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CLASS 3R AND THE UPCOMING CONSUMER LASER SAFETY STANDARD IN EUROPE - A CHALLENGE!

Paper #604

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Abstract

Following a mandate issued by the European Commission to the European standardisation organisation CENELEC, a standard for laser products intended to be sold to consumers is currently developed. The main challenge is to decide if Class 3R products should they be generally permitted as consumer products, or only a subgroup, or not at all. To require the manufacturer to perform a risk analysis is another option that is followed up. This paper reports on some emission parameter combinations where exposure at five times the MPE for retinal thermal damage (the maximum permitted emission of Class 3R lasers) exceeds injury thresholds known from rhesus monkey experiments by more than a factor of two. Although there is data showing that there is some margin between the injury thresholds of the human and the rhesus monkey retina, it might not be sufficient to justify that all Class 3R lasers are sufficiently safe to be used as consumers without eye protection.

Introduction

The international laser safety standard IEC 60825-1 [1] defines laser safety classes based on accessible emission limits (AEL), as well as, depending on the class of the product, requirements for labelling of the product, user information to be given by the manufacturer as well as design requirements for the product [2-4]. The standard currently does not specify which product is acceptable to be sold as consumer product. The practice by most market surveillance authorities in Europe has been that Class 3R, 3B and Class 4 lasers are not seen as sufficiently safe to be made available on the market for consumers. It is generally accepted that Class 1 and Class 2 laser products are acceptable to be used by consumers (as long as they are not toys in which case it is usually required to be Class 1 only) with the understanding that the user is not trained and will not wear eye protection.

Overview of Classes

The basis of Class 1 and Class 2 is that the emission is below the maximum permissible exposure level for the eye for the respective time base, i.e. 0.25 s for Class 2 and a time base representative of intentional long term exposure for Class 1. The rules for the determination of the accessible emission to be compared against the AEL are rather restrictive and for the retinal hazard wavelength range (400 nm to 1400 nm) is defined as to position an aperture with 7 mm diameter at 100 mm from the reference point (typical reference points are the line optics for line lasers or the mirror for scanners) to conservatively asses what level of radiation could, as worst case, be accessible for the unaided human eye (assuming a 7 mm diameter pupil and accommodation to the apparent source at a distance of 100 mm, if the source is extended). The numerical values of the AEL for Class 1 and Class 2 are equivalent to the MPE for the eye for the corresponding time base [2, 5]. The AEL for Class 3R is five times the AEL of Class 2 when the emission is in the visible wavelength range and five times the AEL of Class 1 when outside of the visible wavelength range.

Concept of Class 3R

Class 3R with the basic concept for (compared to Class 3B) reduced manufacturing and reduced user requirements originated in IEC 60825-1 Edition 1.0 (1993) where it was referred to as Class 3B* in a table in Annex D with the * denoting a footnote stating the exceptions for this subclass of Class 3B not exceeding 5 times the limit of Class 2 (see also review of history of Class 3A by D. Sliney at this conference). Following the suggestion of the author of the present paper, in the process of the development of Amendment A2 for Edition 1, a specific class name was defined and decided to be Class 3R.

The basis of the reduced manufacturing and user requirements is the reduced risk for injury as compared to Class 3B lasers. The origin for Class 3R was predominantly alignment lasers, i.e. visible cw emissions with collimated beams used in industry and medicine for alignment and pointing. For this type of emission compared to rhesus monkey injury thresholds, there is a safety margin of about 10 with respect to the AEL of Class 2 of 1 mW (and therefore with respect to the MPE for 0.25 s exposure duration), see review in Reference [6]. Therefore, an exposure to 5 x the MPE (the maximum emission permitted for Class 3R) is still below the injury threshold as schematically shown in Figure 1.

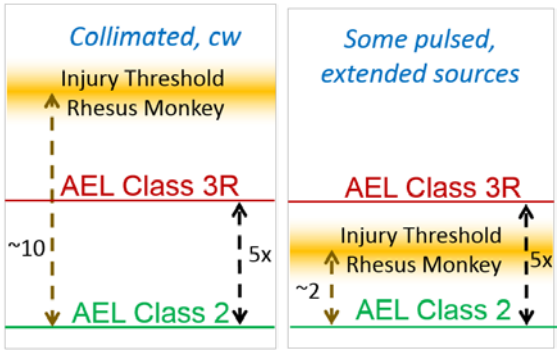

Figure 1. Left: For collimated cw emissions and exposure durations of 0.25 s, in the visible wavelength range, the margin between the injury threshold for rhesus monkeys and the limit is roughly a factor 10; the level of 5 x the limit of Class 2 is still below the injury threshold.

Right: For some pulsed and extended source emissions the margin between the injury threshold for rhesus monkeys and the limit is roughly a factor of 2 – 2.5; the level of 5 x the limit of Class 2 in this case exceeds the injury threshold.

That these kind of cw and collimated lasers of up to 5 mW are sufficiently safe to be also used by consumers has been demonstrated also by experience, since in the USA these type of lasers (denoted Class IIIA under the CDRH Federal Laser Product Performance Standard) has been accepted to be sold as consumer products.

