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WHITE PAPER

EN 50689: European Safety Standard for Consumer Laser Products

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Version 2a
2024.10.18

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1 SUMMARY

In October 2021, a new safety standard for consumer laser products was published by the European standardisation organisation CENELEC. The designation of the standard is EN 50689:2021 and the title is “Safety of laser products - Particular Requirements for Consumer Laser Products”. This is a “European only” standard, i.e. it is applicable only in the European Union and associated countries that also adopt CENELEC standards. The reference to EN 50689:2021 is listed as harmonised standard under both the General Product Safety Directive and the Low Voltage Directive. With regard to the classification of laser products, as well as the engineering, labelling and user information requirements, EN 50689 refers to EN 60825-1:2014 amended by A11:2021.

The main objective of EN 50689:2021 is to define which laser classes are considered sufficiently safe for consumer products. Child appealing laser products may only be Class 1 laser products. Some additional requirements are specified with respect to the maximum permitted irradiance at contact with the product and at the location of the smallest beam diameter. General consumer laser products (i.e., those that are not child appealing) are not permitted to be Class 1M, 2M, 3B or 4. A subset of Class 3R lasers is compliant when a number of conditions are fulfilled. EN 50689:2021 stipulates requirements for the user information (i.e. the user manual) and labelling on the product, that are additional to the requirements of EN 60825-1.

For most consumer laser products that are not child appealing and are classified as Class 1 or Class 2 based on EN 60825-1:2014 with A11:2021 there are no relevant additional requirements for the design or emission of the product. Besides an adjusted labelling, the only potentially relevant requirement pertains to radiation accessible during user maintenance (which can be considered very rare in practice), and that the emission measured through a 3,5 mm aperture stop at the worst-case position in the beam has to be less than the AEL for Class 3B.

2 INTRODUCTION

This white paper is intended to provide background information from the perspective of a member of the standardisation committee responsible for the development of EN 50689:2021. This document is not intended to serve as a comprehensive overview of EN 50689:2021. It does not supersede the necessity for a thorough examination of the original text of EN 50689:2021 in order to ascertain compliance of a product.

Whenever the text in this white paper refers to EN 50689 without the year-specification, the full reference of EN 50689:2021 is implied. Whenever the text refers to EN 60825-1, EN 60825-1:2014 with A11:2021 is implied.

For a discussion on the Amendment A11:2021, see the respective white paper.

3 DOCUMENT REFERENCE

The standard EN 50689 was developed by the technical committee TC 76 of the European standardisation organisation CENELEC. The English title is “Safety of laser products - Particular Requirements for Consumer Laser Products”.

The following is the link to the CENELEC document website:
https://standards.cencenelec.eu/dyn/www/f?p=CENELEC:110:::::FSP_PROJECT,FSP_ORG_ID:65305,1257167&cs=1C096CFE50F911A283F4ED8276BAE8027

This standard is a “European only” document, i.e. there is no equivalent international (IEC) standard. At the beginning of the project, it was discussed in the relevant IEC technical committee IEC TC 76 to make this an IEC standard project with parallel voting for Europe. However, it soon became evident that it would not be possible to agree on the question of how to handle Class 3R laser products on an international level. The project was initiated at the CENELEC level, without involvement of the IEC.

In terms of scope and content, EN 50689 can be seen as an extension of EN 60825-1 [1]. The initial plan was to incorporate this standard into the EN 60825 series with the document designation EN 60825-1-1. However, for a “Europe only” document this was not possible, since CENELEC documents that do not have an IEC parallel document are not permitted to have a 6⋯ number. This original intent and the close relationship to EN 60825-1 are evident in the title of EN 50689 “Safety of laser products…”, which is the title of EN 60825 series of standards.

The standard EN 50689 was issued by CENELEC in November 2021 as the English language version. The translation into German was not available at that time and was published in 2022. As is the case for all CENELEC documents, the standard cannot be purchased from CENELEC, but needs to be purchased from one of the national standardisation organisations. It is mandatory for national standardisation organisations to publish an identical national standard until September 2022 the latest. Several national standardisation organisations that publish English version documents made the document available already in November 2021, such as in the Netherlands[1], where the document is designated NEN-EN 50689:2021. The German version was published by DIN in December 2022 as DIN EN 50689:2022. The title is “Sicherheit von Laserprodukten – Besondere Anforderungen an Verbraucher – Laser - Produkte”. The technical content of these national versions has to be identical with the original English version of EN 50689:2021.

[1] https://www.nen.nl/en/nen-en-50689-2021-en-289322

4 MOTIVATION AND RELATIONSHIP TO EN 60825-1

EN 60825-1 (and the IEC version, IEC 60825-1:2014) applies to all laser products, i.e. to both consumer products and professional laser products[2]. The origin of EN 60825-1 is IEC 825 Edition 1 from 1993, which was developed at a time when all laser products were professional laser products. That is, at the time there was basically no laser product that was a consumer product. Therefore, it was not necessary to define which laser classes are acceptable for consumer products. That concept of IEC 60825-1 was never changed, and IEC 60825-1 still does not distinguish between consumer laser products and non-consumer laser products. For example, a high-power open-beam laser product is compliant with IEC 60825-1, based on a warning label that the product is Class 4 and that eye or skin exposure is hazardous. In accordance with product safety policy in the European Union (but also in many other countries), such a product is not considered sufficiently safe if it is a consumer product. Thus, while compliance with EN 60825-1 (in the current version with Amendment A11:2021) is associated to result in a presumption of conformity with the Low Voltage Directive (LVD) 2014/35/EU [2], compliance with EN 60825-1 does not mean that it is sufficiently safe as a consumer product. This was generally known and is the basis for a note in IEC 60825-1. Note 3 of the scope of IEC 60825-1:2014 (equivalent to Note 4 of the Edition 2 of 2007) says that "*…Class 3B or Class 4 laser product may not be suitable for use as a consumer product.".* Product safety (market surveillance) authorities in the European Union acted accordingly and - based on the requirement for safe products of the General Product Safety Directive (GPSD) 2001/95/EC [3] - regularly took unsafe laser products from the market[3]. The situation with respect to European standards was not satisfactory so that the European Commission issued a decision and a mandate for the development of a standard for consumer laser products[4].

Based on the request by the European Commission, CENELEC had the choice to either amend EN 60825-1 to address in EN 60825-1which products are considered sufficiently safe as consumer products, or to develop a dedicated standard. In order to remain flexible when it comes to EN 60825-1 being ideally identical with IEC 60825-1 (which due to amendment A11 is currently not the case), CENELEC TC 76 decided to develop a standard separate from and additional to EN 60825-1.

An important aspect is that Amendment A11:2021 to EN 60825-1, for consumer products, requires compliance with EN 50689. This way, compliance with EN 60825-1 and the amendment A11 also makes it necessary to comply with EN 50689, when applicable.

The requirements of EN 50689 have to be seen as *additional* to EN 60825-1 with A11. EN 50689 in Clause 4 requires that laser products in the scope of EN 50689 shall comply with EN 60825-1:2014 and the amendment EN 60825-1:2014/A11:2021, including classification, labelling and user instructions.

[2] Professional products (i.e. non-consumer products) are placed on the market to be used solely at the work place, by the military, medical doctors, etc.. See definition of consumer laser product in EN 50689 discussed below.

[3] https://ec.europa.eu/safety-gate-alerts/screen/search?resetSearch=true search for "laser"

[4] See Commission Decision 2014/59/EU https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32014D0059 and Mandate M/531 from 2015 https://ec.europa.eu/growth/tools-databases/mandates/index.cfm?fuseaction=select_attachments.download&doc_id=1570

5 NOTES ON LEGISLATION FOR CONSUMER LASER PRODUCTS

A detailed discussion of legal issues is not in the scope of this white paper. Some comments are provided in the following for some countries in Europe.

Germany has issued formal guidance for consumer laser products, not permitting Class 3R laser products to be placed on the market[5]. This “Technische Spezifikation”, last updated in 2013, has a limited scope of application, not applying to products that fall under a CE-Marking directive such as the LVD, and neither to products where a harmonised standard exists, where, however, standards are listed as examples that have been withdrawn in the meantime[6].

Austria has a by-law to the national transposition of the GPSD, pertaining to laser pointers and not permitting Class 3R or higher[7]. Following the harmonisation of EN 50689 under the GPSD in September 2024, it is planned to repeal this by-law.

Switzerland (not a EU member state) banned the possession and placing on the market of laser pointers of even Class 2, i.e. only permits Class 1 laser pointers[8].

France has a law, prohibiting the ownership and usage, as well as the placing on the market of laser products above Class 2 except for professional usage. In terms of relationship to the Common Market (also called the Single Market) in the EU, the legislation in France[9] is an interesting case, because it is a law (and not a by-law to the national transposition of the GPSD such as in Austria or the Technische Spezifikation in Germany which is neither a law nor a by-law). The standard NF EN 60825-1 is specifically referenced[10] with the edition valid on March 15th 2011, which is Edition 2.0 of EN 60825-1.

