Statement on ICNIRP guidelines on limits of exposure to laser radiation

Content

1. Introduction

The Directive 2006/25/EC [1], adopted in April 2006 by the European Parliament and the Council, lays down the minimum safety requirements regarding the exposure of workers to risks arising from artificial optical radiation. It places a responsibility on employers to assess exposure levels, adopt preventive measures and arrange for the provision of information and training for their employees. Annexes I and II of the Directive provide Exposure Limit Values (ELVs) for incoherent optical radiation and laser radiation, respectively. These ELVs take account of the biological effectiveness of the optical radiation causing harm at different wavelengths, the exposure duration and the optical characteristics of the target tissue. The ELVs[1] are based on the guidelines published by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) - in case of laser radiation, on the "Guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1,000 μm" [2] published in 1996 and the "Revision of guidelines on limits of exposure to laser radiation of wavelengths between 400 nm and 1.4 μm" [3] from 2000.

All European Union member states had to implement the Directive by the end of April 2010. According to Article 12 of the Directive, "every five years Member States shall provide the Commission with a report on the practical implementation of this Directive, indicating the points of view of the social partners", and subsequently "the Commission shall inform the European Parliament, the Council, the European Economic and Social Committee and the Advisory Committee on Safety and Health at Work of the content of these reports, of its assessment of these reports, of developments in the field in question and of any action that may be warranted in the light of new scientific knowledge".

In 2013, ICNIRP has published revisions of the guidelines for incoherent visible and infrared optical radiation ("Guidelines on limits of exposure to incoherent visible and infrared radiation" [4]) as well as the guidelines for laser radiation ("Guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1,000 μm" [5]). According to the Non-binding guide to good practice for implementing Directive 2006/25/EC "Artificial Optical Radiation" [6] drawn up by the Commission, should the guidelines be altered by ICNIRP, "the ELVs in the Directive may subsequently be modified".

In 2015, a group of scientists, experts of accident prevention and insurance associations, industry experts as well as experts responsible for developing regulations and recommendations to protect workers from adverse effects of

[1] The terms Exposure Limit Value (ELV) in the Directive 2006/25/EC and Exposure Limit (EL) in ICNIRP guidelines have the same meaning.

optical radiation[2] had drawn up a statement [7] on the ELVs for incoherent optical radiation currently in force and those of the ICNIRP guidelines. As well as this previous statement, the present statement on laser radiation also points out problems with the practical implementation of the current ELVs and of those of the new ICNIRP recommendations, and draws up proposals in order to further improve safety and health at work.

Comparisons of the ELVs and correction factors of the ICNIRP guidelines from 1996 [2] and 2000 [3] (and hence of the Directive 2006/25/EC [1]) and those of the new ICNIRP guidelines on laser radiation from 2013 [5] are shown in the Annex 1.

2. General remarks

2.1 Margins of protection and reduction factors

ELVs are needed in order to protect exposed persons and to avoid damages due to overexposure. They aim at protecting possibly exposed persons with an optimal level of safety. This includes the selection of sufficient margins of protection / reduction factors[3], when recommending ELVs. A change in the reduction factor from about 10 to 2 in the new ICNIRP guidelines on laser radiation from 2013 [5] is understood as a paradigm change and should be worth to be discussed.

As possible adverse effects of a laser radiation exposure, deterministic effects predominate over stochastic effects. For laser radiation, the difference between the ELV and the level of laser radiation exposure where adverse effects (injuries, damages) occur, determines the level of safety. The level of safety is quantified by a reduction factor, which is the quotient between the radiation exposure level for 50% probability of injury or damage (ED-50) and the ELV. Since injury levels are often not exactly known and vary within a certain extent, in order to avoid damages and injuries in any case, the reduction factors have to be large enough to ensure a sufficient margin of protection. It is questionable whether this applies to the ICNIRP laser guidelines from 2013 [5].

In chapter “Reduction factors” of the ICNIRP laser guidelines [5] it is stated that “where there is less uncertainty, for example in extended source experiments where spot size is well quantified and probit analysis shows a decreased uncertainty in threshold, a reduction factor of two is thought to be sufficient. This was considered to provide an adequate margin of protection against significant or subjectively-detectable acute injury”.

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[2] The majority of experts are members of the Working Group “Non Ionizing Radiation” (Arbeitskreis Nichtionisierende Strahlung - AKNIR) of the German-Swiss Association of Radiation Protection.

[3] ICNIRP has changed the wording from “safety factor” to “reduction factor”.

However, there is e. g. a large step at 400 nm between the ELVs recommendations for ultraviolet (UV) radiation and those against the photochemical retinal hazard above 400 nm. The recommended ELVs below and above 400 nm differ by a factor of 100, and this has an impact on the safety margin (see also 5.2).

In general, the margins of protection in the new ICNIRP guidelines on laser radiation [5] vary in a broad range depending on wavelength, biological effect regarded, exposure duration, etc., maybe partly because of the specific laser radiation properties. The reduction factors vary between 2 and one order of magnitude. A factor of 2 is much lower than the margin of protection used in other fields. Regarding the uncertainties of the results of the biological studies and of the model calculations used when deriving the laser ELVs, it is uncertain whether a reduction factor as low as 2 is sufficient to protect against injuries in any case.

Further, it is arguable whether the slope of the respective probit curve (see Annex 2) is steep enough in order to fulfill the requirement that e. g. microscopic effects do not appear at doses lower than 50% (ED-50) [8]. Such a relation would be equivalent to the case where a reduction factor of 2 is supposed, but sufficient protection would not be guaranteed. Even if the “light and electron microscopy examination of tissue has indicated cellular alterations at exposures in the proximity of the ED-50 derived by ophthalmic examination 24 h after the exposure” [8], a reduction factor of 2 is too low.

It is appreciated that at least for skin exposure a minimum reduction factor of approximately 3 is taken into account. Due to the fact that “for the retina some uncertainty regarding the actual retinal spot size exists” [5], such a low reduction factor should not be recommended. In order to be prudent enough, as far as the ELVs are concerned, a higher reduction factor is necessary.

The recommended ELVs consider verified acute adverse effects. However, neither possible long-term risks nor precautionary actions to protect against potential effects, particularly where there are no deterministic damage values present or known, have been regarded.

According to the ICNIRP statement “General approach to protection against non-ionizing radiation” [9], “some of the immediate effects can be quantified with reasonable precision, and derivation of guidelines will not require a substantial reduction below the observed threshold levels”. But it is also stated that “when the precision and certainty of the relationship between exposure and adverse outcome is lower, a larger reduction may be warranted”. This is the case if photochemically induced injuries are regarded, even in the case of extended sources.

As a matter of scientific judgement we propose to take into account at least a reduction factor of 5 within the wavelength range regarded.

2.2 Beam diameter

Most of the laser beams do not have clearly defined beam profiles, so the beam diameter can be defined in many different ways. Depending on the beam profile, different beam diameters, e. g. d_{86} ($1/e^2$), d_{63} (1/e) or the 2nd moment method, can be used to describe the laser beam propagation. The definition of the correct diameter criterion for a given beam profile is necessary for an appropriate risk evaluation of the photochemical and thermal retinal damage. In the ICNIRP guidelines, only the beam diameter for a Gaussian approximated beam is given with d_{63}. For a correct use of the recommended ELVs and the apertures for the measurement of the irradiance or radiant exposure, a clearly defined beam diameter is needed for possible shapes and sizes of a laser beam. Otherwise, the respective value for the irradiance or radiant exposure used to evaluate the hazard of the eye and the skin might be underestimated. Therefore, a clear definition for a beam diameter is strongly requested in a possible update of the ICNIRP guidelines.

2.3 Averaging apertures for applying the ELVs

The averaging apertures for applying the ELVs are listed in Table 8 of the ICNIRP guidelines on laser radiation from 2013 [5]. Compared to the previous ICNIRP guidelines on laser radiation from 1996 [2], the averaging aperture for the eye exposure has been changed for exposure durations between 1 ns and 10 s in the wavelength range between 180 nm and 400 nm. Instead of the former value of 1 mm for all exposure durations up to 10 s, now two different values are set up: 1 mm for exposure durations between 1 ns and 0.35 s as well as $1.5{\cdot}t^{3/8}$ mm for exposure durations between 0.35 s and 10 s. As far as the recommended ELVs are concerned, the consequences should be explained for comparison.

3. ELVs in the ultraviolet region

Concerning the UV region, there was no change of ELVs for wavelengths between 180 nm and 400 nm. However, ELVs are not set in the wavelength range between 100 nm and 180 nm, since in most cases the absorption of short wavelength optical radiation in air is sufficient to protect the skin. It is, however, questionable whether in case of high intensity laser beams the air absorption will always be sufficient in order to protect persons. Therefore, it is proposed to extend the existing ELVs to the UV region below 180 nm:

- For laser radiation between 100 nm and 180 nm, a limit for the radiant exposure of $H = 30\ J{\cdot}m^{-2}$, as already specified in [2] for $\lambda = 180$ nm ($t > 1$ ns), is recommended.

4. ELVs for the protection against the retinal thermal hazard

4.1 Continuous-wave laser radiation - correction factors C_A and C_C

A comparison of the spectral dependence of the correction factors C_A and C_C with the relative effective spectral absorbance in the retinal pigment epithelium (RPE) is shown in Figure 2 of the new ICNIRP guidelines on laser radiation from 2013 [5]. The inverse of the product of the transmittance of the pre-retinal ocular media (anterior and posterior, excluding retina, choroidea and sclera) and of the absorption in the RPE, $(T{\cdot}A)^{-1}$, represents the energy absorbed in the RPE relative to the energy that enters the eye. The spectral correction factor C_A approximates the reciprocal of the absorbance, A, of the RPE. The spectral correction factor C_C approximates the reciprocal of the spectral transmittance of the pre-retinal ocular media, T. As a result, the product of the spectral correction factor C_A and the spectral correction factor C_C is plotted in Figure 2 of [5]. It has to be emphasized that the correction factor C_C relaxes the corneal ELV in the wavelength range between 1150 nm and 1400 nm, where the ocular media become increasingly attenuating [10]. From the ordinate of Figure 2 it is not clear whether the curves for C_A, $C_A{\cdot}C_C$ and $(T{\cdot}A)^{-1}$ are given as relative magnitudes, as it is stated, or with the respective values according to Table 3 in the ICNIRP guidelines [5]. This complicates a comparison.

Especially remarkable is the increase of the spectral correction factor C_C in the wavelength range between approximately 1250 nm and approximately 1400 nm, if values stated in the ICNIRP guidelines on laser radiation from 2013 [5] are compared to those in the Directive 2006/25/EC [1] (Figure A7 in Annex 1).

There have been various publications in the past dealing with the spectral transmission of the pre-retinal ocular media and the spectral absorption, especially of melanin in the RPE of the eye. Figure 6 in Lund et al. [10] shows a plot based on the direct transmission data, the RPE absorption data and the retinal spot sizes, which is equivalent to an action spectrum for laser induced thermal retinal damage in the rhesus monkey eye. Lund et al. report that “dose-response data were obtained for 35 wavelengths in the visible and NIR spectrum and all exposure durations were 100 ms”. These extramacular threshold data (ED-50) were then compared to the computed action spectra and it is concluded that “the ED-50 values are a factor of 10 higher than the currently defined maximum permissible exposure[4] (MPE) for 100 ms exposures”. As it is pointed out by Lund et al., “full confidence in the observed safety factor still requires an understanding of the damage mechanisms”, as well as that “a simplistic model of the laser / tissue interactions has been used and that the fit may be in part fortuitous”. It is remarkable, however, that for the most interesting wavelength

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[4] The terms Exposure Limit Value (ELV) and Maximum Permissible Exposure (MPE) have the same meaning.

range between 1064 nm and 1330 nm, there are only experimental data for exposure durations of 100 ms. Additionally, since no threshold data for 100 ms exposures were available at 1064 nm and 1330 nm, these have been extrapolated from threshold data for shorter exposure durations using the convention that the threshold varies as the exposure duration to the 3/4 power [10].

The current exposure limits are based on an averaging aperture of 3.5 mm in the wavelength range between 1200 nm and 1400 nm. In order to take all possible hazards into account, it is necessary to consider all beam diameters on the cornea. The reason is that in this wavelength range so-called volumetric absorption takes place [11], i. e. for relatively large beam diameters on the cornea the retinal hazard dominates whereas for relatively small beam diameters on the cornea the corneal hazard dominates. And between both possibilities the damage site varies, not only due to the respective wavelength and the wavelength dependent absorption, but due to the volumetric absorption effect, too. Therefore, the worst-case situation might not be described by the function C_C alone and not for a single averaging aperture only.

