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PRINCIPLES FOR CONSISTENT APPLICATION OF THE IEC LASER PRODUCT SAFETY STANDARD BASED ON LEGAL REQUIREMENTS

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Abstract

It is pointed out that the basis for the development of product safety standard should be to help the manufacturer to comply with product safety legislation. Standards are usually only voluntary and should be written to be 'good enough', when the manufacturer chooses to use them, to help the manufacturer comply with the law and to correspondingly reduce his risk for compensation and forced removal of the product from the market.

Engineering requirements specified in IEC 60825-1 should be orientated on the level of safety that is expected from consumer products and not from industrial materials processing installations, where a certain level of awareness of hazards presented by a machine can be assumed. It is argued that currently, as the classification does not consider radiation accessible to the user during maintenance, we have the unsatisfactory situation where a Class 1 laser product might not comply with general product safety legislation in Europe and most likely also elsewhere.

General principles of tests for classification and the understanding of the classes are discussed which should help to consistently apply the standard to a variety of products as well as to help the manufacturer to reduce the risk for compensation and for withdrawal of the product from the market.

1. Introduction

The standard IEC 60825-1 is the international laser safety standard in terms of product safety, i.e. it specifies requirements that are addressed to manufacturers of products that feature laser sources. In the continued development of IEC 60825-1, discussions in the responsible technical committee, TC 76, and national committee's comments on draft documents often relate to the question "which engineering features should be specified as requirements", or "which engineering features are necessary so that the product can be classified as Class 1". These are difficult questions, as two opposing aspects need to be considered:

- on the one hand, the engineering requirements should not be too stringent, as they usually infer cost to the manufacturer in design and production of the product
- on the other hand, the requirements should be sufficient for the product to be considered as "safe" under product safety legislation, so that the (financial) risk for the manufacturer in terms of product liability and the risk that national market surveillance authorities impose corrective actions (up to withdrawal of the product from the market or even recall from the consumers) is minimised.

The above opposing aspects are complicated as they may well depend on the type of the product, i.e. different criteria will be acceptable for consumer products and for industrial materials processing installations; however, the standard IEC 60825-1 currently applies equally to all laser products and does not provide for differences in product type and usage.

The relationship of the standard to product safety legislation seems to be often neglected in these discussions. We would like to discuss this issue here with emphasis on European product safety legislation – reviewing basic principles first and then presenting the view of the authors on specific current issues relating to the draft second edition of IEC 60825-1.

2. European product safety legislation vs. standards

It is important to note that it is not mandatory within the "New Approach" (which is current legal practice in the European Community plus the signatories of the Agreement on the European Economic Area) to comply to specific product safety standards published by CEN or CENELEC (i.e. to EN 60815-1 which is identical to IEC 60825-1).

"New Approach" of 1985

Essential requirements stated in directives are mandatory and compliance enables free circulation of goods

Standards are voluntary

It is only the 'essential requirements' as defined in the applicable Directives that are mandatory, and these directives need to be transposed into national legislation by all member states. It is an important principle that these essential requirements are only very general and 'superficial', intentionally refraining from giving technical details. Essential requirements define the hazard and risks to be dealt with, but do not specify the technical solutions for doing so. This allows the manufacturer the highest flexibility and does not impede technical progress. Harmonised standards of which the references have been published in the Official Journal of the EC are intended as a *voluntary* tool for the manufacturer that should help him to fulfil the essential requirements – and applying these standards leads to the presumption of conformity with the essential requirements of the directive. But it is not mandatory to use the standards; the manufacturer may choose not to follow a harmonised standard. In this case, he must prove that his product is in conformity with the relevant essential requirements. In 1990 the "Global Approach" introduced a modular system for conformity assessment (e.g. requiring quality systems or third party testing in some cases, depending on the type of product)..By labelling a product with the CE-mark the producer or his representative in the EU declares that the product fulfils the essential requirements of one or (if applicable) more directives. Without CE-mark the product shall not be placed on the market.

These, in short, are the basic principles of the so called New Approach laid down in 1985 and it is all the more striking that standards are frequently portrayed as mandatory even by safety consultants and experts while this basic information on the voluntary application of harmonised standards is freely available [see for instance www.europa.eu.int]. However, it is possible that some standards or certain parts of standards are declared compulsory by national legislation which may lead to some confusion.