The concern (particularly following the increase of the emission limits when transitioning from Edition 2.0 to Edition 3.0) is that for some pulsed and extended source products, it is known that the margin between injury threshold for the rhesus monkey and the MPE is only roughly a factor of 2.5 and might in special cases be only 2 (which is sufficient for the MPE and AEL of Class 1 and Class 2). The emission of Class 3R laser products in these cases, however, exceed the injury threshold for rhesus monkeys, as schematically shown in right part of figure 1.

This relatively large variability of the reduction factor between injury threshold and Class 1 and Class 2 limit (and therefore with respect to Class 3R) was already the topic of an ILSC 2011 [7]. The discussion in the present paper concentrates on examples of injury thresholds for pulsed and extended source emission. The data will show that the assumption that the margin between MPEs and injury threshold is generally 10 is clearly a myth and the data also indicate that exposure at 5 x the MPE might not be sufficiently safe to permit all Class 3R lasers to be placed on the market as consumer products.

European Mandate for New Standard

While the policy of "permitting" open beam Class 3B and Class 4 lasers is well founded for *professional* lasers where the regulations for occupational safety and health enforce user to implement precautions to achieve the necessary level of overall safety, this kind of policy of relying on user precautions (which are difficult for instance when it comes to training or defining controlled areas) is not considered as expect to "work" for laser products to be sold as general consumer products. It is interesting to compare this policy (which is generally supported by IEC technical experts) to other types of products such as power tools or chemicals, which are permitted on the market as consumer products and where the user is supposed to use personal protective equipment or risk severe injury otherwise. The policy with respect to laser products where Class 3B and Class 4 is not deemed acceptable as consumer product is therefore is stricter as compared to many other products. Considering the special nature of laser hazards and also potentially very large hazard areas this is probably appropriate and is not under discussion here.

Where there are deviating views within the responsible technical committee IEC TC 76 (but also within the European mirror committee CENELEC TC 76) is when it comes to Class 3R laser products, if the associated risk for injury is sufficiently low to make them acceptable as consumer products, or not. This discussion of the associated risk for injury assumes that no laser eye protection is worn by the user, or that the exposure of innocent bystanders, who would not wear eye protection, is not controlled well enough by the user (who might even wear eye protection) so that a laser product deemed appropriate for consumers is considered acceptable only if the risk for injury for foreseeable exposure scenarios is sufficiently small.

Generally in the field of technical safety standards, compliance with a safety standard has the consequence that a product is considered as fit (sufficiently safe) to be placed on the market. Although this is the case for IEC 60825-1 for professional laser products, where all laser classes are acceptable, this is not the case for the case of higher laser classes when the product is made available to consumers. Although this limitation *is* noted in the scope of IEC 60825-1 (and therefore also in EN 60825-1) it is not specifically a requirement and it was felt necessary by the European Commission (the Directorate General that is responsible for consumer product safety) to issue a mandate [8] for an amendment so that compliance with the standard also ensures "safe" products when sold to consumer products. The option was to either amend the existing EN 60825-1 (which at the level of Edition 3.0 is identical to IEC 60825-1) or to develop a dedicated safety standard for laser consumer products. The path that was taken was to

develop a dedicated standard, although it would heavily refer to the main standard EN 60825-1, i.e. the new standard would not define different class limits or additional requirements for safety features of the products, it would rather only specify which laser classes are acceptable for consumer products and which are not. The currently envisaged standard designation is EN 60825-1-1. At the time of writing of this paper there is no official Committee Draft yet available. It is also discussed if the project should be lifted to international level and should be "taken over" by IEC TC 76. While it is always advantageous to have international rather than regional product safety standards, the challenge is that there is even less agreement and common positions when it comes to the question how to handle laser products designated as Class 3R based on the AELs of IEC 60825-1 Edition 3.0.

Basics on Risk Associated to Class 3R

Criteria and Main Arguments

The underlying legal requirement in Europe for consumer products such as laser pointers is the General Product Safety Directive [9, 10]. The criteria for acceptance as "safe" consumer product is relatively vague: phrased intentionally shortened, a "safe product" is a product which "does not present any risk or only the minimum risks compatible with the product's use". More information on risk assessment as performed by market surveillance authorities in Europe can be found in [11]. However, also in this official guidance document for market surveillance authorities, the specific level of acceptable risk is not defined. For laser products, it can be inferred that a product is considered as acceptable for consumers, when for normal use and foreseeable misuse (which is a criterion of the General Product Safety Directive) the probability for injury during the lifetime of a given product is very small. There are two main components that are relevant, as already discussed in a related ILSC paper in 2011 [7]: on the one hand the *injury threshold* [3, 12] as compared to the AEL of Class 3R (i.e. 5 x the AEL for Class 2 or Class 1) and on the other hand the scenario of the exposure, i.e. exposure duration, the accommodation state of the eye, and for the case of beam diameters larger than a few millimetres, the diameter of the pupil of the eye.

As noted above, the basis for the "historical" understanding and treatment of Class 3R is that the safety margin between the MPE and the injury threshold is sufficiently large so that exceeding the MPE by a factor of 5 is still below the injury thresholds and does not produce an injury, at least not for momentary exposure durations (i.e. there is some increased level of risk for retinal injury for intentional staring into the beam; this increased level of risk, however, also drastically varies depending on wavelength and other factors.). Put into a simplified wording, Class 3R can be considered as "safe" when the safety margin between the injury threshold and the AEL for Class 1 or Class 2 (depending on wavelength) is at least 5. This simplified presentation at this point neglects cases where the exposure duration is shorter than the time base for classification and where the beam diameter is larger than a few mm at the location of the eye so that the pupil diameter also plays a role.

