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The risk of retinal injury from Class 2 and visible Class 3R lasers, including medical laser aiming beams

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Abstract

Experimental retinal injury threshold data from the literature and computer model data were used to characterize quantitatively the risk of retinal thermal injury for visible laser radiation that exceeds the exposure limit defined by IEC 60825-1 and the European Directive on Artificial Optical Radiation (AOR). This discussion is of particular relevance for medical laser aiming beams with powers up to 5 mW. Exposure to 1 mW (Class 2 emissions) does not appear to be able to cause retinal injury for exposure durations of up to about 5 s. Even though there is uncertainty in the experimental threshold data for collimated beams, experience with laser pointers up to 5 mW shows that there is little risk from accidental momentary exposure to these Class 3R lasers. However, injury threshold data indicate that exposure to some pulsed emission Class 3R lasers as well as extended-source Class 3R lasers with powers above 5 mW could induce retinal injury. Recommendations for amendment of the standards IEC 60825-1 and IEC 60601-2-22 are given that should facilitate an agreement of the involved stakeholders on the necessary user safety precautions of Class 3R laser products and medical aiming beams.

Keywords: Laser; Injury; Risk; Maximum permissible exposure (MPE); Exposure limit; IEC 60825-1; Class 2; Class 3R

Introduction

Laser products that emit visible radiation in the power range of 1–5 mW are widely used for pointing and alignment purposes, from laser pointers to scanners and, particularly in the medical field, as aiming beams (“pilot beam”) for surgical laser equipment. Laser products are classified according to the international laser safety standard IEC 60825-1 [1], or in the USA, according to the classification scheme of the Center for Devices and Radiological Health (CDRH) [2]. Class 2 laser products (Class II in the CDRH scheme) are considered safe even for the untrained user

due to the limitation of the power and the aversion response to bright light. The accessible power of Class 2 products is limited to a value so that for exposure durations of up to 0.25 s, the exposure limit for the eye is not exceeded [3], which for a collimated beam and continuous (cw) emission limits the output power to 1 mW. It is relevant for the discussion in this paper to note that for exposure durations exceeding 0.25 s, Class 2 laser emissions can exceed the exposure limit for the eye (referred to as the maximum permissible exposure (MPE) in IEC 60825-1). The risk of ocular injury for exposure to radiation from Class 2 laser products exceeding 0.25

s is discussed in this paper. This is of relevance when it comes to the practical application of the requirements of the European Directive on Artificial Optical Radiation (AOR) [4], later referred to as the “Directive”, or the “European Directive”, and considering that Reidenbach et al. [5,6] showed that the blink reflex, one of the aversion responses to bright light, is not induced by laser radiation for a large percentage of the population. The characterization of the risk from Class 2 laser products is also relevant when it comes to restricting the power of laser products that are to be sold as consumer products.

Class 3R lasers (in the US: Class IIIa) in the visible wavelength range are allowed to emit powers of up to five times the limit for Class 2; for visible cw radiation and collimated beams, the allowed output power of Class 3R lasers is 5 mW. Since the MPE for exposure durations of 0.25 s is equivalent to the power of 1 mW, the output of Class 3R laser thereby potentially exceeds the MPE for the eye, even for momentary exposures. However, the risk of retinal injury from Class 3R lasers (at least for cw lasers that are classified as “small source”, i.e. $C_6=1$ in the limits specified in IEC 60825-1) is generally considered to be relatively low. This means that, compared to Class 3B and Class 4 lasers, in many countries both the manufacturer requirements and protective measures at the workplace are reduced (the “R” of Class 3R was derived from “reduced”). For instance, in many countries, for applications where it is considered unlikely that eye exposures will occur, and where an appropriate level of “risk awareness” exists, no eye protection is worn by the users of Class 3R lasers at the workplace. Since the common motivation for using Class 3R lasers is the need for increased visibility compared to Class 2 lasers, it would be counterproductive to require that eye protection is worn that would reduce the visibility down to a level of Class 2 or less. This particularly applies to aiming beams (“pilot beams”) of surgical lasers, where the

applicable product safety standard IEC 60601-2-22 [7] allows powers of up to 5 mW (equivalent to a Class 3R laser product were it to be classified separately from the main medical laser). While eye protection clearly needs to be worn to protect against the high power medical working beam, it would not be realistic to wear additional eye protection to reduce the power of the aiming beam to below the MPE. The “historically” established use (without eye protection) of visible cw lasers with powers of up to 5 mW as alignment and aiming beams in medicine and industry – with many thousands of accidental exposures and no reported retinal injuries unless for intentional exposure – presents a certain challenge when it comes to the strict application of the requirements of the European Directive, which requires that workers shall not be exposed above the MPE.

The risk of retinal injuries for exposures above the MPE, i.e. from radiation from Class 2 laser exceeding exposure durations of 0.25 s or from Class 3R lasers is, however, not well characterized. A number of publications deal with the practical issues and qualitative risk associated with laser pointers [8–17], but pertinent retinal injury threshold data have, so far, not been reviewed comprehensively. Recently, we have developed a computer model [18] that was validated against all relevant non-human primate (NHP) damage threshold data. This model is used, together with relevant experimental data, to quantitatively characterize the risk of retinal thermal injury for visible radiation exceeding the MPE, both for the case of the “small source” condition as well as for “extended sources”. Based on the quantitative characterization, recommendations are given for changes in the international standards IEC 60825-1 and IEC 60601-2-22, as well as regarding the application of the European Directive.