4.2 Intermittent, repeated and varying exposures - correction factor C_p

The previous value of the factor $C_p = n^{-0.25}$ seems to be too restrictive. The dependencies under different assumptions and ICNIRP recommendations for occupational safety, however, cannot be easily derived. Since the former ICNIRP guidelines, long-term investigations were carried out with high pulse rates. For up to 600 pulses, the recommendations of the new ICNIRP guidelines on laser radiation from 2013 [5] can be adopted. In order to be on a safe side, for pulse rates of 600 - 100 000, the value of 0.2 should be set for C_p, (a factor of 5) for all spot sizes. For pulse rates higher than 100 000, a factor $C_p = n^{-0.25}$ should be applied.

One example for the factor C_p as a function of the angular subtense α is shown in Figure A9 in Annex 1.

4.3 Dual limits

According to Table 5 of the ICNIRP guidelines on laser radiation from 2013 [5], “Dual limits for 400 - 600 nm visible laser exposure at t > 10 s” exist. However, ELVs against thermally induced retinal injury are set up for 400 nm $\leq \lambda <$ 700 nm. As a consequence, two upper ELVs for thermal retinal hazard exist (at 600 nm and at 700 nm), but only one for the photochemical retinal hazard. This would mean that for 600 nm $\leq \lambda \leq$ 700 nm only thermal ELVs have to be regarded.

4.4 Exposure duration dependence of the retinal thermal ELVs

In the ICNIRP guidelines on laser radiation from 2013 [5], Figure 8 shows the exposure duration dependence of the retinal thermal ELVs for a number of angular subtenses of the source in the wavelength range of 400 nm $\leq \lambda <$ 700 nm. Since the curve progression is not easy to verify from Figure 8 alone, it would have been helpful to include the respective formulas to the figure (with C_E and α_{max} according to Table 2 of [5]):

- For 100 fs $\leq$ t < 10 ps, $H_{EL} = 1.0 \cdot C_E$ mJ·m^{-2}
- For 10 ps $\leq$ t < 5 µs, $H_{EL} = 2.0 \cdot C_E$ mJ·m^{-2}
- For 5 µs $\leq$ t $\leq$ 10 s, $H_{EL} = 18 \cdot C_E \cdot t^{0.75}$ J·m^{-2}

In order to give the intended information to the reader, the exposure durations for the respective inflection points should have been labeled in the diagram, as far as possible. At least a grid would have been of some help.

4.5 Correction factor C_E

In the ICNIRP guidelines on laser radiation from 2013 [5], a correction factor C_E is applied in order to consider the influence of the extension of a laser source on the retinal injury thresholds. It is stated that “for a homogeneous and circular source, the exposure level can be determined with an open field of view γ, i. e. non-restricted, and then the correction factor, C_E, is as defined in the equation:

$$C_E = \frac{\alpha^2}{\alpha_{min} \times \alpha_{max}}$$ ”.

As can be seen from Table 2 in [5], $C_E = \alpha_{max} / \alpha_{min}$ for $\alpha \geq \alpha_{max}$ (with $\gamma = \alpha_{max}$). ELVs can be expressed in terms of radiance for $\alpha > \alpha_{max}$; α_{max} depends on the exposure duration t and is 100 mrad for t > 0.25 s.

From these relations it can be seen that C_E is not limited, since it is a function not only of the angular subtense α of the laser source, but also of the exposure (or pulse) duration t. In the previous guidelines the numerical value of the angular subtense α has been limited to the maximum angular subtense α_{max} = 100 mrad.

In addition, the correction factor C_E (which is referred to as C_6 in the international laser product safety standard IEC 60825-1:2014 [12]) is limited to $C_E = \alpha_{max} / \alpha_{min}$ for $\alpha > \alpha_{max}$, with α_{max} = 100 mrad for t > 0.25 s. Furthermore, the maximum limiting angle of acceptance γ_{th} shall be equal to α_{max}. Thereby, a deviation with respect to the ICNIRP guidelines exists.

It should have been clearly explained in the ICNIRP guidelines that the actual numerical value of α is a measurable property of the laser source depending on the source size and the viewing distance. This value is not physically limited to α_{max} and explains the inequality, whereas contrary to this, α_{max} is related to the thermodynamic relations (e. g. rate and duration of heat flow) in the retina. This would prevent misunderstandings in future.

Additionally, in order to prevent ambiguity, the inequality signs in the definition of C_E in Table 2 in [5] should be rewritten with only one equality sign in each equation:

C_E =	1.0	for	$\alpha \leq \alpha_{min}$
	α / α_{min}	for	$\alpha_{min} < \alpha \leq \alpha_{max}$
	$\alpha_{max} / \alpha_{min}$	for	$\alpha > \alpha_{max}$ (with $\gamma = \alpha_{max}$).

The correction factor C_E is shown in Figure A8 in Annex 1.

5. ELVs for the protection against the photochemical retinal hazard

5.1 Spectral weighting functions for the photochemical retinal hazard in case of laser and incoherent optical radiation

The spectral weighting function C_B for the photochemical retinal hazard in the ICNIRP guidelines on laser radiation from 2013 [5] does not follow the biologically correct action spectrum, but it differs from the spectral weighting function $B(\lambda)$ given in the ICNIRP guidelines on incoherent optical radiation from 2013 [4] (compare Figures 1 and 5 in [5] and [4], respectively). Since the biological effects of optical radiation on eyes and skin do not depend on the coherence property of the optical radiation, the same spectral weighting function should be chosen for laser and for incoherent optical radiation. This applies for the weighting functions of all biological effects treated in either ICNIRP guidelines. The spectral weighting functions should follow the real biological response of the eyes and the skin when exposed to optical radiation. The functions have to be smooth and must not contain steps. Therefore, the spectral weighting function in the ICNIRP guidelines on laser radiation from 2013 [5] should be changed accordingly.

5.2 ELVs and the transmission of the human eye

As mentioned above, ELVs against the photochemical retinal hazard show a large step (factor of 100) at 400 nm. One reason for the large step in the radiant ELVs is the absorption of the anterior parts of the human eye, i. e. the cornea, aqueous humour, lens and the vitreous humour, at 400 nm. The transmittance of the human eye published by the International Commission on Illumination (CIE) [13] shows a change in absorption of more than two orders of magnitude between 300 nm and 700 nm (Annex 3, Figure A22) with a smooth transition at least between approximately 380 nm and approximately 420 nm.

The question is whether a step at 400 nm is a safe approach for the evaluation of the potential optical hazard. As can be seen in Figure A22 of Annex 3, the spectral weighting function for photochemical retinal hazard $B(\lambda)$ defined in the ICNIRP guidelines on incoherent optical radiation from 2013 [4] has a continuous transition between approximately 380 nm and approximately 435 nm.

The radiant ELV against the photochemical retinal hazard in the wavelength range 315 nm ≤ λ < 400 nm stated in the "ICNIRP guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1,000 μm" [5] for exposure durations longer than 10 s is $H = 10\,000\ J{\cdot}m^{-2}$. The photochemical ELV for an exposure duration longer than 10 s in the wavelength range 400 nm ≤ λ < 600 nm is $H = 100{\cdot}C_B\ J{\cdot}m^{-2}$, where the correction factor C_B increases for wavelengths longer than 450 nm and is equal to 1 between 400 nm and 450 nm. The photochemical retinal hazard effective radiant ELV in the guidelines on incoherent optical radiation for an exposure duration of 0.25 s ≤ t < 100 s and wavelengths between 300 nm and 700 nm is $H = 100\ J{\cdot}m^{-2}$. In connection with the spectral weighting function B(λ) the individual wavelength dependent radiant ELVs can be calculated and the results are directly comparable to the respective laser ELVs (Annex 3, Figure A23). Compared to the incoherent radiant ELVs, those derived from the laser guidelines are significantly higher for 380 nm ≤ λ < 400 nm and significantly lower for 400 nm ≤ λ < 420 nm.

The wavelength dependent ELVs can be expressed as a wavelength dependent irradiance or radiant exposure. By multiplying this irradiance or radiant exposure with the spectral transmittance of the human eye, the wavelength dependent exposure penetrating through the cornea, aqueous humour, lens and the vitreous humour directly to the retina can be calculated. It is shown as effective retinal irradiance in Figure A24 (Annex 3). It is obvious that the permissible emission for laser radiation in the range between approximately 380 nm and approximately 400 nm generates a high level of exposure on the retina and is rather restrictive in the range between approximately 400 nm and approximately 420 nm, if compared to the respective values for incoherent optical radiation. This can cause risk evaluation problems for laser sources with an emission in the range of 400 nm. A spectral correction factor between 380 nm and 420 nm (comparable to C_B) and an adjustment of the radiant ELVs might solve this issue.[5]

5.3 Different wavelength ranges for the photochemical retinal hazard in case of laser and incoherent optical radiation

Concerning the photochemical retinal hazard, the ICNIRP guidelines on incoherent optical radiation [4] set ELVs between 300 nm and 700 nm, whereas in the ICNIRP guidelines on laser radiation [5], ELVs are specified between 400 nm and 600 nm. As long as there is no reason for this difference, the wavelength ranges for laser and incoherent optical radiation should be the same. Currently, there are no data reported on retinal damage caused by cumulative exposure for wavelengths above 600 nm.

[5] The UV hazard potential is not treated in this statement.

5.4 ELVs against the photochemical retinal hazard for laser and incoherent optical radiation - exposure duration

The lowest exposure duration for which ELVs for the protection against photochemical retinal hazard are recommended are different in the new ICNIRP guidelines on laser radiation from 2013 [5] ($t \geq 10$ s) and the ICNIRP guidelines on incoherent optical radiation from 2013 [4] ($t \geq 0.25$ s). The reason for this difference is not explained. If below 10 s (or a few seconds) the thermal injury mechanism indeed predominates (see 5.5), then this applies to both laser and incoherent optical radiation, and the ELV recommendations must be the same. Therefore, one of the guidelines, or both of them, should be revised in this respect in order to adjust the ELVs for laser and incoherent optical radiation.

5.5 Impact of eye movements on retinal injury

In the context of the impact of eye movements on retinal injury threshold, the ICNIRP guidelines on laser radiation from 2013 [5] state that solely the thermal injury mechanism exists for exposure durations shorter than 10 s (see 5.4). However, the studies of Lund et al. from 2006 [14] and Lund et al. from 2008 [10] do not allow the conclusion that for exposure durations less than 10 s only the thermal injury mechanism of the retina exists. These publications do not state that photochemical injuries cannot occur below 10 s, but that at short term exposures in the range of seconds or less (e. g. “shorter than 5 s” [14] and “shorter than a few seconds” [10]) the thermal injury mechanism predominates. Therefore, even for exposure durations below 10 s photochemical injuries may occur, or at least cannot be completely excluded. It is also not clear whether the Bunsen-Roscoe-Law is applicable in this exposure duration range, too. In fact, the exposure duration when thermal effects on the retina predominate over photochemical effects cannot be clearly determined from the literature. In general, one might accept the ICNIRP approach, but the sentence in question should be changed accordingly.

Further, it is arguable why only photochemical effects have to be regarded exclusively below 400 nm, i. e. for ultraviolet laser radiation, independent of the exposure duration (in the range between 1 ns and 30 000 s), whereas above 400 nm, a time dependent approach exists. The validity of the ICNIRP setting “10 s” should be described more precisely. Especially in the publication of Lund et al. (2008) [10], it is stated that “the paper is concerned with the action spectrum for thermally induced retinal damage dominating for exposures between 1 ms and 1 s”.

It also seems odd that note c) in Table 5 of the 2013 laser guidelines [5] refers to exposure durations less than 0.35 s although dual limit values for photochemical and thermal effects are specified in the range above 10 s only.

5.6 Angular subtense $\alpha < 11$ mrad and angle of acceptance γ

According to Table 5 of the ICNIRP guidelines on laser radiation from 2013 [5], there is no restriction $\alpha < 11$ mrad in the case of photochemical retinal ELVs, although in Table 2 $\alpha_{min} = 1.5$ mrad is still defined as the minimum angular subtense of a laser source, i. e. a point source.