Some important practical aspects follow from the voluntary nature of the standards which, in the view of the authors, are important in the selection of those requirements that should be stated in a product safety standard:

- the manufacturer remains liable for damage compensation even when he has used appropriate standards
- the harmonised standards are a tool to help the manufacturer to comply with essential requirements, i.e. to design a safe product
- the manufacturer has to decide, based on the current state of science and technology, whether the standard is sufficient ("good enough") for his product
- it is a legal requirement for the manufacturer to build the product following the state of the technical art (the standard might lag behind the state of the art)

Applying the standards and therefore having the presumption of conformity will certainly reduce the risk of liability claims. However, this presumption is not a legal 'guarantee' on behalf of the standardisation body that there is no risk at all.. It might well be that a standard is not "good enough" for the application to the particular product and the manufacturer is liable when it is considered that he should have realised that the standard was not "good enough".

Q: If I manufacture my product in compliance with a harmonised standard will I still be liable for any damage caused by it?

A: Yes. The responsibility for the safety of the product remains with the manufacturer - with or without the use of harmonised standards.

(from: Frequently Asked Questions*, in: New and Global Approach – Multimedia learning tool,* ***EOTC - European Organisation for Conformity Assessment,*** *http://www.eotc.be/)*

Three types of legal risks need to be distinguished:

- penal law which, for instance, relates to prosecution following bodily injury (such as eye damage or skin burns)
- civil or private law including product liability (i.e. financial compensation if bodily or other damage occurred).
- administrative law which empowers authorities to take measures such as withdrawal from the market and administrative fines

2.1 Civil law – product liability

When a manufacturer complies to all appropriate harmonised standards, this is usually sufficient for the manufacturer to be exonerated in terms of penal law.

However, regarding product liability, the manufacturer will still be liable - even if he complied to all relevant standards - because one of the basic principles of

product liability legislation (dir. 85/374/EEC) is that compensation may be claimed without fault on the part of the producer. Therefore he is still liable even if he can prove that he respected his duty of care (for instance that he followed a standard).

A product is considered as 'defective' when it does not provide the safety which a person is entitled to expect[1].

The manufacturer does not need to pay for compensation when

- he can show that the state of scientific and technical knowledge did not enable him to discover the existence of the defect of the product. From this it follows that the manufacturer has to follow the state of the knowledge, and it is important to note that EN standards are not considered to be sufficient in this respect (Court of Justice case C-300/95).

- when the defect was caused due to compliance with mandatory regulations, for instance when a standard is declared as mandatory by national legislation (which however is rather rare, and in Austria is, for instance, only the case for some selected electrical safety standards).

Thus, by following a harmonised standard, it is easier for the manufacturer to argue that he could not have been expected to realise that the product was defective and he thereby reduces his legal risk, but it is not completely precluded. In many cases there is no 'ideal' harmonised standard that fits the product 100 % so that the manufacturer can 'blindly' follow the standard and does not need to consider any specific risks of his product. A harmonised standard also does not necessarily cover all essential requirements and, also, more than one directive may apply.

2.2 The General Product Safety Directive

The General Product Safety Directive (GPSD, 2001/95/EC) is aimed at ensuring that consumer products placed on the EU (EAA) market are safe. This directive complements the network of New Approach Directives in that it provides the legal "safety net" for the safety of consumer products which are not at all or not sufficiently covered by more specific New Approach Directives. An example where the GPSD would become effective is laser pointers which do not fall under the low voltage directive (for the time being the LVD applies only to DC voltages above 75 V) and, in this case, radiation safety is provided for by the general requirement of the GPSD that a consumer product needs to be safe. The GPSD is not a New Approach Directive and does not require CE marking nor a declaration of conformity. However the new GPSD has some elements of New Approach Directives like the publication of standards in the O.J. including a presumption of safety. However, the GPSD uses different terms (eg "general safety requirements").

For the application to laser consumer products and the current discussion in TC 76 it is important to note that a product is considered 'safe' when it 'does not present any risk or only the minimum risks compatible with the product's use under normal or reasonably foreseeable conditions of use including … maintenance…'. Thus

- the GPSD specifically lists maintenance as condition of use

- and it applies not only to normal use but to all reasonably foreseeable conditions of use, which is legally understood to include foreseeable 'non-intended use', or 'incorrect use'.

