**ILSC® 2019 Conference Proceedings**

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**Jan Daem, Annette Frederiksen, John O'Hagan, and Karl Schulmeister**



**Reference information for this proceedings paper**

Citation: ILSC 2019, 403 (2019); doi: 10.2351/1.5118577
Title: Laser product safety standardization projects of CENELEC TC 76
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Proceeding of the International Laser Safety Conference, March 18-21, 2019 USA
Paper 403, Pages 127-136
Published by the Laser Institute of America, 2019, Orlando, Florida, USA

# Laser Product Safety Standardization Projects of CENELEC TC 76

Paper #403

Jan Daem[1], Annette Frederiksen[2], John O'Hagan[3], Karl Schulmeister[4]

[1]BARCO NV, Kortrijk 8500, Belgium
[2]Robert Bosch GmbH – Corporate Research, 71272 Renningen, Germany
[3]Public Health England, Didcot, United Kingdom
[4]Seibersdorf Laboratories, 2444 Seibersdorf, Austria

## Abstract

In this paper, we report on two European laser safety standardization projects that will lead to European standards without corresponding IEC documents. In one project, an amendment A11 for EN 60825-1:2014 is developed. The amendment can be seen as consisting of two parts: first, technical changes which mainly resulted from a German opposition to the listing of EN 60825-1:2014 as a harmonised standard under the Low Voltage Directive at European Commission level; the changes in practice should not have notable effects for manufacturers. The second part of the amendment is the inclusion of the content of the two IEC Interpretation Sheets in an informative annex. The second project is based on a mandate by the European Commission to develop a safety standard for consumer laser products. The main scope is to define criteria, specifically which lasers and classes are sufficiently safe to be placed on the market as consumer products. Due to varying views on the risk associated to Class 3R laser products within the responsible committee, the development of the standard proves to be a challenge.

## Introduction

CENELEC (Comité Européen de Normalisation Électrotechnique) is the European Committee for Electrotechnical Standardization and is responsible for European standardization in the area of electrical engineering. Together with CEN (Comité Européen de Normalisation) and ETSI (European Telecommunications Standards Institute) it forms the officially recognised European Standards Organizations. CENELEC is a non-profit organization founded in 1972, set up under Belgian law and based in Brussels. The members of CENELEC are the national standardization bodies of the 28 European Union member states, the Republic of North Macedonia, Serbia and Turkey plus three countries of the European Free Trade Association (Iceland, Norway and Switzerland). On any voting on standard documents a weighted voting from the Nice Treaty is applied. The connection between the different standardization bodies on international, regional and national (e.g. German) level is summarized in Figure 1.


Figure 1: Standardization landscape.

CENELEC adopts international standards wherever possible through a close collaboration with IEC (International Electrotechnical Commission) defined by the Dresden Agreement process and renewed by the Frankfurt Agreement [1]. Since the stages of the standard development process have different abbreviations at IEC and CENELEC, an overview is given in Figure 2.

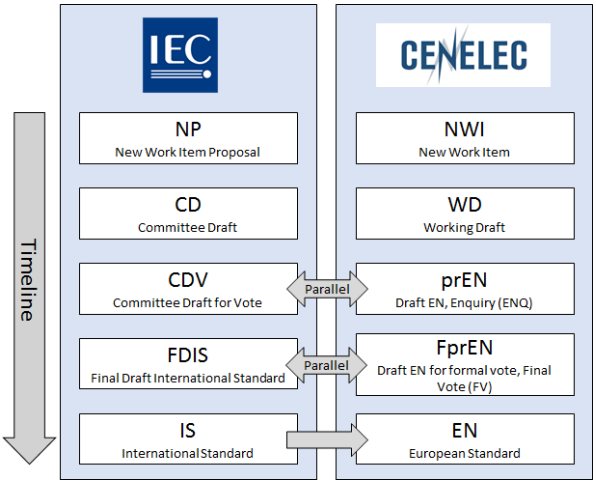


Figure 2: Standard development process at IEC and CENELEC.

The technical committee within CENELEC for "Optical radiation safety and laser equipment" is CLC/TC 76, which is also the European mirror committee of IEC TC 76. Currently CLC/TC 76 is working on two major standardization projects that are not at the same time IEC (parallel) projects:

- Project 64807 to develop an amendment A11 for EN 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements
- Project 65305 to develop a new standard EN 50689 Safety of laser products - Particular Requirements for Consumer Laser Products

As mentioned before, CENELEC tries to adopt most of the IEC standards. In some cases, so-called home-grown standards are developed by CENELEC outside the framework of its cooperation with the IEC (i.e. outside of the Frankfurt Agreement). The second project covering consumer laser products is an example of a home-grown standard. The first project is an amendment to the basic laser safety standard, because the internationally issued interpretation sheets (ISHs) are not available as a document type within CENELEC. Additionally, the amendment covers some further aspects beyond the ISHs. The history, content, current status and planned timeline of these two projects will be presented and discussed in the following two sections.

