2} $</td></tr>
<tr><td>4 s - 10 s</td><td>1 J cm^{-2} §</td></tr>
<tr><td>>10 s</td><td colspan="2">0.1 W cm^{-2} §$</td></tr>
<tr><td colspan="2">Correction factors</td><td colspan="2">$K_\lambda = 10^{0.01(1400-\lambda)}$ for ANSI
C_4 = 5 from 1050 to 1400 nm for IEC (referred to as C_A in ICNIRP and ANSI)</td></tr>
</table>

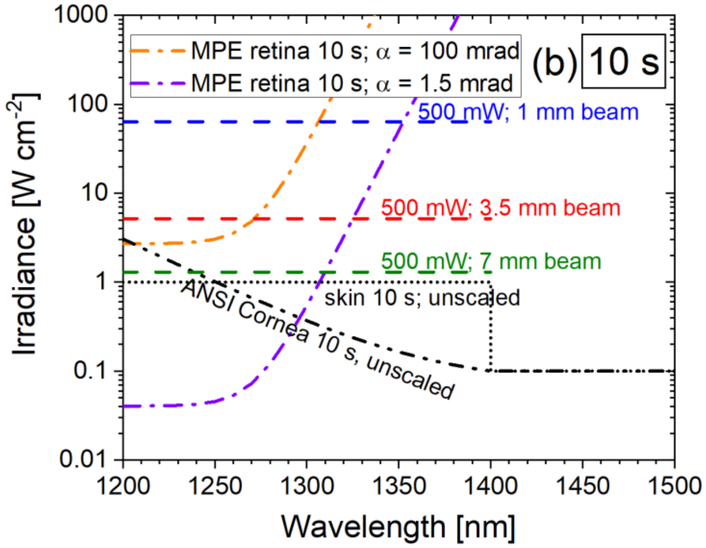
To protect the cornea for wavelengths less than 1400 nm, ICNIRP and IEC recommended that the skin MPEs be applied as an additional limit (footnote d for Table 5 in the 2013 ICNIRP guidelines applicable to the infrared wavelength range, but see also ICNIRP comments[10] 2020; footnote f for Table A.4 in IEC 60825-1:2014 applicable to wavelengths between 1250 nm and 1400 nm). For wavelengths less than 1400 nm, ANSI defines the same MPEs as ICNIRP/IEC to protect the skin, but has a specific set of MPEs to protect the cornea (Table 7f of the ANSI standard). This means that in the ANSI standard, for wavelengths less than 1400 nm, the skin and the corneal MPEs are different.

§ For wavelengths above 1400 nm, the ANSI corneal and skin MPEs are the same.

$ For wavelengths above 1400 nm, the ANSI, IEC and ICNIRP skin MPEs are all the same. While ANSI has deviating corneal limits between 1400 nm and 1500 nm, for ICNIRP and IEC the skin MPEs are the same as the corneal MPEs, and these were not changed in the 2013/2014 revision.

To protect the cornea for wavelengths between 1200 nm and 1400 nm, the ANSI committee developed specific MPEs for the cornea, extending the corneal MPEs which previously applied only to radiation with wavelengths longer than 1400 nm, to 1200 nm. For pulses, the corneal MPEs were increased for wavelengths above 1400 nm, so that the ANSI corneal MPEs avoid a step function at 1400 nm. For wavelengths below 1400 nm, the ANSI corneal MPEs feature a wavelength dependence expressed by the factor K_λ, which ranges from $K_\lambda = 100$ at 1200 nm to $K_\lambda = 1$ at 1400 nm (see Fig. 1(a) and Fig. 1(b)). The ICNIRP 2013 revision[3] and the ICNIRP 2020 comments[10] recommend that the skin MPEs be applied to protect the cornea in the infrared wavelength range (i.e. in principle down to wavelengths equal to 700 nm). IEC 60825-1 notes in the footnote to the MPE tables A.1 to A4 that: *"In the wavelength range between 1 250 nm and 1 400 nm, the limits to protect the retina given in this table may not adequately protect the anterior parts of the eye (cornea, iris, and lens) and caution needs to be exercised. There is no concern for the anterior parts of the eye if the exposure does not exceed the skin MPE values."* We note that for the IEC and ICNIRP exposure limits, for wavelengths above 1400 nm, the skin MPEs are equal to the ocular MPEs to protect the cornea, and at 1400 nm, for an exposure duration of 10 seconds, there is a step function with a discontinuity of a factor of 10. For exposure durations less than 100 ns, there is no step function at 1400 nm. For exposure durations longer than 100 ns the skin MPE for $\lambda < 1400$ nm and therefore the discontinuity at 1400 nm start to increase up to a factor of 10 at 10 seconds exposure duration. The origin of this step function for the skin MPEs at 1400 nm is that for wavelengths above 1400 nm, the MPEs to protect the skin are equal to the MPEs to protect the eye.


(a)
1 s
MPE retina 1 s; α = 100 mrad
MPE retina 1 s; α = 1.5 mrad
500 mW; 1 mm beam
ANSI Cornea 1 s; unscaled
500 mW; 3.5 mm beam
500 mW; 7 mm beam
skin 1 s; unscaled
Irradiance [W cm-2]
Wavelength [nm]
1000
100
10
1
0.1
0.01
1200
1250
1300
1350
1400
1450
1500


(b)
10 s
MPE retina 10 s; α = 100 mrad
MPE retina 10 s; α = 1.5 mrad
500 mW; 1 mm beam
500 mW; 3.5 mm beam
500 mW; 7 mm beam
skin 10 s; unscaled
ANSI Cornea 10 s, unscaled
Irradiance [W cm-2]
Wavelength [nm]
1000
100
10
1
0.1
0.01
1200
1250
1300
1350
1400
1450
1500

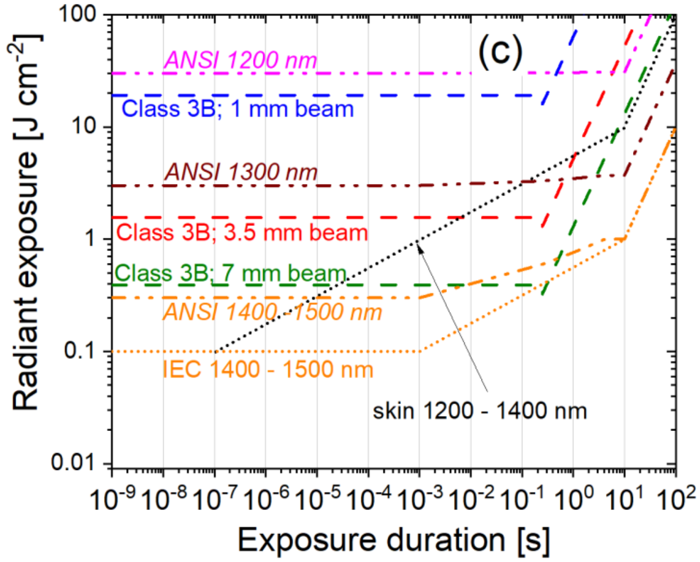


FIG. 1. MPEs and classification emission limits relevant for corneal protection for wavelengths less than 1500 nm. Presented as function of wavelength together with retinal MPEs in (a) for 1 second exposure duration and (b) for 10 seconds. In (c) presented as function of exposure duration. With the exception of the Class 3B limit, the limits are not diameter-scaled, i.e. for a proper comparison of permitted corneal exposure levels, the retinal, ANSI and skin limits apply to beam diameters that are larger than the limiting aperture (see section I.C).