The borderline between 'non-intended' or 'incorrect' use (the German national law uses the term 'Fehlgebrauch' and misuse (in German: 'Missgebrauch') is crucial – 'non-intended' or 'incorrect' could be considered as slight misuse (e.g. by children) and should be taken into account but gross misuse is certainly not included. Naturally, the GPDS does not specify technical criteria for what is considered safe, but rather a generic definition, including the state of the art and expectations of the consumer. It is also interesting to note that the GPSD does not only apply to consumer products that are specified as such by the manufacturer, but also to 'professional' (industrial) products when they are used by consumers.

The GPSD obliges the Member States of the EU to enforce the requirements on producers and distributors by appointing authorities in charge of market surveillance and enforcement. Typically, the authority monitoring the product safety is different to the national authority that monitors safety of the workers at the workplace, just as product safety standards do not relate to safety measures to be taken by the worker. The powers that are given to the authorities are

[1] See for instance http://www.europa.eu.int/comm/consumers/cons_safe/prod_safe/defect_prod/directive_en.htm

regulated in the respective national administrative law. The EC-Directorate General Health and Consumer Protection has already published a list of national contact points for the rapid alert system RAPEX and a list of competent authorities for notifications of dangerous products by companies (see http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/index_en.htm). Following this administrative legal framework, national surveillance authorities have the power to

- organise random and spot checks
- to take samples of products
- to subject them to examination
- to require all necessary technical information from the manufacturer

and they must take action to enforce conformity when they discover that a product is not in compliance with the provisions of the applicable directives. The specific corrective action depends on the degree of non-compliance. E.g. based on the GPSD, in case of substantial non-compliance (which is associated with risk to the health and safety of citizens), if no other measures are sufficient to maintain a high level of consumer protection the authority will ultimately

- restrict or prohibit the placing of the product on the market
- or (additionally) initiate recall from the consumers

In less severe cases of non-compliance or level of hazard, placement of warnings on the product, or engineering safety features can be required. Given the use of referenced harmonised standards in the framework of administrative law, the governmental authority has to prove to the manufacturer that the product is "defective" (i.e. not safe enough). When the manufacturer has followed a harmonised standard and the national authority challenges the safety of the product, this usually also invokes the so called "safeguard clause" which means that the harmonised standard is also challenged and might in consequence, if found to be insufficient to provide the manufacturer with the necessary level of presumption of conformity, be withdrawn from the list of harmonised standards in full or partially.

In practice this means that action against the manufacturer (with corresponding potential financial losses by the manufacturer) can take place even if no accident has occurred and independent of any case of product liability. Complaints by competitors or consumers, as well as general market surveillance activities (random checks), often lead to closer examination of a product and, if considered as not sufficiently safe, to corresponding action.

The authors point out that this principle of product safety legislation is in effect not only in Europe but suspect the basic principle is in operation in many countries of the world. The only instance when the manufacturer is exempt from liability when he complies with the (laser safety) standard is when the requirements are defined as national law or the standard is defined as mandatory by national legislation. One possible example of such a case might be the US system of federally required compliance of laser products with the Product Performance Standard 21 CFR 1040.10 and 1040.11, i.e. the authors suspect that compliance with the letter of this standard precludes product liability.

3. Relevance to IEC 60825-1

The above general principles have some bearing on the laser safety standard IEC 60825-1 or, in particular its European equivalent, EN 60825-1 which are discussed below.

From the nature of standards as a complimentary tool for compliance to legal requirements it follows that in the development of the standard IEC 60825-1, the responsible committee - TC 76 - and the national committees of IEC needs to strive to define requirements such that compliance to the standard reduces the risk for the manufacturer for product liability and for corrective action by market surveillance authorities as far as possible. If the standard is 'not good enough' then the manufacturer faces both of these above risks even if he complied with the standard. It is important to keep in mind that the standard is not the legal basis and it is not correct to believe that all the manufacturer has to do is to comply with the standard for not being liable or for his product to be considered as generally safe. It is of no help for the manufacturer if the standards committee does not specify some engineering safety features which a civil or administrative court would consider necessary! In this sense the responsible TC should have as basic criterion for requirements not what they think is necessary for a product to be safe but rather what a court of law based on applicable product safety legislation considers necessary to comply with legal requirements.

