WHITE PAPER

The European Amendment A11:2021 to EN 60825-1

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NEWSLETTER

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CONTENT

1 SUMMARY

In February 2021, amendment A11 to the laser product safety standard EN 60825-1:2014 was published with the reference “EN 60825-1:2014/A11:2021”. This A11 is a “Europe only” amendment[1], i.e. applicable only in Europe and relevant only for bringing products on the market in the European Union. The content of A11 in terms of requirements for products will affect only a relatively small number of products. However, as one of the additional requirements, compliance with the proposed new European safety standard for consumer laser products, EN 50689 is required[2]. When EN 50689 is published, the requirements of EN 50689 will affect all consumer laser products to some degree. Besides the requirement for consumer laser products to comply with the future EN 50689, amendment A11 has only two requirements that are added to the existing requirements of EN 60825-1:2014. In the wavelength range of 1250 nm to 1400 nm, an additional limit was defined in order to protect the cornea. Also, it was specifically required that a product has to be in the lowest class (i.e. ideally Class 1) that is commensurate with its function, and when possible, the laser radiation has to be enclosed during normal operation. The remainder of the content of amendment A11 clarifies issues about the scope, provides more detailed guidance for extended sources and contains extended versions of the IEC Interpretation sheets ISH1 and ISH2 in an information annex.

2 DATES AND RELEVANCE

2.1 Document reference and availability

The Amendment A11:2021 to EN 60825-1:2014 [1] was developed by the European standardisation organisation CENELEC technical committee TC 76. The author of this White Paper served as project leader for the development of the amendment. The following is the link to the CENELEC project website:

https://www.cenelec.eu/dyn/www/f?p=104:110:593927100065401::::FSP_ORG_ID,FSP_PROJECT,FSP_LANG_ID:1257167,64807,25

The formal document designation for the amendment is EN 60825-1:2014/A11:2021. Amendment A11 is an “European only” amendment to EN 60825-1, i.e. there is no parallel amendment for IEC 60825-1:2014 at the IEC level. This is also the reason why the CENELEC amendment has received the number A11 and not A1, since the amendment designation A1 is reserved for the case of an amendment at the IEC level (which would be developed in parallel also for the European level, a process referred to as parallel voting, i.e. parallel as IEC and as CENELEC document). Due to this “European only” amendment, for the first time since Edition 1 will the European version EN 60825-1 (with amendment A11:2021) not be identical with IEC 60825-1.

The Amendment A11 was published by CENELEC in February 2021 as the English language version. The translation into French and German was not available at that time and will be published at a later date. The amendment A11 cannot be purchased from CENELEC (and neither can other documents), but needs to be purchased from one of the national standardisation organisations. Some national standardisation organisations, such as the British Standards Institution (BSI) apparently only sell the consolidated version, i.e. a document where the changes of A11 have been incorporated into EN 60825-1:2014 (changes are tagged), which results in a corresponding number of pages of that document and the related

[1] See the ILSC 2019 paper [2] for an overview of the structure of CENELEC, of A11 and of the consumer laser product project at the time.

[2] EN 50689 [3] is currently in the stage of a second “enquiry draft” (prEN) and the final draft (FprEN) is in preparation. A11 to EN 60825-1 requires that consumer laser products are compliant with the (future) EN 50689. See also CENELEC project webpage for the consumer laser product standard:
https://www.cenelec.eu/dyn/www/f?p=104:110:181937044641901::::FSP_ORG_ID,FSP_PROJECT,FSP_LANG_ID:1257167,65305,25

price. The consolidated version is only available when national standardisation organisations combine A11:2021 with EN 60825-1:2014, i.e. CENELEC does not do this centrally. The consolidated version, as for instance sold by the British Standards Institute BSI, is referred to as BS EN 60825-1:2014+A11:2021. This reference, using "plus" A11:2021 ("**+**A11:2021") is the way to designate the consolidated version. BSI does not seem to sell the amendment document (17 pages) on its own. Other national standardisation organisations, such as the Estonian[3] and Danish standardisation organisation, sell the Amendment A11 (in English language) on its own, referred to as EVS - EN 60825-1:2014 / A11:2021 and DS/EN 60825-1:2014/A11:2021, respectively. Since national publications are not permitted to deviate in any way from the CENELEC version (other than adding a national foreword, where it is, however, not permitted to change the actual technical content of the amendment), all of these English language versions of A11 are identical. Because translations, such as into German and French language are performed by standardisation organisations and the translations are usually not checked by technical experts of the field of laser product safety, it is possible that there are deviations in details of understanding of the text. It might therefore have some advantages to work with the English originals when it comes to possible variabilities of formulations that might not convey exactly the same meaning as intended by the authors of the amendment, who developed the amendment in English.

