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REGULATIONS REGARDING THE SALE AND USE OF CLASS 3R LASER PRODUCTS IN EUROPE

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Abstract

Depending on the type of product and usage, three different categories of legal requirements are identified that apply for laser products in Europe, in particular for the case that the exposure limit for the eye is or can be exceeded (Class 3R, 3B, 4): product safety legislation, i.e. what is allowed to be placed on the market; work place safety regulations if the product is used at the workplace; and what could be referred as event safety legislation, when the laser radiation can expose general population, for instance the audience in a cinema. All of these legal requirements are to a degree relevant for the manufacturer of laser products even though the latter two not directly. However, if the user of a device has to deal with significant safety measures and restrictions by the authorities, then this is a problematic situation also for the manufacturer of the product in terms of attractiveness of the product. The legal situation will be summarized and commented on for the case of Class 3R laser products and laser shows.

Overview

The three identified groups of legal requirements that affect laser products are summarized in Table 1.

The overview will use laser shows as example, since this is a group of products where some experience exists and which can be affected by all of the listed legal requirements; laser illuminated projectors will also be mentioned, since this is currently a hot-topic.

It depends on the location of use and the category of the user which specific legal "column" in Table 1 becomes applicable. Regarding the question of what is allowed to be placed on the market, professional laser show products fall under the Low Voltage Directive. There is no "problem" to market Class 3R, Class 3B or Class 4 systems for professional use (but it is of course necessary that the manufacturer provides information for the safe use of the product and necessary protective measures). These systems have to be made safe by the specific installation (the other two columns). Devices that are considered as consumer products fall under the general product safety Directive GPSD and the requirements here for a safe product are more stringent, since it cannot be assumed that (if higher power devices are used in the party-room) the user will ensure proper installation such as minimal safety distances.

Table 1. Overview of three legal groups in Europe

	Law regarding Placing on Market	**Work Place Safety Legislation**	**Event Safety Legislation**
	100 % harmonised in Europe; Market Surveillance agencies well networked	Minimum requirements harmonised: AORD; countries can be more restrictive (Laser Safety Officer for instance)	No harmonisation at all within Europe, sometimes not even within one nation (federal responsibility); general practices for laser shows established
Public access (cinemas, discos)	No restrictions beyond EN 60825-1 – Class 4 „allowed"	If exposure of workers > ExpLimit: safety measures; usually no third party analysis, info by manufacturer important	No exposure of public > ExpLimit (installation, guarding); local officials might require third party safety analysis; info by manufacturer can help
Workplace	Same as above	Same as above	N.A
Consumer product (home use)	GPSD – product has to be "safe"; if > Exp Limit: risk for injury analysis	N.A.	N.A.

The second column applies to products used at locations where employees can be exposed, which can be the case for laser shows as well as for projectors. The minimal requirements to protect employees are harmonized in Europe, and for lasers and optical broadband radiation, there is a specific directive under the general European workplace directive, the Artificial Optical Radiation Directive, AORD. The AORD lists the

exposure limits for the eye and skin as "hard" dividing line between having to realize a list of protective measures (such as wearing eye protection) or not. While this would not be such a big deterrent if it would be limited to the projecting room for a laser show or cinema projector, it would be a problem if the exposure limit can be exceeded by employees in the audience room. Also, any restrictions for the employees for products such as data projectors ("beamer") would not be acceptable in terms of effort except for very specialized higher power products with fixed installation where the installation is such that the normal participant in a meeting would not be exposed above the exposure limit (and would not have to be trained, etc.).

The third legal column is often overlooked in the discussion regarding restrictions for the use of laser products, and that is when the general public can be exposed. The safety of the general public is not harmonized within Europe and is governed locally by what could be referred to as "event safety legislation". In many countries, such as Germany and Austria, there is a federal system where the different provinces have their own legislation, so this type of legal requirement is sometimes not even harmonized within a nation. For instance, the province of Vienna in Austria has its own "Cinema-Law" [1]. The legal requirement here is usually very general and does not place specific requirements on laser exposure of the audience other than it has to be safe. Due to this room for interpretation, the practice varies widely across Europe and often also across a given nation. In some cases, an official third party safety assessment is required for each installation; other officials do not require this. The specific standards that exist in some countries, such as DIN 56912 [2] and ÖNORM S1105 [3] are not legally binding requirements as such, but are often used by the authorities as baseline and guidance but with considerable flexibility. IEC TR 60825-3 [4] plays relatively little role in Europe, as it is a technical report and such was not published on the European level as European guideline.

It is clear that in all cases, the manufacturer of the device has a central role in optimizing the safety of the product itself, and if a certain level of emission is necessary for the functioning of the device, to provide information for proper installation.