The authors have also sometimes experienced a tendency by some manufacturers to interpret the standard in a favourable way with the assumption that

in case their product safety concept is challenged, they can always argue 'but this is what the standard says' even if they actually suspected themselves that the standard does not mean the requirement in the way it was interpreted. This tendency of trying to 'bend the rules' needs of course to be discouraged and manufacturers as well as standards experts need to rather interpret the standard (in the sense of deriving specific technical solutions from the requirements stated in the standard) in a way which ensures compliance with product safety legislation. Rather than 'blindly' following the standard or even worse, pretending one did not know better when the rules of the standard were interpreted in a favourable way, the manufacturer is required to critically consider if the requirements given in the standard are sufficient for his specific type of product, and thus in some cases would even have to go beyond the requirements of the standard to make the product 'safe'. An example of such a misinterpretation, in the view of the authors (and a number of other TC 76 experts which were consulted by the authors) is the interpretation that tests for classification can consider do's and don'ts as specified in the user manual rather than performing tests for all technically possible configurations of the product (see below for a more detailed discussion).

In discussions regarding what requirements should be included in the standard, often the argument of the additional cost for a required engineering safety feature is used. Of course it is important to consider the impact of the standard in this respect; however, it should also be considered that substantial cost for the manufacturer might incur if the standards committee does *not* specify some engineering requirement, namely when it would be considered as necessary by a judge to make the product comply with product safety legislation. While not requiring some engineering feature in the standard saves the manufacturer some production cost, it might well cost him compensation if damage to health or property occurs, or if he is forced to withdraw his product from the market, or change the product at a later stage (which may also be enforced without an injury having occurred).

The goal of the laser safety standard IEC 60825-1 is thus to help the manufacturer to design laser products that are considered safe according to product safety legislation, at least for Class 1 products (an open beam Class 3B or Class 4 product is most likely not considered as 'safe' for consumers even if it complies with all requirements of IEC 60825-1, see below).

3.1 Detail of specifications

Sometimes arguments arise in the committee regarding the detail of specification of the engineering controls – it is argued by some that specifying as few details as possible (not even in clarifying notes) leaves the manufacturer the most freedom and flexibility to decide for himself what he has to do to make the product safe. While this is not incorrect, it does not help the manufacturer, who is looking for guidance and legal security, when he decides to follow the standard. Only providing very general requirements does provide the manufacturer with a larger freedom but it also incurs higher cost if the manufacturer has to develop the detailed technical requirements himself rather than following the standard. Put to an extreme it would provide the manufacturer with the highest level of flexibility when IEC 60825-1 would only say "The laser product has to be safe". This is not much help for the manufacturer, as this is what the product safety laws say already.

Obviously it is not possible to specify all necessary technical details in a standard which applies to such a wide variety of products (from toys to medical laser products to industrial machines), but the authors would like to argue that the standard should be as specific as possible and at least should provide clarifying notes and examples, especially for requirements which are complicated to understand and are known to be prone to be misinterpreted. In the past years, during the development of the second edition of IEC 60825-1, proposals to add clarifying notes have also led to a surprising level of discussion, as it turned out that even within TC 76 the existing requirements were interpreted in quite different ways. While it would be simpler for the TC to avoid having to come to a consensus and to leave the requirements without clarifying notes (as this made everybody "happy" before), it is the view of the authors that such a room for different interpretations leading to substantially different levels of product safety shall by all means be avoided. The criterion again should not be to have requirements which were able to reach some level of compromise within the committee but rather requirements that assure that the product is safe according to product safety laws.

3.2 Challenges for IEC 60825-1

A serious challenge which is faced by TC 76 is that a laser product can be one of several categories of products, including toys, general consumer products, medical products or big industrial laser processing machines. The level of safety which is expected from these types of products depends on the type of product

and, at least in Europe, there are also specific Directives for different types of products. Additionally, due to the agreement between CENELEC and IEC, the goal is to have the EN 60825-1 identical to IEC 60825-1 and thus the document needs to satisfy world-wide needs, and product safety laws and their interpretation and application differ from country to country (although the principle is usually the same) all over the world, and even within a given country it is a) likely that different levels of safety apply to different product types (such as toys versus industrial installations) and b) even for a given law that applies in a given country for a given product, the decision of the court might well be different for the same case from court to court. In this respect it is important to note that the views expressed in this paper are those of the authors only, and the actual ruling of a court might well be different.

