ILSC ® 2011 Conference Proceedings

The Widely Varying Risk from Class 3R Laser Products in Light of the Revision of IEC 60825-1

Karl Schulmeister

Reference information for this proceedings paper

Title: *The Widely Varying Risk from Class 3R Laser Products in Light of the Revision of IEC 60825-1*

Author: *Schulmeister K*

Proceeding of the International Laser Safety Conference, March 14-17th 2011
San Jose, California
Page 72-75

Published by the Laser Institute of America, 2011
Orlando, Florida, USA www.lia.org

THE WIDELY VARYING RISK FROM CLASS 3R LASER PRODUCTS IN LIGHT OF THE REVISION OF IEC 60825-1

Paper #103

Karl Schulmeister

Seibersdorf Laboratories; Laser, LED and Lamp Safety Test House, 2444 Seibersdorf, Austria

Abstract

Laser products that emit continuous wave (cw) visible radiation with powers up to 5 mW have been widely used for pointing and alignment purposes for more than 30 years. Under IEC 60825-1 such lasers are classified as Class 3R. Experience shows that these lasers are quite safe for momentary accidental exposure, even though the exposure limit might be exceeded by up to a factor of 5. In this paper a case is made that this general experience of relative safety should not be extrapolated to pulsed emissions and extended sources without a more detailed quantitative risk analysis. Following the update of the exposure limits by ICNIRP, ANSI and IEC, the minimal safety factor of about 2.5 will apply to a much wider range of parameter combinations as compared to the current limits. For the case that Class 3R AEL values remain linked to the MPEs by a factor 5 in all cases, there will be many more products where an exposure can exceed the injury threshold even for momentary accidental exposure.

Introduction

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 3R lasers (in the US CDRH scheme: Class IIIa ‘Danger’) 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) are generally considered to be relatively low risk. This means that, compared to Class 3B and Class 4 lasers, the manufacturer requirements and in many countries also the 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 also 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 [3] 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.

Reduction factor

The main biophysical rational behind the understanding of Class 3R lasers as “relatively safe” or “low risk” is the safety factor (or reduction factor) between the injury threshold and the MPE [4]. The general notion is that this reduction factor is about 10. However, a review of recent experimental data showed [5] that the reduction factor for 100 ms pulses under the extended source condition is only about 2.5, and for a very specific parameter combination (532 nm, 5 mrad angular subtense of the apparent source, 1 – 20 ns pulse duration, single pulse exposure) is only 1, i.e. the injury threshold is almost equal to the current MPE. If a Class 3R product were to exist for such parameter combinations (which is highly unlikely), exposure at close distance would almost certainly lead to retinal injury (within one pulse). It is clear that a reduction factor of 1 is not enough and the bioeffects expert committees of ICNIRP and ANSI have developed amendments of the limits that are currently in the draft stage [6,7]. Following those updates, which will also be adopted by the IEC for IEC 60825-1, the reduction factor will be as low as 2.5 or even only 2 for many more parameter combinations as is currently the case. In particular, due to the time dependency of α_{max}, the reduction factor can be as low as 2.5 also for short and extended sources, where currently there is a large reduction factor of more than 20. More importantly, the rules for multiple pulse exposure will be made significantly less restrictive, where there will be no $N^{-0.25}$ factor in the thermal pulse regime (for pulse durations longer than 5 µs) for small sources, leading to, for instance, an increase in allowed peak power of a factor 7 for the case of 2000 pulses – or in other words a reduction of the currently existing reduction factor by a factor 7. Also, for pulse durations less than 5 µs there will be less conservative pulse analysis rules, with no reduction of the single pulse limit for multiple pulses in many cases. While the basic limit is to be lowered in the nanosecond regime by ICNIRP and ANSI, due to the amendment of the multiple pulse rules, the net effect of the amendment can be an increase of allowed power of up to 2 for small sources and up to 40 for extended sources, compared to the current limit.

In summary, following the adoption of the proposed changes of the retinal thermal exposure limits, there will be many more parameter scenarios where the reduction factor (safety factor) is less than 5, with a minimum of 2 in some cases. Since the exposure limits (MPEs) are in many cases simplifications of the complex dependencies of the injury thresholds on wavelength, pulse duration and spot size as well as pulse patterns, there will be also parameter combinations where the reduction factor is larger than 5.