MPEs and class emission limits

In the following section we summarize the MPEs for the eye in the visible wavelength range in the millisecond and seconds range, and the corresponding limitations for the emission for visible Class 1, Class 2 and visible Class 3R. A detailed discussion can be found in [3].

Both the MPEs given in IEC 60825-1, as well as the exposure limits set out in the European Directive are adopted from the exposure limit guideline issued by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) [19], and these sets of exposure limits for laser radiation are therefore identical. The emission limits (referred to as accessible emission limits (AEL)) for visible Class 1, Class 2 and visible Class 3R are directly derived from the MPEs by multiplication by the area of a 7 mm aperture (for Class 3R with an additional factor of 5). Therefore, when the MPE values (that are stated as irradiance at the cornea, averaged over a 7 mm aperture) are multiplied by the area of a 7 mm aperture, values in terms of power (“Power-MPEs”) are obtained. To compare the power measured through a 7 mm aperture with the “Power-MPEs” is mathematically equivalent to comparing an irradiance averaged over a 7 mm aperture with the “Irradiance-MPEs” [3]. The “Power-MPEs” are then also numerically equal to the AEL for Class 1 and to Class 2 up to exposure durations of 0.25 s, the time base of Class 2. For instance, for cw radiation and “small source” conditions ($C_6 = 1$), both the AEL of Class 2, as well as the MPE for 0.25 s exposure duration, equals 1 mW. Both the emission of the product that is compared to the AEL for the determination of the safety class, as well as the power (in the sense of an exposure level of the eye) that is compared to the MPE, should be determined with a 7 mm aperture. It is to be noted that large diameter collimated beams are not relevant for this discussion and therefore Condition 1 of IEC 60825-1, which requires larger measurement apertures, is not considered here.

Equality of the AEL for Class 2 and the MPE for 0.25 s is to be expected because the emission of Class 2 is limited to a level so that the MPE for 0.25 s exposure duration is not exceeded. At the same time it is important to distinguish the two limits in terms of function and meaning. The AELs limit the emission of a product for a given safety class, where the emission is determined at a distance prescribed by IEC 60825-1; for “small sources” this is 10 cm from the product. The MPEs limit the exposure of the eye, as prescribed by the national legal implementation of the European Directive (where the exposure is determined at the position of the eye).

The AEL for Class 1 as well as the “Power-MPEs” to protect against thermally induced retinal injury for visible radiation in the exposure duration range of 18 μ s to 10 s equals $7 \cdot 10^{-4} C_6 t^{0.75}$ J, which is equivalent to limiting the (pulse peak) power to $7 \cdot 10^{-4} C_6 t^{-0.25}$ W. The AEL for Class 2 is identical to the AEL of Class 1, but for Class 2 t is limited to the time base of 0.25 s. For $t=0.25$ s and the “small source” condition where $C_6 = 1$, the above formula gives 1 mW. The AEL for Class 3R in the visible wavelength range is 5 times the AEL of Class 2. The parameter C_6 is a correction factor that applies to “extended sources”, i.e. for cases where the retinal image that is produced by the laser beam is larger than the minimal dimension of 1.5 mrad [20]. For collimated beams, i.e. beams with small angular beam spread (the default for laser beams), a minimal retinal image is produced and $C_6 = 1$. Only beams with some level of divergence (at least in one direction, such as line lasers) can lead to a value of $C_6 > 1$. Such sources are then referred to as “extended sources”. Photochemically induced retinal injury can occur for long time exposure to wavelengths in the blue and green wavelength range; the corresponding AEL and MPE is only defined for exposure durations above 10 s.

Injury thresholds

For the discussion on injury thresholds, it is necessary to distinguish between the minimal retinal image case, as produced by collimated lasers, and laser beams that produce an extended retinal image. Medical aiming beams, and other alignment lasers that produce a small spot at the target, usually represent “small sources”. However, line lasers, for instance, can produce an extended image on the retina and this would be an example of where the source size correction factor C_6 can be greater than 1 [3].

Fig. 1 shows experimental injury thresholds, in terms of peak power, for the two green wavelengths of 532 nm and 514 nm [21–24] and the red wavelength of 633 nm [25] for pulse durations between 1 ms and 5 s, expressed as ED-50, the exposure level at which 50 % of the experimental exposures lead to a minimal visible lesion (see [26]). The data were obtained *in vivo* with Rhesus monkeys and a collimated laser beam. The retina was examined ophthalmoscopically either one hour or 24 hours after exposure. The injury thresholds for the green wavelengths are somewhat lower than the corresponding data for the red laser, which is due to the stronger absorption of the green radiation in the melanosomes of the retinal pigment epithelium (RPE) and choroid [27]. It is important to note the relatively weak reduction of the damage thresholds for increasing exposure durations. Between the exposure duration of 10 ms and 1 s (i.e. factor 100), the ED-50, specified as power, only decreases by a factor of about 2.