In the past the cost of lasers that represented serious hazards were such that they were self-regulating as too expensive for consumer products or a wide general market and one could assume some level of training or professional usage for higher power (embedded or open) lasers. However, in the past years laser diodes and recently diode pumped solid state lasers have become cheap enough to become generally available and affordable even for 'home use' (as an example, the authors were approached by a distributor who intended to market a 50 mW disco laser (532 nm) for home use – since the scanning was not sufficient to reduce the exposure to below the MPE (when the product was switched on, the beam did not even scan for several seconds) we could convince the distributor that the product is not suited for private home use. This new availability of higher power lasers for 'non-professional' use also changed the scenario for the laser product safety standard in a certain way.

Consequently, TC 76 is faced with the decision whether it should orientate the level of safety rather on consumer products or rather on professional industrial materials processing machines. To discuss this issue it is also important to consider that IEC 60825-1 as a document on its own is really not sufficient to cover the safety of a given product:

1) it only covers potential eye and skin safety; other hazards might have to be dealt with as well, such as electrical safety or fumes for materials processing

2) an open beam Class 3B and Class 4 laser product also fully complies with the requirements of IEC 60825-1 in that it is labelled as hazardous, but it would not comply to most product safety legislation, especially when marketed for non-professional use

Due to this scope and nature of the laser safety standard, IEC 60825-1 is often referenced by the actual product safety standard, for instance by IEC 60601 for medical laser products, where in part 2-22, specific, additional manufacturing requirements are specified. The same applies to audio visual products (IEC 60065), IT equipment (IEC 60950-1), electrical toys (IEC 62115) and laser processing machines (ISO 11553). All of these standards are product specific standards and they reference IEC 60825-1 regarding laser safety, often specifying that the product shall be of Class 1, sometimes even specifying test methods to determine the class which might be considered as to go beyond the test procedures specified in IEC 60825-1 (for instance, according to the toy standard, tests are to be performed including breaking of the toy). The medical laser product safety standard IEC 60601-2-22 'allows' Class 3B and Class 4 for medical products, which is in the nature of the product (actually, the standard only applies to Class 3B and Class 4 lasers), but specifies additional product safety engineering features which are not required under IEC 60825-1.

When a product only complies with IEC 60825-1, without any additional requirements, it is in many cases not considered as a 'safe' product (i.e. is considered as 'defective'), for instance open beam Class 3B and Class 4 lasers. This is often overlooked as it is generally expected from a 'safety standard' that when a product complies with the requirements of the standard, it should also be 'safe'. In that sense, IEC 60825-1 should not really be considered a product safety standard in the usual sense, but it is necessary that IEC 60825-1 is referenced by other, product specific safety standards, which then require either additional engineering features, such as is the case for IEC 60601-2-22 for medical Class 3B and Class 4 lasers, or restrict a certain type of product to Class 1 only. In that sense the authors would like to argue that IEC 60825-1 should not even be listed as harmonised standard under the low voltage directive, as the level of safety just based on the compliance with IEC 60825-1 is in some cases not sufficient to comply with the essential requirement that is stated in the low voltage directive as "radiation which causes danger is not produced". It is rather that the product specific standards listed above are the harmonised standard in the sense of the term, and they should refer to IEC 60825-1 but specify additional requirements or limit the 'allowed' class of the laser product.

The authors would like to argue that a Class 1 product when classified according to the tests specified in IEC 60825-1 should be considered as 'safe' for general consumer products – this should be the basic level of safety that should be achieved, so that consumer product safety standards can simply refer to IEC 60825-1 and require that a product that falls under the scope of their standard shall be for instance Class 1.

The machine laser safety standard ISO 11553 that is the harmonised standard for the machinery directive, does not refer to classes, i.e. 'allows' Class 3B and Class 4 laser products, but requires (as is already an essential requirement in the law) an enclosure. ISO 11553 also covers hazards other than eye and skin hazard. For professional machines, it is acceptable that some engineering safety features that would be considered as necessary for consumer products, may be replaced by user safety measures and the product would still be considered as to comply with machine product safety legislation (but it would not be Class 1). This specific aspect is discussed further below.