Sometimes the argument by those who "defend" Class 3R as generally acceptable for consumers is that Class 3R is not considered as "safe" anyway, but as "low risk". These categorisations of risk, however, are not really helpful because it still leaves the question open if this level of "low risk" is acceptable for consumer products. The author of this paper would like to argue that as soon as the exposure from a given Class 3R product is or might be above the injury threshold for a significant portion of the population for foreseeable exposure scenarios, it is not prudent for a safety standard not to permit these types of products. For this discussion it can also be assumed that the variability of the injury threshold is relatively small, i.e. it is not to be expected that the injury threshold within the human population varies drastically, at least not towards the lower end (i.e. excluding for instance persons with cataract that would result in a very high injury threshold): there is *some* variability expected associated with the retinal degree of pigmentation for some wavelength ranges (and less or no variability for others) but it is not expected that there are significant outliers in terms of threshold, so that for instance 1 out of one million people of mixed pigmentation has a significantly lower threshold as compared to the part of the rest of the group with low injury thresholds. If such outliers were to be expected one could treat them as very low probability and associate them with low risk because of the low probability, and in terms of product safety also possible as acceptable. However, for the expected distribution of injury thresholds in the population (discussing the lower edge of injury thresholds, not the higher ones, where there is much higher variability for instance due to clouded lenses) it is rather that when the exposure associated to a given product exceeds the lower end of the distribution of thresholds, then it does so for a relatively large portion of the population so that the risk for retinal injury in this case is probably not acceptable to be permitted by a safety standard. Cases where the margin between injury thresholds for rhesus monkey and the AEL for Class 1 and Class 2 is only about 2.5 will be shown further below. To argue, or hope that products with these wavelengths, pulse durations and retinal spot sizes will not be used as consumer products once a safety standard specifically permits them is not considered as prudent

by the author of this paper. It can be assumed that the "probability" part of the parameter "risk" (probability and severity) is not meant in the sense of a low probability that a product with potentially critical emission parameters is put on the market as mass product is low.

Main Problem: Raised AELs

What is often forgotten when there is the argument that "Class 3R products so far have proven to be sufficiently safe as consumer products simply based on the experience" is twofold: on the one hand, the types of products that recently became available as consumer products drastically changed from simple laser pointers to complex scanners and pulsed sources often classified as extended sources; and on the other hand the AELs for Class 3R for these very types of products (scanned, pulsed) particularly for extended sources increased dramatically in some cases due to the recent update of IEC 60825-1 Edition 3.0 as compared to Edition 2.0 [13, 14].

It is appropriate to argue that 5 mW visible laser pointers are "safe" and can be said to have low enough associated risk to be acceptable as consumer products [6] since they are in use for many years worldwide with only a handful suspected minor retinal injuries, and these injuries might even need to be questioned in terms of validity if the laser power might have been higher or if there really was an injury.

However, we do not have this level of experience at all for complex products that are pulsed, scanned pulsed and might also be classified as extended sources – because these kind of complex products are new, and especially because for the levels of Class 3R permitted under Edition 3.0 these products have not so far been on the market: Edition 3 does not exist that long and is for instance in the USA still not accepted at the time of writing of this paper.

The type of emission that is potentially problematic for Class 3R lasers are pulsed and particularly extended source products. These will be soon ubiquitous (but fortunately as Class 1 and Class 2 laser products) particularly in the field of 3D computer vision, gesture control and other applications where a 3D information is necessary such as for autonomous cars. It can be assumed, that as soon as there is a safety standard permitting Class 3R emission, then this will be used by manufacturers (many products are limited in performance such as range and brightness due to the safety limits of Class 1 and Class 2).

It is emphasised here that for many of these types of emissions (pulsed, extended source) for the case that Class 3R lasers existed and were on the market, they were classified under Edition 2.0 of IEC 60825-1. With the increase of the AELs for Class 1 and Class 2 under Edition 3.0, many of the previous Class 3R (when pulsed) become Class 2 or Class 1 (depending on wavelength). But on the other hand, what is under Edition 3.0 permitted as emission for Class 3R laser products for pulsed and extended source was previously often associated to Class 3B lasers. Thus the argument that the experience has shown that Class 3R lasers are safe is not valid for the case of pulsed, and particularly pulsed extended source laser products classified under Edition 3.0, for the simple reason that they have not been on the market and that many of them were Class 3B under Edition 2.0 (where it cannot be claimed that experience has shown that Class 3B are safe).

The challenge is heightened by the sheer number of these kind of products which will be soon standard equipment on every smart phone, tablet, laptop and cars (for instance to control the on-board computer) – but again, currently they can be assumed to be designed as Class 1. However, when there is a device that for the usual exposure scenario exceeds the injury threshold for a certain percentage of the population (such as might be possible if the emission were Class 3R), it would be associated to a correspondingly large number of injuries which would be a disaster also for the credibility of laser safety standardisation.