> **Article 2** Modifié par Décret n°2012-1303 du 26 novembre 2012 - art. 1
>
> Au sens du présent décret, on entend par :
>
> -laser sortant : tout dispositif qui peut produire ou amplifier un rayonnement laser dont le faisceau est accessible ;
>
> -rayonnement laser : tout rayonnement électromagnétique compris dans la gamme de longueurs d'onde entre 180 nm et 1 mm, produit par le phénomène d'émission stimulée contrôlée ;
>
> -appareil à laser : tout appareil ou toute combinaison de composants qui constitue, incorpore ou est destiné à incorporer au moins un laser sortant ou un système à laser.
>
> La classe 2 au sens de l'article 68 de la loi n° 2011-267 du 14 mars 2011 susvisée est celle définie à la norme NF EN 60825-1 relative à la sécurité des appareils à laser, dans sa rédaction applicable à la date du 15 mars 2011 et visée par l'avis aux fabricants, importateurs et distributeurs relatif à l'application du décret n° 2007-665 du 2 mai 2007, publié au Journal officiel de la République française n° 0135 du 13 juin 2009.

The French legislation has not been updated based on the publication of Edition 3.0 of EN 60825-1 in 2014, and from the point of view of the author of this white paper appears not to be harmonised with the EU principle of the Common Market, since Edition 3.0 of EN 60825-1 is harmonised under the LVD. For pulsed emission, Edition 3.0 for Class 1 permits higher emission as compared to Edition 2.0. Some Class 1 lasers that are compliant with Edition 3.0 and are apparently considered “safe” under the LVD (and via reference to EN 50689 also under the GPSD), are Class 3R under Edition 2.0 and therefore banned for placing on the market in France, while permitted in other EU member states. This does not appear to be in line with the objective of the Common Market in the EU.

[5] http://www.baua.de/dok/805812

[6] https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/Laserprodukte/Sichere-Laserprodukte.html

[7] https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20000012

[8] https://www.fedlex.admin.ch/eli/cc/2019/183/de

[9] https://www.legifrance.gouv.fr/loda/id/JORFTEXT000026694613/

[10] https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000646998/

6 HARMONISATION UNDER THE LVD AND GPSD

The development of EN 50689 was requested (mandated) at European Commission level by the Directorate General responsible for consumer safety. As discussed in the previous chapter, product safety authorities were not satisfied with the situation that EN 60825-1 does not specify which classes are acceptable for consumers and which are not.

Following the Commission Mandate of 2015, CENELEC TC 76 started a project to develop EN 50689. The Commission desk officers responsible for the LVD as well as for the GPSD followed the development of the standard, reviewed drafts of EN 50589, and provided comments. Annex ZZA and Annex ZZB of EN 50689 provide information about the relationship of the content of EN 50689 with the safety requirements of the GPSD and the LVD, respectively. For the LVD[11] the reference to EN 50689:2021 has been cited[12] in the list of harmonised standards as updated May 10 2022:

Legislation reference (A)	ESO (B)	Reference number of the standard (C)	Title of the standard (D)	Date of start of presumption of conformity (1)	OJ reference for publication in OJ (2)
2014/35/EU	Cenelec	EN 50689:2021	Safety of laser products - Particular Requirements for Consumer Laser Products	10/05/2022	OJ L 133 - 10/05/2022

For the GPSD[13] the reference to EN 50689:2021 has been cited[14] in the Official Journal in September 2024:

ANNEX

(7) the following rows 36(a), 36(b), 52(d), 65(a) are inserted:

'36a	EN 12790-1:2023 Child care articles – Reclined cradles – Part 1: Reclined cradles for children up to when they start to try to sit up
36b	EN 12790-2:2023 Child care articles – Reclined cradles – Part 2: Reclined cradles for children up to when they start to stand up'.

'52d	EN 17191:2021 Children's Furniture – Seating for children – Safety requirements and test methods';

'65a	EN 50689:2021 Safety of laser products – Particular Requirements for Consumer Laser Products'

[11] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage-lvd_en

[12] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AL%3A2022%3A133%3AFULL
summary list: https://ec.europa.eu/docsroom/documents/50039

[13] https://commission.europa.eu/business-economy-euro/doing-business-eu/eu-product-safety-and-labelling/product-safety/general-product-safety-regulation_en

On December 13 2024, the GPSD will be replaced by the General Product Safety Regulation 2023/988. For the discussion in this White Paper, the differences are not relevant.

[14] https://eur-lex.europa.eu/eli/dec_impl/2024/2406/oj

The legal implications of these listings are - as is generally the case for harmonised standards - that compliance with EN 50689:2021 confers a presumption of conformity with the LVD and the GPSD, for the relevant safety aspects. The LVD is applicable only when the product is not battery driven but on 230 Volt mains - as a simplified criterion with respect to products falling under the LVD. The requirements of the LVD (as well as other sector specific CE-marking directives, such as the Machinery Directive) apply to consumer as well as to non-consumer products in the same way, i.e. do not make a differentiation. The GPSD applies only to consumer products, but it applies to all sectors, i.e. to all types of products. The GPSD is not a CE-marking directive. The GPSD has to be seen in parallel, and additionally to all the sector-specific CE-marking directives such as the LVD. Therefore, a product such as a laser show projector operated on mains and not on battery, when sold to consumers, falls both under the LVD as well as under the GPSD, in case that the GPSD covers aspects of product safety that are not covered by the LVD. The large group of battery driven consumer laser products, such as laser pointers, fall under the GPSD only. A good overview of the European product safety legal system can be found in the Blue Guide.

The role of EN 60825-1 with respect to different CE-marking directives is also discussed in the white paper on A11:2021 to EN 60825-1 [4].

It is important to consider that EN 60825-1:2014 was amended in Europe by A11:2021, and A11:2021 has been listed under the LVD in 2021, with a transition period ending in June 2023. According to A11:2021, compliance with A11:2021 requires that the product, when it is a consumer product, also complies with EN 50689:2021 (see also white paper on A11 [4]). This means that when a manufacturer states compliance with EN 60825-1:2014 and A11:2021, it is necessary that the product also complies with EN 50689:2021.

With respect to listing of the reference to EN 50689:2021 under the GPSD - relevant for instance for battery driven laser consumer products - and the question at which point in time products that are brought onto the market in the European Union *have* to be compliant with EN 50689, the following comment is offered in this white paper. Since EN 50689:2021 is a new standard and does not replace an earlier version in the list of harmonised standards, there is no formal “transition period”, neither for the listing under the GPSD nor for the listing under the LVD. “Transition period” would mean a period where the reference to a new standard is listed as harmonised standard, but a standard that was harmonised before can be used alternatively for some time (such as EN 60825-1:2014 without amendment A11:2021 until June 2023 under the LVD).

Legally, as a basic principle of the New Approach and the common market in the European Union, harmonised standards are not mandatory[15]. The requirements of the applicable product safety directives can be fulfilled, as a general principle, without complying to standards. However, in practice this legal principle is very difficult - and often unrealistic - to follow, particularly with respect to laser safety and compliance with EN 60825-1. For instance, in practice it is often challenging to convince market surveillance authorities that a product is sufficiently safe (i.e. has a sufficiently low risk for injury) when the product does not comply with the applicable harmonised safety standards. Relevant for the question at what point in time the standard “has to be applied”, or when a product that is brought onto the market in the European Union “has to be compliant” with EN 50689 is also that the strict safety requirements of the GPSD of course apply also when there is *no* specific safety standard. The safety requirements of the GPSD are very general, and the role of a harmonised standard is to provide specific requirements to achieve sufficiently safe products, in order to assist the

[15] See for instance the Blue Guide. Even though strictly speaking, the GPSD is not a “New approach” directive, that principle also applies for the GPSD.

manufacturer to comply with the requirements of the more general Directive[16]. The safety requirements of the GPSD are also quite strict, and they have to be applied irrespective of the existence of a standard. It could be argued that a product that is not compliant with the safety requirements of EN 50689 might well not have been safe enough to be brought onto the market also in the time before EN 50689 existed – this of course does not apply to details such as a required statement of compliance on the product label. We can also see in the list of products where for many years, market surveillance authorities in EU member states' corrective action frequently involved laser products of Class 3R and higher classes (see footnote 3 on page 6 above), even though EN 50689 did not serve as basis. The corrective actions as listed are formally and generally not based on non-compliance with standards, since standards are not mandatory. The basis for the corrective action was simply the requirement by the GPSD to only bring safe products onto the market and that the products presented a "hazard to the eye". In practice, for EN 60825-1 it is also difficult to argue by the manufacturer that it is not applied, because it is a standard (also as IEC version internationally) that it is generally accepted and applied by manufacturers, so that consumers (and market surveillance authorities) can expect that all laser products comply with EN 60825-1 even it is not legally mandatory. Compliance with EN 60825-1 can be seen as criterion for a *minimum* level of safety. While EN 60825-1:2014 and A11:2021 does not specify which products are sufficiently safe for consumer products, compliance with EN 50689:2021 is a specific requirement in EN 60825-1:2014 as amended by A11:2021.