3.3 LEDs

The inclusion of LEDs in the scope of IEC 60825-1 was for some time a source for hot debate and often the standard, for the European situation, was stated to be 'mandatory' even, for instance, by national industrial associations [LEDs in General Lighting Optical Radiation Safety, Zentralverband Elektrotechnik und Elektronikindustrie eV, March 2002]. As pointed out above, this is clearly incorrect and the voluntary nature of harmonised standards was always an important (and should be a well known) aspect of the New Approach. On this principle, a manufacturer of an LED product could have used broadband incoherent exposure limits given by ICNIRP or IEC 60825-9 to ensure the safety of his product. Following the principle that the product needs to be manufactured to a "high standard", which is potentially beyond the current edition of harmonised standards, it could be argued that, in some cases, the manufacturer would have been obliged to actually use the incoherent limits, for instance to ensure safety for young children using near UV LEDs in toys, as the action spectrum for photochemical retinal damage for the aphacic case might produce lower limits than the near UV laser limit for Class 1.

4. The understanding of the class

As pointed out in the previous section, compliance with the standard IEC 60825-1 does not necessarily make the product safe, i.e. Class 4 and Class 3B laser products are compliant with the standard in as much they are labelled as potentially hazardous. However, it is argued by the authors that the requirements specified for a product to achieve Class 1 shall be such that the product is considered as 'safe' according to general product safety legislation for consumer products. This is what would also be expected from a Class 1 product from third parties who use the standard, where the class bears some basic information that is provided by the manufacturer to characterise the potential hazard of his product and this information is then used by third parties:

- for national legislation (for instance restricting the sale of certain products, such as limiting marketing of laser pointers to Class 2, as is done in some countries of Europe)
- other standards committees (see previous section)
- users (especially professional users of Class 3B and Class 4) to have information if risk analysis is necessary, and following the risk analysis, to decide on any necessary user precautions

The way that Class 1 laser products are generally described in laser safety training courses and treated in user guidelines (for instance IEC 60825-14) or national user regulations should be also considered by TC 76 regarding necessary requirements to achieve the level of safety that is expected from the product when it is labelled as Class 1. Important associated user aspects that are typically associated to Class 1 are:

- no laser safety officer is required
- no training for the user regarding eye or skin safety is necessary
- no risk analysis needs to be performed to determine if user precautions are necessary

These expected 'properties' of Class 1 have a bearing for instance on the question on whether user maintenance should be included in the test for classification or not: if an embedded Class 1 laser product that is correctly classified according to the test requirements of IEC 60825-1 can provide access to hazardous beams for the user (for instance during user maintenance) than the above general understanding of Class 1 is wrong, and in this case a laser safety officer might be necessary for Class 1 laser products so that the user can be appropriately trained and a risk analysis is performed to determined appropriate user precautions, including for instance eye protection for the user when he carries out the maintenance tasks. It is argued that rather to amend the general understanding of Class 1 to include "may require

access to high power hazardous radiation for user performed maintenance“ the test for classification should be amended to include radiation accessible during user performed maintenance.

4.1 Limitations of the standard

Whatever the requirements are that are defined in IEC 60825-1, it is very important that the standard IEC 60825-1 describes in detail any limitation it might have, so that the manufacturer and other standards committees can decide whether the requirements of IEC 60825-1 are ‘good enough’ for them or not. This applies for instance to the case of access to radiation for embedded laser products in special situations such as service, but also regarding assumptions of eye movements (which might not be present during some medical procedures which might make a Class 1 laser product hazardous) as well as assumptions in the measurement criteria to assess the accessible emission level, where for instance viewing with high magnification eye loupes or exposure while using large telescopes might be hazardous for some Class 1 laser products. The second edition of IEC 60825-1 which is currently under development is supposed to include an appendix discussing the limitations of the standard.

4.2 Understanding of Class 3B and Class 4

As discussed above, Class 1 is generally understood and described in simplified descriptions as often presented in laser safety trainings and guidelines as ‘no eye hazard’. The oversimplified and therefore wrong description of Class 3B and Class 4 is often ‘always hazardous’. This misconception of Class 3B and Class 4 as higher power open beam products with large hazard zones (by some laser safety experts referred to as the ‘Star Wars syndrome’) is a major problem for a consistent understanding and treatment of the classification. Class 3B and Class 4 laser products also includes enclosed sources and sources with relatively small NOHDs, as well as sources where higher power levels of radiation only becomes accessible in special situations and not during normal use, such as for the case of a single fault, special settings of the output characteristics, and (depending on the decision of whether to include maintenance or not) maintenance, and so on.