Uncertainty

Uncertainty complicates risk analysis considerably but is important to consider. For instance, the Environmental Protection Agency EPA in the US regularly requires that uncertainty in a risk analysis is characterised by Monte Carlo simulation. Even for a very specific exposure scenario (wavelength, emission level, etc.) it is a daunting task to perform a quantitative probabilistic risk analysis including an uncertainty analysis, and it is certainly not possible for the whole range of types of products. Even if it were possible, there would still be the problem that there is no specified accepted level of risk defined.

In terms of a prudent safety policy for a product safety standard the author argues that if it cannot be stated with good confidence (little uncertainty) that Class 3R emissions for all pulse durations, retinal irradiance profiles and relevant wavelengths are below injury threshold for humans then such a product shall not be permitted in a safety standard for consumer laser products (where the goal is that compliance with the standard lends a presumption of conformity with product safety legislation in Europe and for an IEC standard also elsewhere).

Severity of Injury

When "risk" is discussed, it is necessary to discuss the severity of injury, since "risk" as a quantity is a

combination of probability (or more specifically frequency, i.e. in terms of expected occurrence per unit of time) and severity of injury. Thus for a given frequency, the risk for the case of death is correspondingly higher as the risk for the case of a minor burn of the skin. For retinal injuries, which is the focus in this discussion, there is a significant difference in terms of effect on vision if both eyes are affected or only one, and if the injury is in the fovea or in the periphery of the retina. In the latter case, a retinal injury might not even be noticed. Experience with laser pointers of powers exceeding approximately 20 mW show that retinal injury as reported and published in the literature always, as far as the author of the paper has reviewed, affects the central area of the retina, the fovea.

There is also sometimes the argument that "killing a few RPE cells" is not a significant retinal injury, as this is even used in some medical procedures as treatment of the retina. This argument neglects several issues: firstly, medical treatment associated to minor RPE damage is not applied in the fovea; it is only treatment levels below RPE injury thresholds (see the plenary presentation by Dr. Luttrull of this conference as well as conference paper #102) where the fovea is also exposed. Secondly, the treatment where RPE cells are selectively targeted (also referred to as SRT, selective retinal treatment) is done with relatively small retinal spot sizes so that dead RPE cells are "replaced" by neighbouring intact RPE cells and there is no significant loss of photoreceptors. However, when the injury threshold for RPE death is exceeded for a larger retinal spot size, it can be assumed that there will be loss of photoreceptors in the affected area (since RPE cells are the "support" cells of photoreceptors) with a scotoma resulting, i.e. a black defect in the visual field which is detrimental when in the centrum of high visual acuity.

The author believes that for the case that RPE cell death is possible, which is what is referred to here as retinal injury, then this effect is severe enough as to require a very low frequency of occurrence for a given product so that the risk can be argued to be acceptable for consumer products.

Difference of Non-human Primates to Humans

While the ED50 for non-human primates (NHP) is relatively well characterised for many wavelengths, pulse durations and retinal spot sizes, the threshold data for human is scarce. It is generally accepted that rhesus monkeys are a valid model for the human retina and due to the strong pigmentation are accepted not to be associated with higher thresholds for minimal visible lesion (MVL; for a discussion of "threshold" please refer to reference [12]). The pigmentation differences between NHP and human retinas on the one hand and between humans with different skin type on the other are believed to be more pronounced in the choroid [15]. The pigmentation of the RPE is not believed to vary strongly between species and skin types. As a consequence, the difference between species and skin types will be stronger for red and infrared wavelengths where the absorption of the RPE is decreased and the choroid plays a role as absorption volume. For wavelengths in the yellow one could say that the optical density is roughly balanced between RPE and choroid, and for wavelengths in the green and blue the RPE dominates the absorption and the choroid plays a minor role in terms of the level of threshold. Also the differences between pigmentation of the macula and extra-macula plays a role.

Studies where the same team determined the threshold for humans and NHP are rare. Stuck [15] reviewed retinal laser injury thresholds as reported for humans and compared them to NHP ED-50 for the respective wavelength, pulse duration and retinal spot size. He concludes that for retinal regions *outside the macula*, and wavelengths less than 550 nm the difference between thresholds for humans and rhesus monkey is roughly a factor of 2. For longer wavelengths, the difference increases. For the *macular region*, however, the difference between humans and non-human primates is probably less than 2 and in the wavelength range of less than 550 nm is summarized in the review by Bruce Stuck to be potentially equivalent, i.e. little difference. From a study by Ham for instance, as reviewed by Bruce Stuck [15] it was noted that for a filtered Osram XBO 2500 Watt lamp (400 nm to 800 nm), a retinal image diameter of about 1 mm and 135 ms exposure duration, the retinal injury threshold for Caucasian humans (18 diabetic oedema patients) was 9.3 J cm^{-2} (± 1.56), for darkly pigmented humans of African descend (10 patients) it was 7.9 ± 1.96 J cm^{-2} while for 22 rhesus monkey eyes it was 5.9 ± 1.5 J cm^{-2}, i.e. a factor 1.2 between the two groups of human patients and a factor of 1.34 between the threshold for heavily pigmented humans and rhesus monkeys. Since this data was for a broadband source, it could well be that for wavelengths less than 550 nm the difference is smaller.

It follows that the difference between human and NHP injury thresholds depends heavily on wavelength and it probably also depends heavily on pulse duration (for short pulses with little heat flow, absorption depth is more important as compared to longer exposure durations). Based on the assumption of a large number of devices and for some products frequent exposure, for an overall low risk it is prudent to assume a relatively small (particularly in yellow, green and blue wavelengths), and in some cases, for short pulses, potentially even no relevant difference between the injury threshold of NHP and "sensitive" humans.