In the revision of the guidelines on ELVs for laser radiation of wavelengths between 400 nm and 1.4 μm [3] dual limits for the wavelength range between 400 nm and 600 nm at $t > 10$ s (all for 7-mm limiting aperture) are given. Especially in the case of photochemical retinal damage in the wavelength range from 400 nm to 600 nm, the ELVs have been given in [3] for $\alpha < 11$ mrad for exposure durations between 10 s and 100 s with the additional restriction of $\gamma = 11$ mrad, and for 100 s up to 30 000 s without a restriction on the measurement field of view γ (angle of acceptance).

It is taken for knowledge that an explanation for photochemically induced retinal injuries is given in the current guidelines [5], stating that "for photochemically induced retinal injury there is no spot size dependence for a stabilized image". It is surprising that the cited reference, namely Naidoff and Sliney [15], which has been already well-known in 2000, was not considered in the previous ICNIRP guidelines on laser radiation.

According to the current argumentation, these and other studies of eye-movements during fixation led to the derivation of ELVs protecting against photochemical retinal injury and also led to the ELVs for sources with an angular subtense α less than 11 mrad to be treated equally with ''point-type'' sources for exposure durations between 10 s and 100 s.

But even if for the photochemical retinal ELV, eye movements of the angular extent of 11 mrad are incorporated for exposure durations between 10 s and 100 s, the measurement conditions appear to be contradictory, since according to [5], "for comparison of the exposure from sources smaller than 11 mrad with the photochemical limits, expressed as irradiance or radiant exposure, and for all exposure durations (10 s - 30 ks), any acceptance angle larger than the source size can be used".

According to the measurement recommendation, for $\alpha < 11$ mrad any acceptance angle larger than the source size can be used, i. e. $\gamma > \alpha$. This requirement, however, cannot be taken from Table 5 in [5].

6. ELVs for the protection against thermal injury of the cornea - infrared corneal aversion response

The new ICNIRP guidelines on laser radiation [5], state that “if exposures approached 1000 W·m^{-2} for one second or two, there would be an almost immediate sense of heating of the cornea leading to blinking and rotation of the eye. The infrared corneal aversion response requires further study before user safety requirements are relaxed, but the extreme rarity of infrared laser corneal injuries in the workplace clearly suggests that the corneal aversion response may provide significant protection”. The statement with respect to the infrared (IR) corneal aversion response is not supported by a corresponding literature reference.

The same statement has been used already in the description of the classes and potentially associated hazards in Annex C of the international laser safety standard IEC 60825-1 [12]. For example, it is stated there that “the response to heating of the cornea for far infrared radiation” contributes to limit the risk for Class 3R laser products. Since the accessible emission limit (AEL) for Class 3R laser products is 28 000 W·m^{-2} in the wavelength range between 4000 nm and 10^{6} nm for an emission duration of 1 s, which is equivalent to fivefold of the maximum permissible exposure (MPE) for a point source at the cornea expressed as irradiance for an exposure duration of 1 s, namely 5600 W·m^{-2}, it is questionable whether an even lower exposure value of about 1000 W·m^{-2}, which is the long-term exposure limit, would be sufficient in order to provide a sufficient contribution to the safety of such IR irradiations due to an IR corneal aversion response. Therefore, it seems to be appropriate to have a closer look on the temperature sensitivity of the cornea in literature.

Concerning IR radiation with respect to the effects on the cornea, Moss et al. [16] state that “since exposure to high intensities of far-IR can produce corneal pain, the eyes are reflexively closed and the head averted”. And referring to this, they write that “Sliney … has stated that the sensory nerve endings in the cornea are quite sensitive to small temperature elevations and that a temperature of 45°C (corresponding to approximately 100 kW·m^{-2} absorbed in the cornea) elicits a pain response in humans within a small fraction of a second. Hence, he suggests that a thermally mediated response is initiated before the actual pain stimulus. For this reason, burn lesions are not commonly seen in the usual industrial exposures” (Sliney [17]).

A substantially identical citation is also found in [18], namely “Knowing that a rise in temperature of the cornea to 45°C, corresponding to an irradiance of around 100 kW·m^{-2}, causes in a fraction of a second a painful reaction and an avoidance reflex, it is exceptional to observe burns to the cornea”.

The irradiance value of approximately 100 kW·m^{-2} (which is a factor of ten above the current ELVs for far-IR) can be compared with the data shown in the WHO

Environment Health Criteria 23 [19]. In Figure 14 [19], experimentally achieved threshold data for corneal injury for CO_2 laser radiation are shown and the respective irradiance values are between about 2.5 $W \cdot cm^{-2}$ and 7 $W \cdot cm^{-2}$ for exposure durations between about 1 s and 10 s, whereas many experimental results for minimally visible lesions are centered at about 10 $W \cdot cm^{-2}$ for exposure durations at about 100 ms. The scatter in the results is thought to be mainly due to the use of different corneal image sizes [19].

In [19] it is stated that "the nerve endings of the cornea are quite sensitive to all temperature elevations and an elevation of 10°C causes a pain response", which is in agreement with the description above. On the other hand, it is said that "with full-face exposure, a temperature rise can be felt before corneal pain appears" [19].

An explanation for this finding is given in the investigations described by Kenshalo [20]. He found that although the cornea is innervated by bare nerve endings of greater density than the skin, it could not be verified that the cornea was more sensitive to thermal stimulation than skin. This is especially surprising since the innervations are characterized by a surface proximity of the nerve terminals and the absence of vascular system. If these nerve terminals act as thermal receptors, i. e. as so-called polymodal nociceptive neurons, the cornea should be more sensitive to thermal stimulation than skin. In this study comparisons were made of the thermal sensitivities of the upper lip, forehead, conjunctiva and cornea. Although no thermal sensations were obtained from the cornea by applications of temperatures ranging from 20°C to 55°C, all observers reported sensation changes at certain points on the temperature continuum. These were described in terms of irritation, whereas similar temperatures applied to the other sites felt cool, warm or hot. Stimulus temperatures at which corneal sensations changed were significantly different from the thresholds obtained at the other test sites. It is therefore concluded that the cornea differs both quantitatively and qualitatively in its response to thermal stimulation from the other regions tested, i. e. upper lip, forehead and conjunctiva [20].

Higher temperature sensitivity has also been reported for the upper eyelid compared with the cornea by Beuerman and Tanelian [21], i. e. it was found that the nerve endings of the corneal epithelium are less sensitive to temperature change when compared to the thermal receptors of the eyelid at least in the temperature range between 33°C to 45°C.

As far as the investigations of Gullberg et al. [22] are concerned, they found that "the corneal blink reflex seemed to respond in a very reproducible way to exposure to the laser radiation, and so they used it as an indication of a heat sensation in the cornea". According to these investigations, performed with rabbits, a corneal blink reflex was released at a value roughly a factor of two below the damage dose threshold. For example, according to Gullberg et al. for exposure duration of 1 s the damage will be barely visible if the delivered energy is 0.3 $cal \cdot cm^{-2}$, i. e.

1.25 W·cm^{-2}. This means that the corneal blink reflex is released at about 0.63 W·cm^{-2} (6.3 kW·m^{-2}), but not already at a lower value of about 1 kW·m^{-2}, as stated in the ICNIRP guidelines. According to the experimental data shown in Figure 1 in [22], even for an exposure duration of 5 s, the respective irradiance in order to thermally stimulate the corneal blink reflex might be calculated from the given formula in Figure 1 in [22] to be about 0.33 W·cm^{-2} (3.3 kW·m^{-2}).

Gullberg et al. [22] clearly state that "the blink reflex may offer some protection at very low power levels, but should not be relied on".

Concerning shorter exposure durations it has to be additionally taken into account that "the corneal blink reflex, released after a latent period of 80 ms, acts to close the eyelids, but it is slow enough to make even low power carbon dioxide lasers dangerous to the eye" [22].

In a later study, Randolph and Stuck [23] have investigated the sensitivity of the cornea and surrounding tissues to heat produced by CO_2 laser radiation in rhesus monkeys. The responses occurring at the 4, 8, and 16 mm beam conditions appeared to be directly related to both the size of the area stimulated and the tissues involved. While it was apparent that no sensitivity was present to heat directed at the cornea in the 4 mm condition, the amount of corneal contribution to the 8 mm sensitivity data could be inferred by comparing the 200 mW·cm^{-2} cornea and lid data with the 200 mW·cm^{-2} data obtained from the face alone. No differences were seen in the responses under these two conditions. Thus "the cornea was not found to be sensitive to radiation from the CO_2 system under any of the area conditions" [23].

From these results Randolph and Stuck concluded that the cornea does not appear to be sensitive to heat produced by a CO_2 laser system at irradiances twice the recommended safety level, i. e. at 200 mW·cm^{-2} (2000 W·m^{-2}). On the other hand, the threshold for sensitivity to CO_2 laser radiation with the 8 mm diameter beam was between 25 mW·cm^{-2} and 50 mW·cm^{-2}, while for the 16 mm beam condition it was between 4 mW·cm^{-2} and 20 mW·cm^{-2}. The 8 mm aperture was positioned so that the center of the beam was centered on the cornea, while the outer edges of the beam were on the lids and lid margins. The full 16-mm beam was directed at the cornea, lids, and periocular areas of the rhesus monkeys face and only the 4-mm beam was directed solely onto the cornea. No differences in the rhesus monkey responses were observed between the 8-mm beam directed at the cornea and lids and the same beam directed to a non-hairy area of the face, while responses to the 4-mm diameter beam were different when skin exposures were compared to corneal exposures [23].

It should not be overlooked that in a typical situation in which an individual is exposed to CO_2 laser radiation, the beam diameter will generally be large compared to those values used in the reported study. Therefore, sensation of heat on the face or other parts of the body at low irradiance levels could serve as a warning to the individual that he had intercepted the beam [23]. In addition, it was found that the reaction time for the most intense irradiance for the skin with the 16-mm beam was approximately 3.2 s in order to respond to the stimulus.

It is not disputed, however, that humans have inborn protective aversion responses to pain from high heat so that potentially harmful exposure might be avoided. But, as far as the effectiveness range is regarded, compared to the potentially available irradiance levels for far-IR laser radiation, this is very limited. The fact that up to now only few persons have been injured from such far-IR laser radiation does not prove the contrary, but should be regarded as a fact. Corneal burns should be prevented mainly taking into account safe work procedures.

Since some uncertainty regarding the level of the irradiance exists with respect to an expected corneal aversion response, and in addition it seems that the cornea does not have the greatest sensitivity to heat compared with other parts of the face, it would be better not to support the protection against damage to the cornea in the IR wavelength region on such an effect, but to consider it at most as a certain contribution for protection.

Moreover, it has not been discussed whether it is possible to determine the direction of beam incidence from a heat sensation as a result of absorption of long wavelength laser radiation at all. This would be a prerequisite to move the eye together with the head out of the hazardous beam.

Annex 1 Comparison of the ELVs and correction factors of the Directive 2006/25/EC and the ICNIRP guidelines from 2013

In this Annex ELVs, correction factors and parameters of the ICNIRP guidelines from 1996 [2] and 2000 [3] (and therefore also of the Directive 2006/25/EC [1]) and those of the new ICNIRP guidelines on laser radiation from 2013 [5] are shown.