7 SCOPE

While the scope of EN 50689 - consumer laser products - is rather wide, some product groups have been excluded from the scope of EN 50689.

Consumer laser products that are classified as Class 1C according to EN 60825-1 are not in the scope of EN 50689. These are mostly devices for hair removal and possibly also bio-stimulation (low level laser therapy). The two main safety relevant issues for these devices are the performance of the contact switch as well as a limitation of the maximum exposure level for the skin. The classification as Class 1C under EN 60825-1 implies mandatory application of a specific vertical standard from either the EN 60335 (household products) or EN 60601 (medical products) series. It is the responsibility of these vertical standards to provide safety requirements that are sufficient to result in safe consumer products.

Similarly, electric toys containing lasers are not in the scope of EN 50689, because the safety requirements are covered by EN 62115 "Electric toys – Safety", which is harmonised under the Toy Safety Directive 2009/48/EC.

It was also necessary to take laser products intended for long-term intentional eye exposure with visible radiation out of the scope. The specific wording used is "*…consumer laser products that are designed to project laser radiation in the wavelength range of 380 nm to 780 nm onto the retina, with an intended daily usage duration of potentially many hours (such as for virtual reality or augmented reality applications)…".* Products that are implied are for instance augmented reality or virtual reality devices using laser radiation to project an image onto the retina. The reason for excluding this product category from the scope is that emission levels permitted by Class 1 are extremely bright and potentially too high to preclude any potential adverse effect on the retina, for long term usage, i.e. many hours a day, every day. It can be

[16] The New Approach and the relationship of the essential requirements of Directives with harmonised standards was developed and established for the CE-Marking Directives, but later on, references to standards were also published in the OJEU for the GPSD.

assumed that the levels permitted by Class 1 are not used for such devices, because they would result in severe dazzle and disability glare, and the product would not be functional as a display. In other words, these devices would not make use of the maximum permitted emission level of Class 1 anyway, in order to be in an appropriate brightness range of comfort for the user. However, when the question is what level of maximum emission level is sufficiently safe for devices that are potentially worn for many hours a day every day, there are currently no recommended levels available. For augmented reality devices there is also the challenge that light emitted by the product is *additional* to the light from other sources, and that retinal exposure is additive. Thus, if a safe exposure level were known for the retina for these long-term conditions, the exposure limit would apply to the emission of the laser device together with the exposure from other light sources. This additivity also applies over time, i.e. over days [5] and to light exposure occurring before or after the augmented reality device is used.

An additional challenge and reason to take these devices out of the scope of EN 50689 is related to faults of augmented reality devices. It is not only necessary to avoid faults associated to levels of emission that result in retinal injury, but also to avoid momentary higher levels that cause dazzle or disability glare. After all, any kind of sudden and unexpected high level of brightness might cause accidents when the person operates machinery or a vehicle. There are no standardised maximum levels of emission available to preclude this type of hazard[17].

8 DEFINITIONS

The following terms and definitions were included in EN 50689; the terms and definitions of EN 60825-1 apply additionally.

- Consumer laser product
- Consumer
- Child appealing consumer laser product
- Laser pointer

For the definition of consumer laser product, it is relevant to note that it is relatively wide and includes not only products intended for consumers but also those that are *likely to be used* by consumer under reasonably foreseeable conditions *even though the product is not intended for consumers.*

In practice, from the perspective of market surveillance authorities, the distribution channels are also a criterion for determining whether a product is considered a consumer product or not. For the example of a laser cleaning device (rust removal, etc.) in case it can be rented in a do-it-yourself (home improvement) shop, this is considered as a consumer product.

The development and agreement for the definition of “child appealing” was somewhat of a challenge in the drafting process, since the level of intended restrictiveness varied considerably amongst experts. One contentious issue was the maximum age for the consideration of child appealing. In the end, the definition just referred to “child” without an age limit.

A child appealing consumer laser product is a product that is attractive to children due to its characteristics such as function, movement, colour, characters, sounds, lights, shape, texture, size, smell or taste. There are three criteria in the definition - a laser product is considered child appealing when one of them, or more, are fulfilled.

[17] Due to the lack of scientifically based maximum exposure levels both for the nominal emission for long term intended usage as well as for fault emissions, the author of this White Paper has also recommended that visible radiation is taken out of the scope of IEC TS 60825-20, which is under development
https://www.iec.ch/dyn/www/f?p=103:38:6935955410995::::FSP_ORG_ID,FSP_APEX_PAGE,FSP_PROJECT_ID:1264,23,104384

- The first criterion is that the laser product is intended for use by children.
- The second criterion is that the laser product resembles something that is commonly recognised as being appealing to children.
- The third criterion is that the laser product has a feature or characteristic that is likely to be appealing to children.

The definition of child appealing laser product is potentially vague and therefore examples and notes are added to attempt to clarify and avoid ambiguity. Examples of child appealing products are laser products that resemble cartoon characters, toys, guns, watches, telephones, musical instruments, vehicles, human body or parts of the human body, animals, food or beverages. The key here is that the laser product *resembles* these products, but it is not actually such a product. For instance, a normal smart phone, mobile phone or tablet is not considered as child appealing. When the smart phone, however, is made to look like a cartoon character, then it is child appealing. When the laser product resembles a smart phone but is not an actual phone, it is also child appealing.

More examples given are laser products playing notes or sounds, having flashing lights, moving parts or other entertaining features.

In a note it is clarified that the emission of a visible laser beam as such does not make a laser product child appealing. Therefore, for instance, a normal laser pointer is also not child-appealing according to the definition of the standard. A laser pointer could, however, be made child appealing when it looks like a cartoon character or when it produces sounds, for instance. EN 50689 does not permit a laser pointer to be child appealing, as a requirement in Clause 6.

It is also noted in the standard that “child appealing” depends on a case-by-case assessment of the character of the product with a reference to the New Declaration of ADCO on Child Appealing Appliances, LVDWP/14/4 (2015).

9 CHILD APPEALING LASER PRODUCTS

Requirements for the case that the laser product is a child appealing laser product (for simplicity, the abbreviation CALP is used in the following) are defined in Clause 5 of the standard.

The general requirement is that a CALP shall be a Class 1 laser product. Some additional restrictions, i.e. more stringent than the ones of EN 60825-1 for Class 1, are found in EN 50689, as discussed in the following.

The classification distance in EN 60825-1 for the wavelength range of 302,5 nm to 4000 nm for measurement Condition 3 is based on a minimum distance of 100 mm from the reference point. This permits relatively high irradiance levels at the closest point of human access (i.e. touching the device) when the beam is diverging and particularly when the Class 1 AEL is based on an extended source. A significant hazard for the skin or the anterior parts of the eye can result when exposure occurs to these high irradiance levels. EN 60825-1:2014 requires a warning label in Subclause 7.13 if the accessible emission determined with a circular 3,5 mm aperture stop exceeds the AEL of Class 3B.

For consumer laser products, CENELEC TC 76 did not consider such a warning label as sufficient to address the potential risk. Therefore, for child appealing laser products, EN 50689 requires that the accessible emission determined at the closest point of human access shall not exceed the maximum permissible exposure (MPE) values for the skin as specified in EN 60825-1 in Table A.5. This requirement not only applies to the closest point of human

access (i.e. determination of the accessible emission at the exit aperture) but additionally to the “point of highest accessible emission” which for converging beams is outside of the protective housing. For circularly symmetric beams, this point is the beam waist.

The skin MPE values are used here as product emission limit, not as exposure limit. The skin MPE can be seen as additional, or in parallel, with the Class 1 AEL and the respective measurement conditions to determine the accessible emission to be compared with the Class 1 AEL. For the determination of the accessible emission to be compared with the skin MPE, a circular limiting aperture (which functions as averaging aperture to average irradiance or radiant exposure) with a diameter of 1 mm is defined for the determination of the irradiance or radiant exposure to be compared against the MPE. This limiting aperture is more conservative than the 3,5 mm limiting aperture permitted for an MPE analysis in Annex A of EN 60825-1. For this additional requirement, EN 50689 defines a time base of 10 s for wavelengths above 400 nm. In this wavelength range, for $t \geq 10$ s, the skin MPEs assume a constant irradiance value. For extended source products with divergent beams, this requirement can be significantly more restrictive than what would be permitted for Class 1. The skin MPE in the wavelength range of 400 nm to 700 nm for $t \geq 10$ s equals 2000 W m^{-2}. This level is reached when 1,6 mW of power (for pulsed emission, average power) pass through a 1 mm aperture stop. For a wavelength of, for instance, 905 nm, 4,0 mW of power is permitted to pass through a 1 mm aperture stop.