## Amendment A11 for EN 60825-1:2014

### Overview

The CENELEC project to develop an amendment A11 for EN 60825-1:2014 involves two parts: firstly, technical amendments in the normative part, and secondly, a new informative annex to include the content of the IEC Interpretation Sheets (ISH) that at the IEC level relate to IEC 60825-1:2014. To include the IEC ISH material into an informative annex appeared to be the best way to publish the material by CENELEC and European National committees, since the document type "Interpretation Sheet" does not exist at CENELEC level. While EN 60825-1:2014 is identical with IEC 60825-1:2014, since Amendment A11 applies only to the European version, following the publication of A11, the document EN 60825-1:2014 + A11:2019 (assuming publication date at the end of 2019 or early 2020) is going to deviate from the IEC version. However, in practice, very little or no impact on requirements for products and manufacturers is foreseen, because the amendment in principle only specifies in more detail what is implied in the standard anyway and was and is common practice for responsible manufacturers. Consequently there is a good chance that for Edition 4, IEC and EN 60825-1 are going to be almost identical again. The changes specified in A11 were necessary to address concerns by the European Commission Directorate General "Enterprise and Industry" (DG ENTR, now DG GROWTH, stationed in Brussels) that a standard harmonised under the Low Voltage Directive (LVD [2]) has to have sufficient level of specificity. The requirement that consumer products have to comply with the future EN 50689 also makes an amendment of EN 60825-1 necessary.

### Initiating events

The initiating event for the amendment of the normative part of EN 60825-1:2014 (i.e. the technical changes) was the opposition of the German representation (Federal Ministry of Labour and Social Affairs) in the LVD Working Party (LVD WP) of August 2014 addressed to the European Commission DG ENTR (Document number 11 for Meeting number 19 of LVD WP). Three concerns were raised by Germany, with the conclusion that because of significant safety-related deficiencies, the new standard EN 60825-1:2014 is not suitable for listing as harmonized standard under the LVD:

- "New laser class 1C", noting that the emission may be of levels of Class 3B or 4 lasers and that by the designation 1C users are misled and might be exposed to unnecessary risks.
- "Changes of emission limits", noting that in some cases, the permitted emission for Class 1 can be 20 times higher as compared to the previous standard and that lasers that were under Edition 2 Class 3B might be made available on the market as Class 1 lasers without the warnings as provided for Class 3B. The German LVD WP document stated that "The health and safety of persons as required in the LVD can therefore not be ensured if the new standard is applied".
- "Inconsistency with Directive 2006/25/EC", noting that some new emission limits of EN 60825-1:2014 are higher than the exposure limit values of the European Directive 2006/25/EC (the Artificial Optical Radiation Directive, AORD) and products might be made available on the market which are Class 1 and without labeling while the exposure limits of the AORD are exceeded and protective measures at the workplace are necessary.

Following these concerns raised by Germany at the LVD WP in 2014, there was a meeting in Brussels in January 2015 with representatives of CLC/TC 76, representatives from the German ministry, BAuA (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, engl.: Federal Institute for Occupational Safety and Health) and BG (Berufsgenossenschaft, engl.: German Social Accident Insurance Institution), DG ENTR and

DG SANCO (now DG JUST, responsible for the General Product Safety Directive, GPSD [3]). With respect to Class 1C it was pointed out by CLC/TC 76 that at that point in time, no Class 1C product could be legally on the market since it is required in EN 60825-1:2014 that the product has to comply with a specific vertical standard with requirements to limit the emission towards the skin to a safe level as is consistent with the type of product. With respect to the changes of the emission limits and differences to the exposure limits of the AORD it was pointed out by CLC/TC 76 that the new limits are based on the new ICNIRP exposure limit Guidelines of 2013 [4] and can be considered as state of science (the exposure limits of the AORD and Edition 2 of EN 60825-1 are based on the earlier version of the ICNIRP Guidelines); it has to be noted that most limits remained the same, some were raised, where justified, but some were also lowered. Limits were raised only where earlier limits were needlessly low and the new Class 1 limits still assure a safe product. In this case, according to product safety legislation, there is no warning label needed, irrespective of exposure limits of the AORD being exceeded or not. This had been confirmed in September 2013 by DG EMPL and national ministries responsible for workplace safety in emails to CENELEC experts. At the meeting, DG ENTR confirmed that product safety emission limits have no direct relationship to exposure limits of directives which address the safety of employees at the workplace, and pointed out that any concerns about these differences should be addressed to DG EMPL (stationed in Luxemburg); workplace safety issues are legally not related to the Common Market and product safety legislation.