Particularly when the ED50 (the centre of the dose response curve, see for instance [12]) of NHP is used in the discussion, it needs to be acknowledged that exposure to doses lower than the ED50 led to a MVL (depending on the slope of the dose response curve). A simplified comparison can be based on both neglecting the slope of the dose response curve (i.e. taking the ED50 as actual "threshold") but at the same time also neglecting the difference between sensitive humans and NHP, particularly for critical wavelength ranges in the visible (i.e. green and blue and potentially also yellow, particularly in the macula lutea, the "yellow spot").

Another relevant issue is that the ED50 as usually experimentally obtained is determined ophthalmoscopically (minimum ophthalmoscopically visible lesion, MOVL, see also Ref. 12) as barely detectable change of the optical appearance of the fundus of the retina. It cannot be excluded that RPE damage also results at somewhat lower levels.

Some additional information can also be obtained from parameters used for medical treatment which is attempted in paper #102 of these proceedings.

Risk Associated to Class 3R - cw Collimated

A collimated laser beam (very small divergence) results in a minimum retinal spot size [2,3]. In the visible wavelength range, continuous wave (cw) collimated beams are the typical Class 3R (in the USA: Class IIIA) alignment lasers and also laser pointers with emission levels up to 5 mW. The author of this paper agrees [6] that these kind of lasers are associated with a negligible risk for injury even when used by laypersons and children, which is the case for laser pointers. This is not the issue of this paper.

Risk Associated to Some Pulsed Lasers

In the following, some examples of experimental data which demonstrate a relatively small margin of safety between the AEL of Class 1 or Class 2 is given. It is emphasized that for Class 1 and Class 2 to be associated to "negligible risk for injury" the safety margin is sufficient, but the question here is if an exposure to five times the AEL of Class 1 and Class 2 (i.e. to Class 3R levels) can still be argued to be associated to an acceptably low level of risk so that the product is fit to be placed on the market as consumer products. Only a few examples are given and only a few examples are sufficient in the discussion as counterargument that Class 3R is *generally* safe enough to be placed on the market as consumer products.

Nanosecond Pulses as Function of Spot Size

Figure 2 shows ED50 data for rhesus monkeys from a spot-size study by Zuclich, Lund et al. [16]. The wavelength was 532 nm and the pulse duration was 5 ns; the exposure was to single pulses. The ED50 were determined 24 h after exposure. The retinal spot diameters are given in the lower abscissa where it should be noted that the ED50 for the well collimated beam is plotted here at the "nominal" 25 µm diameter position and there is some uncertainty about the actual spot diameter in the rhesus monkey eye. The data would also be consistent when the actual spot diameter for the minimal case is about 80 µm. The upper abscissa is the angular subtense of the retinal spot as associated to a nominal human eye with a length of 17 mm.

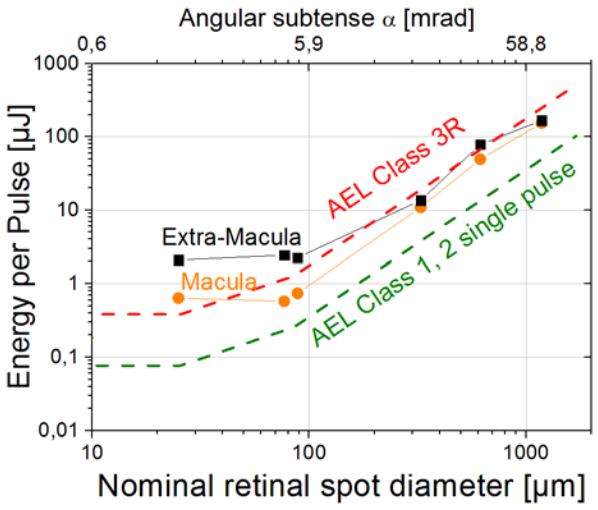

Figure 2. ED50 and AEL as function of retinal spot diameter for 532 nm, 5 ns single pulse exposures.

We note in figure 2 that the ED50 in the macula are lower than outside the macula, as consistent with other experiments. The difference is small for larger spot sizes but significant for minimum retinal spot diameters up to about 5 mrad. Also shown is the AEL for Class 1 and Class 2 (for individual pulses the AEL of Class 2 is equal to the AEL of Class 1). It can be seen that the margin between AEL and ED50 for the macula for the minimum spot condition is roughly 10 (more exactly for the above dataset it is 8.4). Due to the uncertainty of the spot size it is possible that where the data is plotted for 25 µm it really was a larger spot and would have to be plotted at a different position. Since it is possible that the spot from a well collimated beam for the awake human is smaller as compared to the anaesthetised monkey, the reduction factor of about 10 for minimum spots is prudent. For a spot size of about 5 mrad, the factor between ED50 and AEL for Class 1 equals 2.5. *The AEL of Class 3R for a single pulse therefore exceeds the ED50 for an MOVL in the rhesus monkey by a factor of 2*. Starting at 5 mrad, the AEL in terms of dependence on retinal spot size follows the ED50 trend very well (based on a value of α_{max} of 5 mrad; the AEL was expressed in terms of $C_6 = \alpha^2 / (\alpha_{min}\, \alpha_{max})$ for spot sizes larger than α_{max}, consistent with a comparison of energy per pulse determined with an "open" angle of

acceptance, i.e. not limited to α_{max}), i.e. the ED50 show an α^2 dependence. It follows that also the margin between ED50 and AEL remains approximately the same and equals 3.1 for instance for the largest spot size. It is emphasised that already *one single pulse* nanosecond pulses at levels permitted for Class 3R exceeds the rhesus monkey ED50 by a factor of about 2. Therefore the argument that Class 3R is "safe" for momentary exposures (non-intentional exposures) and only potentially hazardous for intentional staring into the beam is not supported by the above data.