C. The effect of the measurement aperture

Selection of appropriate averaging apertures are important to determine the irradiance or radiant exposure that is compared to the MPE, particularly with small beam diameters or beams with hotspots. Consequently, for the safety assessment of ocular and skin exposure, both the MPEs and the averaging aperture are relevant. While ANSI, IEC and ICNIRP use the term "limiting apertures", in terms of the radiometric effect[11,12,13] it is actually an *averaging* aperture, because the irradiance and radiant exposure is averaged over the respective aperture area. The average irradiance is determined by dividing the power that passes through the aperture by the area of the aperture. If the beam is smaller than the aperture, or if there are hotspots in the beam smaller than the aperture, then this averaged irradiance will be less than the actual irradiance. Thus, compared to the actual corneal irradiance, the exposure level that is compared against the MPE is reduced. This reduction of the irradiance level is relevant for the comparison of the MPEs with injury thresholds, because if the *averaged* exposure level is equal to the MPE, the *actual* exposure of the cornea (at least when there are no eye movements) will be greater than the MPE and thus closer to the injury threshold than the MPE value implies. Thus, the averaging aperture has the effect of reducing the margin between the exposure level permitted by the MPE and the injury threshold. For example, if the laser beam profile on the cornea is a top-hat with a diameter of 1 mm and the averaging aperture has a diameter of 3.5 mm, the actual irradiance is a factor of $3.5^2 = 12.3$ higher than the averaged irradiance. Generally, for top-hat beam profiles that are smaller than the limiting aperture, the ratio, here given the symbol κ, between actual irradiance and the averaged irradiance is equal to the ratio of the area of the limiting aperture to the area of the beam. The effect of the averaging aperture, when comparing injury thresholds with MPEs, must be considered in conjunction with eye movements. Animal experiments and computer modeling to determine injury thresholds are performed with a stationary beam and a stationary target tissue. For long-duration exposure of an awake human, some relative movement can be assumed, resulting in a reduction of the effective irradiance. However, these movements are not well defined and are difficult to account for quantitatively in a comparison of the injury thresholds with MPEs to characterize the effective safety margin. Therefore, the primary analysis and comparison is done in this paper for the assumption of a stationary beam and stationary tissue.

In some research papers on skin injury, the injury thresholds were reduced based on the effect of the averaging aperture for comparison with the MPE[14]. Instead of reducing the injury threshold by the factor κ, we prefer to increase the MPE by the factor κ for the comparison with injury thresholds. We prefer this approach, because the experimental injury threshold determined with a stationary beam and a stationary target tissue is governed by physical and biological properties that are not related to the averaging apertures defined in the standards. The MPEs that are increased by the factor κ are in this paper referred to as "scaled" MPEs. This scaling is only necessary when comparing biological thresholds with MPEs to determine the safety margin. For a workplace hazard analysis (which is based on MPEs rather than injury thresholds), the MPEs are used as defined in the standards and it is the exposure level that is "scaled" (averaged by the measurement aperture). Again, we note that such a comparison is based on the assumption of a stationary beam and a stationary tissue target, which for 10 second exposure durations for normally behaving humans is not applicable.

All standards and the ICNIRP guidelines define a 7 mm-diameter limiting aperture for the retinal MPE analysis from 400 nm to 1400 nm and a constant diameter of 3.5 mm for the skin MPE analysis for wavelengths up to 100 µm. For MPEs to protect the cornea in the infrared wavelength range, the diameter of the limiting aperture depends on the exposure duration t, as summarized in Table II.

Table II. Limiting apertures defined for the determination of the exposure level to be compared against the MPEs to protect the cornea in the infrared wavelength range up to a wavelength of 100 µm.

Document	**Location in document**	**Formulas; *t* in seconds**	**Comments**
ANSI Z136.1-2022	Table 10a	1 mm for $t \leq 0.30$ s 1.5 $t^{0.375}$ mm for 0.30 s < t < 10 s 3.5 mm for $t \leq$ 10 s	
ICNIRP 2013	Table 5 for wavelengths above 1400 nm	1 mm for $t \leq 0.35$ s 1.5 $t^{0.375}$ mm for 0.35 s < t < 10 s 3.5 mm for $t \leq$ 10 s	The application of the skin MPEs to protect the cornea, and the reference to the time-varying limiting aperture was clarified in the 2020 ICNIRP statement
IEC 60825-1:2014	Table A.6, for the eye above 1400 nm	Same as ICNIRP	It stands to reason to apply this limiting aperture when the skin MPEs is used to protect the cornea, even though this is not mentioned in IEC 60825-1

The diameters of the averaging (limiting) apertures used to determine corneal and skin exposure levels are defined in an equivalent way in the ANSI, ICNIRP and IEC documents. The ANSI standard, contrary to IEC and ICNIRP, specifically refers to limits to protect the retina, cornea and skin (Table 10a of the ANSI standard). For wavelengths above 1400 nm, for the MPEs to protect the cornea, all standards define an averaging aperture diameter that depends on exposure duration[†]: the diameter equals 1 mm for exposure durations up to 0.35 seconds (0.3 seconds in ANSI), and then increases with a $t^{0.375}$ dependence (i.e. $t^{3/8}$) to a diameter of 3.5 mm for an exposure duration of 10 seconds. The main rationale for the increasing averaging aperture for determining the corneal exposure level is the assumption of eye movements that result in a decrease of the effective relevant exposure level. It is clear that, with the exception of medically immobilized eyes, a certain extent of eye movements can be assumed for a 10-second exposure duration, so increasing the averaging aperture diameter seems justified. In turn, this means that increasing the MPE with κ, as in the analysis below, for 10-second exposure duration is overly restrictive, as it assumes a stationary beam and a stationary target. Therefore, for a more balanced discussion, more weight is given to the 1-second exposure duration, where the averaging aperture diameter is 1.5 mm and where the eye movements relative to a stationary beam might be small.

Table 10a of the ANSI standard specifies the time-dependent limiting aperture for the cornea including for wavelengths less than 1400 nm, where the ANSI standard has a specific set of MPEs to protect the cornea. IEC and ICNIRP recommend using the skin limit as additional limit to protect the cornea in the 1200 nm to 1400 nm wavelength range. While ICNIRP clarified in the 2020 Comment publication[10] that the limiting aperture that is defined for the cornea is to be used, the IEC standard does not specifically state what limiting aperture to use for the measurement to be compared to the skin MPEs when applied to protect the cornea. It would stand to reason from biophysical and consistency principles to conservatively apply the time-dependent aperture to protect the cornea for wavelengths less than 1400 nm, rather than the 3.5 mm aperture that is defined for skin hazard analysis. The diameter scaling of the MPEs in this paper was generally performed with the time-dependent limiting aperture.

The scaling of limits is also applied for the case of the Class 3B AEL which is defined as additional emission limit by IEC 60825-1. This AEL is expressed as power or energy, such as 500 mW, and is to be compared with the accessible emission determined with a circular aperture stop. The AEL of 500 mW can be converted to an irradiance AEL by dividing the AEL by the area of the 7 mm aperture; for the example of 500 mW, this results in an irradiance AEL equal to 1.3 W cm^{-2}. In effect, this permitted irradiance is also a permitted average irradiance in the same way as for the MPEs. In this paper, for comparison with injury thresholds, the actual permitted, scaled irradiance or radiant exposure AEL is used, i.e. obtained by dividing the AEL by the area of the beam top-hat beam profile and not by the area of the 7-mm aperture.

[†] Thus, while the MPEs are the same for the skin and eye for wavelengths above 1400 nm, the averaging aperture is different, which can make a difference for exposure to pulses when the diameter of the beam is smaller than 3.5 mm, or has irradiance hot-spots.

D. Introduction to product safety limits (AEL)

The AELs defined in IEC 60825-1 for classification of products as Class 1 limit the emission level of the device – referred to as accessible emission – in terms of power or energy determined with a defined aperture stop diameter and position. Thus, Class 1 AELs are product safety limits and not exposure limits. Numerically, however, the AELs applicable to the retina up to 1400 nm and the cornea above 1400 nm, are equal to the MPEs for the eye multiplied by the area of the defined limiting aperture[11,12,13]. The use of AELs by ANSI is equivalent to the IEC AELs. However, ANSI Z136.1 is not a product safety standard; in the U.S., the applicable product safety legislation is the Code of Federal Regulation CFR[15] under FDA/CDRH responsibility (the CDRH accepts Edition 3 or IEC 60825-1 under Laser Notice[16] 56). Particularly for the discussion on corneal protection for wavelengths below 1400 nm, product safety emission limits for the classification of laser products must be distinguished from MPEs discussed in the sections above. While the IEC standard recommends the application of the skin MPEs as an additional limit to protect the cornea in the informative Annex A, the normative AEL restriction for Class 1, 1M and 3R is based on the Class 3B AEL as a limit with the intent to protect the cornea in the wavelength range between 1250 nm and 1400 nm. In the European amendment A11, an additional classification emission limit is derived from the skin MPEs, as discussed in the following sections.

For classification of products based on the IEC standard, the correct term for the dependence of the AEL on t is emission duration, while the term used for the dependence of the MPEs on t is exposure duration. For simplicity, we use the term exposure duration even though the discussion includes the Class 3B AELs as well as the emission limit of A11, derived from the skin MPEs.