There is some uncertainty regarding the actual retinal spot size for a collimated laser beam entering the eye, and this is a key factor for the discussion of the risk of retinal injury from collimated beams for exposures above the MPE. So far, it has been assumed that a collimated beam would produce a retinal image diameter of the order of 25–30 μm [28]. However, experimental studies, where the nominal retinal spot size was varied [29], show that the observed trend is more consistent with a

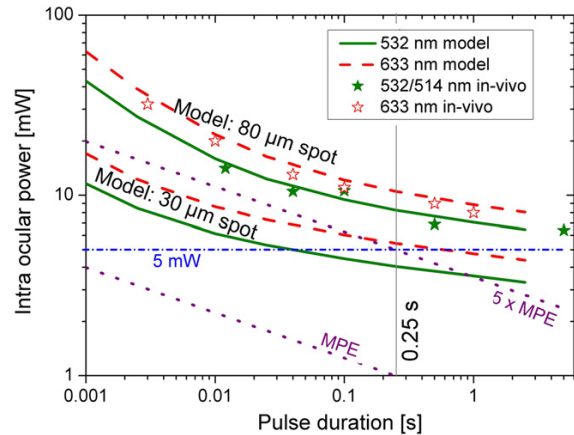


Fig. 1. *In vivo* minimal visible injury threshold data for exposure to 633 nm (red open stars) and 532 or 514 nm (green full stars) for a range of pulse durations, obtained with collimated laser beams. The lines are from a computer model; upper set: for an assumed retinal spot size of 80 μm , lower set: for an assumed retinal spot size of 30 μm .

spot size of about 80–100 μm , even if the nominal (theoretical) retinal spot is smaller, as shown in Fig. 2, where the *in-vivo* injury thresholds remain at a constant energy level. In the optimization process of the thermal injury computer model, we have found that the collection of available *in-vivo* threshold data can only be modeled well for both the “extended source” data as well as the data that was published as “small source” exposures, when the computer model assumes a minimal retinal image size in the visible wavelength range of 80 μm rather than 30 μm . The 80 μm spot size computer-model data shown in Fig. 1 fit the *in-vivo* data very well, while the computer-model thresholds, calculated for a spot size of 30 μm , is lower by about a factor of 3. This trend can also be seen in Fig. 2 for pulse durations of 100 ms, where the *in-vivo* data remain at a constant energy level for nominal spot sizes less than about 100 μm . However the computer model data, as well as the *ex-vivo* data (ex-plants from bovine eyes, bare RPE) continue to decrease for decreasing spot size. There are two basic explanations [18] for the observed data: (1) the minimal retinal spot size is 80 μm rather than the currently assumed 25 μm (possibly due to scattering), or (2) the retinal spot size could be as small as 25 μm , and injury could occur at the

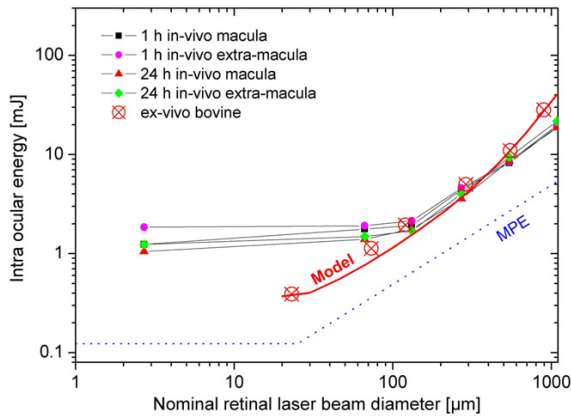


Fig. 2. *In vivo*, *ex vivo* and computer model threshold data for 514 nm wavelength and pulse durations of 100 ms for a range of nominal retinal spot sizes. For spot sizes less than about 100 μm , the *in-vivo* data thresholds remain at a constant level, while the *ex vivo* (bare RPE) and computer model data decrease to a lower level (adopted from [18]).

levels predicted by the computer model for 30 μm spot size, but a higher level of exposure is necessary to produce a lesion that can be ophthalmoscopically detected. For the latter case, the ophthalmoscopically observed injury thresholds would constitute a “super-threshold” exposure. It is due to this uncertainty for the minimal spot size that a safety factor, which in recent ICNIRP documents is referred to as a “reduction factor”, between the injury threshold values and the MPEs of a factor of 10 is needed [30]. For retinal spot sizes above 100 μm , in the case of 100 ms pulse duration in the green wavelength range, as shown in Fig. 2, the reduction factor equals around 3, which is believed to be sufficient for the cases where there is some uncertainty [26,30]. Were it not for the uncertainty in spot size and the potential of retinal damage at levels lower than observed ophthalmoscopically in the NHP model, the small spot MPE could be raised by a factor of 3 (resulting in a Class 2 AEL of 3 mW).

In Figs. 1 and 2 the MPEs are also plotted for retinal thermal injury in the visible wavelength range. A reduction factor of 10 between the *in-vivo* injury thresholds and the MPE can be observed in Fig. 1 for exposure durations around 0.25 s. Regarding the exposure duration dependence, the slight dependence of the injury thresholds is also approximated by

the time dependence of the MPE of $t^{-0.25}$, although the injury threshold data in that range appear to have an even slighter dependence on pulse duration than the MPE, leading to a somewhat larger reduction factor (safety factor) for exposure in the seconds regime compared to the millisecond regime. Different time dependencies of MPEs and damage thresholds result in a varying reduction factor in the microsecond and nanosecond (ns) regime. Due to a change in the injury mechanism from a thermal one to micro-cavity induced damage [31,32], the injury thresholds in the ns regime continue to decrease for pulse durations shorter than 18 μs , while the MPE remains at a constant radiant exposure level [33,34]. This leads to a reduction factor in the ns range of only about 3 for collimated laser beams and to practically no safety factor for “extended sources” [34,35]. ICNIRP is developing updated exposure limits (EL) where the EL in the ns pulse duration regime can be expected to be reduced by a factor of at least 2.5 [30].