Multiple Pulse Data

The ED50 data in the previous section was for single pulse exposures, both for macula and extra-macular regions. Together with the revision of the retinal spot size dependence (time dependent α_{max}), the rules for the analysis of multiple pulses was also revised in IEC 60825-1 Edition 3.0 compared to Edition 2.0. The update was based on the ICNIRP 2013 revision [17] and is also equivalent to the revision of ANSI Z136.1 (2014) [18]. For pulse durations less than 5 µs and wavelengths between 400 nm and 1050 nm, for Class 2 laser products, the reduction factor C_5 = 1 in both IEC 60825-1 as well as ANSI Z136.1. For time bases longer than 0.25 s (i.e. Class 1) and more than 600 pulses, IEC 60825-1 and ICNIRP defines a reduction factor C_5 less than one, while ANSI Z136.1 does not introduce a reduction factor for these short pulses.

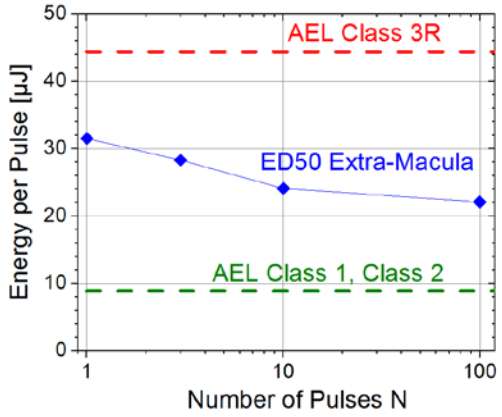

Figure 3. ED50 for extra-macular regions as function of number of pulses for 532 nm and 7 ns pulse duration. The spot size was 500 µm.

Figure 3 shows data from a study by Lund et al. [19] which was obtained with a laser wavelength of 532 nm, a pulse duration of 7 ns and for a spot size of 100 µm as well as 500 µm. The data shown is for 24 h determination of the ED50. It is important to note that the exposure area in the retina was only extra-macular, and no macular ED50 were determined (see the data in the previous section to compare macula and extra-macular ED50). The pulse repetition rate was 10 Hz and the number of pulses was varied from 1 to 1000 pulses for the 100 µm spot diameter and from to 100 pulses for the 500 µm spot size. In figure 3, only the 500 µm data is shown, compared to the AEL of Class 1 and Class 2 (since the number of pulses is less than 100, there is no difference between Class 1 and Class 2). The reduction of the ED50 with number of pulses is less pronounced than the $N^{-1/4}$ trend of earlier editions of the safety standard, but there is still some reduction with larger number of pulses, reducing the margin between the ED50 and Class 1 and Class 2 and at the same increasing the factor by how much Class 3R exceeds the ED50.

The data from the multiple pulse study also compares well with the ED50 for single pulses discussed in the previous section (see figure 4 below). The single pulse ED50 both for 100 µm as well as 500 µm from the multiple pulse study, shown in figure 4 with blue full diamonds, are fully consistent with the extra-macula ED50 of the earlier single pulse study. Figure 4 also shows the multiple pulse data for higher number of N with open blue diamonds. It can be seen that for the 100 µm spot size, the extra-macula ED50 for 1000 pulses approaches the single pulse macular ED50.

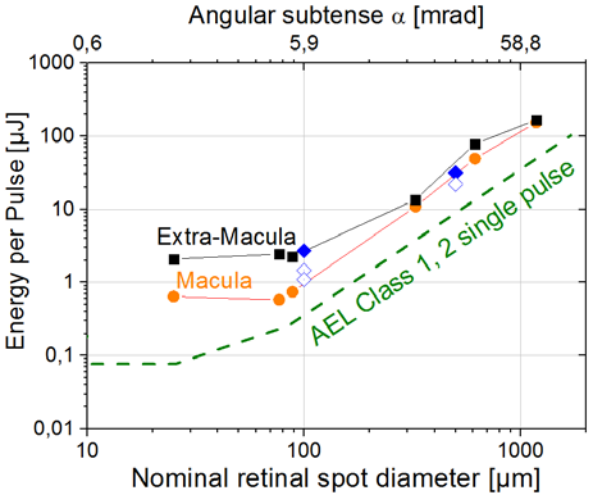

Figure 4. The single pulse data from the previous section shown together with the extra-macular ED50 from the multiple pulse study (blue diamonds).

The big question here is how much lower the multiple pulse ED50 would be for the macular region as compared to the extra-macular data. For the 500 µm spot size data, the ED50 for 100 pulses (extra-macular) is lower than the single pulse macular ED50 trend, which indicates that macular multiple pulse ED50 might well also be lower than the macular single pulse ED50.