E. Class 3B AEL as additional limit

For the classification of products as Class 1, Class 1M or Class 3R, in IEC 60825-1:2014, the additional limit to protect the anterior parts of the eye for wavelengths between 1250 nm and 1400 nm was set as the AEL of Class 3B. The accessible emission is measured through a 7 mm diameter aperture stop at the location where the accessible emission is determined for the retinal thermal AEL. For continuous wave emission (emission duration greater than 0.25 s), the AEL of Class 3B in the respective wavelength range equals 500 mW; for emission durations between 1 ns and 0.25 s, the AEL of Class 3B equals 0.15 J. When comparing the corneal exposure permitted by the Class 3B AEL with injury thresholds, it has to be kept in mind that varying beam diameters at the cornea can result in drastically varying permitted corneal irradiance levels. 500 mW corresponds to irradiances of 1.3 W cm^{-2}, 5.2 W cm^{-2} and 64 W cm^{-2} for beam diameters of 7 mm, 3.5 mm, and 1 mm, respectively. These levels, derived from the Class 3B AEL are also shown in Fig. 1. We see in Fig. 1c that for an exposure duration of 10 seconds and above, for a 7 mm beam diameter (or larger) the 500 mW limit is very close to the skin MPE. For a 3.5 mm beam, the diameter-scaled Class 3B limit of 500 mW is equal to the skin MPE at about 1 second and for 10 second exposure duration is about a factor of 5 above the skin MPE. For a 1 mm beam, the scaled Class 3B limit is significantly above the skin MPEs for all exposure durations.

F. European amendment A11

To protect the cornea for wavelengths between 1250 nm and 1400 nm, the European amendment[4] A11:2021 to EN 60825-1:2014 defined emission limits equivalent to the skin MPEs in addition to the Class 3B limits. Since emission limits are usually specified in terms of "power through aperture" level (or more precisely, it is the accessible emission that is defined in this way to be compared with the emission limits), the limits in A11 were derived from the skin MPEs by multiplication with the area of the time-dependent limiting aperture discussed above. This results in the following limits (t in seconds):

For $t < 10^{-9}$ s:	7.9×10^{5} W	Aperture stop diameter: 1 mm
For 10^{-9} s $\leq t < 10^{-7}$ s:	7.9×10^{-4} J	Aperture stop diameter: 1 mm
For 10^{-7} s $\leq t < 0.35$ s:	$4.3 \times 10^{-2}\ t^{0.25}$ J	Aperture stop diameter: 1 mm
For $t \geq 0.35$ s:	0.1 W	Ap. stop diameter: 0.35 s $\leq t < 10$ s: 1.5 $t^{3/8}$ mm
		$t \geq 10$ s: 3.5 mm

These limits are additional AELs for classification of products as Class 1, 1M, and 3R. When the accessible emission is measured with the corresponding aperture stop, the analysis is identical to determining the irradiance or radiant exposure averaged over the aperture stop and comparison to the skin MPEs given as irradiance or radiant exposure. Consequently, when the remainder of the discussion refers to the skin MPE, the corresponding emission limit of A11 is included.

We note that for emission durations greater than 0.35 s, the increase of the area of the aperture with t compensates for the decrease of the MPEs specified as irradiance, resulting in a constant power - AEL of 100 mW. It is interesting to compare the AEL of 100 mW permitted through a 3.5 mm aperture with the Class 3B limit of 500 mW through a 7 mm aperture. For a top-hat beam profile with a diameter equal to or greater than 7 mm, the limit of 100 mW through a 3.5 mm aperture corresponds to 400 mW permitted power passing through a 7 mm aperture. Thus, for large beam diameters, the Class 3B AEL of 500 mW through a 7 mm aperture is close to the skin MPE and affords a comparable degree of protection.

G. Comparison of limits

In addition to the Class 3B limitation, the ANSI and IEC/ICNIRP MPEs are plotted in Fig. 1. We see that the ANSI corneal MPEs have a significant dependence on wavelength while the skin MPEs and the Class 3B AEL do not. On the other hand, the skin limits shown in Fig. 1(c) have a pronounced dependence on exposure duration while the Class 3B limits and the ANSI corneal limits for wavelengths less than 1400 nm have a relatively weak dependence on exposure duration. For wavelengths just below 1400 nm, the skin MPEs are a factor of 10 higher than the ANSI corneal limits for 10 second exposure duration and a factor of 5 higher for 1 second exposure duration, respectively. Because the ANSI corneal limits feature a wavelength dependence while the skin limits do not, the skin limits are lower than the ANSI corneal limits for wavelengths below 1250 nm for 10 seconds exposure duration.

In the process of defining a specific corneal limit for wavelengths less than 1400 nm, the ANSI corneal MPEs for wavelengths between 1400 nm and 1500 nm and for pulse durations less than 1 ms were increased by a factor of 3 compared to the MPEs in the 2007 edition of ANSI Z136.1. For exposure durations of 10 seconds, the ANSI limits for wavelengths above 1400 nm remained unchanged, and are therefore the same as the ICNIRP and IEC limits (compare the two orange curves in Fig. 1(c)). Thus, while ICNIRP kept the previous MPEs for wavelengths between 1400 nm and 1500 nm, ANSI adjusted the limits in this wavelength range for exposures shorter than 10 seconds, so that for the ANSI cornea limit, there is no step-function at 1400 nm. ANSI also adjusted the skin limits in the 1400 nm to 1500 nm wavelength range to match the new corneal limits.

II. RESULTS

Corneal injury thresholds were calculated with the Seibersdorf Laboratories model. For the calculations, the corneal irradiance profile was a top-hat, i.e. a constant circular irradiance profile. Exposure (pulse) durations varied from 10 µs to 100 seconds and corneal beam diameters from 250 µm to 6 mm. The computer model was validated with experimental data in the nanosecond pulse duration regime. However, in the wavelength range of interest, the injury thresholds when presented as corneal radiant exposure do not exhibit a dependence on pulse duration for pulse durations shorter than roughly 1 ms. The figures show data for exposure durations between 10 ms and 100 s.

Fig. 2a shows the dependence on corneal beam diameter for a range of exposure durations for the wavelength of 1320 nm. As is known from retinal injury thresholds for long exposure durations, the injury thresholds expressed as radiant exposure at the tissue decrease with increasing diameter of the irradiance profile (see for instance Lund *et al.*[18] and Schulmeister *et al.*[19,20]). The shorter the exposure duration, the more the beam diameter dependence is limited to small beam diameters. For exposure durations equal to or less than about 1 ms, the threshold is no longer dependent on the beam diameter in the modeled range of beam diameters (greater than 0.25 mm). In contrast to the thermal retinal MPEs, which depend on retinal image diameter, the corneal MPEs and the skin MPEs do not depend on the beam diameter of the radiation incident on the cornea or skin. However, when the beam diameter is smaller than the averaging (limiting) aperture, the permitted actual irradiance is higher the smaller the beam diameter is. As can be seen in Fig. 2, this is a stronger effect than the dependence of the injury threshold on diameter, but a trend in the same direction. For Fig. 2, the skin MPEs were applied as recommended by ICNIRP and IEC, while the averaging aperture was taken as that for the cornea. The scaled MPEs increase for the case that the beam diameter is smaller than the limiting aperture, producing an indirect beam diameter-squared dependence of the MPE. It is again emphasized that the threshold calculations and animal experiments are performed for a stationary beam and a stationary cornea, whereas for all but medical intentional exposures on an immobilized eye, the cornea will move relative to the beam, and will most likely move out of the beam in a time much less than 10 seconds. A more realistic risk analysis can be based on comparing the 10 second-limit with the 1 s injury threshold. Since the skin MPEs in this wavelength range do not feature a wavelength dependence, the safety margin for 1390 nm (Fig. 2(b)) is smaller than compared to Fig. 2(a) for 1320 nm.