Many of the alignment and aiming laser beams are red, but recently in some applications 532 nm frequency-doubled Nd:YAG lasers are used, because for a given power, green has a much better visibility. For completeness of the discussion on the risk of retinal injury, the wavelength with the lowest injury threshold needs to be identified. The computer model needs to be identified. The computer model

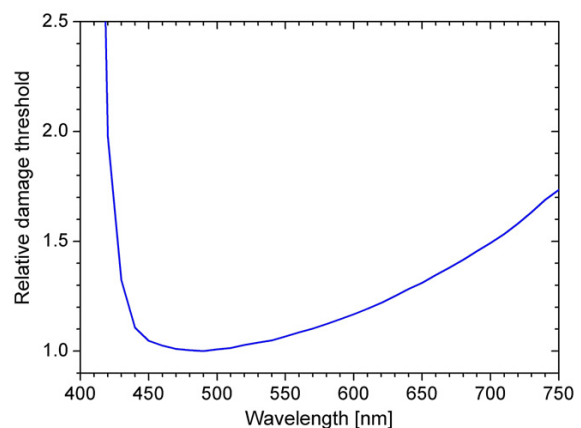


Fig. 3. Relative increase of the injury thresholds for retinal thermal damage for exposure durations of 0.25 s as calculated by the computer model.

needs to be identified. The computer model was used to calculate the damage thresholds as function of wavelength for exposure durations of 0.25 s, which is shown as relative values in Fig. 3. The minimum is found at a wavelength of 490 nm, however, the thresholds in the wavelength range between 440 and 550 nm differ by less than 10 %. The damage threshold at 532 nm is only 4 % higher than the minimum threshold that is found at 490 nm, and therefore the experimental data shown in Figs. 1 and 2 for 514 and 532 nm may be considered as worst case values. In the validation of the computer model, we did not include the threshold value for 441 nm and 1 s exposure duration reported by Ham et al. [36] since this value was shown by Lund et al. [37] to be too low by a factor of 10.

Discussion

ED-50 as basis for risk characterization

While the injury thresholds stated at the ED-50 level forms the basis of a discussion on the risk of injury, it is not the only parameter that needs to be considered. Although the ED-50 value is often referred to as the “threshold” for injury, retinal injury will also occur at energies somewhat below the ED-50, since the ED-50 is the centre of the dose-response curve that describes the uncertainty and variability of the thresholds (see [26] for a more detailed discussion on the dose-response curve). However, for a well-designed study, the dose-response curve is relatively steep, approximating a true sharp threshold, where usually no lesion is detected for energies that are a factor of at least 1.3 below the ED-50. Also it should be noted that quantitative threshold studies for humans, although covering only a few laser parameters, produced thresholds that were higher than for the NHP model [26]. Due the limitation of the human studies in terms of number of exposures, dosimetry, and the variation of pigmentation of the human choroid for different skin types, it is prudent to apply the NHP data also to

humans. For completeness it is to be noted that the risk of injury also depends on the probability that an exposure actually occurs, but this factor is not discussed here in detail; the discussion on risk centers on the likelihood that an injury occurs following exposure to a certain exposure level for a certain duration.

Exposure duration longer than 0.25 s for Class 2

When the results of the study by Reidenbach et al. [5,6] on the lack of the blink reflex for many people became known, there was a concern that Class 2 was no longer safe [38–40]. While the “blink reflex” was used in user training materials and courses as a simple explanation why Class 2 is considered “safe”, the actual reason for Class 2 emissions being safe is the limitation to the power of 1 mW (for cw radiation and the “small source” case), together with the slight decrease of the damage threshold for increasing exposure duration. When the small spot model data is considered as the worst-case damage threshold for collimated laser beams, shown in Fig. 1, the level of 1 mW is a factor of 3 below the injury threshold even for a 5 s exposure duration to 532 nm radiation. Computer model calculations have shown that the reduction factor of 2–3 also applies to the case of extended ($C_6 > 1$) Class 2 laser products for exposure durations of 0.25 s and longer (compare Fig. 3). Since for exposure durations longer than roughly 5 s, blood flow and eye movement reduce the laser induced temperature rise, Class 2 laser radiation is not expected to be able to induce thermal retinal injury even for intentional staring into the beam. However, for blue and green wavelengths, prolonged staring into the beam for at least 5 s can induce retinal injury via a photochemical pathway [28,36,37] (the conclusion by Ham et al. [36] regarding a 1 s exposure duration to 441 nm radiation to produce photochemical injury was shown later on to be incorrect [37]). This is particularly relevant in cases where the aversion

response to bright light is reduced, such as for sedated patients or patients under anesthesia.

Exposure to Class 3R radiation – “small source”

The characterization of the potential risk from accidental, i.e. short-time, exposures to radiation from a Class 3R laser, is more difficult than for long-term exposure to Class 2 laser radiation. For collimated beams that produce a minimal image on the retina, there is an uncertainty factor of 3 regarding the actual injury threshold.

If the ophthalmoscopically visible lesion thresholds that are found in NHP *in-vivo* studies were also to apply for human exposures, then Class 3R radiation (5 mW)

would be below levels that are expected to produce an injury, even for exposure durations of the order of 1 s, as can be seen in Fig. 1. However, at the moment, it cannot be ruled out that retinal injury can occur at levels lower than those determined *in vitro* in the NHP eye, as is indicated by computer model and bovine *ex-vivo* data for direct exposure of the RPE [18], shown in Figs. 1 and 2. Compared to these lower injury thresholds, an exposure of 5 mW would produce a lesion. From the *ex-vivo* bovine data where cellular viability at the RPE level is the endpoint, it can be concluded that the basic damage site of such a low level threshold lesion is the RPE cell layer [18].