The UV wavelength range is treated differently. While it does not appear likely or appropriate that a CALP emits in the UV, it cannot be excluded. It would be appropriate to require “no UV emission” for CALP, but this would imply a limit of equal to 0 W m^{-2}, which is not possible to confirm by measurement. Thus, an emission limit was also defined in the UV wavelength range. For wavelengths less than and equal to 400 nm, a time base of 1000 s is defined in EN 50689. For the wavelength range of 315 nm to 400 nm, the time base of 1000 s is consistent with the exposure duration from which onwards the skin MPE is given as constant irradiance of 10 W m^{-2}. For wavelengths less than 315 nm, a time base of 1000 s might not appear sufficiently restrictive. However, for this wavelength range, a limit of 0,001 W m^{-2} is given specifically in EN 50689, which overrules the requirement based on the skin MPE determined for a time base of 1000 s. The limit of 0,001 W m^{-2} was derived from the skin MPE of 30 J m^{-2} defined for wavelengths of 180 nm to 302,5 nm for an assumed exposure duration of 30 000 s (about 8 days), i.e. 30 J m^{-2} / 30 000 s = 0,001 W m^{-2}. As such, this is a worst-case value in terms of skin MPEs, not only with respect to the assumed exposure duration but also because for wavelengths between 302,5 nm to 315 nm, the skin MPE is higher, given by C_2 J m^{-2}. In effect this is equivalent to defining the time base as equal to 30 000 s and setting the MPE to 30 J m^{-2} also for the wavelength range of 302 nm to 315 nm instead of the increased limit as given by C_2 J m^{-2}. For the case of pulsed emission, while it is not stated specifically in EN 50689, the limit of 0,001 W m^{-2} has to be understood as to apply to the average irradiance and not the peak irradiance of a pulse. The basis is the underlying radiant exposure limit of 30 J m^{-2}.

Based on a comment from the EU Commission, the requirement that a CALP shall comply with the battery safety requirements from EN IEC 62115:2020 „Electric Toys – Safety” was included.

10 NON-CHILD APPEALING LASER PRODUCTS

10.1 Introduction

In Clause 6, the standard defines the requirements for laser products that are not child appealing laser products. Clause 6 is organised into requirements that apply generically to all consumer laser products that are not child appealing and requirements that apply additionally for the case of Class 3R consumer laser products.

10.2 Generic requirements

10.2.1 Basic issues

The requirements as discussed in this subchapter 10.2 (given in subclause 6.1 of EN 50689) apply to all consumer laser products that are not child appealing laser products.

As an underlying requirement, the requirements of EN 60825-1:2014 and EN 60825-1:2014/A11:2021 with respect to classification, engineering, labelling and information for the user apply.

Consumer laser products shall not be Class 1M, Class 2M, Class 3B or Class 4. Some Class 3R consumer laser products are permitted if they comply with the restrictions defined in subclause 6.2 of the standard.

Some additional requirements will be discussed below.

10.2.2 Class 1M and Class 2M

While it was apparent from the beginning of the project that products with Class 3B and Class 4 classification are not permitted for consumer laser products, the issue was not so clear-cut for Class 1M and Class 2M. Class 1M and Class 2M implies that the emitted laser beam is collimated and has a diameter that is larger than 7 mm. The following is a simplified discussion and applies to the retinal hazard wavelength range of 400 nm to 1400 nm. A product is classified as Class 1M or Class 2M, if the accessible emission determined with an aperture diameter of 7 mm (Condition 3) is below the AEL of Class 1 or Class 2, respectively, but the accessible emission determined with an aperture diameter of 50 mm (not closer than 2 m from the product, Condition 1) exceeds the AEL of Class 1 or Class 2. The associated meaning is that exposure of the unaided is safe (with the meaning of “safe” as implied by the class limits), while there is a potential hazard for retinal injury when exposure with binoculars and telescopes occurs. For instance, let us assume the beam is very well collimated so that $C_6 = 1$ also applies for binoculars and telescopes with the magnification of 7 x as assumed for Condition 1, and the beam irradiance profile diameter is larger than 50 mm and homogeneous within the 50 mm. For this example, the laser power that can potentially pass through the 50 mm binocular and into the eye is a factor of 51 higher (the ratio of the respective areas) than the power passing through a 7 mm pupil of the unaided eye. In other words, when the accessible emission for the unaided eye is equal to the Class 1 or Class 2 limit, then with a 50 mm binocular, the respective limit is exceeded in this simplified example by a factor of 51. Clearly even when considering some safety margin between the injury threshold and the AEL, such an exposure level has a high potential to exceed the injury threshold of the retina even for short exposure durations. The exposure level will be lower if the binocular used is not a 50 mm binocular (a 7 x 50 or 10 x 50 binocular is often used by hunters to compensate for lower light conditions) but a smaller binocular, such as the more common 7 x 35 mm. Also for a 7 x 50 binocular, the AEL is exceeded by a factor smaller than 51 if the laser beam diameter is smaller than 50 mm. The factor by how much the limit is exceeded for exposure with a binocular depends on the beam diameter, the divergence, the exposure distance, the objective lens diameter and the

magnification of the binocular (in case the retinal image becomes extended due to the magnification).

If it is assumed that retinal injury occurs for a given exposure with a binocular or other telescope, then the risk for injury (such as the probability per hour of using the product, or the probability per lifetime of the product) is equal to the probability that retinal exposure occurs to the Class 1M or Class 2M laser beam through a binocular. There are two requisites for retinal exposure to occur and the probability for retinal exposure (and therefore retinal injury) is a combination of the two respective probabilities: the probability of the laser beam being incident on a binocular used by a person (such as per hour of using the binocular), and that the person has the laser within the field of view of the binocular - that is, is looking towards the laser. The combined probability for retinal exposure will strongly depend on the type of the laser device (where the laser beam is pointed) and the usage scenario of binoculars, i.e. the density of binoculars and where they are pointed at.

Since the criteria for a sufficiently safe product in the sense of the GPSD are strict, and because for some scenarios the probability for exposure can be relatively high, it was decided not to include Class 1M and Class 2M lasers as compliant with EN 50689. It should be noted, however, that compliance with EN 50689 is not legally mandatory. If the higher emission level is necessary for the given type of product, and the associated risk can be demonstrated to be acceptable, then the product can be seen as viable for a consumer product that although not compliant with EN 50689 might be considered as sufficiently safe based on the GPSD (compliance with EN 60825-1 is implied, with the exception of the requirement of EN 60825-1 of being compliant with EN 50689). The argument and case for the risk to be correspondingly small (ideally, negligible) would have to be strong in order to convince market surveillance authorities that even without compliance with EN 50689, the product is sufficiently safe to comply with the GPSD. Should experience of the application of EN 50689 reveal that there is a well-defined group of products where Class 1M or Class 2M is necessary as emission level and at the same time the risk can be documented to be sufficiently small an amendment of EN 50689 is an option.

10.2.3 Limitation to Class 3B AEL

As already discussed in the chapter on child appealing laser products, EN 60825-1 permits that the emission of Class 1 laser products in the wavelength range of 302,5 nm to 4000 nm exceeds Class 3B limits at contact with only a label warning about the potential risk for skin and corneal injury at contact. For consumer products, this was not considered acceptable by the CENELEC TC 76 experts. Consequently, EN 50689 requires that the accessible emission determined at the closest point of human access and at the point of the highest accessible emission (such as an external beam waist) with a circular aperture stop with a diameter of 3,5 mm shall not exceed the AEL of Class 3B. In other words, while according to EN 60825-1 subclause 7.13, exceeding Class 3B limits at the closest point of human access results in a warning label, such a product (as consumer product) would not be compliant with EN 50689.

10.2.4 User maintenance

EN 60825-1, for Class 1 and Class 2 laser products permits access to Class 3R levels of laser radiation during user maintenance[18]. However, in this case, the access panel that needs to be opened for the user maintenance procedure, according to subclause 6.3 of EN 60825-1, has to be protected by a safety interlock. Consequently, for maintenance to result in access to Class 3R levels, a mechanism to override the safety interlock is necessary. According to

[18] See subclause 6.2.1 of EN 60825-1: "*Maintenance of Class 1, 1C, 1M, 2, 2M, or 3R laser products shall not permit human access to levels of laser radiation of Class 3B or Class 4*.".