With the discussion at the January 2015 meeting and associated statements, all concerns by Germany could be addressed, with the exception of clarifying cases where compliance with EN 60825-1 (i.e. without vertical standards), with respect to hazards to the skin and eye, does not provide the presumption of conformity with the LVD. A proposal by Germany was received after the meeting, reflecting the notion that for Class 3R, 3B and Class 4, compliance with EN 60825-1 alone would not lead to a safe product under the LVD and additional requirements of other standards are needed. It was clarified in a reply by CLC/TC 76 that this is correct only for consumer products and this issue is going to be covered by the specific standard for consumer laser products under development (also discussed in this ILSC paper). The reply by CLC/TC 76 noted that for professional products that fall under the LVD, the requirements of EN 60825-1 alone are sufficient to result in a safe product in the sense of the LVD and with respect to the scope of EN 60825-1 (eye and skin hazard), i.e. that full harmonization under the LVD is justified and compliance with EN 60825-1 results in the presumption of conformity with the LVD. It is only for products that fall under other directives, such as toys, medical products or laser processing machines, where additional requirements with respect to hazards to the eye and skin might be needed. For example, for toys to restrict to Class 1 even for the case of damage to the product, or for medical lasers to limit the power of alignment lasers to 5 mW and to require a display of the emission level. For these types of products, specific standards are available and listed under the respective directive, such as the Medical Device Directive or the Machinery Directive (where EN 60825-1 is *not* a harmonized standard). In the process of the discussion with DG ENTR on the issue, it was pointed out by DG ENTR that EN 60825-1 needs to specifically require to reduce the emitted level of radiation to the lowest class that is commensurate with the function of the product (however, this is not a requirement to reduce the class to Class 1 in all cases). Together with the clarification on the cases where compliance with EN 60825-1 alone is not sufficient to achieve the presumption of conformity as based on the concern by Germany, a draft amendment text was developed in 2015 that was also informally "approved" by DG ENTR. The draft was presented by CLC/TC 76 representatives at the November 2015 meeting of the LVD WP, where a representative of DG SANCO (responsible for GPSD) was also present. Subsequently, the draft amendment was further matured by CLC/TC 76 to form the basis of a new work item proposal in April 2017 (approved under BT156/DG10516/DV). In the next phase, the material of the IEC interpretation sheets was included as an informative annex and a working draft was made available on CENELEC Collaboration Tools in June 2018. The received comments were discussed at the September 2018 project group meeting in Kista, Sweden and subsequently an "Enquiry" document prA11 was made available to CCMC (CEN-CENELEC Management Centre) to be issued in early 2019. With the assumption of an FprEN in the second half of 2019, or that it is possible to skip the final draft stage (FprEN), publication of the Amendment A11 should be possible by the end of 2019.

## Compliance Requirements

While the three original concerns from German product safety authorities could be clarified, the discussion process about the "compliance logic" of EN 60825-1 and relationship to European product safety directives resulted in a proposal by Germany for an amended scope, to specify in more detail when compliance with other standards is needed to achieve a safe product. This amendment was needed in order to maintain the full status of "harmonized standard" under the LVD. It was necessary to clarify in the discussion (and to address in

the text of prA11), the dual role that EN 60825-1 plays in Europe. On the one hand, EN 60825-1 is harmonized (Edition 3.0 was automatically harmonized because Edition 2.0 had been harmonized) under the LVD and therefore compliance with EN 60825-1 is to afford presumption of conformity with the LVD with respect to hazards to the eye and skin (note that EN 60825-1 is identical with IEC 60825-1 both as Edition 2.0 as well as Edition 3.0). On the other hand, for products falling under other directives, EN 60825-1 is not necessarily sufficient with respect to eye and skin hazards and is also not harmonized. In this sense, for products under the LVD, EN 60825-1 is (or should be) of a sufficiently specific and complete nature to result in a safe product (with respect to skin and eye hazard) in the sense of the LVD. Following the inclusion of the requirement for compliance with EN 50689, compliance with the amended EN 60825-1 also results in a safe product in the sense of the GPSD, although the listing of EN 60825-1 under the GPSD is optional, because only EN 50689 might be listed under the GPSD. For other types of products, not falling under the LVD, such as medical devices, EN 60825-1 is more of a generic and horizontal standard, where additional requirements might be needed. An example for the latter are medical lasers, where EN 60601-2-22 is harmonized under the Medical Device Directive (and EN 60825-1 is not). This compliance logic is sketched in Figure 3.

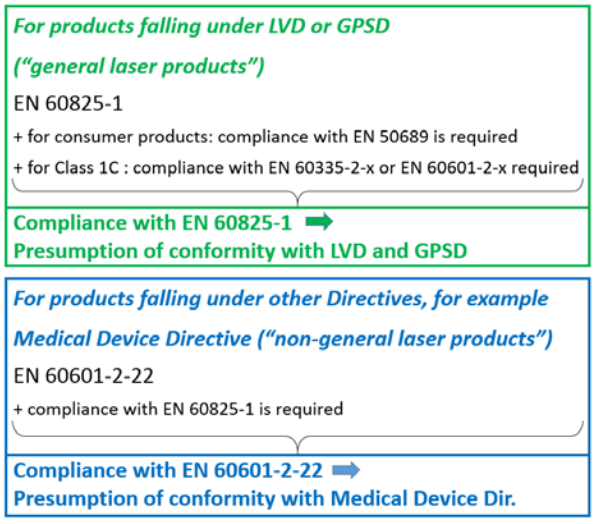


Figure 3: "Compliance logic" and different roles that EN 60825-1 plays depending on which product safety directive is applicable. Note that in this compliance logic, EN 60825-1 is defined to only cover the hazards with respect to eye and skin, not other hazards (such as electrical hazards).

Following the compliance logic, a definition of products was needed that in Europe fall under the LVD and for which compliance with the amended EN 60825-1:2014 affords presumption of conformity with the LVD for both consumer and professional products (the LVD does not distinguish between consumer or non-consumer products). CLC/TC 76 was advised by DG ENTR that it is not possible to refer to directives in the body of the standard, as the references to directives are formally limited to Annex ZZ. Consequently it was necessary to find a definition for these types of products, avoiding references to European directives. This resulted in a definition which is probably difficult to interpret without additional background understanding (at the time of development of the first draft, the intended designation of the consumer laser product standard was EN 60825-1-1 which would have made Note 3 to entry of definition 3.92 (reproduced below), and that the consumer laser standard is not "another EN standard", more consistent). The definition text, reproduced below, was satisfactory for the department of DG ENTR responsible for the LVD.