2.2 Harmonisation under the LVD

It can be assumed that in the next update of the reference list of harmonised standards under the Low Voltage Directive [4] (the abbreviation LVD is used here as a simplified version of LVD2, which is the accurate reference to 2014/35/EU), amendment A11 is going to be listed in the Official Journal of the European Union (OJ) as harmonized standard in the same way as EN 60825-1:2014 is listed under the LVD[4].

It can also be assumed that when A11 is going to be listed in the Official Journal, there will be the usual three year transition period, i.e. the transition period would end February 2024. This date, February 2024 is expected to be stated as *"Date of withdrawal from OJ (end of presumption of conformity)"* for EN 60825-1:2014, i.e. for the base standard without the amendment. This means that in this transition period, compliance with EN 60825-1:2014 without the amendment A11 as well as compliance with EN 60825-1:2014 together with the amendment A11 confers a presumption of conformity with the LVD. Starting in February 2024, only EN 60825-1 *with* the amendment will result in a presumption of conformity with the LVD. Following the system of referencing standards in the OJ, the reference of EN 60825-1:2014 together with the Amendment A11 (i.e. as a "package") is going to be:

EN 60825-1:2014,
EN 60825-1:2014/A11:2021

3 CONFUSION OF SELF-REFERENCE

On two occasions, the text of the amendment references the amendment itself. However, due to a mishap in the editorial process of progressing from final draft to the published amendment, these self-references were not updated and still refer to the final draft version of the amendment from 2020 "FprAA:2020" when the amendment was referred to as AA and not yet designated A11 (i.e. in the development process of the amendment, the name of the document changed from AA to A11).

[3] https://www.evs.ee/en/evs-en-60825-1-2014-a11-2021

[4] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage_en

The specific passages are on Page 3, in the amendment of the scope:

> 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 506891 (see 9.5 in EN 60825 1:2014/FprAA:2020).

and in a note on page 6:

> NOTE EN 506891 will be made available after the publication of EN 60825 1:2014/FprAA:2020.

The text marked here with yellow background should read "EN 60825-1:2014/A11:2021", in the sense of "this amendment A11".

4 CHANGES OF SCOPE AND TERMS

The CENELEC project to develop an amendment to EN 60825-1:2014 was initiated by concerns of the European Commission Directorate General "Enterprise and Industry" (DG ENTR, now DG GROW, stationed in Brussels) and of the German representative in the LVD Working Party, that a standard that is harmonised under the Low Voltage Directive has to have a certain level of specificity as well as that the requirements have to be complete so that compliance with the requirements of the standard results in a product that complies (within the limits of the scope of the standard) with the safety objectives of the LVD. The requirement that consumer laser products have to comply with the future EN 50689 also made an amendment of EN 60825-1 necessary. A more detailed discussion of the history of changes and the phases of the development of the amendment can be found in the ILSC 2019 proceedings paper [2].

The scope of EN 60825-1:2014 was correspondingly amended to reflect the following issues.

It is now stated in the scope, that EN 60825-1 "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…". As a related aspect to this statement, the reader is reminded in the updated scope that in order to classify a product as[5] Class 1C, it is a requirement of EN 60825-1 that the product shall comply with an applicable specific standard of either the EN 60601 series for medical products or of the EN 60335 series for house-hold equipment.

The text marked above in blue intends to state that the (amended) requirements of EN 60825-1 are sufficient to justify the presumption of conformity with the LVD and the GPSD [6] with respect to laser hazards. The actual requirement to comply with the future EN 50689 as well as the applicable vertical standards that define specific requirements for Class 1C laser products is then given in Subclause 9.5, which was amended:

> Consumer laser products shall comply with applicable requirements for laser products of their class as well as with EN 50689. In addition, these products may be subject to specific safety standards such as EN 62368-1 (AV/ICT equipment). Products that are classified as Class 1C need to comply with the requirements of the respective specific vertical standard of the EN 60335 series or the EN 60601 series.

The term "general laser product" used in the amended scope can be seen as code-word to mean laser products that fall under the LVD and/or the GPSD, contrary to laser products that fall under other New Approach ("CE-marking") directives[6], such as the Toy Safety Directive,

[5] For a discussion of the changes of EN 60825-1 Edition 3.0 of 2014 compared to Edition 2.0, including the introduction of Class 1C, see for instance our White Paper [5].