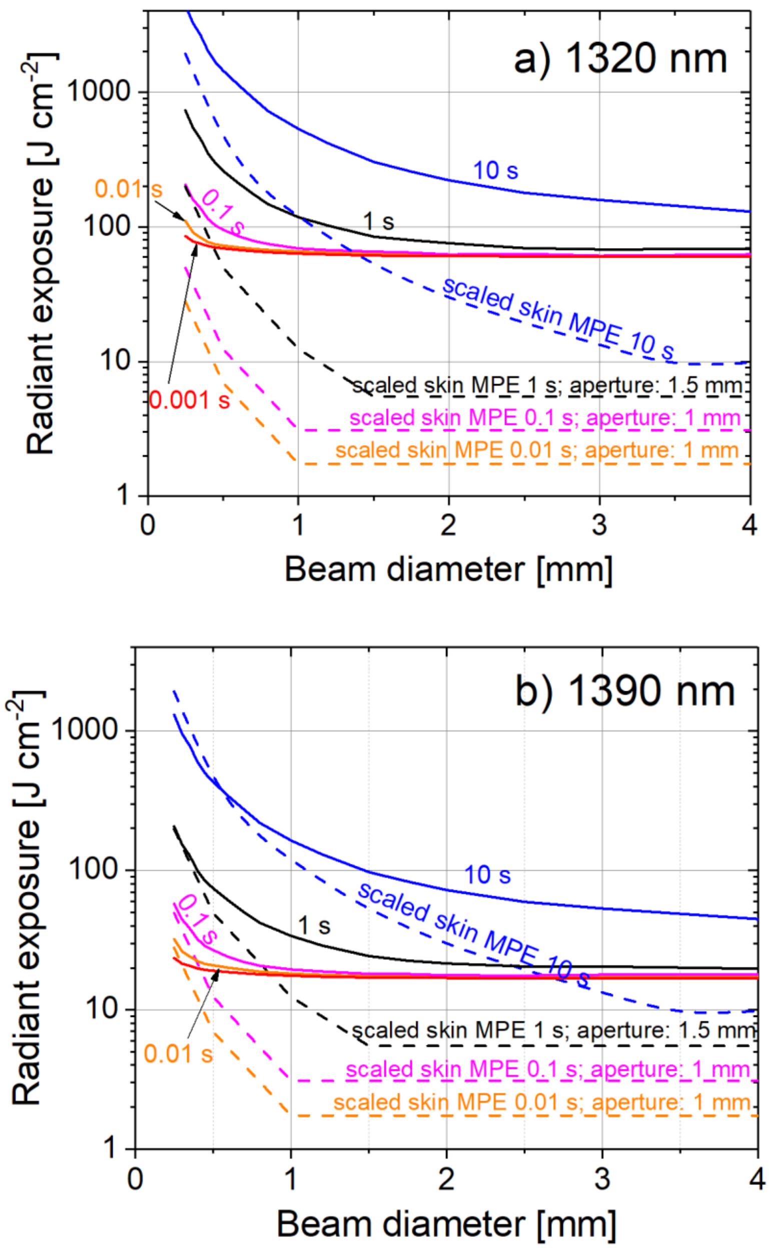
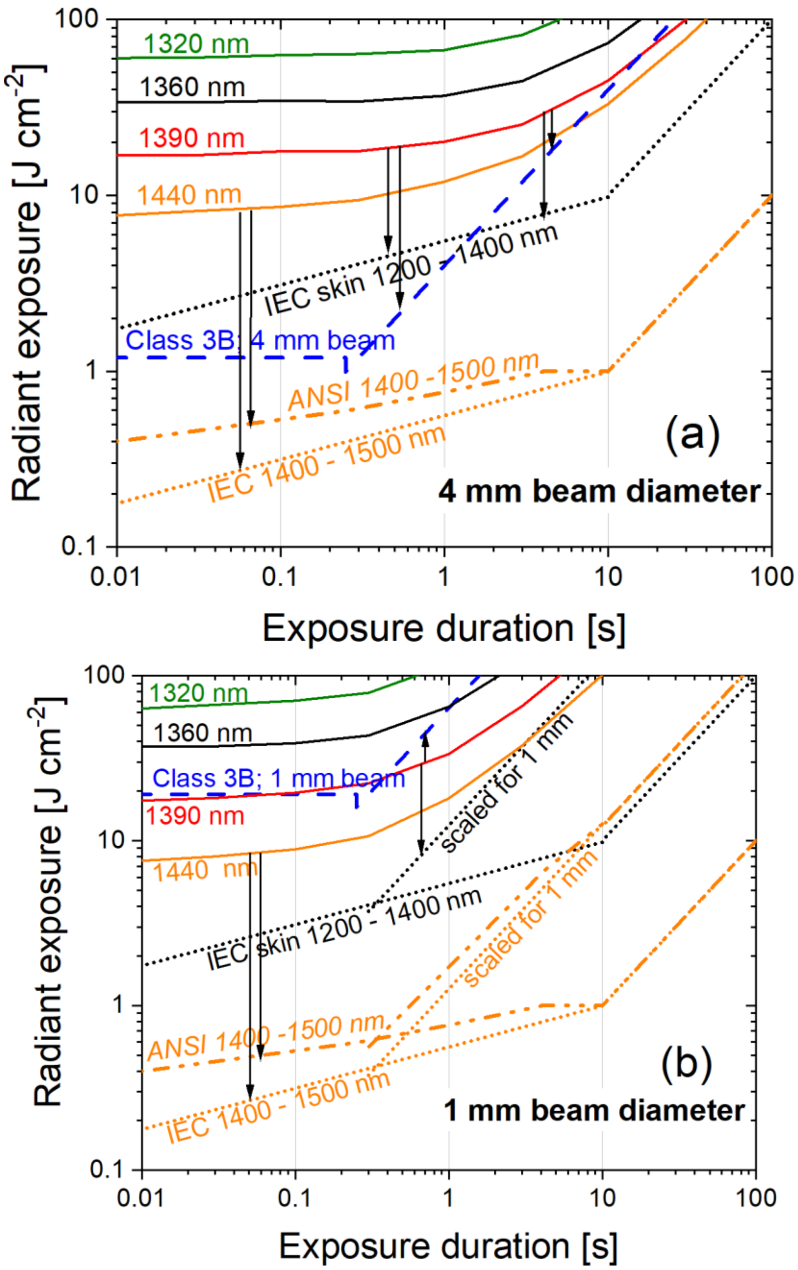


FIG. 2. Predicted corneal thresholds as function of beam diameter for a number of exposure durations (solid lines); the IEC/ ICNIRP skin MPEs are shown scaled with the effect of the limiting aperture on permitted exposure levels. The specific ANSI corneal limits are lower than the skin limits) and are not shown here.

Predicted corneal thresholds are shown as a function of exposure duration in Fig. 3 and as a function of wavelength in Fig. 4 and 5. For the comparison with the limits in Fig. 3 and Fig. 5, a top-hat profile diameter of 1 mm and 4 mm was chosen. ANSI corneal and the IEC/ICNIRP skin MPEs are shown, as well as the Class 3B classification limit, expressed as permitted corneal irradiance. Where applicable, these limits are scaled depending on the beam diameter and the aperture diameter.