100 ms Data

In the two previous sections, pulse durations in the short nanosecond regime were discussed and it was shown that the AEL of Class 3R can be about a factor 2 above the MOVL ED50 for rhesus monkeys, even for a single

pulse exposure. In this section, relatively long pulses of 100 ms pulse duration are presented [20], obtained in the macula and extra-macula for a wavelength of 514 nm (figure 5).

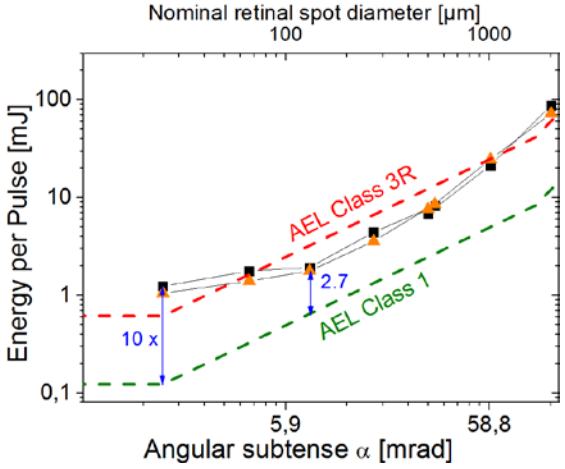

Figure 5. ED50 for single pulses with duration of 100 ms as function of retinal spot size (macula: orange triangles; extra-macula: black squares). The wavelength was 514 nm.

The margin between the ED50 and the AEL of Class 1 and Class 2 (which are equal for a single pulse) is less than 3 in the spot diameter regime of 6 mrad to about 30 mrad, so that the AEL for Class 3R exceeds the MOVL ED50 for rhesus monkey by a factor of more than 1.5. Since the data is for a pulse duration of 100 ms (not far away from 250 ms), it cannot even be excluded that exposure to cw emissions, when classified as Class 3R and as extended source is not potentially problematic.

Exposure Parameters

This paper concentrated on discussion of MOVL ED50 for rhesus monkeys compared to the emission permitted for Class 3R. Examples were shown where particularly for extended source conditions (when the permitted emission level is used to the full extent), the AEL of Class 3R is up to a factor of 2 above the ED50. The data was presented in terms of "energy per pulse" that enters the eye (in biomedical studies also referred to as the "intraocular energy"). Classification as Class 3R is based on the energy that passes through a 7 mm circular aperture positioned 100 mm from a reference point, which is usually equivalent to the beam waist, as "origin" of a divergent beam (for a collimated beam the position of the aperture has little effect).

In order to classify a given product as extended source, it is necessary that the divergence of the beam is at least as large as the angular subtense α (since accommodation to infinity results in α being equal to the divergence angle, α cannot be larger than the divergence). Therefore, the larger the value of α, the larger the minimum divergence is (the divergence can also be larger than α). The divergence of the beam is relevant because the intraocular energy is reduced when the beam diameter is larger than the pupil of the eye.

In the discussion of the risk associated to Class 3R it is often argued by those who argue for "low risk" that to assume a 7 mm pupil in all but dark environmental conditions is not reasonably foreseeable. For this discussion, however, it has to be emphasised that the pupil diameter only plays a role when the beam is larger than the pupil, which is only the case for relatively large divergence values (assuming a relatively small beam waist). A 7 mm aperture placed at 100 mm from a reference point spans an angular subtense of 7/100 = 70 mrad. If the pupil is for instance 4 mm in diameter and at a distance of 100 mm from the reference point, the angular subtense of the pupil as seen from the reference point equals 40 mrad. Therefore, for this example, only beams with divergences (and therefore apparent source angles) larger than about 40 mrad would be associated to divergence angles that are large enough so that the 4 mm pupil as compared to the 7 mm test aperture has an effect on the intraocular energy of about a factor of at least 3, which can be the basis to argue that Class 3R is associated with low risk. For smaller divergence angles and smaller values of α, this argument, however, does not hold as the full beam can pass through the 4 mm pupil. Since not only relatively large extended sources are associated with small safety margins but also typically for 5 mrad, there is a relatively large range where pupils smaller than 7 mm (but see next paragraph) would not have an effect simply because the beam diameter is still smaller than the pupil.

The argument that a "pupil of 7 mm diameter is unlikely" also only holds for the case of short exposure distances and short accommodation distances. Only in this case can it be argued that due to the near triad of accommodation, the pupil should constrict for close accommodation (see further discussion in Ref. [21]).

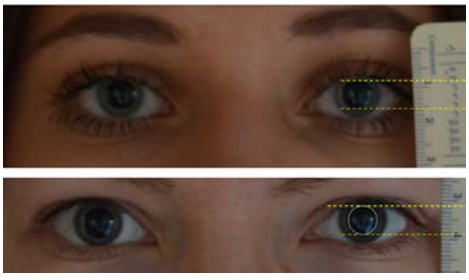

Figure 6. Examples of pupils with 7 mm diameter – photographs taken in the corridor in front of the office of the author with members of the group, 18 and 23 years of age; the luminance was about 15-30 cd m^{-2}, a normally lit corridor.