Table 1. Summary of all available medical case studies on laser pointer-induced retinal injury.

Reference	Laser power, wavelength according to label	Exposure	Perception by patient	Results	Vision
Chen 1991 [43]	“Low-energy He-Ne”	Repeated consecutive exposure		Pigmented foveal change, small central scotoma, FA: window defect type hyperfluorescence	
Luttrull 1999 [44]	Label: < 5 mW, 670 nm	Self-exposure for 30–60 s	Red scotoma, resolved by the following day	FA: window defect type hyperfluorescence	20/20
Zamir 1999 [45]	Label: Class 2, < 1 mW, 670 nm	Self-exposure for 10 s	Decreased visual acuity	FA: mild hyperfluorescence. 10-2 threshold test: small scotoma, hypopigmented ring around fovea	20/40, 20/20 within 8 weeks
Sell 1999 [46]	“Laser pointer”	Class mate wanted to determine whether laser would cause papillary constriction; several multisecond exposures	Decreased vision, central scotoma	FA: mild early transmission defect; Amsler grid: central scotoma; pigment clumping	20/60 three weeks after exposure; 20/25 11 months after injury
Israeli 2000 [47]	Label: < 5 mW, 670 nm	Children “horseplay”, friends exposed him for approx. 20 s	Red scotoma, resolved within 2 days	FA: window defect type hyperfluorescence	Normal
Wong 2007 [48]	Label < 5 mW, 825–880* nm	Son exposed him twice for 1–2 s	Scotoma	FA: two hyperfluorescent spots; OCT: serious retinal detachment	

* The wavelength is probably a misprint in journal.

FA = Fluorescein angiogram; OCT = Optical coherence tomography.

A laser spot diameter of about 30 μm would, at the threshold, lead to about one to three damaged RPE cells. Whether these damaged RPE cells could also induce damage of their associated photoreceptors is not entirely clear. It should be kept in mind that such a lesion would not be visible upon examination with an ophthalmoscope, and it could be that it would also not lead to a decrease of visual acuity, unless it would be located in the fovea.

Two “laser pointer” studies have been performed on human donor eyes. Robertsen et al. exposed human eyes to red [41] and green [42] wavelength laser pointers for exposure durations of between 60 s and 15 min. At a wavelength of 659 nm and a power level of 5 mW, no change in visual acuity or other changes in the retina could be detected. A number of evaluation methods, including fluorescence angiography were employed. The green laser pointer (532 nm) with powers of 3–7 mW, also using exposure durations of between 60 s and 15 min, did produce an ophthalmoscopically visible retinal effect (a discoloration).

Compared to the number of exposures to red (and recently green) cw Class 3R (in the USA: Class IIIa) laser pointers with powers up to 5 mW, reports in the medical literature of retinal injuries are rare. Six case reports were identified and reviewed [43–48] and are summarized in Table 1.

It should be noted that all case reports are for intentional exposure. In none of the cases was the laser power actually measured, and because of frequent mislabeling [14], no firm conclusions could be drawn from these reports. We also note that retinal detachment, as reported by Wong et al. [48] does not appear to result from laser exposure. The authors pointed out that the patient could have already suffered from idiopathic central serous chorioidopathy and that the laser exposure could have been co-incidental. Regarding the case report for the laser pointer that was labeled as Class 2, it was pointed out that the results contradicted the carefully performed minimal visible lesion studies

shown above, and that it is known that Class 2 laser pointers, in particular, are frequently mislabeled, i.e. the output power is often higher than 1 mW. O’Hagan [14] reported that from eight randomly selected laser pointers labeled as Class 2, only one of them did not exceed 1 mW, and two had output powers of 4 mW.

It is also of some relevance that there is more than ten years of practical experience based on many thousands of exposures to 3–5 mW red laser pointers and alignment beams, as well as more recently also to green laser pointers. From this it can generally be concluded, that accidental, short-time exposure to cw visible laser beams with powers of up to 5 mW bears a relatively small risk of retinal injury.

So far, both the data and the discussion related to cw radiation only. The case for pulsed emission is different because the reduction factor between the injury threshold and the MPE depends on pulse duration. This is due to the difference depending on pulse duration of the MPE and the injury threshold. In the thermal injury regime, the reduction factor is smallest at exposure durations of around 10 ms. Because of the smaller reduction factors for pulsed emissions, particularly in the ns regime, the risk of injury for Class 3R exposure can be higher than for the cw case. Also, in contrast to cw emission, there has been very little “experience” with these pulsed Class 3R lasers, since they are not as ubiquitous as cw Class 3R lasers.

Exposure to Class 3R radiation – “extended source”

Visible Class 3R lasers are usually classified as “small sources” where the AEL for the cw case equals 5 mW (i.e. the source size correction factor is $C_6 = 1$). It is currently relatively rare that Class 3R lasers are classified as “extended sources”, i.e. with a value of the AEL of 5 mW where $C_6 > 1$, for instance for $C_6 = 4$, the emission limit would be 20 mW. In contrast to the typical Class 3R lasers for which the power is limited to 5 mW, no case can be made for “extended source” Class 3R products in

terms of long-term experience with accidental human exposure.