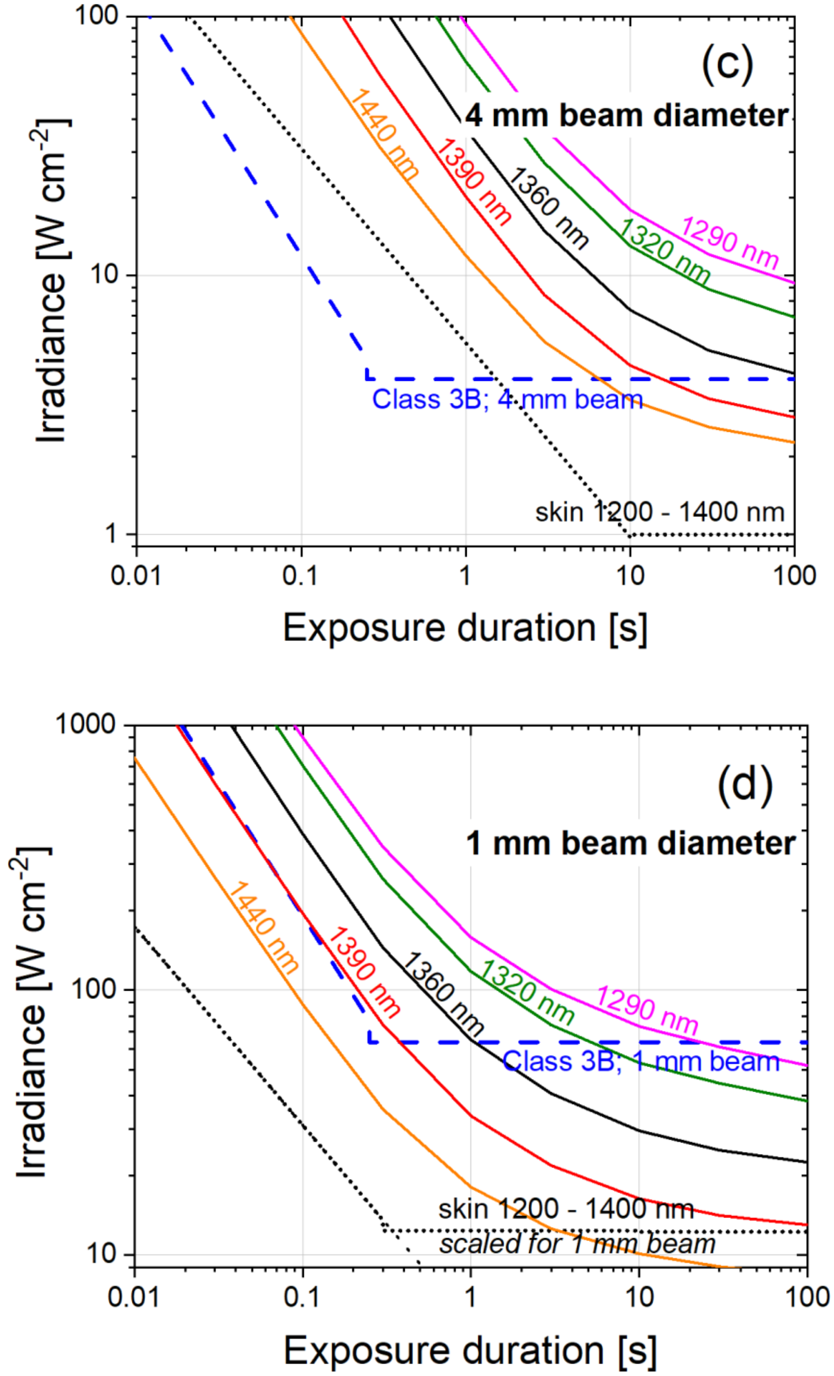


FIG. 3. Predicted injury thresholds for a beam diameter of 4 mm (a) and 1 mm (b) as function of exposure duration for a number of wavelengths between 1290 nm and 1440 nm, plotted as radiant exposure at the cornea. Class 3B AEL (500 mW) as well as the skin MPEs recommended by ICNIRP/IEC to protect the cornea are diameter-scaled where applicable. In (c) and (d) the data are shown as irradiance and with a reduced ordinate range.

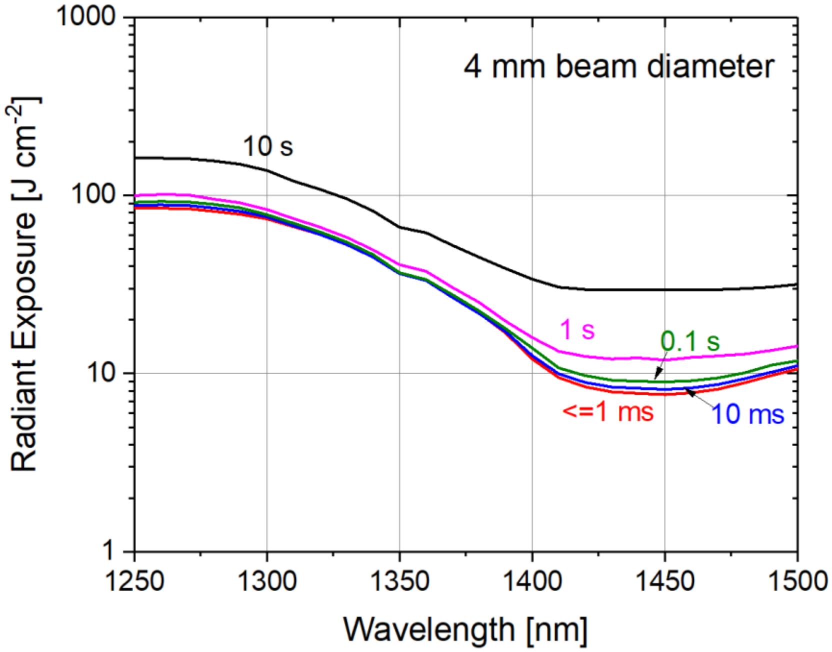


FIG. 4. Predicted injury thresholds for a beam diameter of 4 mm as function of wavelength between 1250 nm and 1500 nm.

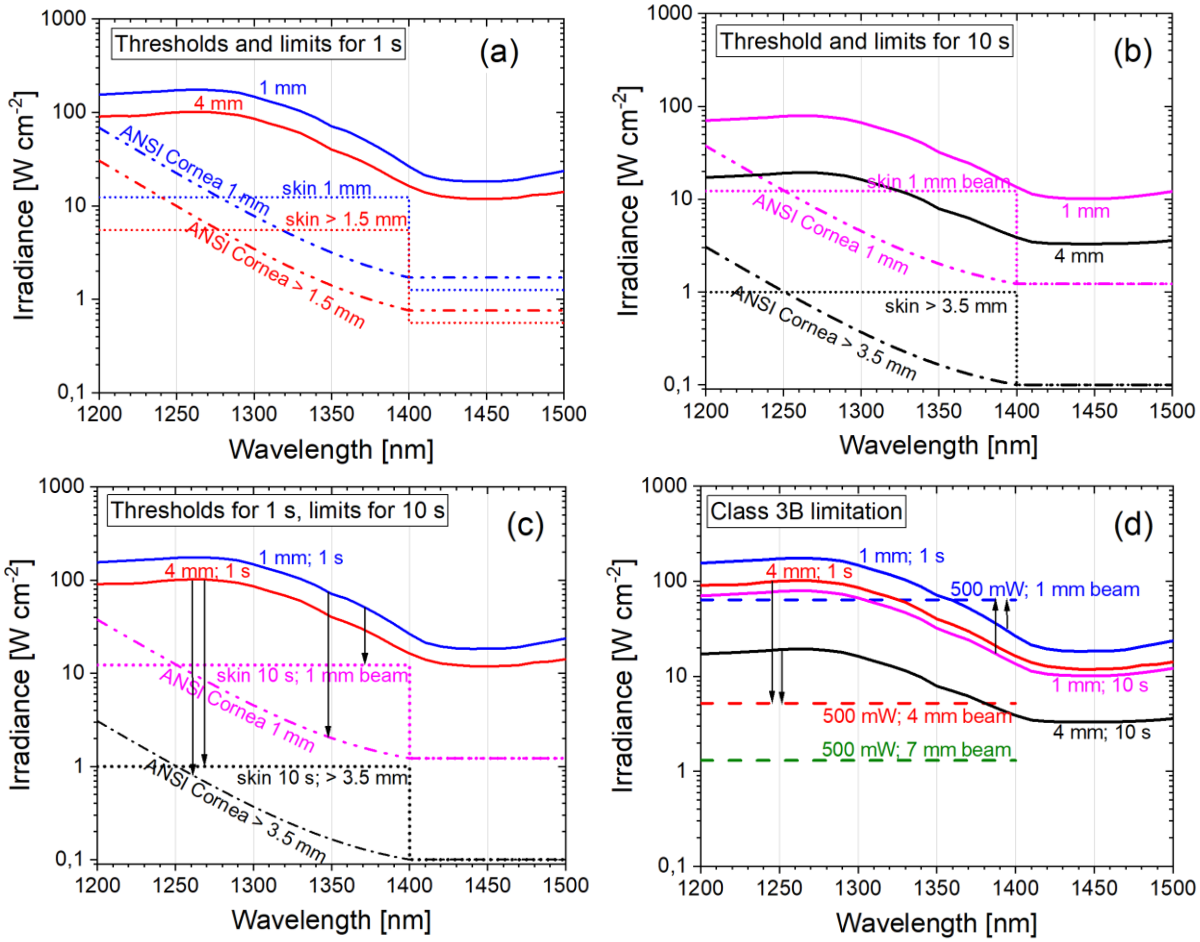


FIG. 5. Predicted injury thresholds for a beam diameter of 1 mm and 4 mm as function of wavelength between 1200 nm and 1500 nm. In (a) for 1 s exposure duration, in (b) for 10 s exposure duration, in (c) the limits are shown for 10 s exposure duration while the thresholds are shown for both 1 s exposure duration and in (d) the thresholds are compared with the Class 3B limitations. All limits are diameter-scaled.