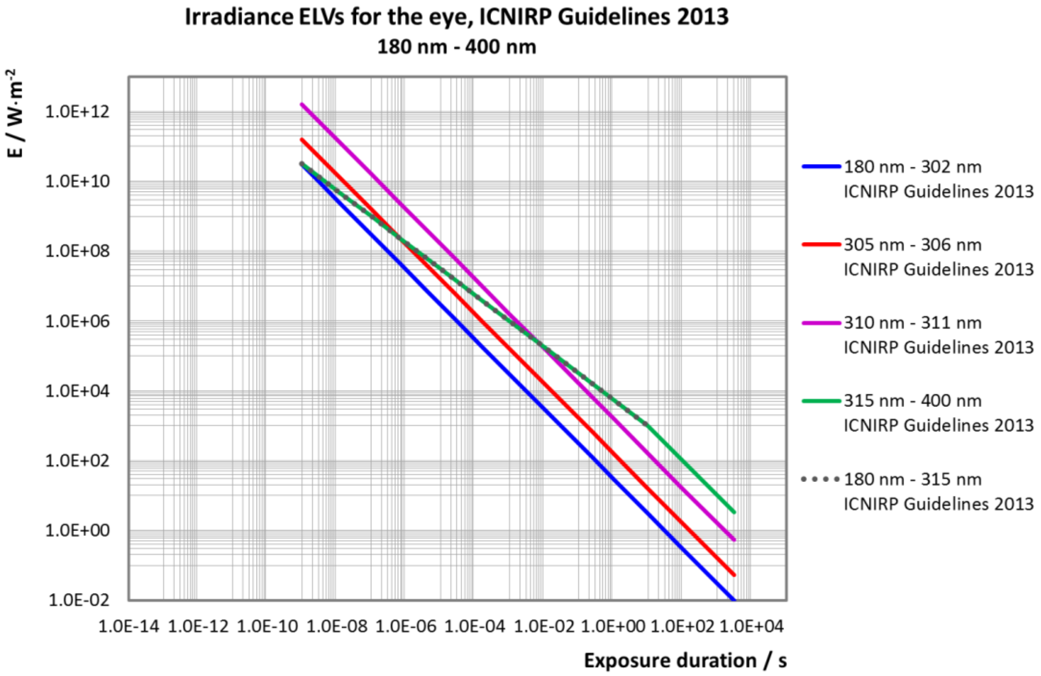

Figure A1: Irradiance ELVs for the eye of the ICNIRP guidelines on laser radiation [5] in the UV wavelength range between 180 nm and 400 nm. For exposure durations from 1 ns and 10 s, ELVs between 180 nm and 315 nm should not be exceeded (dotted line).

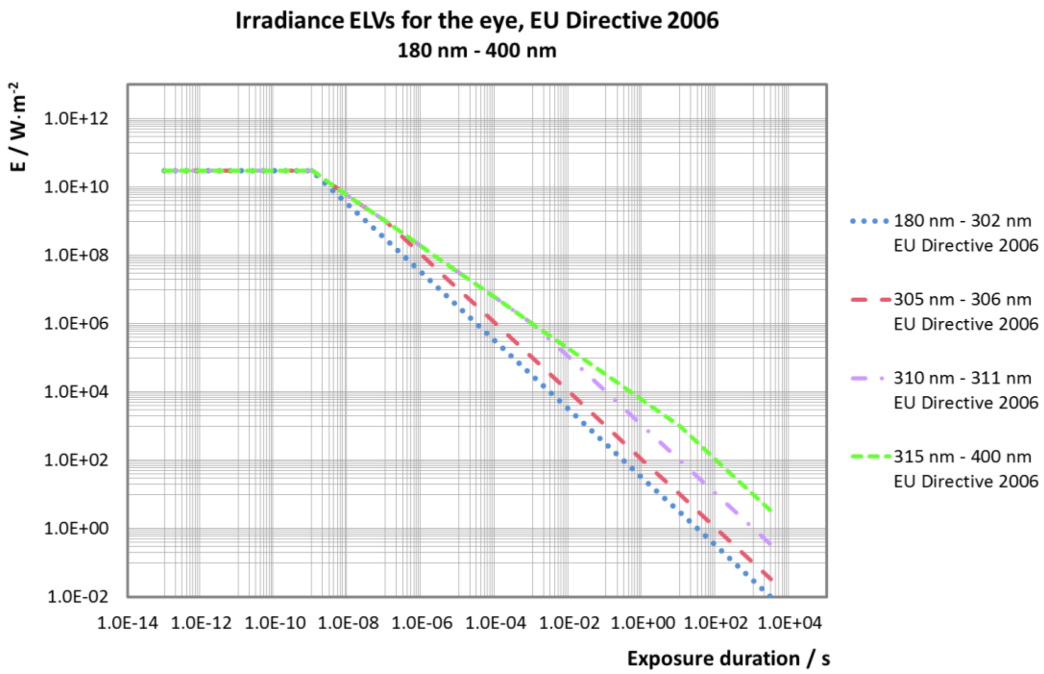

Figure A2: Irradiance ELVs for the eye of the Directive 2006/25/EC [1] in the UV wavelength range between 180 nm and 400 nm.

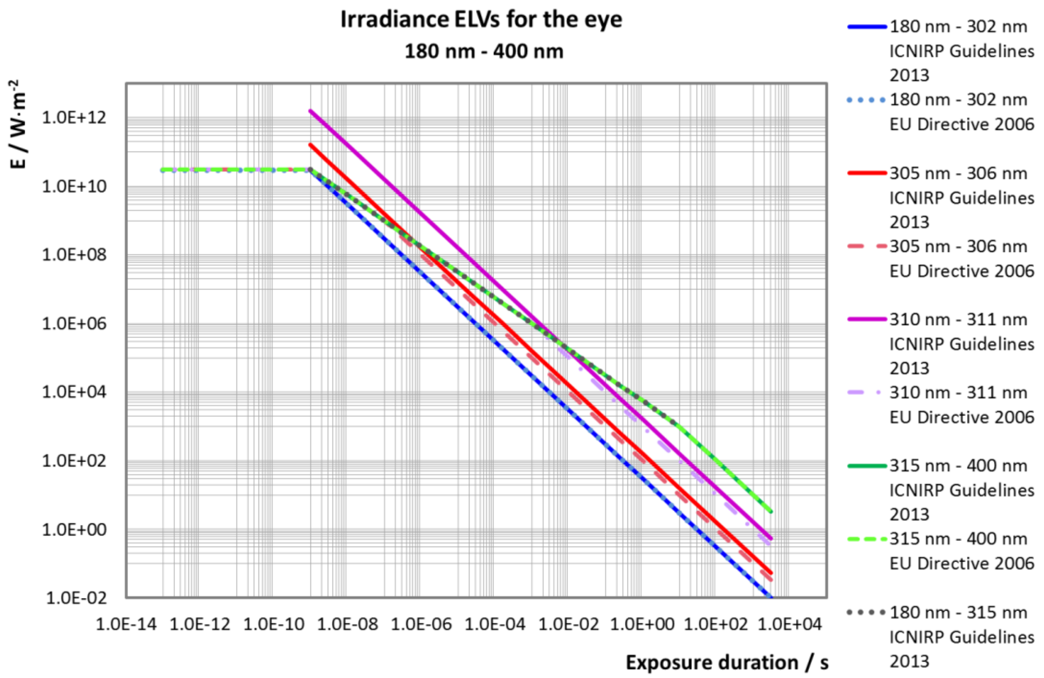

Figure A3: Irradiance ELVs for the eye of the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1] in the UV wavelength range between 180 nm and 400 nm.

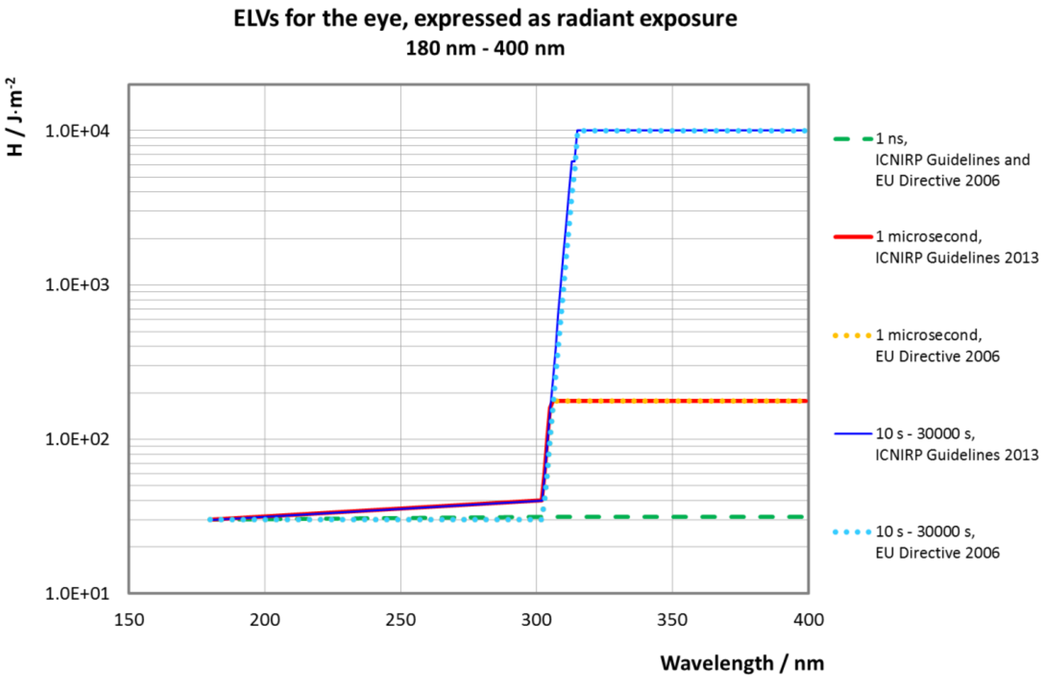

Figure A4: ELVs for the eye, expressed as radiant exposure, of the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1] in UV wavelength range (180 nm - 400 nm). The ELVs for the skin in this wavelength region are the same as the ELVs for the eye.

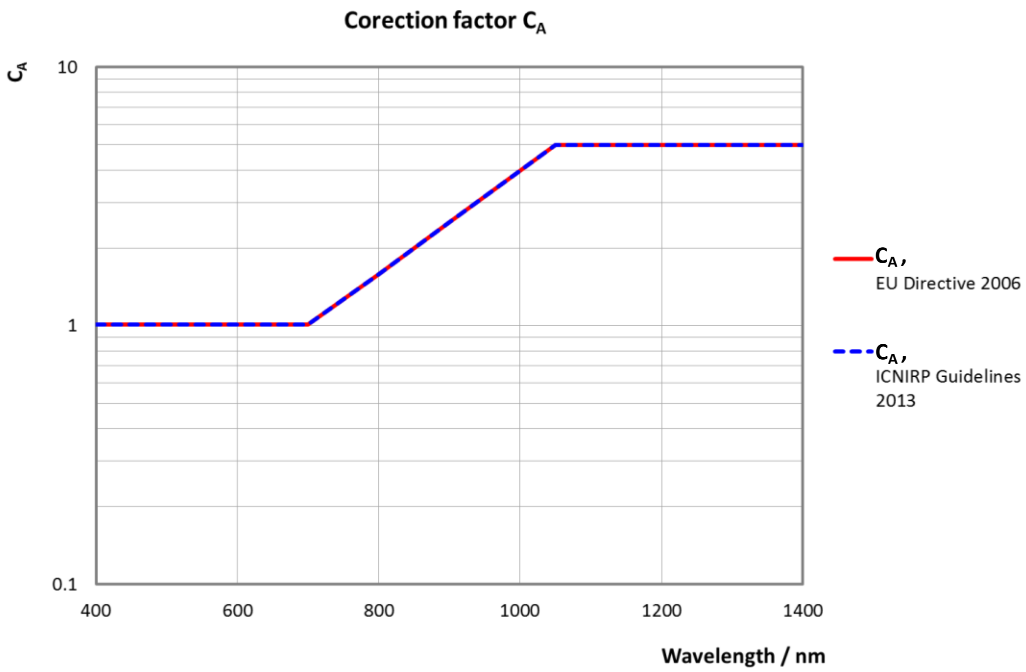

Figure A5: Correction factor C_A as a function of wavelength according to the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1]. C_A approximates the reciprocal of the absorbance of the retinal pigment epithelium (RPE). The factor is also used for skin ELVs.