Product Safety Legislation

The legal system in Europe for placing laser products on the market differs from the US, as in the US there is a required compliance with very specific rules for laser products in the form of 21 CFR § 1040, and it is also necessary to submit specific information to the CDRH for each type of laser product placed in the market. In Europe, there is no specific regulation for placing laser products on the market and they fall under the respective product safety directive, depending on the type of product, Low Voltage Directive, Medical Device Directive, Toy Directive, Machinery Directive, or for consumer products also under the General Product Safety Directive (GPSD); for more detailed information see for instance the blue guide [5], or for lasers a discussion in [6]. There is no reference made in these legal requirements regarding a certain permissible classification of a laser product, but it is the general requirement that the product has to be "safe", i.e. the associated risk is to be considered acceptable. For the GPSD, there is official guidance regarding a formal risk analysis process specified in the form of a European Commission decision [7] which serves national market surveillance authorities as basis to decide if action against a certain product is to be taken or not. This set of legal requirements is completely harmonized within the European Union and is the core of the common market. Also, particularly for consumer products, the national market surveillance authorities are well networked and use an internet data-base to exchange information on unsafe products (RAPEX). A mere compliance with EN 60825-1 is not sufficient for many cases, particularly for consumer products where an open Class 3B beam, for instance, will usually not be considered as sufficiently safe. For professional laser shows, for instance, mere compliance with EN 60825-1 (classification as Class 3B or Class 4 and warning labels) is sufficient, and it is the responsibility of the installer and event manager to insure that the workers and the public is safe. Thus, EN 60825-1 has the status of a harmonized standard only under the Low Voltage Directive, not under the GPSD. The European Commission plans to mandate CENELEC (the European equivalent of IEC, responsible for standardization of electrical products) to develop a standard where the compliance with the standard lends a presumption of conformity for the GPSD, and this standard will then be listed as harmonized standard under the GPSD. However, this mandate at the time of writing is only a draft. For laser pointers sold as consumer products, the common interpretation of the GPSD is that the power should be limited to Class 2, and Austria has issued a national by-law to the law that transposes the GPSD especially for placing laser pointers on the market ("laser pointer by-law" [8]).

The concept of the draft mandate allows the standard (that is to be developed) emissions higher than Class 2 if it is necessary for the design of the product. However, clearly, the stringent requirements of the GPSD to permit only "safe" products would still apply, i.e. the product would still have to be "safe" (which does not mean absolute safety, i.e. a knife in that sense is also considered as safe, since its sharpness is necessary for the functioning, a safer design is not practically possible and it is generally known that a knife is sharp and careful usage is necessary). According to the principles of product safety, a product primarily has to be made safe by design, and only if this is not possible or the cost to reduce the risk by design not in proportion to the risk, are user precautions permissible. Also, for consumer products where the point is to see the laser radiation, such as alignment lasers or projectors, to wear eye protection would not make sense.

A laser pointer to be used indoors to point at objects will usually not need to have a higher power than 1 mW to be properly seen, particularly if it is in the green wavelength range, and the argument that a higher power is needed for the functioning of the product will probably not hold when a laser pointer with for instance 5 mW (Class 3R) is placed on the market and market surveillance authorities take action. However, other products, such as leveling lasers to be used outdoors which rotate or fan out, if the output can be shown to be "safe" (with negligible risk for retinal injury) in principle comply with the requirements of the GPSD. For such an argument it will also be necessary to demonstrate that tolerance from device to device is small as well as that reasonably foreseeable single faults do not lead to higher emission levels, as otherwise the market authorities could still insist on Class 2 levels with the argument that some buffer is needed to account for variability in the output power. If it cannot be shown that the risk for injury is negligible and the product cannot be made safe by design, there is the risk that market authorities will take action. This can also apply to Class 3R products following the update of IEC 60825-1 which allow significantly higher emission levels for pulsed sources, so that, depending on the product, Class 3R cannot generally be regarded as "very low risk" [9]. Of course, as is argued by some colleagues, the risk is lower than for a Class 3B laser product with the same wavelength, beam geometry and pulse pattern, but the criterion is not to be less hazardous than Class 3B, the criterion is not to exceed acceptable levels of risk on an objective level, which might not be possible to show for some Class 3R (pulsed for instance) according to the 3rd edition of IEC 60825-1. As the minimum action, a risk analysis is necessary to characterize potential exposure scenarios and the respective risk for injury.