**3.92 general laser product**

laser product that does not fall within the scope of another EN standard that addresses the safety of a specific category of laser products

Note 1 to entry: Examples of products where such other EN Standards exist are medical lasers (EN 60601-2-22), toys (EN 62115) or laser processing machines (EN ISO 11553-1, EN ISO 11553-2).

Note 2 to entry: General laser products are for instance laboratory equipment, laser products for measurements, laser pointers, display lasers and laser illuminated projectors.

Note 3 to entry: EN 50689 is not considered as another EN standard that addresses the safety of a specific category of laser products, since it applies to all consumer laser products.

With the above definition it was possible to extend the scope, which satisfies the concerns of German product safety authorities as well as DG ENTR:

This Part 1 describes requirements that are considered sufficient to achieve the required level of product safety for general laser products with respect to hazards to the eye and skin posed by laser radiation, provided that consumer laser products comply with EN 50689 (see 9.5 in EN 60825-1 Ed. 3.11). Also, as required in 5.3 b) of EN 60825-1, laser products that are classified as Class 1C shall comply with the respective applicable part of either the EN 60601 series or the EN 60335 series that contains requirements for the safe exposure of the skin (note that the exposure of the skin is not necessarily limited to the MPE values of the skin), if applicable, as well as specific requirements for the performance and testing of the safeguard that prevents hazardous emission towards the eye. Depending on the type of the product, laser products such as medical lasers, machines or toys may be required to conform to the applicable performance and testing requirements of other relevant product safety standards.

## Notes on the apparent source

Additional to the changes discussed above, NOTE 3 of 4.3 c) "Radiation from extended sources" was significantly extended to provide information on types of sources that may be extended sources, and those that will not, such as non-scanned circular high quality beams. Also common mistakes are noted, such as to associate the beam diameter at the laser aperture with the apparent source.

## Dual limit to protect the cornea

For the special case of emissions in the wavelength range between 1350 nm and 1400 nm, comprehensive information on corneal injury thresholds became available at the time of the IEC/TC 76 meeting in Kista, Sweden [5] (see also the paper in these ILSC proceedings) demonstrating that for small beam diameters, the exposure of the cornea permitted by the Class 3B limit given in IEC 60825-1:2014 (and therefore also in EN 60825-1:2014) does not assure a sufficient level of safety. At the IEC/TC 76 meeting, Working Group 1 recommended, for the case of fiber optics, to specify the value of the skin MPEs as dual limit to protect the cornea. This recommendation was adopted for the Enquiry draft of A11 to replace the reference to Class 3B as a dual limit in the AEL tables:

| | | |
|---|---|---|
| For $t < 10^{-9}$ s: | $7{,}9 \times 10^{5}$ W | $D_{ap}$: 1 mm |
| For $10^{-9}$ s $\le t < 10^{-7}$ s: | $7{,}9 \times 10^{-4}$ J | $D_{ap}$: 1 mm |
| For $10^{-7}$ s $\le t <$ 0,35 s: | $4{,}3 \times 10^{-2}\ t^{0{,}25}$ J | $D_{ap}$: 1 mm |
| For $t \ge$ 0,35 s: | 0,1 W | $D_{ap}$: 0,35 s $\le t <$ 10 s: 1,5 $t^{3/8}$<br>t ≥ 10 s: 3,5 mm |

These values, specified in units of watt or joule (such as 100 mW for the cw case) were derived by multiplication of the skin MPEs with the area of the limiting aperture (using the same diameter of the limiting aperture $D_{ap}$ as specified for the corneal limits that apply to longer than 1400 nm). Measurement of the accessible emission in units of watt or joule to be compared against these dual limits is then to be performed with the specified diameters for the aperture stop, to make the assessment in principle an MPE assessment, but specified in terms of "power through aperture". We note that for an irradiance profile that is homogeneous over a diameter of 7 mm, the skin MPE analysis can be done in an equivalent way with a larger limiting aperture (averaging aperture for irradiance) of 7 mm diameter, and the equivalent limit value given as power (derived by multiplication of the skin MPE with the area of the 7 mm "averaging" aperture) then equals 400 mW for the cw case – which is not much lower than the Class 3B limitation. However, for smaller beam diameters, the Class 3B limitation of 500 mW, where the accessible emission in IEC 60825-1 is determined with a 7 mm aperture, for wavelengths between 1350 nm and 1400 nm, results in irradiance levels at the cornea which are significantly larger than the skin MPE.