For “extended sources”, the uncertainty regarding detection of the lesion and the spot size on the retina is small compared to the case of “small sources”. This is also the basis for the reduction factor (safety factor) in the MPEs for retinal image diameters above 100 μm which are only about 3 for pulse durations around 0.25 s, and for pulse durations in the millisecond range only 2.5. This reduction factor of 2.5–3 also means, however, that exposure at 5 x the MPE, at least in the NHP model, will produce an ophthalmoscopically visible lesion. In order to discuss the risk for retinal injury from “extended” Class 3R products, the probability that retinal exposure above injury threshold levels is actually realized, needs to be characterized. Two issues are important in this respect: (1) the divergence of the beam and (2) the diameter of the pupil of the eye. In order for a Class 3R laser product to be classified as “extended source”, the beam would have to have a divergence that is at least as large as the angular subtense (α) of the apparent source used for the determination of C_6 [3,20]. Thus, for example, a retinal image size of 100 μm that corresponds to an angular subtense of $\alpha=6$ mrad can only be produced by a laser beam that has a divergence of at least 6 mrad (typical collimated laser beams and laser pointers have a divergence of between 1 and 2 mrad). With a divergence of the beam of at least 6 mrad, the beam diameter will correspondingly increase with increasing distance from the product. The second issue to consider is the pupil size. While the safety standards are based on the worst-case assumption of a fully dilated pupil with a diameter of 7 mm, this will usually only be the case for exposure in the dark. For common exposure scenarios, the pupil will have a diameter of 3 mm or less. For a divergence of 6 mrad, the laser beam will be larger than a 3 mm pupil at a distance of about 30 cm onwards, reducing the intraocular power compared to the total power of the beam. Thus, retinal exposure levels above the NHP injury threshold can

for “extended source” Class 3R laser products, i.e. where $\alpha > 6$ mrad was used to determine the AEL, only be realized at distances closer than roughly 50 cm from the product, or at somewhat larger distances i.e. roughly 2 m, for a dilated pupil as would occur in the dark. Usually, if a product is actually classified as Class 3R using the “extended source” condition, the divergence will be larger than 6 mrad (such as for line lasers) and the respective critical distances will be further reduced.

Medical laser aiming beams

The product safety standard IEC 6060-2-22 for medical laser products (in Europe harmonized as EN 60601-2-22 under the Medical Devices Directive) allows aiming beam output powers of up to 5 mW. The aiming beam alone is not assigned a laser safety class, since according to IEC 60825-1 the laser class is determined for the whole device (which is Class 4 due to the working beam), however, if classified separately, the aiming beam would be a Class 3R laser. The discussion above on the risk of retinal injury for Class 3R lasers that are classified under the “small-source” condition (with powers limited to 5 mW) therefore applies also directly to aiming beams with powers up to 5 mW.

Usually, the wavelength of the aiming beam is red; for aiming beams for CO₂ lasers, due to the absorption of the lens material, zinc selenide (ZnSe), in the green and blue wavelength region, red is the only option. Intentional ocular exposure of patients or personnel should obviously be avoided, particularly when patients are sedated or under anesthesia and the aversion responses do not function. However, short accidental exposures of either the patient or personnel, for instance due to reflections from mirror-like surfaces, does not pose a realistic risk of retinal injury, as discussed above. However, the historically established use of Class 3R lasers at the workplace and of medical laser aiming beams in particular, might prompt some discussion in Europe regarding compliance with the requirements of the European Directive. In Article 5(4)

the Directive states that “Workers shall not be exposed above the exposure limit values”. In order to determine if the MPE is (or can be) exceeded, both the nominal ocular hazard distance (NOHD), i.e. the distance where the MPE of the aiming beam is exceeded, and the (worst case) distance of usage should be characterized and compared. Obviously the aiming beam would usually point away from the eyes of any operator or personnel, but accidental exposure, including from reflecting surfaces, cannot be completely ruled out. While the NOHD for handpieces with short focal length (such as 50 mm) is relatively small (of the order of 20 cm), for handpieces with a focal length of 125 mm, and an aiming beam diameter at the focusing lens of, for instance, 4 mm, the NOHD will be roughly of the order of 60 cm. Therefore, it cannot be assumed that exposure above the MPE can be completely ruled out. It follows that according to Article 5(2) of the Directive, there is a need to “devise and implement an action plan comprising technical and/or organizational measures designed to prevent the exposure exceeding the limit values”. Wearing eye protection for the aiming beam (to reduce the ocular exposure below 1 mW) in addition to the eye protection for the working laser beam is not realistic (a combined filter that provides protection from the working beam and also an optical density of 0.7 for the aiming beam is not commercially available). Also, the power of the aiming beam can often not be adjusted at the medical laser and the higher visibility of the 5 mW level is needed for the medical procedure (under bright operation lights). The only practical measure that could satisfy the requirements of the Directive (and equivalent national work place safety legislation) appears to be of an organizational nature. The employees, who operate the laser, should be warned that it is possible to be within the NOHD but still exceed the MPEs for the eye. Therefore the operator should be instructed to take care to prevent exposure to the aiming beam. Since the hazard area that arises from the working