It needs to be accepted by users, manufacturers and work place safety inspectors that these products might well be considered safe for regular professional use in the workplace and the classification as Class 3B and Class 4 indicates that there are situations (which might be rare) where the higher level of radiation can become accessible. Based on this information of the class, some level of risk analysis is called for and some level of training of the worker. For a well designed, safe product, this level of risk analysis and level of training is typically not very time consuming. All too often the meaning of ‘open high power beam’ is mistakenly and automatically associated with Class 3B and Class 4, so that it happens that the work place inspector asks for eye protection to be worn in the room where an enclosed laser machine (which fully complies with ISO 11553 and the machine safety legislation) is located, which is Class 4 for instance because it does not feature automatic detection of walk in access.

Some people argue that these kind of ‘safe professional installations’ should be Class 1 to indicate their level of safety, even if there are situations that make the beam accessible, but which can be covered by user precautions. It is argued by the authors of this paper that while this is an understandable proposal for professional industrial laser machines, in the general case, it would undermine the meaning of Class 1 which currently is that it does not require any user precautions and risk analysis. Also it needs to be considered that the classification rules apply to all products in the same way so that currently it is not provided for to have different criteria for different applications and types of products. This would also be difficult in practice, as even within the product type category of “machines” there is a wide variety of products, some of them are not used in industrial settings but for instance in office supply shops where rubber stamps are engraved with a CO_2 laser product or trophies are engraved or cut out. These products, it could be argued, need to be oriented rather on the consumer product level of safety rather than professional industrial machines operated by personnel with some level of appreciation of hazards presented by machines.

One way out of the dilemma of different understandings of Class 3B and Class 4, especially for those countries who have binding user regulations that (wrongly) treat Class 3B and Class 4 lasers as ‘always hazardous – wear eye protection’, would be to define a national procedure for user classification of laser installations: the laser product would be classified according to IEC 60825-1 by the manufacturer where it might well be that a safe laser machine is classified as Class 4, for instance because it does not feature an automatic walk-in-access detection system, or no roof, or the guarding material would not be able to withstand direct reflection from highly reflective targets which is not relevant if the machine is just used for cutting wood or cloth. The user, after some risk analysis and consideration of the specific environment and mode of usage could then assign some ‘user class’ which could be Class 1 according to the national user standard. The

US user standard ANSI Z136.1 already provides such a 'user classification' system.

4.3 User Maintenance

General product safety legislation in Europe (and it is suspected also elsewhere) clearly indicates that user performed maintenance also needs to be safe. In fact, the European general product safety directive specifically includes maintenance as one mode of using the product. Since the class is generally understood as an information of the manufacturer to the user regarding the level of hazards that can be encountered using the product (and it is not understood to only refer to regular use excluding maintenance), this general understanding needs to be taken (also by legal requirement of the product safety directive) as the basis what level of safety is expected by the consumer. Therefore it follows logically that tests for the determination of the class needs not only be restricted to radiation accessible during use, but also during user performed maintenance. After all, the general level of safety that is expected from a Class 1 product is that it is safe for the 'user', and not only safe during use (without considering user performed maintenance).

Currently, classification tests only refer to 'use' excluding maintenance. It follows that it is possible for a Class 1 embedded laser product to require the user to override an interlock, open an access panel and achieve access to the high power laser beam. This would most likely not be acceptable for a consumer product, i.e. such a product would be considered as 'defective' in legal terms. Thus there might be products which are correctly classified according to the present tests as Class 1 but which violate product safety laws and put the manufacturer at risk for compensation as well as for withdrawal of the product from the market! The standard clearly, in this case, does not live up to its expectations of being a means of helping the manufacturer to achieve compliance with product safety legislation and reducing the risk!