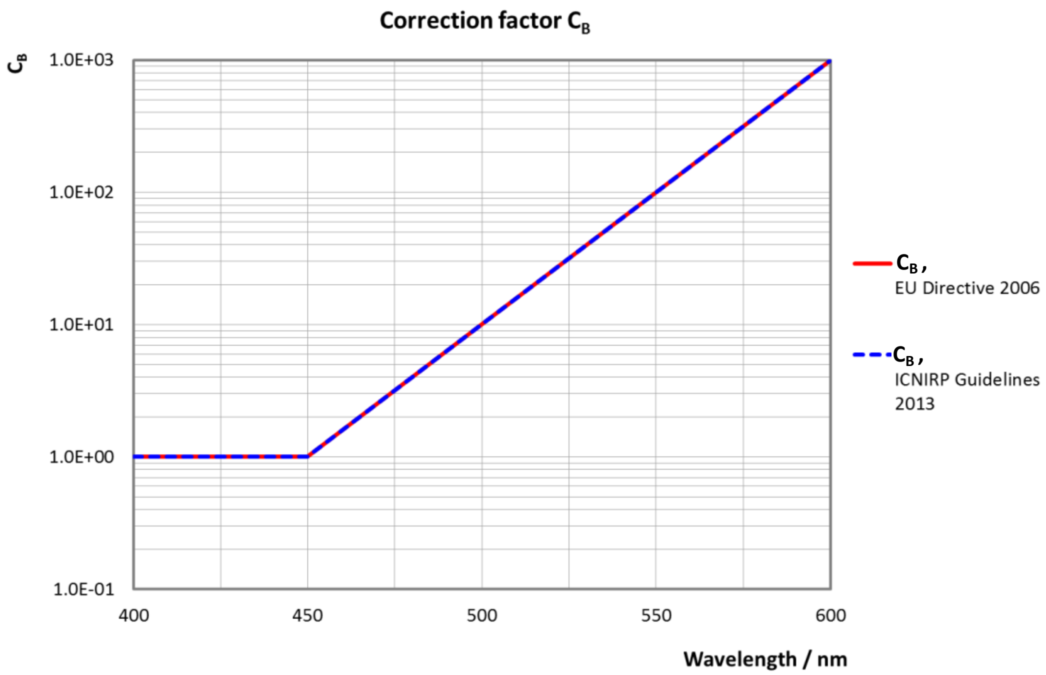

Figure A6: Correction factor C_B as a function of wavelength according to the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1]. C_B is related to the wavelength dependence of photochemically induced retinal injury applicable to exposure durations greater than 10 s in the visible wavelength range.

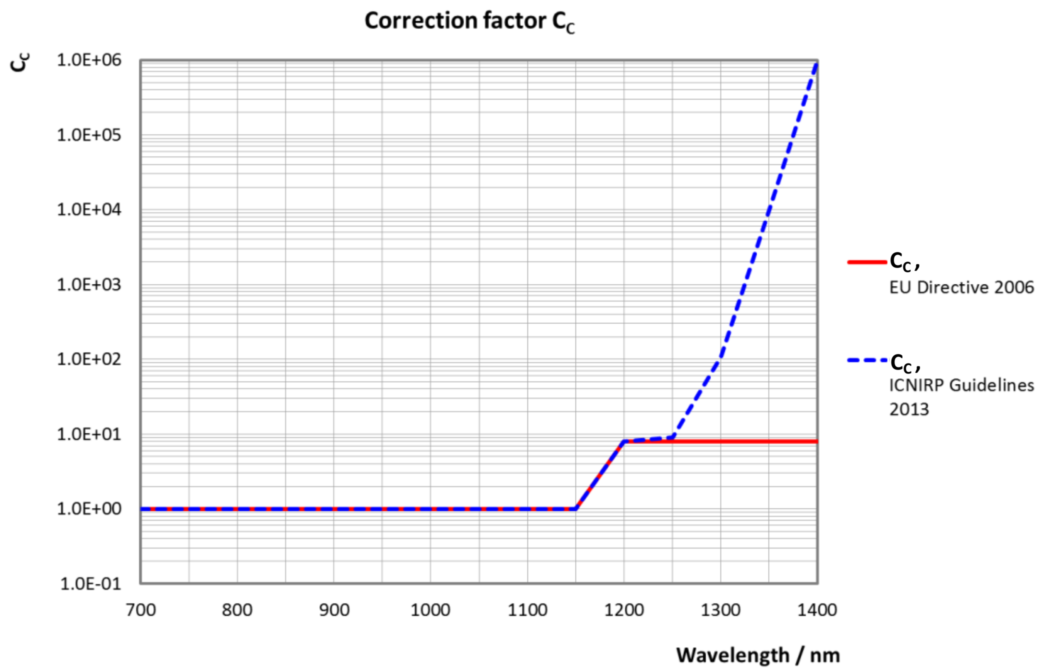

Figure A7: Correction factor C_C as a function of wavelength according to the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1]. C_C approximates the reciprocal of the spectral transmittance of the pre-retinal ocular media.

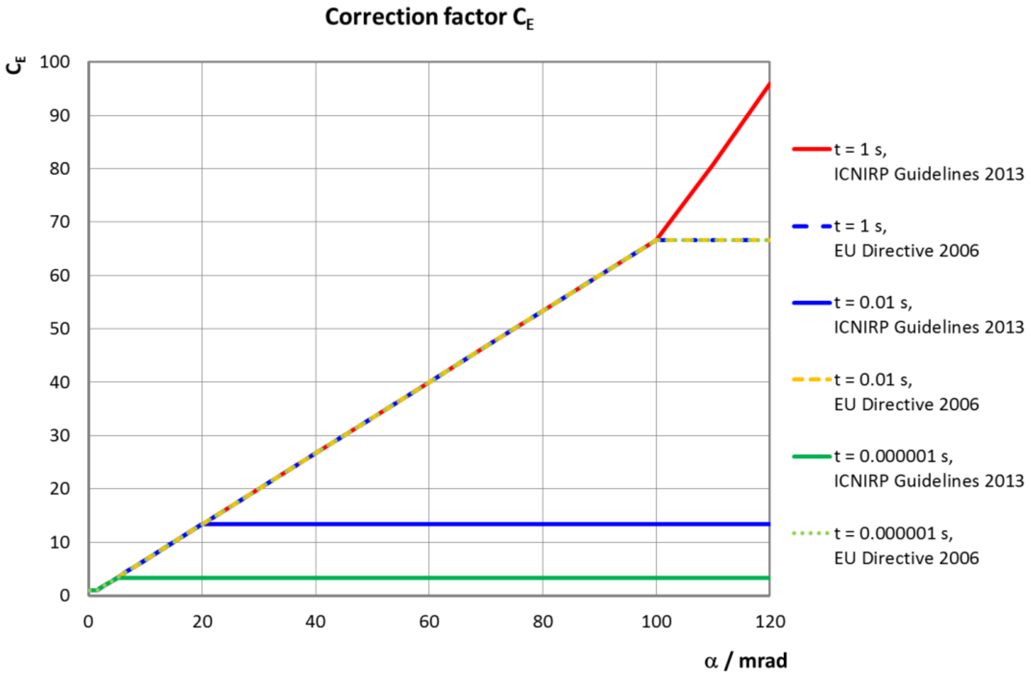

Figure A8: Correction factor C_E as a function of the angular subtense α of a laser source, according to the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1]. For t = 1 s and $\alpha \geq \alpha_{max}$, C_E has been calculated according to the equation (5) in [5], where "for a homogeneous and circular source, the exposure level can be determined with an open field of view", i. e. the angle of acceptance γ is not equal to α_{max}. C_E accounts for the variation of retinal injury threshold with source size, which is characterized by the angular subtense of the apparent source α.

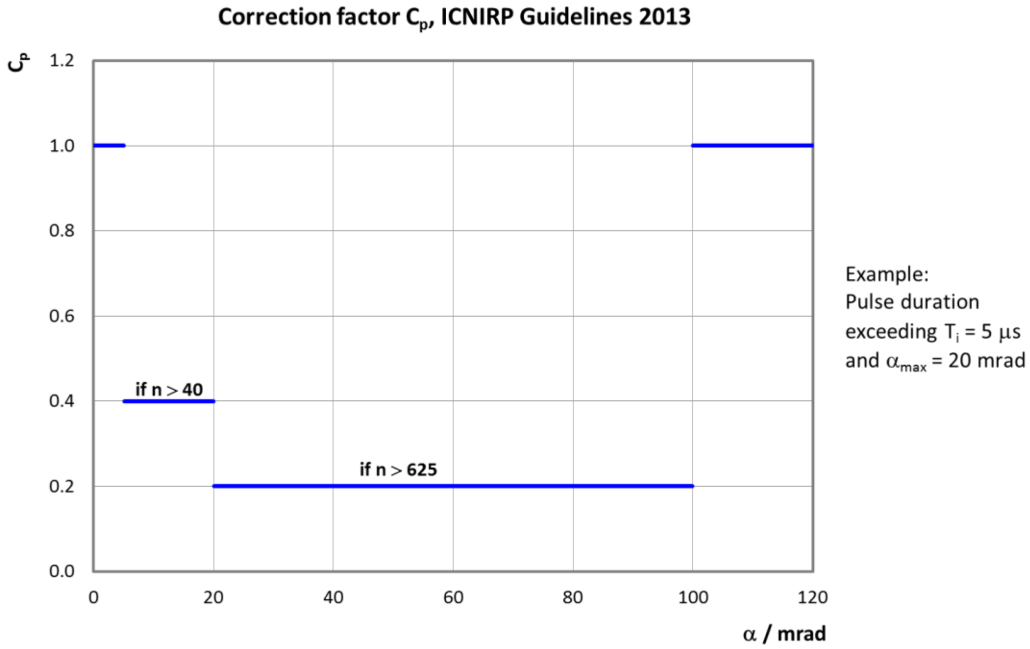

Figure A9: Correction factor C_p as a function of the angular subtense α of a laser source according to the ICNIRP guidelines on laser radiation [5] for a pulse duration exceeding $T_i = 5\ \mu s$ and $\alpha_{max} = 20$ mrad (t = 0.01 s). The factor accounts for the additivity of multiple pulses for thermally induced injury.

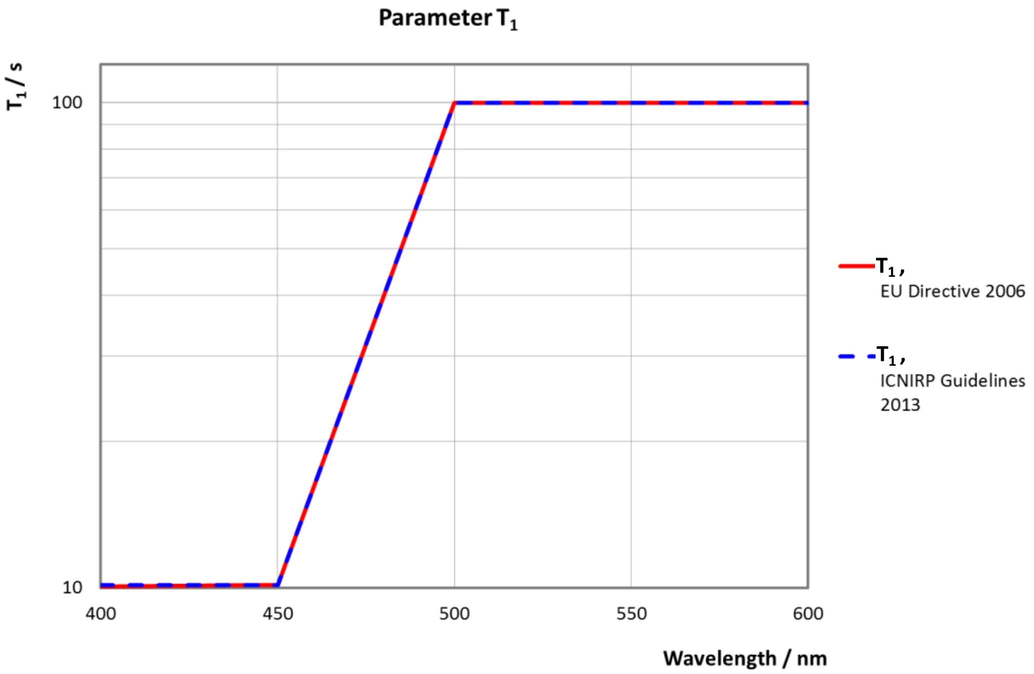

Figure A10: Parameter T_1 as a function of wavelength according to the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1]. The time T_1 applies for small sources ($\alpha \leq \alpha_{min}$, $C_E = 1$). It is the exposure time below which the retinal thermal ELV is lower than the photochemical ELV.