beam needs to be identified with laser warning signs, a special sign regarding the aiming beam does not appear to be necessary, considering the low level of risk that can be accounted for in the risk assessment that is required according to Article 4(1) of the Directive. In this context it should be remembered that there is a similar issue with the potential exposure of the skin to the working beam above the MPE which can result in severe burns. To the knowledge of the authors it is accepted world-wide by workplace authorities that training and careful use of the medical laser is the only safety measure that is practicable, in contrast, for example, to wearing protective laser gloves. It appears that an equivalent approach, based on instruction and careful handling to reduce the risk to a low level (even if the MPE can be exceeded), could be applied also to 5 mW aiming beams in medical lasers and could be deemed acceptable to satisfy the requirements of the European Directive. Since the aiming laser beam does exceed the internationally harmonized MPE for laser radiation, and an NOHD is associated with the aiming laser, it appears prudent to include minimal information regarding potential risks associated with the aiming beam and instructions for safe usage in the manual of the medical laser. This is not the case for many medical lasers, and it is also not required by IEC 60601-2-22. In the view of the authors, such information would be necessary to fully satisfy the requirements of the European Medical Device Directive with regard to necessary information in the manual, i.e. as required for products to obtain the CE-mark and for placing them on the market. We cite Annex I of the Medical Device Directive: (Article 11.4.1 of Annex I). “The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.” We therefore recommend that IEC 60601-2-22 is amended to require that the user manual

contains appropriate information on the aiming beam, which on the European level appears necessary in order to fulfill the role as a harmonized standard under the Medical Device Directive. This information would also provide valuable help in the risk analysis and the definition of organizational safety measures that the national implementations of the European Directive require from the employer in terms of workplace safety requirements.

User safety measures for visible Class 3R lasers

Since there is a wide variety of types of Class 3R lasers (including pulsed or “extended sources”), as well as of the training level and general risk awareness of the respective users, it is beyond the scope of this paper to discuss what “acceptable” applications for Class 3R lasers (including those potentially for consumer products) and what user measures are required to satisfy the requirements of the European Directive. These issues need to be decided by the responsible national authorities, i.e. the national market surveillance agencies for placing products on the market in Europe and the national workplace health and safety agency and their inspectors for workplace safety. International safety standards for specific types of products, such as toys or audio-visual equipment would ideally also limit any laser emission to an appropriate class and thereby play an important role in helping to define what level of emission is appropriate for what kind of product. Some guidance for user precautions is provided by documents such as IEC TR 60825-14 [49], a statement by ICNIRP on laser pointers [8] as well as a WHO fact sheet on Health Risks from Laser Pointers [9].

For workplace safety in Europe, based on the requirements of the European Directive, the appropriate safety measures at the workplace are in principle to be decided based on the results of a specific risk analysis (as is generally required by existing legislation for the health and safety at the workplace). Therefore, the Directive

does not introduce any new legal requirements; it only states more specifically the requirements for lasers and sources of optical radiation. Information such as the safety class can provide a valuable basis for such a workplace risk analysis. For instance, the Austrian Workplace Health and Safety Central Office (Zentrales Arbeitsinspektorat) has issued a document for the simplified evaluation of workplaces based on the laser safety classes of EN 60825-1 and for broadband sources on the Risk Groups defined in EN 62471 [50].

The NHP data threshold data that were reviewed here do provide information on the risk of injury for low power lasers, but a workplace risk analysis performed by the employer would rarely make use of such information. These kinds of data, however, are considered by international and national agencies, as well as by scientific and standards committees, who give guidance in this field and who define product safety classes. Regarding the risk that is generally associated with exposure to radiation from Class 3R lasers, we want to stress that we have identified a significant difference in risk of retinal injury for the case of exposure to cw collimated Class 3R lasers with maximum output powers of 5 mW on the one hand and pulsed or “extended source” Class 3R lasers on the other. Exposure to power levels allowed for “extended source” Class 3R radiation at close distances (where the beam diameter is smaller than a typical 3 mm pupil) produces retinal exposure levels that in NHP studies induced ophthalmoscopically visible retinal lesions. On the other hand, experience has shown that many thousands of accidental exposures to cw visible Class 3R radiation up to 5 mW did not lead to retinal injuries. Based on this documented experience on the one hand and NHP threshold data on the other, there appears to be a marked difference of risk between visible Class 3R lasers with powers limited to 5 mW and pulsed or “extended source” Class 3R lasers. These differences prevent a simple understanding of Class 3R lasers, and the

general treatment of Class 3R lasers as “relatively safe” provided they are either carefully installed or hand-operated so that ocular exposure is rare and only accidental and the user is appropriately instructed. It would greatly help the interpretation and characterization of the risk associated with Class 3R lasers if IEC TC 76, the technical committee responsible for IEC 60825-1, would decide to limit Class 3R to products with cw output and to $C_6 = 1$, which in the visible range would limit the accessible power to 5 mW, even for those cases where the product would represent an “extended source”.

Glare and dazzle

Irrespective of the question of retinal injury, visible Class 3R and Class 2 (and to some extent even Class 1) laser beams can cause temporary “blindness” (flash-blindness) or glare, which can present a considerable risk when the person affected is operating a machine, a vehicle or an airplane. A detailed discussion of this issue is beyond the scope of this paper.

Summary and conclusions

The risk of retinal injury from exposure to radiation from Class 2 and visible Class 3R lasers was characterized based on *in vivo* NHP injury threshold data and thresholds predicted by a computer model.