III. DISCUSSION

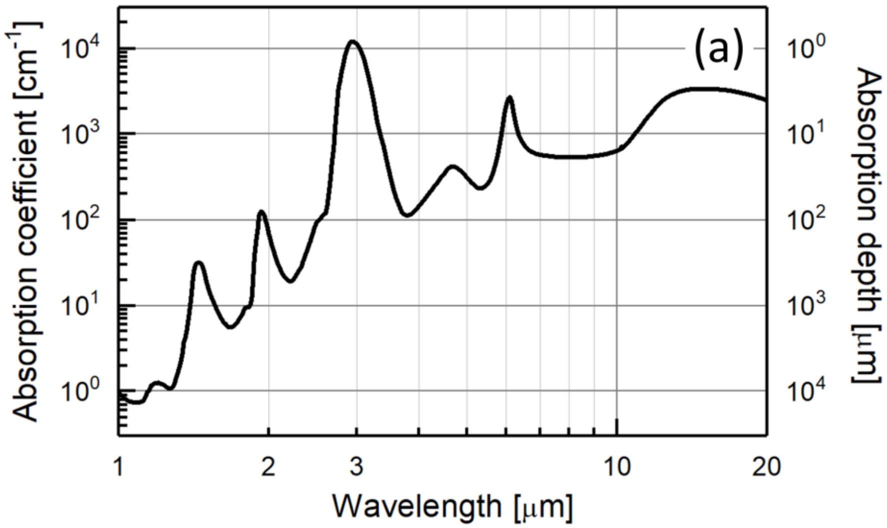
A. Biophysical trends

Thermally induced injury occurs when a critical temperature is exceeded in the tissue[21]. This critical temperature is lower for longer exposures, but the reduction of the critical temperature for longer exposure durations is relatively weak[3,22].

The biophysical background of the dependence of the corneal thresholds on beam diameter (Fig. 2) is equivalent to that of the retinal thermal limits, which has been discussed in detail elsewhere[18,19,20]. For exposure durations of 1 ms or less, there is essentially no dependence on beam diameter for the diameter range that was modeled (the smallest beam diameter was 250 µm). For longer exposure durations, the region of beam diameters where there is no, or very little, dependence on beam diameter shifts to larger beam diameters. In this regime, due to more effective radial cooling of smaller beam diameters, smaller beam diameters are associated with higher injury thresholds. The longer the exposure duration, the wider the range becomes where there is a beam-diameter dependence. We see in Fig. 2 for 1 s and 10 s exposure duration that the increase of the threshold for smaller beam diameters is not as strong as the effect of the limiting aperture for the scaled MPEs. This reduces the safety margin (referred to as “reduction factor” by ICNIRP) between the threshold and the permitted exposure. For 1320 nm, for a beam diameter of 250 µm, the safety margin still appears to be sufficient. The trend of the dependence on beam diameter (i.e. the relative change for small and large beam diameters) is equivalent for wavelengths up to 1500 nm.

The dependence on pulse duration for varying wavelengths (Fig. 3) and the dependence on wavelength (Fig. 4) can be understood by the interplay of optical absorption depth (which is strongly dependent on the wavelength) with the thermal diffusion distance (which is dependent on the exposure duration).

When it is assumed that absorption follows the Beer-Lambert law[23] with an exponential decrease of irradiance with depth of the cornea, the absorption depth is defined as the depth at which the irradiance equals 1/e of the irradiance at depth zero, i.e. the surface of the cornea. The absorption depth is the inverse of the absorption coefficient. The absorption coefficient of the cornea, as given in a CIE report[24] is shown in Fig. 6. In the CIE report, for wavelengths above 1150 nm, the absorption coefficient of saline water was used to characterize the absorption depth in the cornea. Although the absorption depth at 1400 nm is less than 1 mm, compared to absorption depths for wavelengths above about 2600 nm, this still constitutes a rather weak absorption. The absorption depth for the cornea in the infrared wavelength range has a very strong dependence on wavelength and varies from 1 cm (10^4 µm) at a wavelength of 1000 nm to an absorption depth of 1 µm (i.e. within the tear layer) at a wavelength of 3 µm. The absorption depth as function of wavelength is shown in Fig. 6(b) for the retinal-to-corneal hazard transition wavelength range. The strong variation in absorption depth with wavelength has a corresponding effect on the temperature increase for a given irradiance level at the cornea and therefore on the injury threshold.



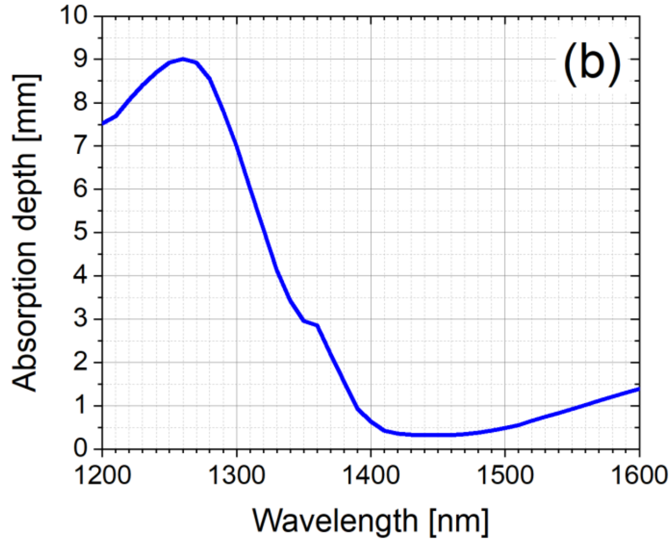


FIG. 6. In (a), the absorption coefficient for the cornea is plotted as function of wavelength for an extended wavelength range. The corresponding absorption depth is given on the right ordinate in µm. In (b), the section between 1200 nm and 1600 nm is shown with a linear ordinate plotted as absorption depth in mm.

Below a certain exposure duration, the threshold curves shown in Fig. 3(a) as radiant exposure do not show a dependence on exposure duration (i.e., pulse duration). The shorter the wavelength (associated with greater absorption depth), the more this regime of constant injury thresholds extends to longer exposure durations, such as about 1 second for 1320 nm. In the pulse duration regime shown, for the wavelength of 1440 nm, this regime of constant threshold applies to pulse durations shorter than approximately 0.01 s. In Fig. 3(a), the wavelength dependence is characterized by the separation of the threshold curves. For an exposure duration of 0.01 s, the separation is wider (associated with a stronger wavelength dependence) as compared to, for example, for an exposure duration of 10 seconds. This reduction in wavelength dependence for longer exposure durations is also seen in Fig. 4 for wavelengths above about 1360 nm: the wavelength dependence for an exposure duration of 1 s is less pronounced than the wavelength dependence for shorter exposure durations. This can be understood if we consider that heat flow has an effect and evens out the wavelength dependence resulting from the variation of the absorption depth. A characteristic parameter for heat flow is the thermal diffusion length[25,26] r_{therm}, which is the approximate distance that a heat wave travels in time t, where D_{th} is the thermal diffusion coefficient, which can be taken as that of water[27], for the example of 50°C with D_{th} = 0.0015 cm^2 s^{-1} (Eq. (1)).

$$r_{\text{therm}} \approx \sqrt{2D_{\text{th}} \times t} \qquad (1)$$

As a very rough approximation, heat flow into the depth of the tissue has an effect on temperature if the thermal diffusion length is greater than the optical absorption depth. To facilitate this understanding, we assume that the diameter of the irradiance profile at the cornea is sufficiently large so that radial heat flow does not affect the center and only heat flow into the depth of the eye is relevant. The discussion is also more directly applicable when the diameter of the laser beam is larger than the optical absorption depth, so that the absorbing volume is more like disk-shaped. Clearly this is not true for wavelengths towards 1200 nm, but the assumption allows a relatively simple understanding of the wavelength and pulse duration trend.