Risk for Injury

It is clear that it is necessary to distinguish visible cw Class 3R lasers with a collimated beam, which are the classical alignment lasers and laser pointers, from pulsed sources and sources that are classified under the extended source condition. It is only for the ubiquitous laser pointers (in earlier times: HeNe lasers used for alignment in research, industry and medicine) that it is possible to say from 30 year long experience that the risk for injury for accidental exposure is very low. For powers up to 5 mW, there are only a handful of reported retinal injuries and typically only for purposeful staring into the product (reviewed in reference [8]). It needs to be kept in mind that this experience (or anecdotal evidence) only applies to cw lasers with powers up to 5 mW, and it is clear from the above discussion on safety factors that pulsed sources need to be distinguished from cw sources and sources where $C_6 = 1$ is used for classification from those where the allowed power is increased by using $C_6 > 1$.

When the safety factor (reduction factor) between the injury threshold and the MPE can be as low as 2, a product that emits up to 5 times the level of the MPE can lead to exposures of a factor of up to 2.5 above the injury threshold determined with non-human primate models.

While some limited threshold data from human volunteer studies are available (reviewed in reference [4]) that indicated somewhat higher injury thresholds for the human case compared to equivalent exposures in the Rhesus monkey model, this can not be generally stated. Human data is available for an extremely small selection of laser parameters in the ‘three dimensional space’ of wavelength, pulse duration and spot size dependence. Differences in the pigmentation of the choroid, for instance, might have no influence on injury threshold depending on wavelength and pulse duration (since for shorter wavelengths and short pulses, it is only absorption in the RPE which is relevant for injury). There are even data that imply that the spot size for exposure of the human fovea could be smaller than observed in NHP studies, so that it can not be excluded that the injury threshold for the human fovea might be lower than observed for minimal spot exposures of the NHP (which is also the reason why a reduction factor of 10 is needed for small spot exposures, see discussion in references [5,9]).

In summary, without more detailed experiments with humans carried out by researchers that are experienced in detecting laser induced minimal lesions, it is necessary to assume that the injury thresholds determined for the non-human primate (NHP) model also applies to the human case.

The risk for injury for a given Class 3R laser product, however, does not only depend on the reduction factor of the underlying MPEs. The risk for injury also depends on the conditions of exposure, in particular how much power actually enters the eye for a given exposure position, and the likelihood that exposure occurs, and for how long. A factor in the overall picture is that in order for a source to be extended (where the safety factor can be lower), the beam can not be well collimated, i.e. the divergence of the beam needs to be at least as large as the angular subtense of the apparent source [10,11]. For a beam with a certain divergence, the power that enters the eye through the pupil will depend on both the position in the beam and on the pupil diameter. The MPEs are based on the assumption of a 7 mm pupil, while under normal lighting conditions the pupil will be smaller. Also, classification is based on determining the accessible emission at a distance of 10 cm from the beam waist, and exposure levels at greater distances can for divergent beams be correspondingly lower. However, the divergence can not be used as a generally applicable argument that extended sources = divergent beams have a low associated risk: the reduction factor can be as low as 2.5 already for 5 mrad source size.

While all these factors can in principle be accounted for in a risk analysis, such a risk analysis will be rather complex and requires expertise. General guidelines can not be given, for instance in an IEC document, because the risk depends highly on the specific product and mode of usage.

Implications for Edition 3 of IEC 60825-1

While the accessible emission limits for Class 1 and Class 2 will be 'automatically' updated for the next edition of IEC 60825-1 based on the updates of the ICNIRP guidelines, IEC TC 76 has at least two options regarding the definition of Class 3R limits:

1) Define the AEL of Class 3R as 5 x the AEL of Class 1 generally, as is currently the case

2) Restrict Class 3R lasers to products where it can be inferred from experience and animal experiment injury data that accidental exposure does not produce a retinal injury

For the choice of either 1) or 2), it has to be kept in mind that ICNIRP in many cases considerably reduces the reduction factor, which means that the allowed power will in many cases increased also for Class 1 and Class 2, particularly for pulsed sources. Thus, many sources with pulsed emission that are currently Class 3R will become Class 2, or potentially even Class 1 (for instance if pulsed and extended). If the strategy summarized in 1) is followed, also the allowed output powers for Class 3R would for the respective parameter combinations be higher than currently. While this has the advantage of being the less restrictive choice, it would in the view of the author also necessitate that a risk analysis is performed for each product to decide on the appropriate precautions and protective measures, particularly if eye protection should be worn or not. This would in most legal systems have to be performed by the manufacturer or on his behalf by a competent expert. It is the duty of the manufacturer to characterize the potential hazards of the product and provide information for safe use. The user at the workplace could base his decision regarding safety measures on the information given by the manufacturer. This would have the disadvantage that the risk within a certain class varies widely, reducing the value of that class in terms of providing information of a certain range of risks and indicating 'default' user safety measures.