## Requirement for lowest class

In the discussion with DG ENTR in 2015, if compliance with EN 60825-1 results in safe products in the sense of the LVD (i.e. not distinguishing consumer products from non-consumer products) it was noted by DG ENTR that EN 50689 and the limitations of the classes therein applies to consumer products only and it was questioned how the limitations of the classes are handled for non-consumer (professional) products, i.e. within EN 60825-1. It was further pointed out by CLC/TC 76 experts that also for professional products, when it is feasible to enclose the laser radiation for normal operation, or to even achieve a lower class, this is done in practice (motivated by advantages for the user to avoid safety measures, and based on general good engineering practice). It was felt necessary by DG ENTR to include this requirement specifically in the amendment of EN 60825-1. The current draft amendment of 6.2.1 reads:

> Each laser product shall have a protective housing which, when in place, prevents human access to laser radiation (including errant laser radiation) in excess of the AEL for Class 1, unless human access to laser radiation is necessary for the performance of the function(s) of the product. Where human access to radiation levels above the AEL for Class 1 is necessary, the product shall be in the lowest feasible class commensurate with this function.
>
> NOTE Where such human access is necessary only at certain times and not during routine operation of the product (e.g. to allow specific maintenance procedures, which are described in the information for the user, to be undertaken by the user) the protective housing prevents human access to laser radiation in excess of the AEL for Class 1 during routine operation. This requirement for a protective housing does not mean that the product needs to meet all the requirements for, and to be classified as, Class 1. This is because classification as Class 1 cannot be achieved when access to levels of laser radiation of Class 3B or Class 4 is necessary during specific maintenance procedures.

The note clarifies that while a protective housing is necessary, where feasible, to reduce the accessible emission, and ideally also to reduce the class of the product, it is not a hard requirement to reduce the class, such as to Class 1, in all cases. This kind of approach is common practice anyway and therefore should present no actual additional restriction for the design of products. An example where a product is in practice designed to be Class 1, is a professional laser printing device where access to laser radiation is not necessary, neither during normal operation nor during maintenance of the equipment by the user (for classification under IEC 60825-1, the product is classified as Class 3B or Class 4 when the respective radiation becomes accessible during maintenance procedures that are specified in the information for the user). An example where the protective housing prevents access to higher level of radiation in normal operation only are many

materials processing lasers (but they would not fall under the LVD) where maintenance procedures result in access to higher levels of radiation and the product is therefore classified as Class 4. An example for a product falling under the LVD is a cell counting device, where a cell container is inserted into the measurement chamber, which during measurement does not permit access to higher levels of radiation. However, user laser alignment procedures might be necessary and consequently, the product is Class 3B. This is a safe product under the LVD due to the user safety measures specified by the manufacturer in the information for the user (and in this example it is assumed that it is not feasible, with a reasonable effort, to design the product so that alignment can be done without access to the beam). Examples for Class 3B or Class 4 laser products with fully open beams that satisfy the requirements of prA11 (and are considered as safe under the LVD) are scientific lasers or laser shows, where the emission of the beam of a certain power level is required for the functioning of the device as intended.

### Informative Annex to include IEC ISHs

The content of the two IEC Interpretation Sheets (ISH) [6, 7] was adopted as an informative annex to be published in amendment A11. The currently anticipated designation is Annex Y in order avoid conflicts with existing Annexes A to G. While there was a limitation on the extent of the content (on the length of the document) for the ISH at the IEC level, resulting in having to delete examples and notes developed for the IEC draft, the amendment of a standard does not have these kind of limitations. Consequently, for A11, the earlier longer versions are used which provide further clarifying information. Also, in Y.4, a clarification on interlocks for access panels was included which was not possible to include in the IEC ISH. Y.1 contains general remarks, Y.2 contains the material of ISH1, and Y.3 contains the material of ISH2.

## New European Standard for Consumer Laser Products

The current European standard for laser products EN 60825-1:2014 [8] defines how to assess the hazard of laser products, by way of assigning laser classes, and the corresponding warning labels. However, the classification of laser products does not ensure that it is safe to be used by consumers. This in combination with the increasing availability of laser products for consumers, e.g. hand-held, battery-powered laser pointers, is the reason for a request from the European Commission to develop a new European standard or amend the current European standard [9]. This request is supported by two European mandates [10, 11]. In the Commission Decision [9] of 5 February 2014 it is stated that “there is a widespread consensus that laser products corresponding to classes 1, 1M, 2 and 2M […] can be considered safe when used by consumers […]. This is not the case however for laser products of other laser classes.”

At the beginning, there was an attempt to create an IEC standard, namely IEC 60825-1-1, in order to standardize which classes of laser products are suitable for consumer products on an international level. This failed due to the full acceptance of Class 3R in the United States. Therefore, this undertaking became a purely European standardization project with the scope of defining which classes of laser products are considered acceptable to be made available on the Common Market in Europe as consumer products. The proposal for the new work item was submitted on 26th June 2017 and accepted on 6th September 2017 under BT157/DG10634/DV, mentioning that it will support the General Product Safety Directive [3] and the Low Voltage Directive [2] and will not be offered to IEC. Since the new European standard will only cover European aspects, it cannot be a subpart of EN 60825-1 (standard designation numbers starting with “6” are reserved for standards with an equivalent IEC version) and will receive a European standard number, more specifically EN 50689 (numbers starting with “5” denote a European-only standard). A consumer laser product is, according to the definition used in the current draft of EN 50689, a product or assembly of components that constitutes or incorporates a laser or laser system and that is intended for consumers, or is likely to be used by consumers under reasonable foreseeable conditions even though it is not intended for them.

During the 23rd meeting of CLC/TC 76 held on 13th June 2017 in London the first draft was discussed among the participating experts. The draft proposal intended to limit consumer products to Class 1 or Class 2 unless there is a justified and documented need for a higher emission level than Class 1 or Class 2. Laser pointers are permitted to be Class 1 and Class 2 only. Laser products that are child appealing are permitted to be Class 1 only. For other types of laser products (not child appealing and not laser pointers) to be made available as consumer products with accessible emission levels in the range of Class 1M, 2M and Class 3R, this draft required a product specific risk assessment that demonstrated that the risk associated to the product is acceptable. Class 3B and Class 4 were generally not permitted as consumer products. Devices not fulfilling the criteria above shall not be sold to consumers.