EN 60825-1, the use of the override has to result in a visible or audible warning. Overall, this appears to be relatively restrictive as well as probably not relevant for consumer products. However, in order to be conservative, EN 50689 requires that during user maintenance, access to laser radiation in excess of the assigned laser class shall not be possible. Consequently, during user maintenance as defined in the user manual of the product, only radiation of levels of Class 1 or Class 2 are permitted to be accessible, based on the definition of human access in EN 60825-1 (3.40). It is permitted, however, that Class 2 levels of radiation become accessible during maintenance, when the product is classified as Class 1. According to subclause 6.3 of EN 60825-1, in this case it is also not necessary to protect the maintenance access panel with an interlock - but it is necessary to label the access panel.

10.2.5 "Inherent compliance" of embedded Class 1 products

The impetus for the development of EN 50689 stemmed from laser products that emit laser radiation and was not related to embedded laser products, such as Class 1 CD players or laser printers. Due to the added requirement pertaining to user maintenance (see previous subchapter) it was not possible to take embedded laser products out of the scope of EN 50689 all-together.

In order to support that embedded laser products of Class 1 are designated as compliant with EN 50689 with a minimum effort, a note (Note 4) was added to subclause 6.1 of EN 50689, noting that embedded Class 1 laser products with no human access to laser radiation during operation or maintenance (i.e. which are fully enclosed and if an interlocked access panel exists, there is no override mechanism) will comply with all requirements of Clauses 4 to 6 of EN 50689. This note was intended to support that no specific or additional compliance testing with respect to these requirements is necessary. This also applies to products that are classified as Class 1 products based on subclause 4.4 of EN 60825-1 (laser products designed to function as conventional lamps [6, 7]).

For complete compliance with EN 50689, however, a respective compliance statement (subclause 7.1 of EN 50689) is required also for embedded laser products.

10.3 Additional requirements for Class 3R

10.3.1 Background

The question of how to deal with Class 3R laser products, i.e. whether or not to consider them sufficiently safe for consumer laser products, was a point of repeated debates and the main reason for the relatively long development duration of the standard. Some experts argued that Class 3R is generally not permissible for consumer products, others argued that all Class 3R laser products are associated to sufficiently low risk to be acceptable as consumer products (for instance on the background that most Class 3R laser products are considered acceptable as consumer products in the USA for many years).

After various approaches in the drafting stage, agreement was reached by permitting a subgroup of Class 3R products as consumer products, with several conditions. The permitted types of Class 3R products are those where there is solid scientific evidence and general experience from products on the market (such as in the USA) that the associated level of risk for injury is sufficiently small, basically equivalent with the level of risk that is associated to Class 1 or Class 2 products.

The requirements for Class 3R products to be compliant when they are consumer laser products are given in subclause 6.2 of EN 50689. The requirements are organised into eight paragraphs, labelled from a) to h). All of the eight requirements have to be fulfilled in order for

the product to be compliant with EN 50689, with the subsequent implication that the product is sufficiently safe (together with required labelling and user information) to be compliant with the GPSD.

10.3.2 Need for higher emission to be documented

The generic requirement to avoid higher classes when feasible, based on the intended function of the product, was already given in Clause 4 of EN 50689. In other words, when the intended functionality of the product can be achieved with Class 1 or Class 2 classification, then according to Clause 4 of EN 50689, Class 3R is not permitted. Subclause 6.2 b) requires that the respective deliberations for the need of Class 3R levels of emission are included in the user manual. In this statement it needs to be justified why the higher levels of a Class 3R are required for the functioning and application of the respective product and why Class 1 or Class 2 is not adequate.

Candidates for Class 3R laser products where the above is fulfilled are, from the point of view of the author of this white paper, for instance, lasers that are incorporated in spirit levels or other alignment tools as typically sold in do-it-yourself (home improvement) shops. When used outdoors in sunshine, even for a wavelength in the green wavelength range, the limitation to 1 mW and Class 2 makes the laser-dot often difficult to see. Another example could be distance measurement devices where the emission permitted for Class 1 or Class 2 is not sufficient to achieve the required distance range.

10.3.3 Limitation of emission

Subclause 6.2 e) to h) relate to limitations of the emission of the laser product in order to be acceptable as Class 3R.

6.2 e) defines that the emitted wavelength that is associated to Class 3R levels has to be in the range of 400 nm to 1250 nm. Thus, within what is referred to the retinal hazard wavelength range, wavelengths greater than 1250 nm and up to 1400 nm are not permitted. This limitation is based on smaller potential safety margins and also some uncertainties about the injury threshold for the retina in the wavelength range above 1250 nm [8].

6.2 f) limits the emission to Class 3R AEL values that are determined with $C_6 = 1$. Thus, even if the source is an extended source, the AELs for Class 3R are determined with $C_6 = 1$. This is based on minimum safety margins (also referred to as reduction factors in the bioeffects community) for extended sources of the order of 2,5 when comparing the AEL of Class 1 or Class 2 for extended sources ($C_6 > 1$) with the injury threshold of non-human primates (see references [9,10]). Since Class 3R AELs are defined to be 5 x the AEL of Class 1 or Class 2 (depending on the wavelength range), the emission of some extended source Class 3R products with $C_6 > 1$ would exceed the injury threshold as determined by non-human primate studies. The actual risk for injury is a complex issue and depends on several factors, a discussion of which is not on the scope of this white paper.

For continuous wave (cw) emission in the wavelength range of 400 nm to 700 nm, the restriction of $C_6 = 1$ means that the AEL for Class 3R is equal to 5 mW. For the wavelength range of 700 nm to 1250 nm, the wavelength correction factors $C_4 \times C_7$ come into play, so that the Class 3R AEL for cw emission and $C_6 = 1$ equals $2 \times C_4 \times C_7$ mW. As an example, for 905 nm the AEL equals 5,1 mW and for 1064 nm it equals 10,7 mW, respectively. That the Class 3R AEL for 905 nm (where $C_4 = 2{,}57$) is almost equal to the Class 3R in the visible wavelength range is based on the time base of 0,25 s for the visible wavelength range while it is 100 seconds for wavelengths above 700 nm and the AEL decreases, when expressed as power value, down to 5,1 mW for $T_2 = 10$ seconds.

While the AEL value for Class 3R is limited to the one obtained with C_6 = 1, it is still possible to perform a normal classification as extended source for Class 1 and Class 2. When the angular subtense of the apparent source is sufficiently large, this is less restrictive (i.e. higher emission levels are permitted) than the Class 3R limitation with C_6 = 1. Classification as Class 1 or Class 2 is in this case even required by Clause 4 of EN 50689.

Detailed arguments and references to demonstrate the low level of risk for the abovementioned emission levels are found for instance in references [11 and 12]. As a short summary for visible laser emission, a level of 5 mW is associated to a negligible risk for injury for the implied exposure conditions based on the following sources of information:

- Non-human primate studies for collimated beams and conditions without eye movements for green and red emission wavelengths and varying exposure durations (figure 1 in [12]).
- Experiments with human volunteers [13,14].
- The experience we have with laser pointers with powers up to 5 mW which are permitted as consumer products for instance in the USA.

The characterisation as negligible risk for injury even for somewhat longer than “momentary” exposure durations is possible for thermally induced retinal injury. For the case of laser radiation in the blue wavelength range, power levels up to 5 mW with a certain staring duration into a collimated beam can be assumed to result in photochemically induced retinal injury. This hazard, however, is consistent with the meaning of Class 2 levels and respective warnings against staring into the beam. Thus, the level of risk associated to 5 mW in the blue wavelength range is equivalent to the risk commonly associated to Class 2, which is considered safe for consumer products when they are not child appealing laser products.

The above arguments and discussion pertained to cw emission. For pulsed emission and *extended* sources, in some cases, as discussed in reference [9], the reduction factor for Class 1 is also only about 2,5 (Class 1 AELs apply to Class 2 products in the pulsed regime). For the condition of *minimal* retinal images (also referred to as small apparent source) where in an AEL analysis C_6 = 1 is used, the reduction factor for non-human primate studies is larger. However, there is also an uncertainty about the reduction factor for humans. It cannot be guaranteed that for pulsed emission and small apparent sources the reduction factor for humans is sufficiently large to consider exceeding the AEL of Class 1 by a factor of up to 5 to be sufficiently low risk for consumer products. Consequently, to err on the cautious side, the cw limit discussed above (such as 5 mW in the visible wavelength range) is defined in subclause 6.2 g) and h) to be applied as a limitation to the peak power of any pulse. In other words, while for emission durations less than 0,25 seconds, the AEL for Class 3R when expressed as power increases with $t^{0,25}$, this increased AEL is not permitted to be applied for compliant consumer products. For short enough pulses, this requirement is more restrictive than the “normal” Class 1 and Class 2 limitation. In this case, Class 1 and Class 2 classification permits higher emission levels than the requirement to limit Class 3R peak power levels to the Class 3R cw limit. Of course, it is again not only permitted but even required to classify a product as Class 1 or Class 2 when possible.