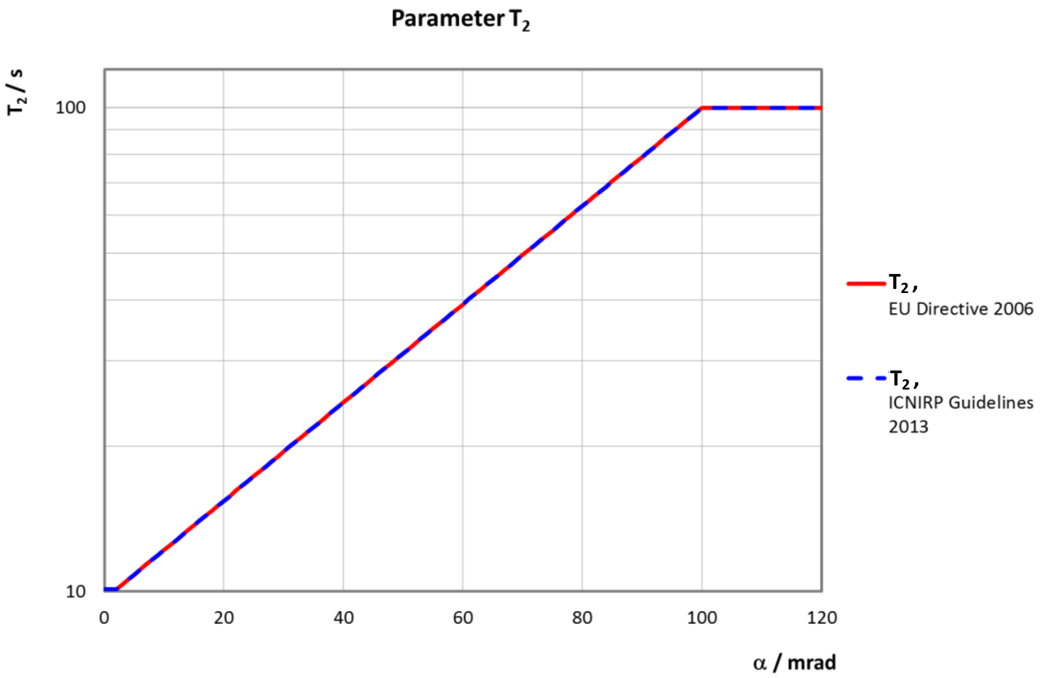

Figure A11: Parameter T_2 as a function of wavelength according to the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1]. In addition to the correction factor C_E, T_2 accounts for the effect of the source size as well. It is a brake-point in viewing time at which eye movements compensate for the increased risk of thermal injury for increased retinal exposure durations if the eye was immobilized. For $t > T_2$, the retinal thermal ELV is given as constant irradiance.

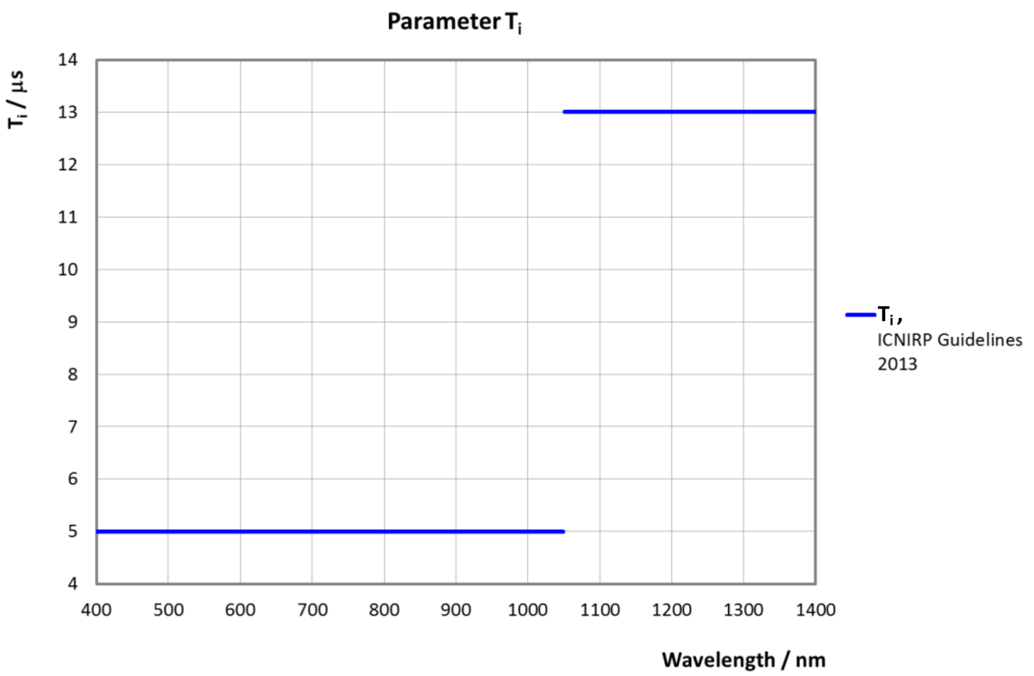

Figure A12: Parameter T_i as a function of wavelength according to the ICNIRP guidelines on laser radiation [5].

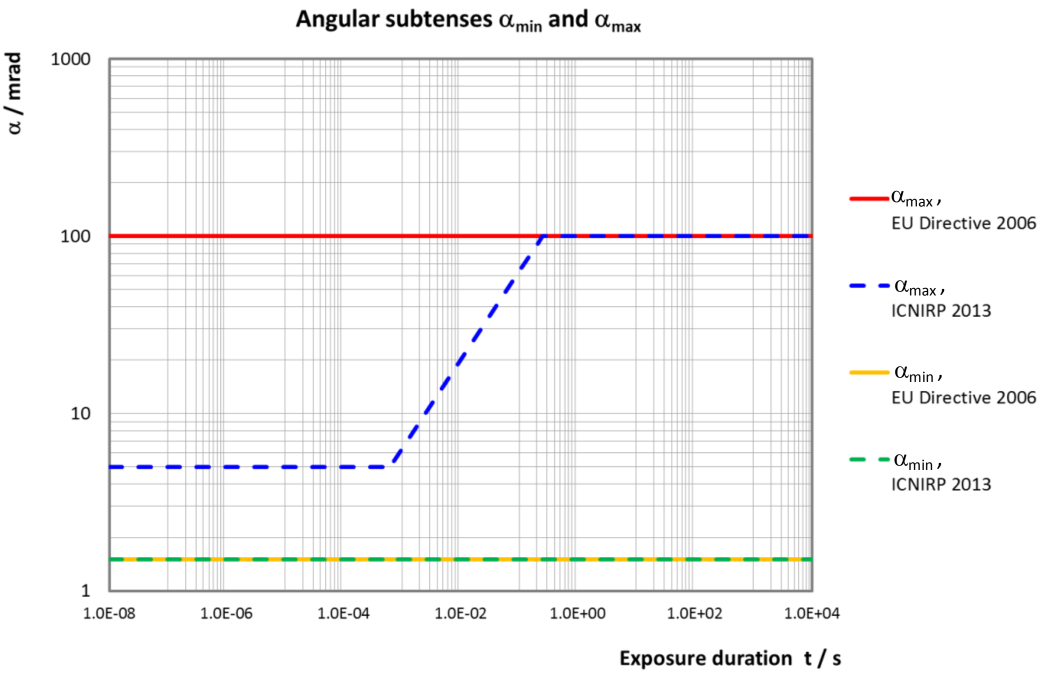

Figure A13: Limiting angles α_{min} and α_{max} of the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1].

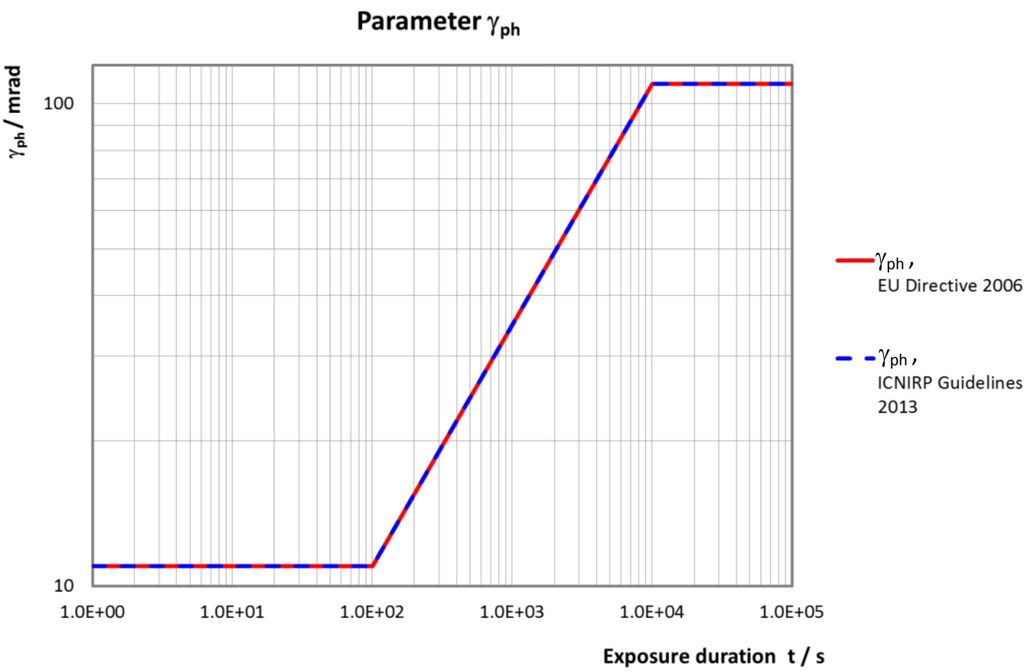

Figure A14: Parameter γ_{ph}, as a function of exposure duration, of the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1]. γ_{ph} is the measurement field of view (angle of acceptance).

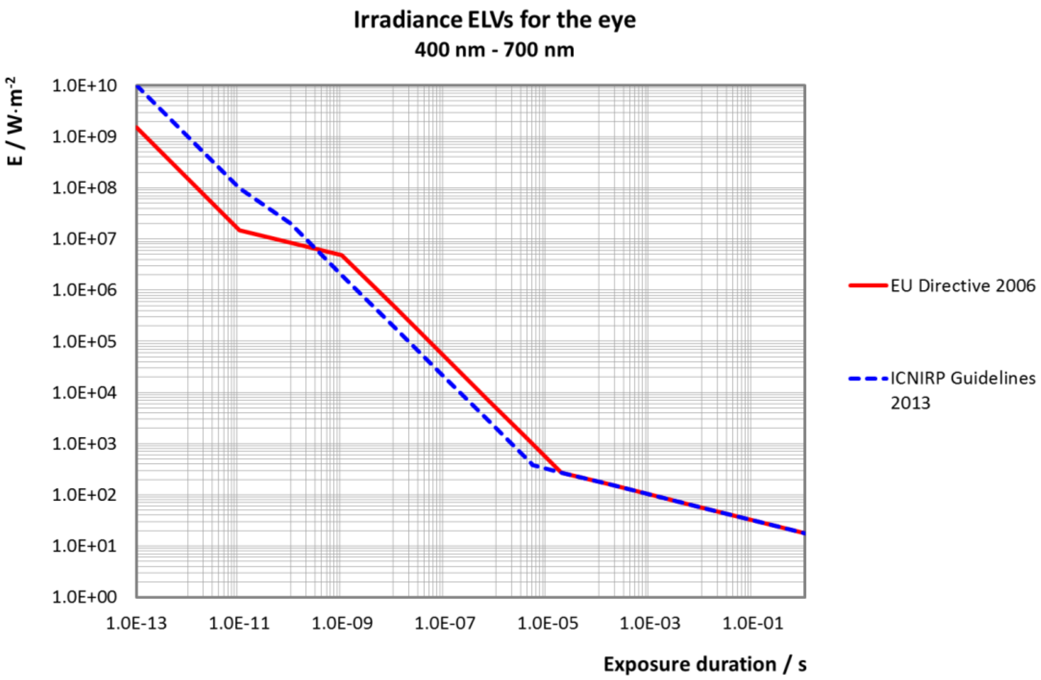

Figure A15: Irradiance ELVs of the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1] in the visible wavelength range (between 400 nm and 700 nm).