In the period of 2017 it was discussed that a proposed additional restricted sale for Class 3R will create extra

complexity for market surveillance and manufactures and the following question was raised “Is restricted sales creating extra benefits if the product’s risk analysis confirms that the level of risk is acceptable?”. Restricted sales means that the product shall not be made available without the seller being personally able to inform/train the buyer. To provide guidance and verification criteria how to validate the conformity to the “restricted sales” requirement is very hard in this type of generic standard.

Therefore, the first working draft circulated via Collaboration Tools had two versions, one with and one without restricted sale and the national committees were asked which of the two versions is supported. The deadline for the feedback concerning the first working draft was the 6th of October 2017. In total six countries (CZ, DE, FR, GB, NL and SE) submitted comments. Three national committees were in favour of the version without restricted sale, one was in favour of the version with restricted sale, one abstained and one did not support the drafts.

Subsequently, the draft without requirements for a restricted sale was, after some further internal revision, submitted to “enquiry” from the 2nd March 2018 to 25th May 2018. This prEN 50689 (Draft European Standard) of 2018 was accepted by the national committees of 16 countries and rejected by one country resulting in a proportion of positive weighted votes of 87.97%. In total more than 100 comments were submitted.

The content of prEN 50689 from March 2018 can be briefly summarized as follows:

- Class 3B and 4 are not permitted as consumer products
- Child appealing lasers are limited to Class 1
- Laser pointers are limited to Class 2
- Class 3R is permitted if
  - the higher emission is required for the functioning of the product and
  - a formal probabilistic risk analysis demonstrates a sufficiently low level of risk (e.g. probability less than $10^{-9}$ per hour of usage) and
  - additional wording “SUITABLE FOR CONSUMER USE” is used

Main discussion points from the comments that were received were the definition of child appealing, the wording and labelling for consumer laser products and the risk analysis for Class 3R products.

The introduction of the risk analysis of this draft resulted in splitting Class 3R into two categories: laser products of Class 3R suitable for consumers and laser products of Class 3R not suitable for consumers. This started the discussion if a new class is needed and therefore the German National Committee proposed, in its comments, two new European classes for consumer laser products, Class 3RA and Class 3BA, see Figure 4 (“A” stands for “analysis” in risk analysis). A consumer laser product shall be sufficiently safe, i.e. at most a tolerable risk is permitted, for any laser product placed on the market intended for consumers, or likely to be used by consumers, even if not intended for them, under reasonably foreseeable conditions including momentary accidental or unintentional exposure. For this it was proposed to either provide technical means limiting the radiation to the MPEs (Maximum Permissible Exposure), or a risk analysis for the application of the respective product to prove a tolerable risk under normal or reasonably foreseeable conditions of use, even if not intended for them.

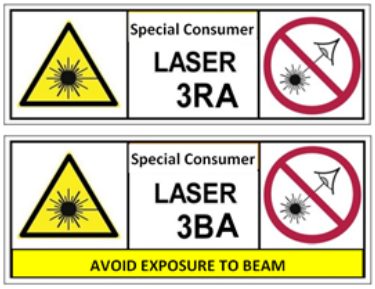


Figure 4: German proposal for two new European classes for consumer laser products.

During the annual meeting of CLC/TC 76 on 12th June 2018 in Vienna, the European Commission, represented by Mr. Thomas Fairley (Directorate General for Justice and Consumers, Product Safety and Rapid Alert System), presented the following view on the prEN 50689 of 2018 [12]:

- *As we understand, when the specific application of the product requires laser classes higher than Class 1 or Class 2, the products (referred to as "speciality products requiring a risk analysis") can be Class 1M, Class 2M or Class 3R and a "probabilistic risk analysis shall be performed to document an eye injury risk level that is sufficiently low for the application of the respective product, including reasonably foreseeable misuse".*
- *In our view, products cannot be deemed to be safe for consumers simply by performing a risk analysis and as long as the standard is written in this way (without providing specific technical requirements on wave emission, wavelength range etc. which have to be met) we do not think that it would be possible to publish the reference of the standard in the OJEU under the GPSD and the LVD.*

- *A further problem is that, as you are aware, there is a clear consensus amongst national market surveillance authorities in the EU (reflected in specific legislation in some Member States) that Class 3R products should not be made available to consumers.*
- *For our part, we understand that the laser beams from Class 3R products exceed the Maximum Permissible Exposure value for accidental viewing and can potentially cause eye injuries (even if the risk of injury in most cases is relatively low).*
- *Concerning the mention in the progress report of the (RAPEX) risk assessment guidelines (Commission Decision 2010/15/EU), please note that there appears to be a misunderstanding: a "low" risk level does not mean that the product is safe for consumers.*

In summary, the request from the European Commission is to ensure a high level of safety and that harmonization of the standard under the GPSD and the LVD needs specific requirements for products and not only a risk assessment. Nevertheless, it should not block innovation and Class 3R has not necessarily to be excluded. Therefore, a new approach for a second prEN 50689 (to be published early 2019) was documented during the CLC/TC 76 Vienna 2018 meeting [12]:

- No risk assessment as a compliance criterion for the manufacturer
- Specify which types of emission for Class 3R are considered as sufficiently safe for consumers
- Do not allow Class 1M, 2M and Class 3R products not covered by EN 50689; we note that in the future, vertical standards could be developed for specific groups of products to define deviating and overruling permissions, for instance to permit Class 2M lasers as maritime distress signals

This new approach is sketched in Figure 5.