10.3.4 Laser pointers are not permitted

Requirement 6.2 a) states that Class 3R is not permitted for laser pointers, even when the other conditions of 6.2 are fulfilled. The associated low risk for injury, as discussed above, would also apply to laser pointers (actually, the experience that we have with Class 3R laser pointers for instance in the USA was part of the basis for the levels that are permitted for Class 3R). Thus, in terms of risk for retinal injury, Class 3R could have been considered to be permitted also for laser pointers. However, the intent of EN 50689 was to be restrictive and for

the case of laser pointers also considers the potential for causing temporal visual effects that are not associated to retinal injury. Terms used for these temporal visual effects are flash blindness and disability glare. When a person that steers a vehicle or operates machinery, or performs other critical tasks, is targeted and suffers temporary compromised visual acuity, the consequences might be severe, causing injury or even death. Compared to other products such as levelling lasers or lasers used for distance measurements, laser pointers have a far greater distribution and have a far greater potential to being misused (such as to intentionally target a driver).

10.3.5 Deliberate emission feature

Subclause 6.2 c) requires a technical feature which prevents instantaneous emission and requires some deliberate action by the user prior to emission of laser radiation. This requirement is intended to avoid unexpected exposure. Examples are given in a note as a long press activation button, double press action, key switch, or an unlock feature by sliding or twisting.

10.3.6 Emission indicator

Subclause 6.2 c) also requires an emission indication. Such an emission indicator is required in EN 60825-1 for Class 3R laser products only for emission outside of the visible wavelength range, and in EN 60825-1 is permitted to be either audible or visible. EN 50689 does not specify if the emission indication has to be visible or is permitted to be audible. The examples given in Note 4 refer to visible emission indication: a symbol on a LCD display, backlight LCD illumination, or a visible status LED.

10.3.7 Intrabeam viewing not intended or necessary

Subclause 6.2 d) requires that intrabeam viewing is not intended or necessary for the function of the product. Intrabeam viewing is the term used when the laser beam is pointed towards the eye and the person looks at the laser, i.e. into the laser beam.

11 USER INFORMATION AND LABELING

11.1 Added wording

Clause 7 of EN 50689 contains requirements on labelling of the product as well as information to be provided to the user in the user instructions or manual.

EN 50689 in Clause 7 repeats the requirement of Clause of EN 50689 that requirements of EN 60825-1 apply. In EN 60825-1, requirements for labelling are given in Clause 7 and for user information are given in Clause 8, respectively.

Additionally to the user information required by EN 60825-1, EN 50689 requires a statement of compliance with EN 50689 to be included in the information for the user. In the user information, the product’s intended use has to be described.

To show that the product is compliant with EN 50689, the reference to the standard has to be included on the explanatory label on the product. Examples are given further below. According to EN 50689, this reference can be in lieu of the reference to EN 60825-1 with A11 or additionally to the reference to EN 60825-1 with A11. For consumer laser products that are also used professionally (which applies to many types of products), it seems advisable to add the reference to EN 60825-1 with A11 in any case, since EN 60825-1 is well known, and many professional users will appreciate the respective information.

Although not noted in EN 50689, a reference to IEC 60825-1:2014 can be added to demonstrate compliance with the international standard for which there is no amendment. This is an option to avoid multiple versions of the label for products marketed internationally and where compliance with IEC 60825-1 is relevant.

Note that for the case of classification as Class 1 or Class 1M under EN 60825-1 with A11:2021, it is permitted to include the explanatory-label statement into the user information instead of onto the product - see last sentence in subclause 7.2 of EN 60825-1, as well as IEC 60825-1: "Instead of the above labels on the product, at the discretion of the manufacturer, the same statements may be included in the information for the user." The same policy applies for the explanatory label under EN 50689:

"For Class 1 consumer laser products, with the exception of laser products classified as Class 1 based on EN 60825-1:2014, 4.4 and EN 60825-1:2014/A11:2021, instead of the above label on the product, at the discretion of the manufacturer, the same statement may be included in the information for the user. For consumer laser products designed to function as conventional lamps where the emission is classified based on the EN 62471 series, the labelling requirements given in EN 60825-1:2014, 4.4 and EN 60825-1:2014/A11:2021 apply."

With respect to labelling on the product, EN 50689 requires adding "CONSUMER" when EN 60825-1 uses the wording "laser product". An example is "CLASS 2 CONSUMER LASER PRODUCT" on the explanatory label for Class 2 instead of "CLASS 2 LASER PRODUCT" as required by EN 60825-1:

LASER RADIATION
DO NOT STARE INTO BEAM
CLASS 2 CONSUMER LASER PRODUCT
EN 50689:2021

Alternatively, "CONSUMER LASER PRODUCT" can be added separately to the wording as required by EN 60825-1 (this example also shows the additional optional reference to EN 60825-1 with Amendment A11[19]):

LASER RADIATION
DO NOT STARE INTO BEAM
CLASS 2 LASER PRODUCT
CONSUMER LASER PRODUCT
EN 50689:2021
EN 60825-1:2014+A11:2021

The two options for the labelling in case of Class 3R laser products, are:

LASER RADIATION
AVOID DIRECT EYE EXPOSURE
CLASS 3R LASER PRODUCT
CONSUMER LASER PRODUCT
EN 50689:2021

Or alternatively:

LASER RADIATION
AVOID DIRECT EYE EXPOSURE
CLASS 3R CONSUMER LASER PRODUCT
EN 50689:2021

[19] The version with a „+" was chosen here for the amended EN 60825-1, which formally denotes the consolidated version. It is also possible to use the reference EN 60825-1:2014, EN 60825-1:2014/A11:2021. See also the White Paper on A11.

The two options for the labelling in case of Class 1 laser products are (but see note above for the option to include the statement into the user information):

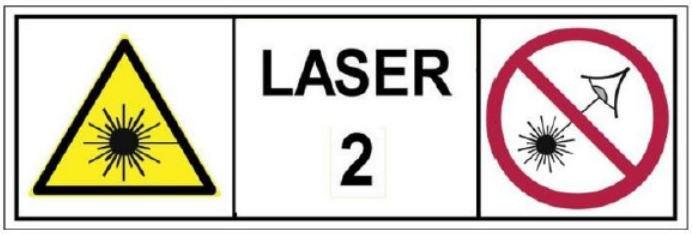
CLASS 1 LASER PRODUCT
CONSUMER LASER PRODUCT
EN 50689:2021

and (it is optional to additionally refer to EN 60825-1):

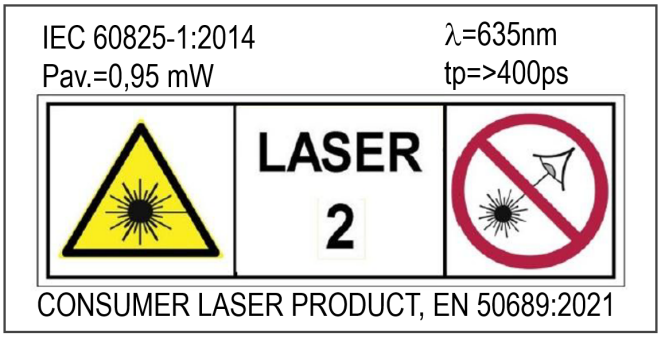
CLASS 1 CONSUMER LASER PRODUCT
EN 50689:2021

11.2 Alternative labels

EN 50689 states that the wording “CONSUMER LASER PRODUCT” can be added to the respective alternative labels (using symbols instead of wording). There is no guidance or specific information given in EN 50689 on how to apply this within the alternative labels. The alternative labels all contain the word “LASER”:



The author of this white paper assumes that a compliant option is to write “CONSUMER LASER PRODUCT” instead of “LASER”. But there are also other options, and the following combination of information on the explanatory label was seen on a product:



It was not discussed in the CENELEC project group nor in the standard how to handle different languages when alternative labels are used. After all, the point of the alternative labels is to avoid multiple-language versions as far as possible. As a personal comment by the author of this white paper, it could possibly be considered permissible to use “CONSUMER LASER PRODUCT” in English language only, in case alternative labels are used (or potentially also in another language of the European Union), since this is not a warning and since the main addressee group of this information is market surveillance authorities. The main issue for compliance with EN 50689 is the compliance of the technical design and emission as well as relevant safety information in the user information, which is understood to have to be in local language. The content of the alternative labels for Class 2 and Class 3R that have the nature of a warning are the triangular yellow laser hazard symbol and the circular red “do not” symbol

– so that the warning conveyed by the alternative labels does not have to be in all the different local languages. Therefore, the warning aspect of the label is covered by the symbols and the information “CONSUMER LASER PRODUCT” could be seen as not that critical in terms of using the local language where the product is brought onto the market.