It seems difficult in IEC TC 76 to achieve a satisfying consensus on including maintenance in the test requirements. One of the arguments is that it does not make a product safer by leaving everything the same but just calling it Class 4 instead of Class 1. This is of course correct but for Class 4 at least there is information on the hazard that is consistent with the level of radiation that is accessible for the user. The higher class would indicate that some level of user training (awareness) of the potential hazard is necessary, and potentially some other user precautions. Once the user is trained and safe procedures to perform the maintenance are established, which might require the use of eye protection, one way to treat this issue would be, as described above, to provide for a national means for user-reclassification of the product, so that these professional installations can, after some risk analysis, be treated as Class 1.

If maintenance is not going to be included into the assessment of the potentially accessible levels of emission, then it needs to be pointed out to other standards committees and to the users that there might be Class 1 products that would require user training, risk analysis, and to perform this nomination of a laser safety officer. Since the label does not provide information whether it is an embedded laser product or not, each and every laser product would have to be examined in the workplace (including laser printers, etc) whether it might be a product which requires access to a potentially hazardous beam or not. It seems that while not including maintenance would make it 'simpler' for some cases of industrial laser machines which could currently be classified as Class 1 but would upon inclusion of maintenance become Class 4, the consequences for users to evaluate the safety of all Class 1 products would be extreme. It is pointed out that there are institutions in the UK where all laser products are evaluated in this respect, including all Class 1 lasers.

4.4 General principles of tests for classification

For a consistent application of the standard to a wide variety of laser products, it might be helpful to discuss some basic principles of classification.

The class is determined by comparing the accessible emission level to the respective AEL. There are rules of how to determine the accessible emission level. In simplified terms, radiation is considered accessible when there are no engineering controls that prevent the accessibility or reduce the level of radiation. The determination of the accessible emission level includes possible reflections within the housing for higher power lasers, as well as single fault conditions. This also means that it might well be that the radiation is usually (in normal mode) not accessible, or the level which was used to determine the class is higher than the level of radiation emitted during normal operation.

Another important principle in the view of the authors (and of a number of other members of TC 76 which were consulted) is that the class applies to the product based on engineering features, and can not be based on the user complying to requirements on behaviour as specified in the user manual. Thus it is not acceptable to base the determination of the accessible level of emission on specifications given in the user manual in the sense that 'operation' as used in the standard is the

state of the product as defined in the user manual of how the product is to be operated, and how it is not to be operated. This is clearly not a valid interpretation of the use of 'operation' in the standard and would place the manufacturer at risk regarding product liability and forced withdrawal from the market. It is rather that when the product can operate, i.e. emit radiation, this level of radiation is to be used as accessible radiation to be compared to the AEL to determine the class. As an oversimplified example, if the output power can be adjusted by turning a button, and the user manual says that the product shall not be operated with a setting of above 500 mW but the maximum output power is actually several watts, the product would still be Class 4, and not Class 3B. Also if it says in the manual 'don't' go in' if there is walk in access, but the laser can operate when somebody is inside, this level of radiation is considered accessible during operation of the product (i.e. it can operate – emit - while somebody is inside). Another example which is very common: some part of the product which reduces the emission can be removed by simple screwing it off, for instance filters or some caps. Even when the manual says 'don't screw the filter off' it is certainly reasonably foreseeable that the filter is taken off and then higher power levels of radiation than would be indicated by the class could user specifications be used for classification would become accessible. Put to an extreme, any laser product could be classified Class 1 when the instructions of the user manual could be used determine the accessible radiation, the manual only needs to specify 'don't get into the beam'.

The principle is clearly that prevention or reduction of accessible radiation to achieve a certain class is based on engineering features that can be realised by the manufacturer and determination of accessible emission levels can not consider the appropriate behaviour of the user as specified in the user manual. It also follows from this principle and from general product safety legislation principles that some level of 'incorrect' use or 'mild' misuse needs to be assumed. For instance, the authors were involved in the safety assessment of a low level laser therapy product that consistent of a 20 mW laser diode but featured a fibre tip output so that the emitted beam was highly divergent. The fibre endpiece could was protected by a mechanical interlock mechanism so that the (collimated) 20 mW could not be emitted when the endpiece was removed. We would argue that this automatic system is necessary to classify the product as Class 2M, rather than relying on the user instruction which would have to say "don't operate the laser when the fibre endpiece is taken off".

Some level of specification of appropriate use can be considered in machine safety analysis, for instance when the materials that shall not be cut with a laser materials processing machine are listed in the user information and specifications of the machine. However, again, this can not have any bearing on the classification of the product.

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