The second choice would basically mean that Class 3R lasers would be restricted to cw lasers (or pulsed lasers where the peak power is limited to 5 mW) and $C_6 = 1$. While this might make some current Class 3R lasers into Class 3B lasers, it would have the advantage that Class 3R has a better defined understanding of risk, namely the level of risk as it was understood so far, as 'low risk' with reduced user requirements (such as no eye protection) in most countries.

Conclusions and Summary

It was pointed out that the current understanding of Class 3R lasers as 'low risk' can only be argued for cw output and when the accessible emission level was determined for $C_6 = 1$. For pulsed sources and for pulsed extended sources, the risk strongly depends on pulse duration, wavelength, spot size, distance of exposure, pupil diameter and other factors.

The currently ongoing revision of the retinal thermal exposure limits by ICNIRP and ANSI, if applied to the current principle of Class 3R allowing up to 5 x the MPE level at close distance, would allow output levels that, depending on laser parameters and exposure conditions, exceed the injury thresholds. The consequence would be that, in contrast to the principle of classification, the risk within a certain class would vary widely, from the relatively safe cw alignment lasers to pulsed lasers that would produce a retinal injury within milliseconds of exposure. Thus the class information on its own can no longer be used as guide for the appropriate user requirements and safety measures, and the general understanding of Class 3R also might have to be amended. A risk analysis would have to be carried out for each specific laser parameter combination and mode of usage.

The alternative to above scenario would be to limit Class 3R lasers to those types of lasers where experience has shown that they are low risk, which has the advantage of making risk analysis and the decision on appropriate user safety measures much easier, but has the disadvantage of being, for some lasers, more restrictive than the current definition.

References

[1] IEC 60825-1 Ed. 2.0 2007

[2] Code of Federal Regulations, 21CFR1040.10, FDA

[3] IEC 60601-2-22 (2007) Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment, IEC Geneva.

[4] Sliney DH, Mellerio J, Gabel VP, Schulmeister K. (2002) What is the meaning of threshold in laser injury experiments? Implications for human exposure limits. Health Phys 82:335-347.

[5] Schulmeister K., Stuck B.E., Lund D.J. & Sliney D.H. (2011) Review of thresholds and recommendations for revised exposure limits for laser and optical radiation for thermally induced retinal injury, Health Physics 100, 210-220.

[6] Guidelines on Limits for Laser Radiation, ICNIRP draft (2011), ICNIRP, Munich

[7] ANSI Z136.1 (2011) Draft, Laser Institute of America

[8] Schulmeister K. & Jean M. (2010) The risk of retinal injury from Class 2 and visible Class 3R lasers, including medical laser aiming beams, Medical Laser Application 25, 99–110.

[9] Schulmeister K., Husinsky J., Seiser B., Edthofer F., Fekete B., Farmer L. & Lund D.J. (2008) Ex vivo and computer model study on retinal thermal laser-induced damage in the visible wavelength range, J Biomed Opt 13: 054038.

[10] Laser Safety, Henderson R and Schulmeister K, Taylor & Francis, London, New York, (2003) Chapter 3

[11] Schulmeister K, ‘The apparent source’ – a multiple misnomer, ILSC 2005, ISBN 0-912035-79-X, Laser Institute of America, p. 91-98

Meet the Author

Karl Schulmeister, PhD, is a consultant on laser and broadband radiation safety at the Seibersdorf Laboratories, where also a specialized accredited test house is operated. Karl is a member of ICNIRP, the commission responsible for developing exposure limits for laser and broadband radiation on an international level. He is also the secretary of IEC TC 76 WG1, the working group responsible for IEC 60825-1. The research in his group over the last six years concentrated on thermally induced injury, leading to the development of a computer model that was validated for quantitative analysis of the risk for injury for a wide range of wavelengths and pulse durations.