11.3 Compliance with IEC 60825-1

EN 50689 does not specifically note that to the labels as required by EN 50689 are also compliant with EN 60825-1 or IEC 60825-1. Outside of the European Union, EN 50689 does not apply and then only IEC 60825-1 (or national transpositions) are applicable, with the respective labelling requirements. IEC 60825-1 specifies the wording “CLASS 2 LASER PRODUCT” and “CLASS 3R LASER PRODUCT”, not “CLASS 2 CONSUMER LASER PRODUCT” or “CLASS 3R CONSUMER LASER PRODUCT”, respectively. It can be assumed that many manufacturers who distribute products world-wide prefer to have one label (at least when the warning label is in English language) that covers both IEC 60825-1 as well as EN 50689. The question then could be whether “CLASS 3R CONSUMER LASER PRODUCT” is compliant with IEC 60825-1. This aspect is not commented in EN 50689 and it was not discussed in the CENELEC project group. However, since EN 50689 requires compliance with EN 60825-1, it is implicit that the wording as given in EN 50689 also complies with EN 60825-1. Since IEC 60825-1:2014 in terms of labelling is identical with EN 60825-1 (with or without A11, since A11 does not affect labelling), it can be assumed that to add “CONSUMER” is also not a compliance issue with respect to IEC 60825-1. Important for this issue is that IEC 60825-1 in subclause 7.1 specifically states that

“The wording of labels shown in Clause 7 is recommended but not mandatory. Other wording that conveys the same meaning (including warning labels per earlier editions of IEC 60825-1) may be substituted.”

For the situation outside of the European Union, some caution is advisable with respect to the local policy and the legal requirements for bringing consumer laser products onto the market. Outside of the European Union, compliance with EN 50689 and the labelling “CONSUMER PRODUCT” does not necessarily mean that the product is considered compliant with product safety legislation locally, outside the European Union (and even within the European Union, there is the interesting question about the legislation in France pertaining to consumer laser products, noted in Chapter 5 above).

11.4 Class 1

For the labelling of a Class 1 product, the same options and requirements as given in EN 60825-1 (identical to the ones in IEC 60825-1) apply. For Class 1 laser products, with the exception of laser products classified as Class 1 based on subclause 4.4 of EN 60825-1, instead of the label on the product, the same statement may be included in the information for the user. For laser products classified as Class 1 based on subclause 4.4 of EN 60825-1 this option does not apply, because subclause 4.4 requires labelling on the product in any case, and the label on the product is required to include the Risk Group classification based on the EN 62471 series.

11.5 Relevance in practice

Most Class 1 and Class 2 consumer laser products that comply with EN 60825-1 and already have been on the market in the European Union will also comply with the requirements of Clauses 5 and 6 of EN 50689. In other words, the requirements of Clauses 5 for child appealing laser products and Clause 6, that are additional[20] to EN 60825-1 are not relevant for most

[20] For Class 1 and Class 2 laser products that are not child appealing and that are not embedded laser products, the only additional, or more restrictive requirement is that the accessible emission through a 3,5 mm aperture stop for comparison with

Class 1 and Class 2 products that already are on the market as consumer products (and are considered as safe products under the GPSD and LVD). In this case, the only additional requirement is the compliance statement with EN 50689:2021 in the user information and a reference to EN 50689:2021 on the explanatory label, and the addition of “CONSUMER”.

With respect to corrective action by market surveillance authorities, it does not necessarily mean that when the compliance statement and reference to EN 50689:2021 is missing for Class 1 and Class 2 products that in terms of emission and design complies with EN 60825-1, this is seen as a significant issue. In the strict sense, the compliance statement is not safety relevant (it is not a warning about a hazard or information about safe use).

11.6 User information for Class 3R

For Class 3R consumer laser products, EN 50689 in subclause 7.1 requires information to be included in the information for the user (additionally to those required by EN 60825-1). The following information has to be included (for the complete and exact wording of the requirements, see EN 50689):

a) A statement that the user should not deliberately (intentionally) irradiate themself or anyone else with the laser beam. For intended outdoor use, information shall be provided to avoid non-intentional exposure of other people.

b) Information on the emission indicator.

c) A technical specification of the feature that ensures the product can only be activated through deliberate action.

d) Information that the Class 3R classification was determined with $C_6 = 1$ according to EN 60825-1 as amended by A11.

e) A justification why a Class 3R consumer laser product is necessary for the intended application.

f) A statement that the product complies with EN 50689 (requirements 6.2 a) to h)).

g) The date of the statement of compliance with EN 50689 and the identity of the manufacturer or/and supplier.

the Class 3B AEL is not only required at the closest point of human access but also at external beams waists, and that the Class 3B AEL is an actual emission limit and not just a criterion for a warning label as in Subclause 7.13 of EN 60825-1.

12 FLOWCHART

The conditions and requirements of Clauses 5 and 6 for a consumer laser product to be compliant with EN 50689 are summarised in flowchart for EN 50689 that is found in the informative Annex A.

In the following, an alternative flowchart with overall equivalent content is shown. While the flowchart in EN 50689 is organised horizontally for all classes in one combined flowchart, here the requirements are organised vertically, and organised into several flowcharts. The starting point for both approaches is the class of the product as determined following EN 60825-1:2014 with A11:2021. The requirement given in EN 50689 that the product shall be compliant with EN 60825-1 is not specifically shown in the flowchart. The requirements shown are additionally to the ones of EN 60825-1. Three requirements apply in all cases, and these are organised here in a “General Block”, shown in Figure 1, which can be considered as the decision-tree that is entered at the end of the class-specific flow charts shown further below in Figure 2 and Figure 3.

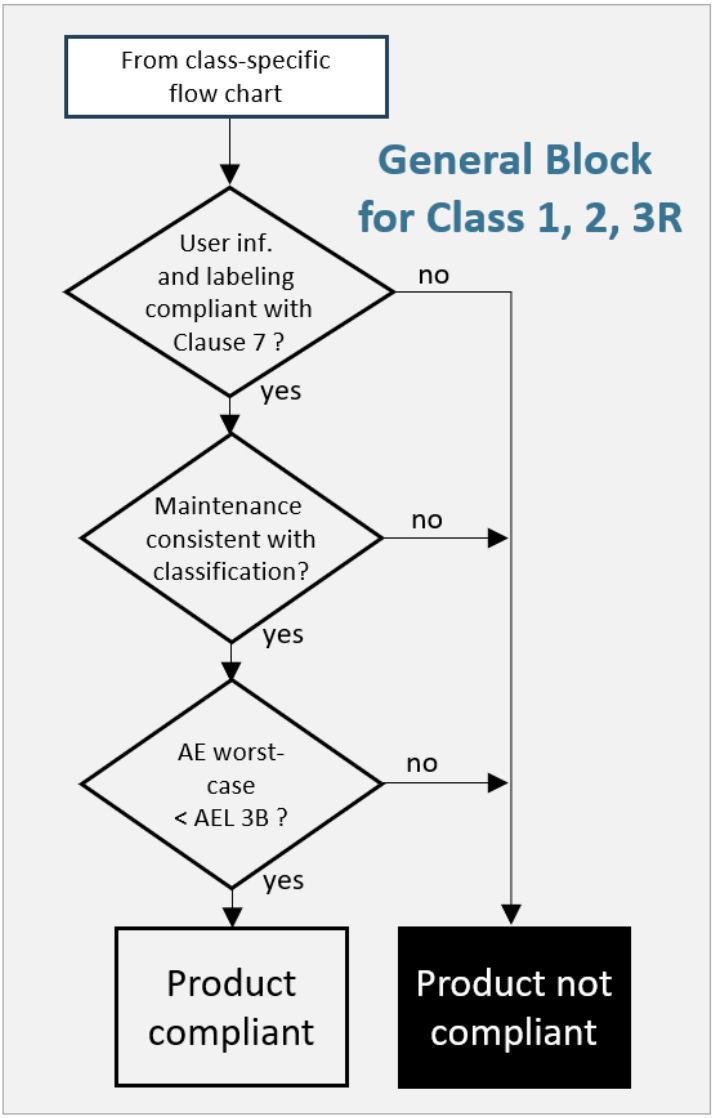


Figure 1. Three conditions that apply in all cases are defined as “General Block”.