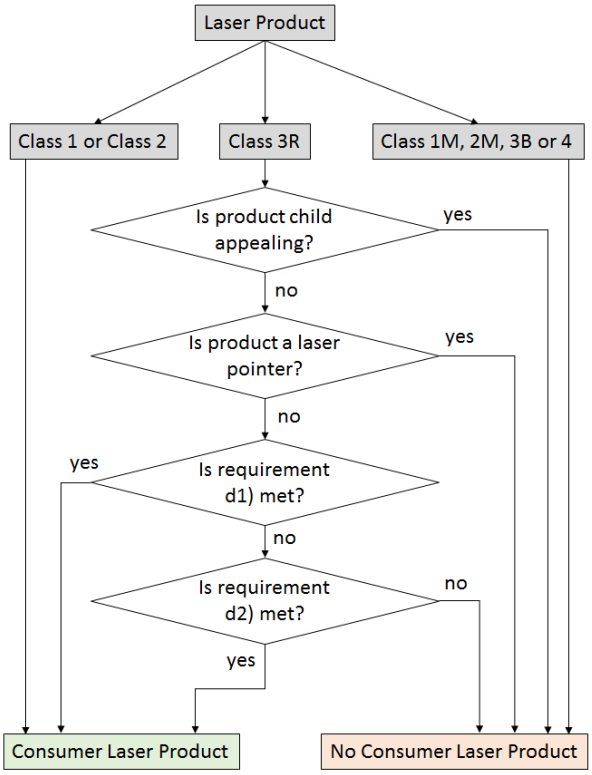


Figure 5: Laser products that according to the second prEN 50689 (2019) are either compliant and permitted to be made available on the market as consumer products, or are not compliant and not permitted as consumer laser products. Note that child appealing laser products are permitted to be Class 1 only (not reflected in flow-chart).

According to Figure 5, a Class 3R laser product, which is not child appealing and not a laser pointer, is allowed as consumer laser product if requirement d1) *or* d2) is met. The two requirements are as follows:

- d1) the accessible emission (AE) shall be limited to five times the accessible emission limit (AEL) of Class 1 or Class 2 provided that all of the following restrictions are met:
  - the wavelength shall be within the range of 400 nm to 1400 nm
  - the AEL that is applied for classification shall be based on $C_6$ = 1 (i.e. using the simplified (default) method in subclause 5.4.1 from EN 60825-1:2014);
  - either the accessible emission is continuous wave (i.e. not pulsed with pulse durations less than 0.25 s) or the peak power shall be below the cw Class 3R AEL (i.e. below 5 mW for 400 nm to 700 nm and for longer wavelengths below the Class 3R AEL for $T_2$=10 s;

- d2) the AE shall be limited:
  - to twice the AEL of Class 2 for 400 nm < λ ≤ 500 nm;
  - to 1.5 times the AEL of Class 2 for 500 nm < λ ≤ 600 nm;
  - to twice the AEL of Class 2 for 600 nm < λ ≤ 700 nm
  - irrespective of the angular subtense of the apparent source or pulse duration, and provided that the following restriction is met: the wavelength shall be within the range of 400 nm – 700 nm

It was originally intended to apply d2) not only up to a wavelength of 700 nm but to permit twice the AEL of Class 1 also above 700 nm in the near infrared. Due to a misunderstanding when transferring changes between different draft versions, the prEN document that is published refers to the range up to 700 nm only. If the concept of permitting emissions above Class 1 and Class 2 finds sufficient support, it is intended to extend the range into the near infrared.

Additionally, the second enquiry draft requires that it shall be documented in the information for the user that an emission level of Class 3R is necessary for the functioning of the product. Also, additional wording is required on the explanatory label. An example label is shown in Figure 6. The wording "EN 50689:2019" shows that the product is suitable for consumers.

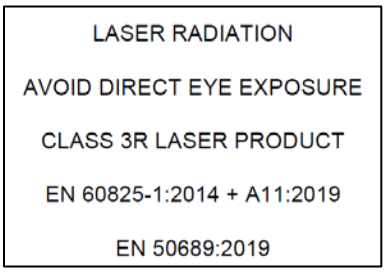


Figure 6: Example of wording for explanatory label of a Class 3R laser product that meets the requirements defined in prEN 50689 and is suitable for consumers.

Requirement d2) defines how much the AEL of Class 1 and Class 2 can be exceeded for a consumer laser product using factors between 1.5 and 2. What is the rational for these factors? In principle the factors are based on a worst-case (minimum) margin [4, 13,] between the AEL of Class 1 and Class 2 and a level where an exposure can still be characterised, with a good reliability as very low risk for leading to retinal injury for reasonably foreseeable exposure conditions. "Worst-case" (minimum) factor here means that for most pulse duration ranges, retinal spot sizes and number of pulses the margin is larger, in some cases considerably larger. The values can be seen as a trade-off between having very complex rules (e.g. different factors for different pulse durations and repetition rates; however, with the challenge that this would not only be very complex but the exact safety margin is also not known for all wavelength/ pulse duration/ exposure duration combinations) and having the permitted factors based on the worst case with the lowest safety margin. The definition of the factors distinguishing between a number of wavelength ranges has an acceptable level of complexity and the lower factor of 1.5 addresses the fact that generally the injury threshold is lowest for green/yellow wavelengths.