Absorbed laser radiation results in a temperature increase, i.e. radiant energy is converted into heat. As an approximation, we can assume that a certain cylindrical volume in the eye is heated, which is defined by the laser top-hat irradiance diameter at the cornea and the optical absorption depth r_{abs}. Both thermally and optically for wavelengths above approximately 1200 nm, the pre-retinal media can be well approximated by the properties of saline water, so that in this simplified discussion we do not need to distinguish the cornea from other pre-retinal media. Heat flow from the heated volume reduces the temperature within the heated volume, but it takes some time. For short pulse durations, there is no relevant heat flow out of the center of the heated volume, and the threshold does not depend on pulse duration. This regime of no dependence on pulse duration is referred to as “thermal confinement” regime since the heat does not leave the absorption volume (at least not the center of the volume) during the pulse duration. In other words, the laser exposure is terminated before heat flow can cause cooling of the volume where the radiation was absorbed. In this regime, heat flow does not play a role for the temperature at the center of the absorbing volume as it develops during the pulse duration. The laser-induced temperature rise at the end of the pulse duration depends solely on the absorption volume and the energy absorbed in that volume, resulting in a certain volumetric energy density (measured in J cm^{-3}). The temperature rise at the end of the exposure is then approximated by dividing the energy density by the volumetric specific heat C_{V}. The volumetric energy density can be approximated by the radiant exposure H incident on the cornea (neglecting reflection losses) divided by the absorption depth. In the pulse duration regime where heat flow from the center of the heated volume into the depth of the eye can be neglected, the temperature increase ΔT at the end of the laser exposure can be approximated by (Eq. (2)):

$$\Delta T \approx \frac{H}{D_{abs} \cdot C_V} \qquad (2)$$

Since the injury threshold, expressed as radiant exposure incident on the cornea, is associated with a certain peak temperature in the tissue, the wavelength dependence of the injury thresholds in the thermal confinement regime closely follows the trend of the absorption depth. This regime can be understood as “dominance” of absorption depth over thermal diffusion length. Roughly speaking, in the thermal confinement regime, the absorption depth (as function of wavelength) is greater than the thermal diffusion length (as function of exposure duration). This is also the basis for the understanding that for a given exposure duration and therefore, for a given thermal diffusion length, the smaller the penetration depth is, the shorter the thermal confinement time becomes.

For wavelengths with very small optical absorption depths, and relatively long exposure durations, the heat flow evens out the wavelength dependence, i.e. the wavelength dependence is not as pronounced as it is for short exposure durations. This is seen more drastically in the wider wavelength range shown in a ILSC 2011 paper[28], but can also be seen in Fig. 3(a) and Fig. 4.

B. Comparison with ICNIRP and IEC MPEs

This subsection compares the corneal injury thresholds with the ICNIRP and IEC skin MPEs. This discussion also applies to the emission limit specified in the European amendment A11. The data are shown as function of exposure duration in Fig. 3 and as function of wavelength in Fig. 5. Due to the strongly varying absorption depth between 1300 nm and 1400 nm, the corneal injury threshold decreases in that range by a factor of about 10. Since the skin MPEs do not feature a wavelength dependence in that regime, the reduction factor between the threshold and the limit decreases with increasing wavelength, i.e. is smallest at 1400 nm. For wavelengths above 1400 nm, compared to the skin MPE at 1400 nm, the corneal MPE is lower by a factor of 10; the reduction factor is correspondingly larger making this regime less critical. For the wavelength range of 1200 nm to 1300 nm and 1 s exposure duration (Fig. 5(a)), the reduction factor between injury thresholds and skin MPEs is about 11 (for the worst-case of large beam diameters at the cornea); for 10 s exposure duration in this wavelength range, the reduction factor for an immobilized eye and a 1 mm beam diameter is about 5 relative to the 10 s injury threshold. For these deeply penetrating wavelengths, the skin MPEs have a relatively large reduction factor. For a wavelength of slightly less than 1400 nm, where the skin limits still apply, and a beam diameter of 4 mm (Fig. 3(a) and Fig. 4(c)), the reduction factor between thresholds and MPEs equals 2.5 for 100 s exposure duration, about 4 for 10 s exposure duration and about 3 for 1 s exposure duration. For shorter exposure durations, the reduction factor is somewhat larger. Considering that the reduction factor is determined for the stationary case (the beam does not move relative to the tissue), these reduction factors, for beams larger than 3.5 mm, appear to be adequate to prevent injury at exposure levels equal to the MPE. While the typical exposure duration assumed for an MPE analysis is 10 seconds, it is theoretically possible to assume an exposure duration of 1 second. In this case, the 1 s MPE needs to be compared with the 1 s injury threshold. However, if 10 s is assumed for the MPE analysis, then it is more relevant, and also more realistic, to compare the 10 s MPE with the injury threshold for an exposure duration of 1 s, as is shown in Fig. 5(c). This can be justified with relative movements of the beam vs. the tissue, particularly considering heat sensation. The safety margin is then correspondingly larger.

For a 1 mm beam diameter, the averaging effect of the limiting aperture must be taken into account. For an MPE analysis assuming a 1 s exposure duration, the averaging effect reduces the margin by a factor of 2.3. If the averaging effect is not considered (the unscaled MPEs are compared with the predicted injury thresholds) the reduction factor is 5 for 1390 nm, leaving a reduction factor of about 2 when the averaging effect is accounted for. A reduction factor of 2 should be sufficient, but there is also some uncertainty associated to the computer model. However, it is rare that an

MPE analysis is performed for a 1 s exposure duration. When the limit is applied as emission limit in amendment A11, this is not an option anyway. For 10 s exposure duration (or emission duration if used as emission limit in A11), the reduction factor, based on the 10 s injury threshold, for the unscaled MPE equals 14 so that with an averaging effect of 12.3, the reduction factor is close to 1. However, this applies only for a stationary scenario. If the body is not immobilized, the risk for injury should still be low if the safety analysis is based on an exposure duration of 10 seconds. This can be supported by comparing the 10 s limit with the 1 s injury threshold, which is most easily done with Fig. 3(d) where the data are plotted as W cm^{-2}, but see also Fig. 5(c). In Fig. 3(d), due to the time-dependence of the limiting aperture, the scaled skin MPEs are constant for exposure durations greater than 0.35 s. While the margin for a wavelength of 1390 nm is small for 10 s exposure duration, it is equal to 2.7 for 1 s exposure duration. The data in the pulsed regime also make it clear that it is not justified to apply the "skin" limiting aperture of 3.5 mm.

For beam diameters less than 1 mm, the question arises if the scaled skin MPEs are sufficiently protective, particularly for wavelengths approaching 1400 nm. The data shown in Fig. 2(b) indicate that for a beam diameter of 250 µm the scaled MPEs are essentially equal to the predicted injury threshold. This is also the case when the MPEs for 10 seconds are compared with the injury threshold predicted for a 1 s exposure duration. A beam diameter of 0.5 mm appears to be less problematic. It can be concluded that for beam diameters smaller than approximately 0.5 mm, for wavelengths approaching 1400 nm, the limiting aperture should be smaller than defined. The underlying reason for the small safety margin at 1390 nm compared to, for instance, 1320 nm is the lack of wavelength dependence of the skin MPEs. A specific limit to protect the cornea would be advantageous to avoid potential hazards to the cornea when the skin MPEs are used to protect the cornea for wavelengths less than 1400 nm. We note that in the ICNIRP 2013 laser guidelines[3], for the limits to protect the cornea for wavelengths above 1400 nm, a footnote states that for beam diameters less than 1 mm and pulse durations less than 0.35 s, the actual (non-averaged) radiant exposure should be compared to the exposure limit. This appears prudent and should also be applied for the case of exposure durations longer than 0.35 s.

C. Comparison with IEC Class 3B limits

For the classification of a product as Class 1, IEC 60825-1:2014 defines the Class 3B AEL as a limit to protect the cornea, additionally to the Class 1 AEL to protect the retina. Since the Class 3B AEL is not wavelength dependent, but the corneal injury thresholds for wavelengths approaching 1400 nm are significantly lower than for a wavelength of 1300 nm (factor ~10) or even 1350 nm (factor ~ 2.5), the longer wavelengths are more critical. Due to the 7 mm aperture stop, the beam diameter is of central importance. For 1390 nm and a beam diameter of 4 mm, the factor between the injury threshold and the Class 3B limitation is equal to about 4 for 1 s exposure duration, and for an exposure duration of 10 s (Fig. 5(d)), the predicted 10 s threshold is approximately equal to the level permitted by the Class 3B limit. Based on usual eye movements and aversion responses, more emphasis can be placed on the comparison with the 1 s injury threshold (the Class 3B limit expressed in W cm^{-2} is constant), for beam diameters of 4 mm and somewhat smaller beams, the Class 3B limit can be assumed to provide adequate protection even for the critical wavelengths approaching 1400 nm. However, for the wavelength of 1390 nm and a beam diameter of 1 mm (Fig. 3(b) and 3(d)), the Class 3B limit of 500 mW for t = 0.25 s is almost equal to the predicted injury threshold for an exposure duration of 0.25 s. For exposure durations longer than 0.25 s, the irradiance permitted by the 500 mW Class 3B AEL significantly exceeds the injury threshold (for a stabilized beam and eye) because the injury threshold, when expressed as irradiance, continues to decrease. For small beam diameters and wavelengths approaching 1400 nm, it is likely that the response time is not fast enough to prevent injury when exposure occurs at the Class 3B AEL. For 1390 nm, for the case of pulsed emission where the 0.15 J Class 3B limit applies, the permitted radiant exposure for a 1 mm beam is essentially equal to the predicted injury threshold.