Work Place Safety Legislation

Class 3R is somewhat of a problematic laser class on the back ground of the AORD in Europe as the output can exceed the exposure limit, but the emission (and exposure) is known to be of low risk, at least for cw beams. While in some countries such as Germany, there were rather strict work place safety rules in place also before the AORD and there, Class 3R was treated in the same way as Class 3B in terms of user requirements, in other countries such as in Austria, Class 3R for professional use, such as alignment lasers on building sites, was not seen as critical and usually would not require special protective measure with the exception of telling the employee not to look into the beam. With the installment of the AORD and the national transpositions, it is not possible to be less restrictive than the AORD (it is allowed to be more restrictive) and the AORD takes the exposure limits as strict dividing line between safe and potentially hazardous not to be exceeded in any case. This is a difference to product safety legislation where the actual risk associated to a product is the legal criterion; for the workplace in Europe, strict exposure limits are given in the directive and national by-laws with little freedom. For the case of professional alignment lasers as used in medical lasers (as aiming beams) or for industrial cutting laser machines, it can be the result of a "risk evaluation" (to be performed for every work place by the employer), that no exposure to the beam will occur because of the orientation of the beam and because employees are trained, so that the exposure limit is not exceeded and eye protection is not needed; this is the concept as developed in Austria by the responsible Ministry to be issued in a formal guideline where the author was involved. The low risk for injury for the case that exposure does occur is the basis to accept that there is a remaining probability for exposure in the abovementioned scenario, for instance due to reflections. If the application is such (for an alignment laser used at the height of the heads and people looking towards the laser) that it cannot be argued that exposure is not expected to occur, then eye protection is needed also for Class 3R. In Germany, the national transposition of the AORD (OStrV [10]) is more restrictive, as a laser safety officer is required also for Class 3R for instance. For Class 3B and Class 4 (obviously also in Austria), the criteria for wearing eye protection and for the treatment of hazard area are stricter regarding what is accepted as argument that exposure will not occur (for instance including potential reflections) as compared to Class 3R. For the case of higher power beams of Class 3B and Class 4, if exposure above the exposure limit can occur, then eye

protection within the hazard area is needed, as well as training of the employees regarding potential hazards, safe working procedures and personal protective equipment. Also, the hazard zone needs to be marked and access restricted to trained personnel. While these measures are commonplace and generally accepted for instance for industrial or medical lasers, they will be problematic for products such as data projectors where the hazard zone (zone where the exposure limits are exceeded) extends into areas where employees (participants at a meeting for the case of a meeting room projector, or employees selling pop-corn in a cinema, or bar keepers in a bar with a laser show) can be exposed. Clearly the installation needs to be in such a way that the exposure limit is not exceeded for these generally accessible areas. These requirements (prevent exposure above the exposure limit for generally accessible areas) are equivalent to the requirements of event safety laws to protect the public. For the projection room, labeling, training and personal protective equipment should be less of a problematic issue.

Event Safety Legislation

This type of legal requirements is not harmonized at all in Europe, and often not even within a state. The requirements regarding generally accessible areas will be very similar in practice to the requirements for work place safety, namely that exposure above the exposure limit needs to be prevented by installation, i.e. either by selecting a proper height of the beam above the audience, or by restricting access to areas close to the projector where the exposure limit is exceeded. As mentioned in the overview, the respective laws are rather general and vague and the practice depends in a significant way on the interpretation by and vigor of the local authorities. Since no exposure limits are prescribed on a legal basis, there is somewhat more of a potential freedom to argue with levels of safety even for the case that exposure limits are exceeded for instance because they are based on 7 mm pupils. In some cases, local officials require an expert opinion of a radiation protection/laser safety expert to analyze the installation. If the conclusion is that the installation is considered safe, then the local authorities usually do not require further safety measures; but again it is emphasized that the situation is highly non-homogenous and not only depends on local regulations but also on the interpretation and vigor by the individual local inspector.

Conclusions and Summary

Three groups of legal requirement that can impose safety measures or restrict the use and sale of laser products in Europe were identified and briefly discussed. The level of harmonization for these three columns vary widely: from a completely harmonized situation for product safety legislation which is the foundation of the free market in Europe, to minimal requirements laid down for work-place safety, where national requirements can be stricter, to the completely non-harmonized requirements by event safety legislation when the laser is used in publically accessible areas.

Also the legal status of exposure limits is different: since the adoption of the AORD, exposure limits for laser and optical radiation are legally binding and one cannot argue with a certain safety factor in the exposure limits, which is to a degree possible for the GPSD as well as, depending on the national legislation and interpretation thereof, for the event safety.

Only the product safety legislation (the national transpositions of the Low Voltage Directive, or the General Product Safety Directive) are directly addressed to the manufacturer; however, the other two groups of legal requirements

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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. He is the secretary of IEC TC 76 WG1, the working group responsible for IEC 60825-1. The research in his group over the last eight 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 both for laser as well as for broadband radiation. Karl also served as consultant for the Austrian Ministries responsible for the transposition of the AORD and of the GPSD.