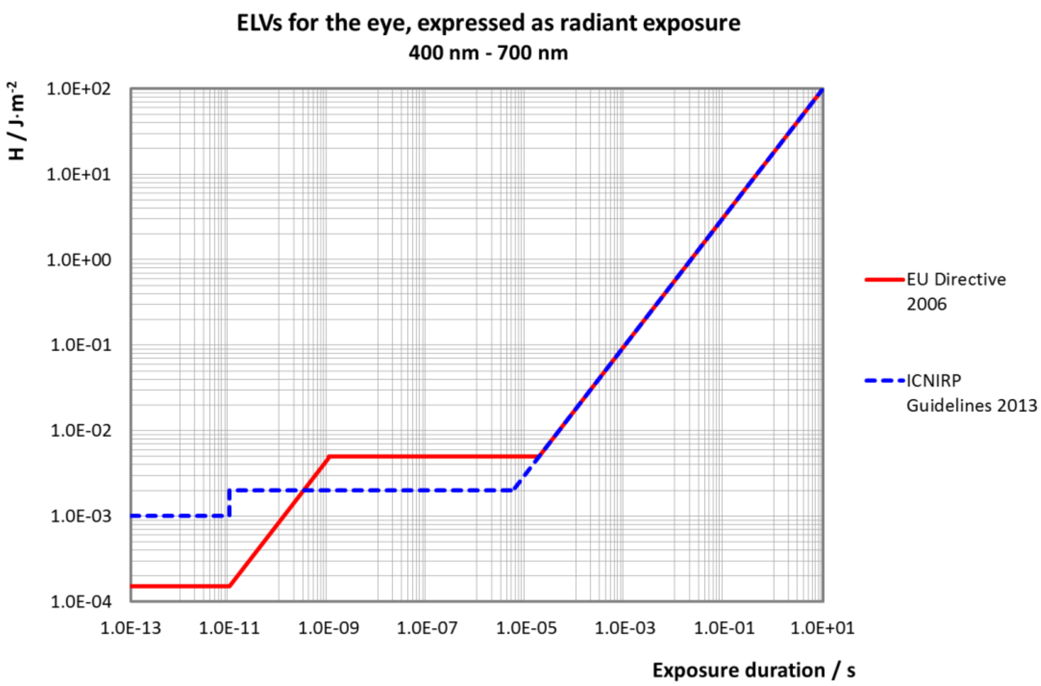

Figure A16: ELVs for the eye, expressed as radiant exposure, of the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1] in the visible wavelength range (between 400 nm and 700 nm).

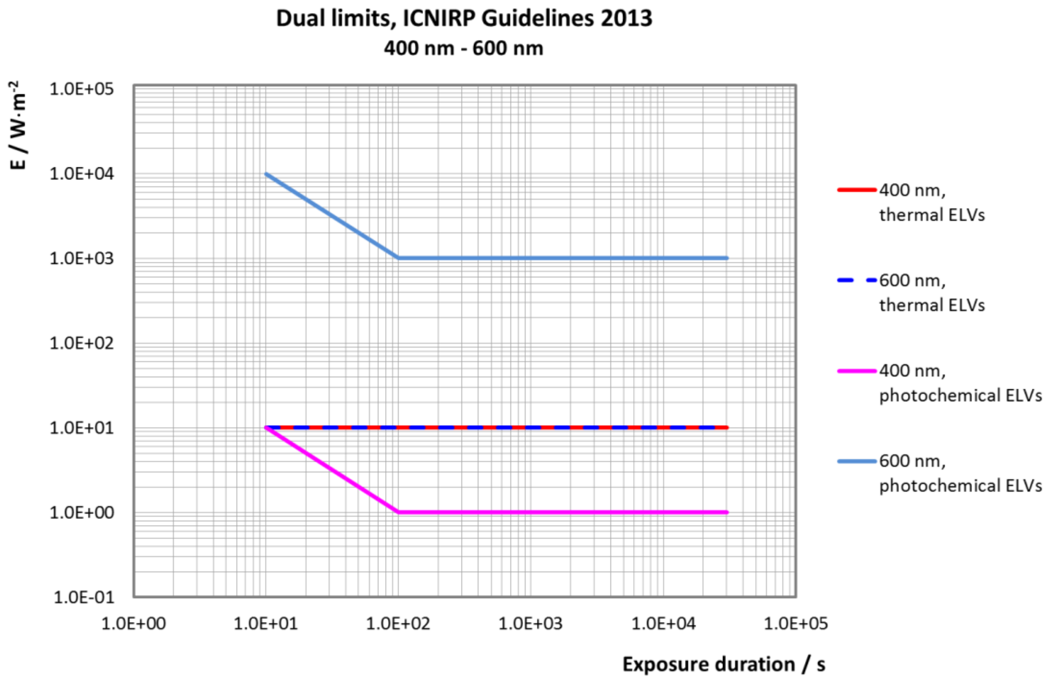

Figure A17: Dual ELVs (photochemical and thermal) of the ICNIRP guidelines on laser radiation [5] in the wavelength range between 400 nm and 600 nm, for exposure durations longer than 10 s and for small sources ($\alpha \leq 1.5$ mrad). According to note e) of Table 5 in [5], the dual ELVs reduce to the thermal ELVs for times less than T_1 and to photochemical ELVs for longer times. For λ = 400 nm, T_1 = 10 s and for λ = 600 nm, T_1 = 100 s (see Figure A10).

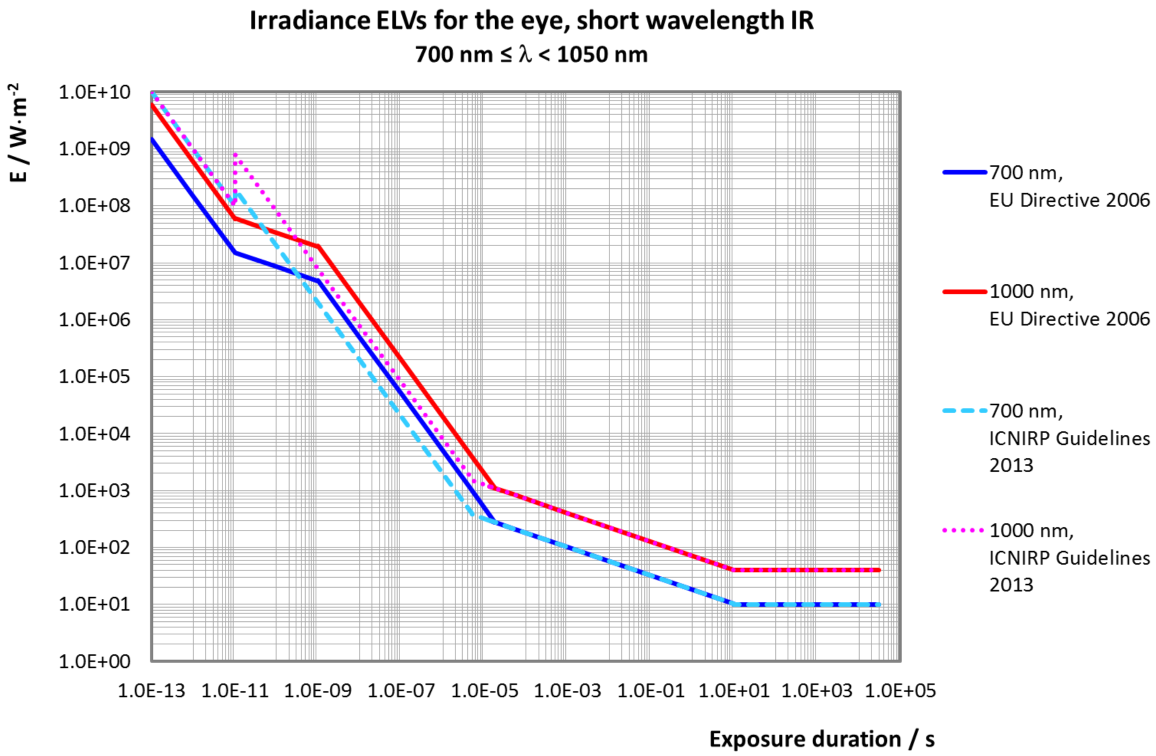

Figure A18: Irradiance ELVs for the eye of the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1] for wavelengths between 700 nm and 1050 nm and small sources ($\alpha \leq 1.5$ mrad, $C_E = 1$).

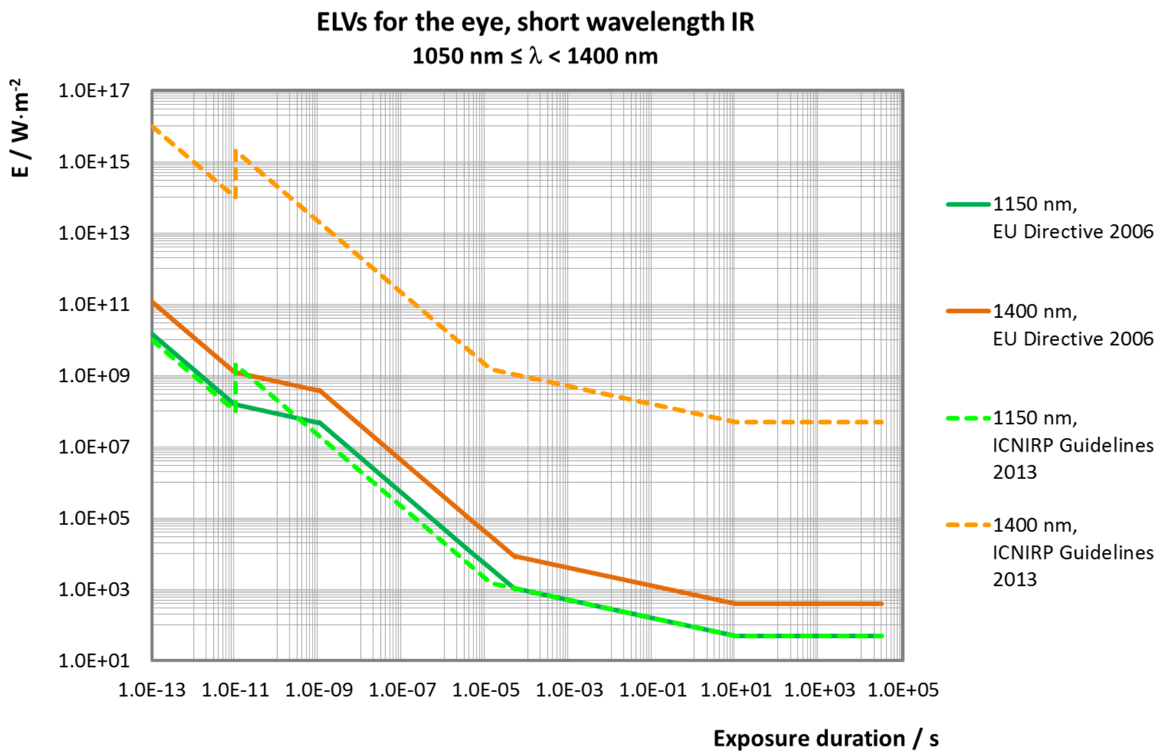

Figure A19: Irradiance ELVs for the eye of the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1] for wavelengths between 1050 nm and 1400 nm and small sources ($\alpha \leq 1.5$ mrad, $C_E = 1$). The footnote of the Table 3 in [5] states: "C_C becomes large as the wavelength approaches 1400 nm. However, the calculated exposure limit from Table 5 must then be compared with the skin exposure limit or 2 × the skin exposure limit in accordance with note C of Table 5. The lower of the two limits applies."

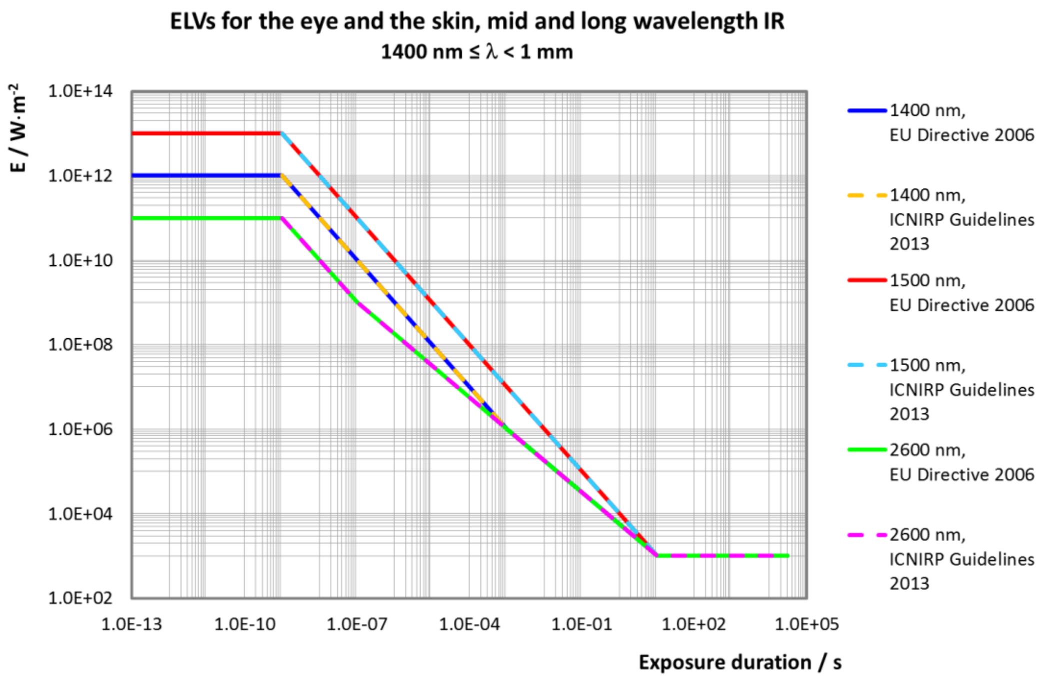

Figure A20: Irradiance ELVs of the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1] for the eye and the skin for wavelengths between 1400 nm and 1 mm.