For somewhat further distances from the visual target (or the apparent source), when the accommodation effort is not so great, it is very common that the pupil diameter is 7 mm even in environments where there is no complete darkness (see examples in figure 6). Apparently these individuals also have good vision even for 7 mm pupils (the reduced optical quality of the eye outside of the central corneal region leading to enlarged spot sizes is also sometimes used as argument). The author of this paper has measured pupils of co-workers and when on travel and 7 mm pupils in conditions of indoor lighting such as in a corridor or a hotel check-in desk are common, particularly for young adolescents. This observation was also confirmed by personal communications from vision research experts [22, 23].

It is summarized that ***if*** the pupil is smaller than 7 mm then the divergence still needs to be sufficient to result in a beam diameter that is larger than the pupil for the smaller pupil to be of relevance. For a divergence of for instance 20 mrad, the beam diameter at 200 mm distance can be 4 mm. Since the factor between ED50 and the Class 1 and Class 2 limit was shown for the above data to be a factor 2 for angular subtense values as small as α = 5 mrad, reduced pupil sizes would not have a significant effect. Also for indoor lighting conditions such as in corridors, many individuals, particularly of young age of about 18 to 25 years, regularly have pupil diameters of 7 mm when not accommodating to very close objects. For these above two reasons, the argument of a 7 mm pupil being unrealistic and significantly reducing the risk for injury (by reducing the probability that the full beam enters the eye) might not be as strong as hoped for when Class 3R is argued to be generally acceptable for consumer products.

Summary and Conclusions

The question of the risk associated to Class 3R lasers is complex for several reasons:

- the variation of the "safety margin" with pulse duration, wavelength, retinal spot size and number of pulses
- the uncertainty if some relevant cellular effects are possible below the minimal ophthalmoscopically visible lesion (MOVL) threshold
- the uncertainty about the difference of human vs. non-human primate injury thresholds
- the hugely different types of products and emissions
- variations in exposure factors such as location of accommodation and pupil diameter

However, it is still possible to conclude from a small number of high quality studies with non-human primates that it cannot be argued with a high level of confidence that the risk for all possible types of Class 3R lasers is sufficiently low that they can be placed on the market as consumer products, and that Class 3R lasers should be generally "permitted" as consumer products in a standard that is developed in Europe. The argument that experience has shown that Class 3R lasers are safe is not valid in the general sense, for the simple reason that products with emission of potential concern (classified according to IEC 60825-1 Edition 3.0) are not yet on the market. With the increase of the AEL under Edition 3.0, the products under concern would have been previously often classified as Class 3B.

The author of this paper agrees that many Class 3R products are sufficiently safe to be placed on the market as consumer products, but that is not the concern. The concern that it is not possible to argue that *all* types of Class 3R lasers are associated with sufficiently low levels of risk. For the decision what is defined to be acceptable in a new safety standard for consumer laser products in Europe, some simplifications have to be made on the conservative side (such as when the difference between human and NHP thresholds is not known for all relevant wavelengths and pulse duration) and it is necessary to only permit those products where there is good confidence (low uncertainty) that reasonably foreseeable exposure levels do not cause retinal injury.

Since there is scientific data that shows that the emission of some Class 3R lasers exceeds the MOVL ED50 of non-human primates by a factor of up to 2 and possibly a little higher in special cases, and the difference between non-human primates and humans was found in some cases to be as small as 1.3, and considering that the ED50 is the *centre* of the dose- response curve where also somewhat smaller exposures have resulted in an MOVL, then the author is concerned about statements that Class 3R is *generally* associated to "low risk" with the implication of being generally acceptable as consumer product.

The author has argued at ILSC 2011 - at a time when IEC 60825-1 Edition 3 was still under development - to restrict Class 3R lasers to only those where there is good confidence from long term experience and scientific data that the risk for injury is sufficiently low, but this proposal was not met with support at the time. At present, with IEC 60825-1 in place, to change the definition of Class 3R (to for instance only collimated cw as well as large divergence angles) is not a short-time option to deal with the issue. For the new consumer product standard (which does not change requirements for classification, it just defines which classes are acceptable for consumers and which are not acceptable) it is not an attractive option to permit some Class 3R and not to permit others, since the user and market surveillance authorities would still not know if the

product at hand, labeled as class 3R, is acceptable or not, i.e. potentially hazardous or not. Not permitting *any* Class 3R is a simple option but is obviously also a restrictive one – however, at least in Europe this is common practice by many market surveillance authorities anyway. What currently is a possible way forward is to require the manufacturer to perform a formal risk assessment if Class 3R laser products are to be made available on the market for consumers. Some guidance for this can be given in an annex of the standard, and for collimated cw lasers this analysis can be relatively simple as there is sufficient data available to provide corresponding guidance in the annex of the standard. However, for other products, particularly for pulsed emissions, such a risk analysis is often very complex and has to be performed with the necessary level of experience and expertise; for instance it is not sufficient to "pick out" some threshold study with comparable wavelengths and pulse durations, as there are thresholds in the literature which are too high (because for instance only determined 1 hour after the exposure and in the extra-macula). Also in many cases, particularly for multiple pulses, no experimental ED50 is available that fits the case at hand in terms of wavelength, pulse duration, retinal spot size and interpolation would have to be performed. The practical value of requiring the manufacturer to perform a formal risk analysis is therefore limited. It might be best to simply just not permit Class 3R lasers for consumer products in the new European consumer laser product safety standard, or maybe only for cw collimated beams.

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