Since there are major changes compared to the first prEN draft, a second Enquiry (prEN) will be made available, rather than continuing to a FprEN with a final vote, as the possibilities for changes at that stage would be very limited. This draft is currently (December 2018) edited by CCMC (CEN-CENELEC Management Centre) and will be sent to translation into German and French at the beginning of January 2019. The end of the Enquiry is currently scheduled for 24th May 2019. It remains to be seen if the proposed text of the second Enquiry is adopted in this way and published as a standard which is then listed under the GPSD (the listing under the LVD is optional, since EN 60825-1 is listed under the LVD and EN 60825-1 requires compliance with EN 50689), or if it might be necessary to revise the draft to pursue a more restrictive approach with respect to Class 3R in order to achieve full acceptance also at the European Commission level.

## References

[1] Koch HJ (2017). Practical Guide to International Standardization for Electrical Engineers: Impact on Smart Grid and e-Mobility Markets. Wiley.

[2] Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

[3] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

[4] ICNIRP (2013) Guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1000 µm; Health Physics 105: 271-295.

[5] Schulmeister K., Jean M., Lund D.J., Stuck B.E. (2019) Comparison of laser induced corneal injury thresholds with safety limits; submitted to Journ Laser Appl.

[6] IEC 60825-1:2014/ISH1:2017 Interpretation sheet 1 - Safety of laser products - Part 1: Equipment classification and requirements.

[7] IEC 60825-1:2014/ISH1:2017 Interpretation sheet 2 - Safety of laser products - Part 1: Equipment classification and requirements.

[8] EN 60825-1:2014 Safety of laser products – Part 1: Equipment classification and requirements.

[9] 2014/59/EU: Commission Decision of 5 February 2014 on the safety requirements to be met by European standards for consumer laser products pursuant to Directive 2001/95/EC of the European Parliament and of the Council on general product safety.

[10] M/511 Standardisation mandate to CEN, CENELEC and ETSI relating to harmonised standards in the field of the Low Voltage Directive.

[11] M/531 Commission Implementing Decision C(2015) 557 of 5.2.2015 on a standardisation request to the European Committee for Electrotechnical Standardisation concerning consumer laser products pursuant to Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive 2001/95/EC of the European Parliament and of the Council.

[12] TC76/Sec00125/RM: Minutes of the 24th meeting of CLC/TC 76 held on 12 June 2018 at OVE, Vienna, Austria

[13] Sliney D.H., Mellerio J., Gabel V.P. & Schulmeister K. (2002) What is the meaning of threshold in laser injury experiments? Health Physics 82: 335-347.

## Meet the Authors

Jan Daem is an Optical radiation safety expert and ECO officer at BARCO and ex-Chairman of the Laser Illuminated Projector Association (LIPA) 2014-2018. Jan Daem supports the worldwide introduction of laser illuminated projector systems. Jan is experienced in optical radiation evaluation as well as interacting with regulatory officials at region, state and EU Commission levels. Jan is also active on the IEC TC-76 Committees. Jan Daem is chair of CENELEC CLC TC 76.

Annette Frederiksen, PhD, is a research engineer in the Corporate Research and Advanced Engineering department at Robert Bosch GmbH. Her working topics are simulation, development and prototyping of new concepts for display and optical sensor technologies. Annette is deeply involved in eye safety evaluation of complex laser products and actively participates as an expert in the German (DKE/GK 841), European (CLC/TC 76) and international (IEC TC 76) standardization committees for optical radiation safety. In 2017, she became Secretary of CLC/TC 76 and in 2018 Assistant Secretary of IEC TC 76.

John O'Hagan, PhD, heads the Laser and Optical Radiation Dosimetry Group at Public Health England. He is responsible for providing advice to the UK Government and others on laser and optical radiation safety. He is also a Visiting Professor at Loughborough University. John is a member of the Scientific Expert Group of ICNIRP, Director of Division 6 "Photobiology and Photochemistry" of the International Commission on Illumination and is a member of the World Health Organization Core Group drafting international standards and recommendations for non-ionizing radiation safety. He is the UK representative on CLC/TC76 and Chairs the UK shadow BSI Committee, EPL/76.

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 the ICNIRP Scientific Expert Group. He served as project leader for the development of IEC 60825-1 Edition 3 and is project leader for the CENELEC project A11 for EN 60825-1. The research in his group over the last ten years concentrated on thermally induced eye and skin injury that also provided the scientific background for amending the spot size dependence and multiple pulse rules of the retinal thermal limits.

# Laser product safety standardization projects of CENELEC TC 76

Jan Daem, Annette Frederiksen, John O'Hagan, and Karl Schulmeister

Citation: ILSC **2019**, 403 (2019); doi: 10.2351/1.5118577
View online: https://doi.org/10.2351/1.5118577
View Table of Contents: https://lia.scitation.org/toc/ils/2019/1
Published by the Laser Institute of America