For the more common wavelength of 1350 nm (as a conservative value, the data for 1360 nm can be used) and a 1 mm beam diameter, the injury threshold is approximately equal to the Class 3B limit for 1 s exposure duration and is exceeded for exposure durations longer than about 1 s (Fig. 3(d)). This is not a sufficiently low risk for a Class 1 laser product. The determination of the level that is compared against the Class 3B AEL is at the "retinal" assessment distance of 100 mm from the reference point specified in IEC 60825-1, and for diverging beams, exposure levels may be higher at closer distances. For 1350 nm and a 4 mm beam (Fig. 3(c)), the factor between the injury threshold for 10 s exposure duration and the Class 3B limit is about 1.8; for 1 s exposure duration the factor is about 10. This indicates that the Class 3B limit should provide adequate protection for wavelengths around 1350 nm when the beam diameter at the classification distance is greater than 3-4 mm. For diverging beams, there is some potential risk if exposure occurs closer than the 100 mm classification distance, but there is a warning requirement when the Class 3B limit is exceeded with a 3.5 mm aperture at contact with the product. For a 1 mm beam diameter, the Class 3B AEL appears to provide adequate protection only for wavelengths of 1300 nm and less. At the wavelength of 1300 nm, a 1 mm beam and a 1 s exposure duration, the margin between the injury threshold and the Class 3B limit is only 2.5.

D. Comparison with ANSI limits

The ANSI limit differs from the IEC/ICNIRP limits for wavelengths less than 1500 nm, particularly in the wavelength range below 1400 nm where ANSI Z136.1 has specific MPEs to protect the cornea whereas ICNIRP/IEC refers to the skin MPEs. Not surprisingly, the ANSI limits more closely follow the injury thresholds in terms of wavelength dependence (factor K_λ), at least in the wavelength range above 1300 nm, and in terms of dependence on exposure duration. The smallest safety margin was found to be 7 for a 1 mm beam and 1 s - 10 s exposure duration, as well as for a 4 mm beam in the exposure duration range of 10 ms to 100 ms. For a 4 mm beam and 1 s exposure duration, the smallest reduction factor is about 10; for 10 s exposure duration, it is about 30, with relatively little dependence on wavelength and pulse duration, i.e. the ANSI MPEs follow the injury threshold trends in wavelength well, with a reduction factor that is not less than 7.

E. Multiple pulses

Since the 2013/2014 revision of the guidelines and standards, for the wavelength range above 1400 nm, the reduction factor C_p (C_5 in IEC) for the ocular MPE analysis of multiple pulses is no longer required, nor is C_5 required for the AEL analysis based on the IEC standard. Consequently, a MPE analysis for repetitive exposure is based on limiting the radiant exposure of each pulse based on the pulse duration and additionally limiting the average irradiance by the respective long-term limit, typically for 10 seconds exposure duration. A systematic comparison of injury thresholds for repetitive exposure with these two MPE requirements is beyond the scope of this paper, but can be found in an ILSC 2019 paper[8]. The issue can be discussed on the basis of biophysical principles. The rationale to support the notion that a reduction factor is not needed is straightforward for the deeply penetrating wavelengths with correspondingly long thermal confinement times. For a wavelength of 1440 nm shown in Fig. 3(a) and Fig. 3(b), in the regime up to roughly 1 second, although the injury thresholds are not completely independent of exposure duration, the dependence on exposure duration is very small. In this regime it is clear that the average irradiance criterion is sufficient, since averaging irradiance over some period of time is equal to adding radiant exposure over that period and dividing by the averaging duration.

IV. SUMMARY AND CONCLUSIONS

A systematic comparison of computer model corneal injury thresholds with the MPEs and classification limits specified to protect the cornea in the wavelength range of 1200 nm to 1500 nm by ANSI Z136.1, IEC 60825-1, the European A11 and ICNIRP was performed.

Between 1400 nm and 1500 nm, for exposure durations less than 10 seconds, the ANSI limits are up to a factor of 3 higher than the ICNIRP/IEC limits; the reduction factor of the ANSI limits can be characterized as sufficient.

Due to the significant increase of the retinal thermal limits for wavelengths between 1300 nm and 1400 nm in the 2013/2014 revisions, it became necessary to introduce an additional limit to protect the cornea in this wavelength range. The IEC and ICNIRP guidelines recommend using the skin limits for an MPE analysis, while ANSI has introduced a specific limit to protect the cornea. The ANSI limit follows the trend of injury threshold with wavelength and pulse duration well and the reduction factor is at least 7. While ANSI specifies exposure duration dependent averaging apertures to be used for wavelengths less than 1400 nm, IEC does not provide specific guidance on the diameter of the averaging aperture to be used to assess the ocular exposure for comparison with skin MPE values. Irradiance levels that would be permitted for a 3.5 mm aperture clearly show that averaging over 3.5 mm is not permissible for smaller beam diameters and wavelengths tending towards 1400 nm. As is noted in an ICNIRP[10] comment of 2020, the exposure duration dependent averaging aperture as defined for the eye for wavelengths exceeding 1400 nm should be used.

Due to the lack of wavelength dependence of the skin MPEs, but reduced corneal injury thresholds for wavelengths approaching 1400 nm, the reduction factor for the skin MPEs to protect the cornea is relatively small for wavelengths close to 1400 nm. However, the skin MPEs should be sufficiently low to avoid corneal injury, at least for beam diameters not significantly smaller than 1 mm. For a 4 mm beam diameter, the reduction factor is about 4 for a 10 s exposure duration and of the order of 3 if the hazard analysis is based on a 1 s exposure duration, i.e. using the MPE for t = 1 s. Using a 10 s exposure duration for the MPE analysis (which is the typical value), for a 1 mm beam diameter and an averaging aperture of 3.5 mm, the permitted actual irradiance is equal to the injury threshold for wavelengths close to 1400 nm, in the absence of eye movements. However, eye movements, both natural and due to aversion responses, will smear out the exposure and reduce the effective irradiance for such small beams, so that it should be acceptable to apply the skin MPE. This can be supported by comparing the 10 s MPE with the 1 s injury threshold. However, for exposures relatively close to the injury threshold it is not clear what the pain sensation will be: if the pain is excessive or noxious, such a high level of permitted exposure might not be seen as appropriate even if, due to aversion responses, an actual burn is avoided. The 3.5 mm diameter limiting aperture permits irradiance levels at the MPE that for a diameter of 250 µm are essentially equal to the predicted injury thresholds. This issue is not adequately addressed in ICNIRP, IEC 60825-1 and the European amendment A11.

The Class 3B limit defined by IEC 60825-1:2014 for Class 1 laser products to protect the cornea, for emission durations longer than 0.25 s permits a power of 500 mW to pass through a 7 mm aperture at 100 mm distance. While for a 7 mm beam the irradiance permitted by the Class 3B limit is well below the corneal injury threshold for wavelengths close to 1400 nm, the irradiance permitted for a 1 mm beam for wavelengths approaching 1400 nm exceeds the injury threshold within 0.25 seconds, an exposure duration where significant eye movements are unlikely. For the wavelength of 1350 nm common in telecommunication, the Class 3B limit appears sufficient to protect the cornea provided the beam diameter at the exposure distance is larger than 4 mm. It follows that two aspects of Class 3B AELs as a limit to protect the cornea are problematic: firstly, the aperture stop diameter of 7 mm permitting high irradiances for small beam diameters; secondly, while the injury thresholds decrease by a factor of 10 between 1300 nm and 1400 nm, the Class 3B AELs remain constant.

As an interim limit to protect the cornea for wavelengths between 1250 nm and 1400 nm, the skin MPEs lend themselves as classification limit additionally to the Class 1 retinal AEL. The skin MPEs are over-restrictive for wavelengths less than 1300 nm. It might not be ideal that exposure at the skin MPE at wavelengths close to 1400 nm will probably induce pain and aversion responses when the product is Class 1, but the skin MPEs should be sufficient to prevent corneal injuries because of normal eye movements and aversion responses. While the wavelength dependence of the corneal injury thresholds is not reflected by the skin MPEs, the skin MPEs appear useful as a limit to protect the cornea until the overall safety limit system is updated by ICNIRP and IEC, where the wavelength dependence of the corneal injury thresholds can be accounted for.

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AUTHOR DECLARATIONS

Conflict of interest

The authors have no conflicts to disclose.

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