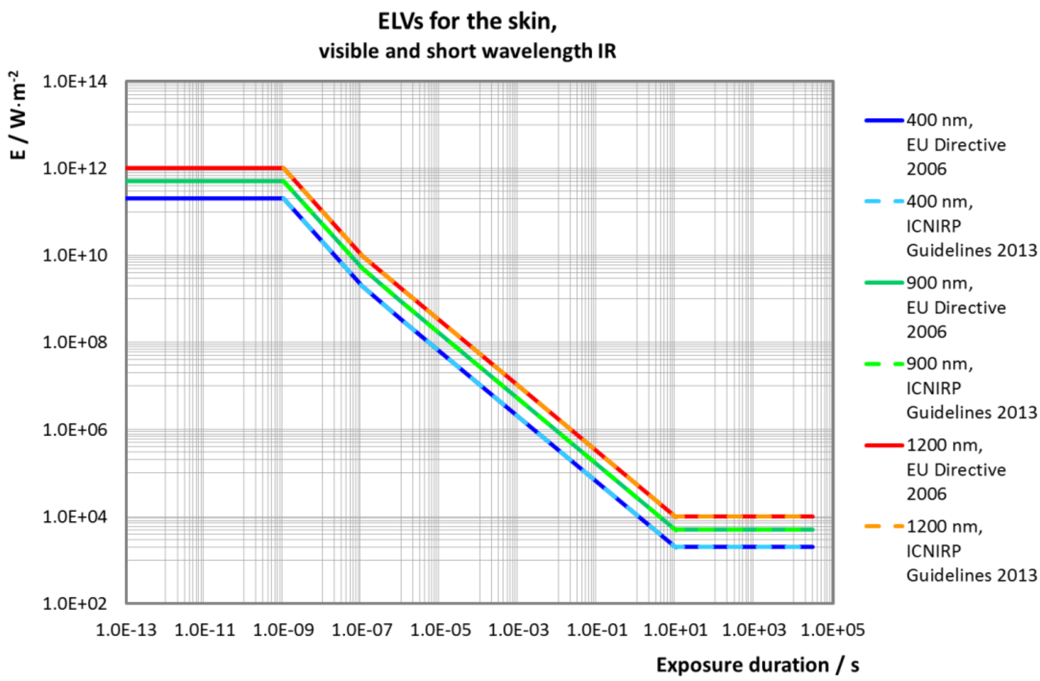

Figure A21: Irradiance ELVs of the ICNIRP guidelines on laser radiation [5] and the Directive 2006/25/EC [1] for the skin in the visible and the short IR wavelength range.

Annex 2 Comment on probit-analysis and optical properties of the applied laser beams

In the ICNIRP guidelines it is proposed that under certain circumstances, the reduction factor (previously safety factor) so far could be reduced from 10 to 2. It is only required that the probit-analysis shows a small value of the ED-50 uncertainty. This condition is unsatisfactory.

Presumably, all publications concerning damage to the retina use the probit method to evaluate the test results. However, not all of the 6 so-called numbers of the probit analysis are published [24]. The conditions under which a reduction of reduction or safety factors can be made arising from the use of the probit method are:

a) All 6 numbers of the probit analysis are available.
b) The number of required samples is observed [25, 26].
c) The probit-diagram is conservatively evaluated (Figure 5 in [24]).
d) A confidence of 5σ (σ, standard deviation) is required in order to allow reliable predictions for the future, as it is usual for natural laws. If tests are performed using live animals, this statistical security can be reduced to an ethical value.
e) The curvature in the probit-diagram does not indicate that a limit does not exist. See also the discussion in [24], chapter „Probit with non-normal distributions".

In addition to the requirements stated in the ICNIRP guidelines on laser radiation from 2013 [5], for lower reduction factors it seems necessary to have information in the cited articles about the optical properties of the applied laser beams in the respective studies. It is suggested to provide at least a measured intensity profile or even better a whole caustic with focus position, radius and beam propagation factor as defined in ISO 11146 [27]. For pulsed laser beams measured pulse shapes should be given.

Annex 3 Functional relationships between ELVs and transmission of the human eye

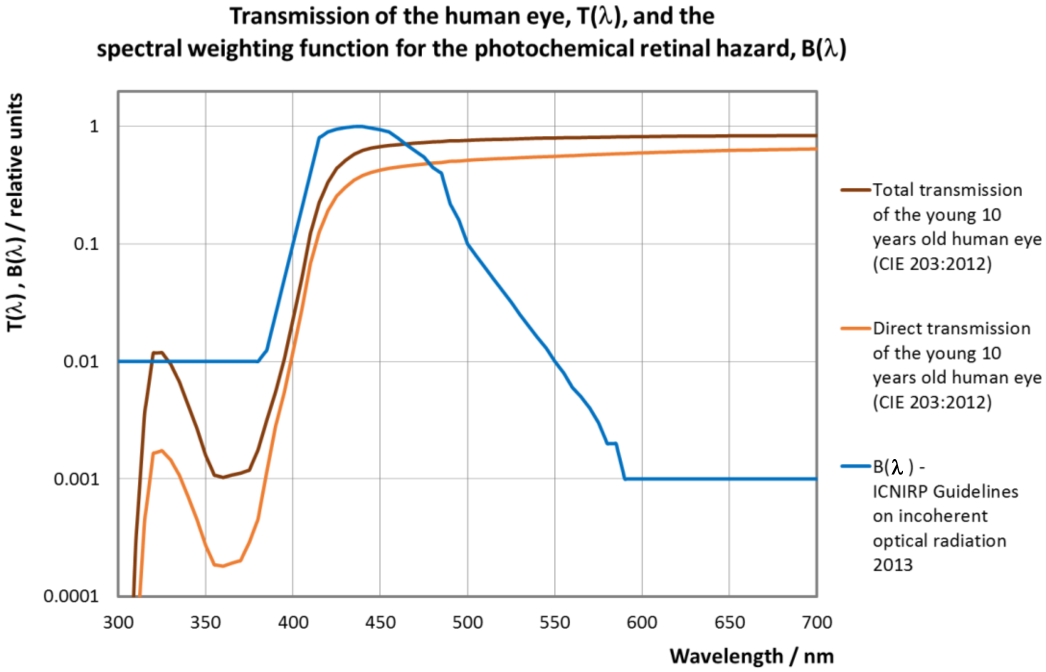

Figure A22: Transmission of the human eye, T(λ) [13] and the spectral weighting function B(λ) for retinal photochemical injury of the ICNIRP Guidelines on incoherent optical radiation from 2013 [4].

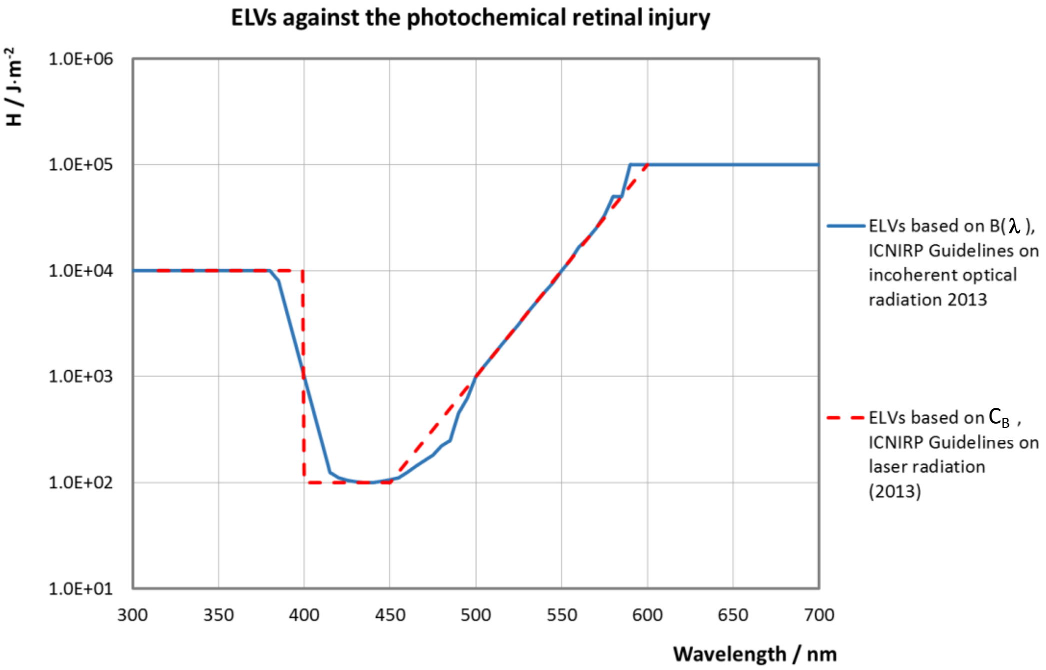

Figure A23: Comparison of ELVs against the photochemical retinal injury expressed as radiant exposure for laser and incoherent optical radiation.

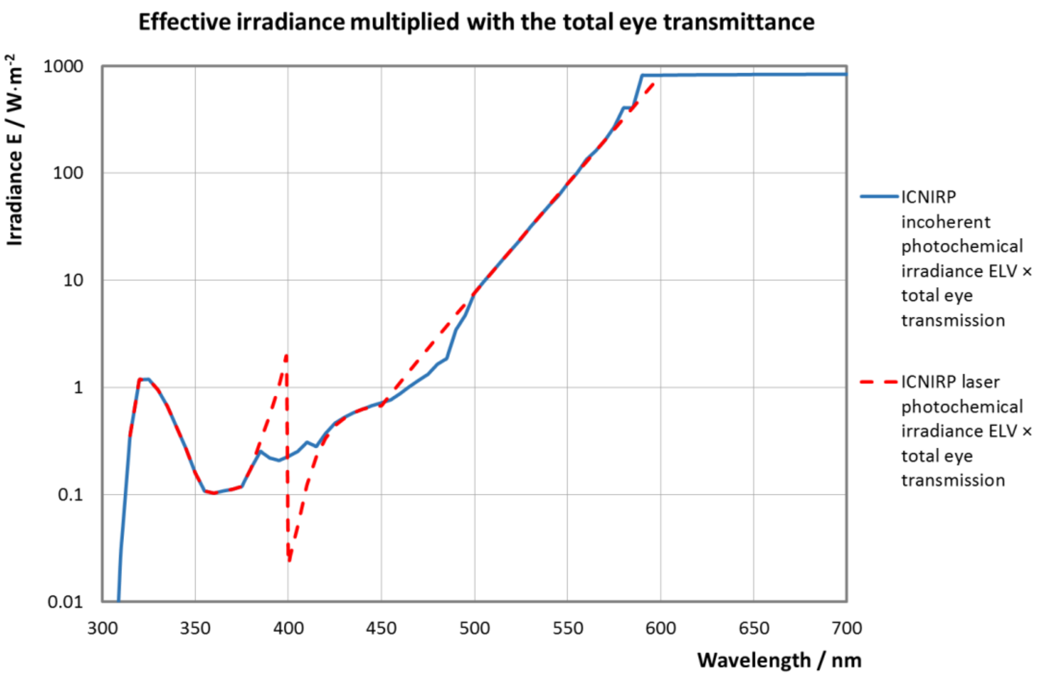

Figure A24: Comparison of the effective irradiance ELVs multiplied with the total eye transmission for laser and incoherent optical radiation.

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