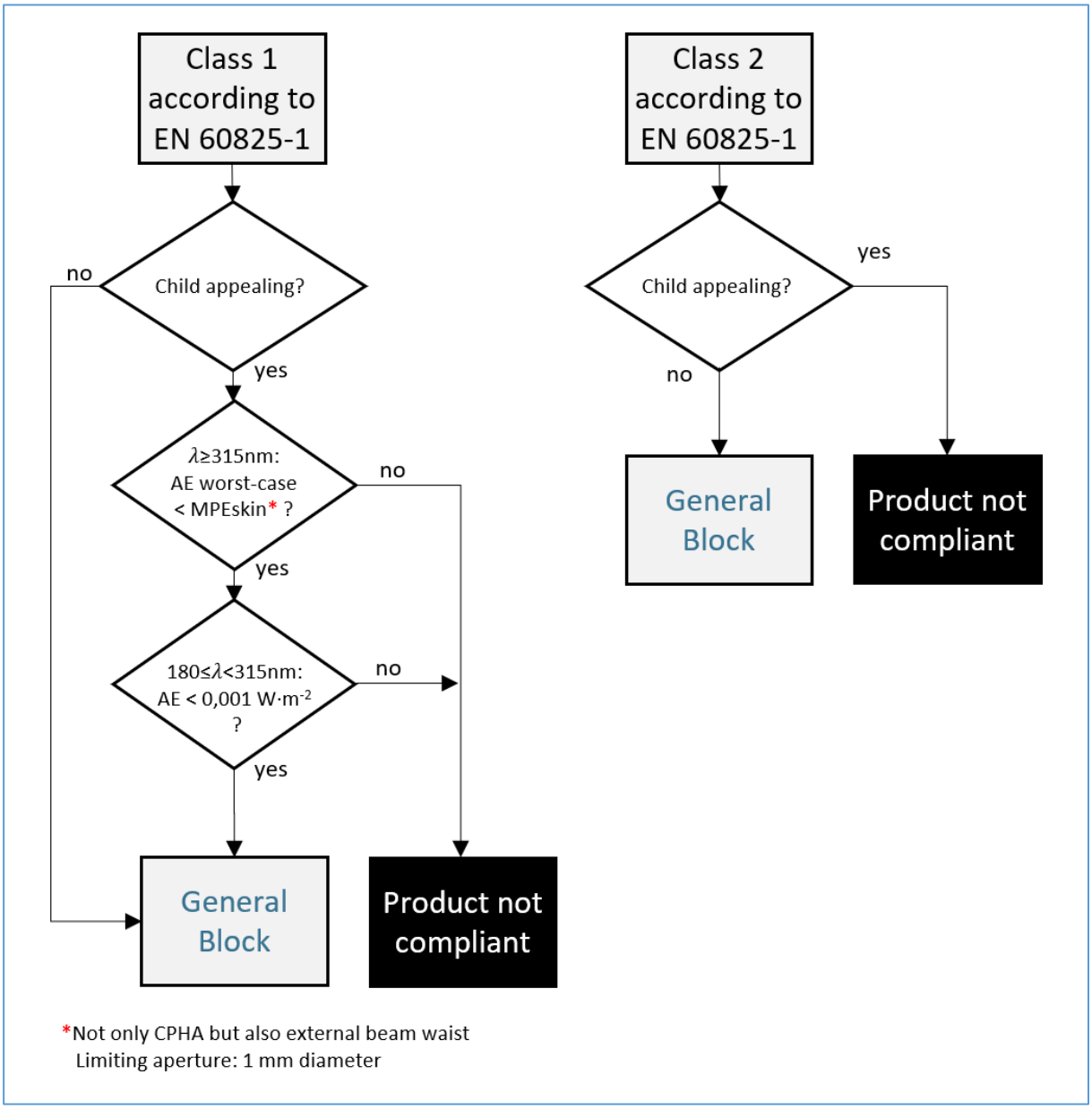


Figure 2. An overview of conditions and requirements for Class 1 and Class 2 consumer laser products, additionally to those of EN 60825-1.

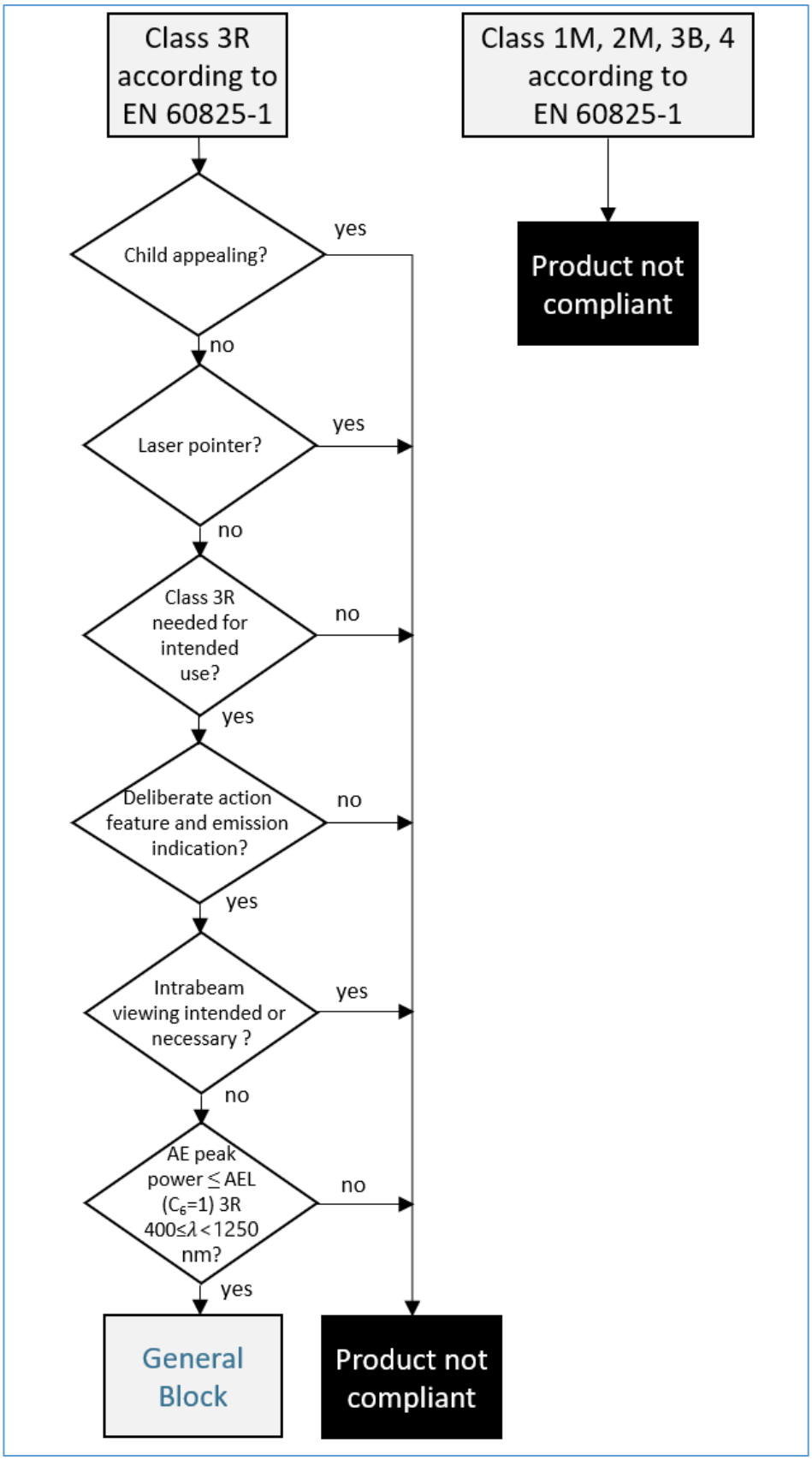


Figure 3. For Class 3R products, an overview of conditions and requirements additionally to those of EN 60825-1. Class 1M, 2M, 3B and 4 products are not compliant.

13 MEET THE AUTHOR

Karl Schulmeister, Ph.D., is a senior consultant on laser and optical broadband radiation safety at the Seibersdorf Laboratories in Austria. In 1995, his group achieved accreditation as test house for Laser, Lamp and LED Safety. The research activities in his group concentrate on thermally induced injury of the skin and eye, and these also provided scientific input for amending the retinal image diameter dependence and multiple pulse rules of the current retinal thermal exposure limits, as well as the classification limits for IEC 60825-1:2014 and the updated limits in the IEC 62471 series.

Dr. Schulmeister is a member of the ICNIRP Scientific Expert Group and was a member of the ICNIRP Main Commission for the 2013 revision of the ICNIRP Exposure Limit Guidelines for laser and for incoherent broadband optical radiation. He served as the project leader for the development of IEC 60825-1:2014 as well as of the CENELEC amendment A11:2021 to EN 60825-1. He was a member of the CENELEC expert team responsible for developing EN 50689 and he coordinated addressing Commission comments throughout the document's development. He is member of the ANSI Z136 Technical Subcommittee "Laser Bioeffects" and Fellow of the Laser Institute of America.

Dr. Schulmeister is co-author of the book "Laser Safety" and has published more than 100 scientific papers and tutorial texts.

Linkedin

Google Scholar

Research Gate

14 REFERENCES

Please note that most of the publications of the *Laser, LED and Lamp Safety* group can be downloaded from the website:
http://laser-led-lamp-safety.seibersdorf-laboratories.at.

Where downloads are available, the respective link has been provided below.

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[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.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014L0035

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