For Class 2 lasers it can be concluded that exposure should not produce retinal injury even for exposure durations of several seconds. Although the output power of 1 mW exceeds the MPE that applies for an exposure duration that is longer than 0.25 s, 1 mW is sufficiently below even a worst-case injury threshold for exposures up to 5 s. The only risk of injury exists for intentional long-term staring into beams with wavelengths in the blue and, to a lesser degree, in the green wavelength range, which can result in photochemically induced retinal injury. Such an exposure scenario, however, necessitates overcoming the natural aversion responses to bright light or intentional ocular exposure of an

anesthetized patient. Concerns that Class 2 lasers are not “safe” due to the lack of the blink reflex do not appear to be substantiated.

The risk of retinal injury following exposure to visible radiation from Class 3R lasers depends on the type of the emission. We distinguish three types as follows:

- (1) For cw emission with classification as a “small source”, where the output power is limited to 5 mW, there has been more than 10 years experience with many thousands of exposures that did not lead to retinal injury. Reported cases of retinal injury all involved intentional exposure for several seconds. For this type of emission, experimental animal threshold data are uncertain due to uncertainty as to the actual retinal spot size. Based on this uncertainty, as well as on the medical reports of retinal injury (even though rare), and the “legal” nicety that the MPE is exceeded, it appears prudent that this type of Class 3R laser should only be used by trained operators who are aware of the residual risk, and in applications where the eyes are usually not exposed. However, in such a scenario, as is the case for medical laser aiming beams, it should be possible to argue that the residual risk is small enough to satisfy the requirements of the European Directive on AOR by organizational measures and that there should be no requirement to wear eye protection.
- (2) For pulsed emission, due to the smaller “reduction” factor between the injury threshold and the MPE, exposure to five times the level of the MPE can for some exposure durations produce retinal injury in experimental animals. For instance, for pulse durations in the ns regime and for green wavelengths, the reduction factor for collimated beams is currently only about 3. This type of product is, so far, rare and arguments regarding experience with exposures to laser pointers do not apply. Following a revision of the

international exposure limits for lasers, the characterization of the risk for pulsed emission Class 3R lasers can also be up-dated. The thermal model can be applied to characterize the risk for specific pulse durations and repetitive pulse patterns for pulse durations above 50 μ s.

- (3) The third type of Class 3R laser product is where an extended retinal image is produced and a factor of $C_6 > 1$ is used to allow accessible output powers above 5 mW. This type of product is, so far, also rare and as for (2), arguments regarding experience with exposures to laser pointers do not apply. Experimental animal threshold data indicate that exposure to the respective levels can lead to retinal injury. While this type of product, due to its inherent beam divergence, has a smaller hazard range in terms of distance to the product where a correspondingly high retinal exposure can be produced (particularly with non-dilated pupils), the risk of retinal injury is, in principle, higher than for cw collimated Class 3R lasers where the output power is limited to 5 mW.

We conclude that an amendment of IEC 60825-1 to restrict Class 3R to type (1) as described above, i.e. to a cw output with accessible power levels limited to 5 mW (i.e. $C_6 = 1$ even for "extended sources") would allow a general description as "low risk (safe) for momentary un-intentional exposure". Such a restriction of Class 3R to cw lasers would help to reach a generally accepted understanding of what level of risk of retinal injury applies. This would consequently also make it easier for national and international agencies to provide guidance for appropriate types of applications and user precautions and specifically allow professional applications of Class 3R products with a minimum amount of organizational safety measures and without the need for eye protection.

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Zusammenfassung

Charakterisierung des Risikos für Netzhautschädigungen durch Laser der Klasse 2 und sichtbare Laser der Klasse 3R, inklusive Pilotlasern von chirurgischen Lasern

Anhand experimenteller Schädigungsschwellwerte, die aus der Literatur gewonnen bzw. mittels eines Computer-Modells ermittelt wurden, konnte das Risiko für eine thermische Schädigung der Netzhaut bei Bestrahlung mit sichtbarer Laserstrahlung, die die in der IEC-Norm 60825-1 und der EU-Richtlinie über künstliche optische Strahlung definierten Grenzwerte überschreitet, quantitativ bestimmt werden. Die Diskussion ist besonders für medizinische Pilotlaser mit Leistungen bis zu 5 mW relevant. Eine Strahlungsexposition mit einer Leistung von 1 mW (Klasse 2-Strahlung) mit Bestrahlungsdauern bis zu 5 s scheint demnach nicht zu einer Netzhautschädigung zu führen. Obwohl es bei den experimentellen Schädigungsschwellwerten für kollimierte Strahlen Unsicherheiten gibt, zeigt uns die Erfahrung mit Laserpointern mit Leistungen bis 5 mW, dass das Risiko für Netzhautschädigungen bei einer zufälligen kurzzeitigen Bestrahlung mit solchen Lasern gering ist. Die Schädigungsschwellwerte lassen jedoch den Schluss zu, dass die Bestrahlung mit manchen gepulsten Lasern der Klasse 3R sowie mit Lasern der Klasse 3R, die als ausgedehnte Quellen klassifiziert sind und daher Ausgangsleistungen über 5 mW haben, zur Schädigung der Netzhaut führen können. Es werden Empfehlungen für Änderungen der Normen IEC 60825-1 und IEC 60601-2-22 gegeben, die helfen sollen, eine Einigung der involvierten Parteien über die notwendigen Anwendersicherheitsmaßnahmen bei Lasern der

Klasse 3R und bei medizinischen
Pilotlasern zu erreichen.

Schlüsselwörter: Laser; Schädigung;
Risiko; Maximal zulässige Bestrahlung
(MZB); Grenzwert; IEC 60825-1; Klasse 2;
Klasse 3R

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