[6] See for instance https://boss.cen.eu/reference-material/guidancedoc/pages/newapproach

the Machinery Directive or the Medical Device Directive. In other words, the requirements of the amended EN 60825-1 (with respect to hazards to the eye and skin posed by laser radiation) are considered sufficient to achieve the level of product safety required by the Low Voltage Directive. Since the LVD does not distinguish between consumer products and professional products, this statement in the scope applies to both consumer products and professional products that fall under the LVD. For consumer products, the General Product Safety Directive GPSD applies additionally to the New Approach directives and also covers battery powered products. Compliance with the amended EN 60825-1 and the future EN 50689 (these two standards, for consumer laser products, require mutual compliance) will result in laser products that are sufficiently safe also with respect to the GPSD.

The term “general laser product” was introduced in the amendment to mean “laser products falling under the LVD or the GPSD”. This new term was necessary because on the one hand, it was intended to express that following the amendment, products that are compliant with the amended EN 60825-1 benefit from the presumption of conformity with the LVD (and the GPSD, once EN 50689 is available), but on the other hand, TC 76 was informed by the European Commission that is not permitted in the body of the standard (i.e. other than Annex ZZ) to actually refer to the LVD. The term “general laser product” can therefore be seen as a work-around for not being permitted to refer to the LVD specifically, and that was a satisfactory wording for the European Commission. Without that background information, the definition of the term “general laser product” is probably somewhat strange:

> **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

What this is intended to mean is “laser product that falls under the LVD or the GPDS”.

The notes in the definition of “general laser product” attempt to clarify what is meant, but these notes also needed to avoid reference to the LVD and the GPSD:

> Note 1 to entry: Examples of products where such other EN Standards exist are medical lasers (EN 60601-2-22), electric 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.

Additionally, it was necessary to clarify that a consumer laser product, where additional requirements are given in the future EN 50689, is also considered a “general laser product”:

> 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.“

Besides the amendment with respect to enclosing laser radiation where possible to achieve the lowest class commensurate with the application, discussed below, it was important for the European Commission desk officer responsible for the LVD that the requirements of the amended EN 60825-1 are complete with respect to resulting in a sufficient level of safety. For this goal it was important that the amended EN 60825-1 requires compliance with the future EN 50689 for consumer laser products. For laser products classified as Class 1C it was important to require compliance with either a specific part of the EN 60601 series for medical applications or of the EN 60335 series for household products, i.e. cosmetic applications. Thus for a statement of compliance with the amended EN 60825-1 it is necessary to also comply with the stated standards, where they are applicable. This level of completeness of the overall set of requirements (together with the other standards mentioned here, as applicable) is the justification to have the status of “harmonised standard” under the LVD, and also a possible

listing under the GPSD. It is intended that the reference to either the future EN 50689 or the amended EN 60825-1 are listed under the GPSD[7]; in a way it does not matter which of the two standards are listed under the GPSD since they both require compliance with the respective other standard.

Based on this level of completeness of requirements afforded by the amended EN 60825-1 it is then also justified for standards harmonised under the LVD, such as the one for the safety of electrical equipment for measurement, control, and laboratory use EN 61010-1 to simply require compliance with EN 60825-1 for the case of laser products; no additional requirement is necessary.

While compliance with the amended EN 60825-1 results in a presumption of conformity with the LVD and the GPSD (i.e. for "general laser products"), it has to be noted at the same time that for products falling under other New Approach directives, EN 60825-1 is *NOT* harmonised under these other New Approach directives. For other New Approach directives, product-specific standards apply (referred to as "another" EN standard in the definition of general laser product), such as EN 60601-2-22 for medical laser products, or EN ISO 11553-1 for laser processing machines. It is these sector-specific standards that are harmonized under the respective directive, i.e. the Medical Device Directive and the Machinery Directive, respectively. These sector-specific standards (on an international level also often referred to as "vertical standards") adjust the requirements of EN 60825-1 so that they are appropriate for the respective sector, as well as where necessary, define additional requirements. An example is the additional requirement for an emergency switch and other engineering safety features for medical laser products according to EN 60601-2-22. Another example for a sector-specific standard is EN 62115 for electric toys (harmonized under the Toy Safety Directive), which requires that electric toys that contain lasers are Class 1. The system with respect to these "other" EN standards is that they require compliance with EN 60825-1 (for instance, the classification is based on EN 60825-1), not the other way around, i.e. EN 60825-1 does not *require* compliance with EN 60601-2-22 for the example of a medical laser product. In this way, compliance with EN 60825-1 can be stated independently from other safety standards, with the exception of classification as Class 1C and for consumer laser products, where compliance with other standards is a requirement. With respect to these other sector-specific standards, such as for machines, toys and medical products, EN 60825-1 has the function of a "horizontal standard" with respect to the hazards represented by laser radiation to the eyes and skin. Usually, vertical standards then also cover other types of hazards, such as electrical hazards.

Thus EN 60825-1 has two functions (these basic functions already applied in principle to EN 60825-1 before the amendment A11, but A11 has complemented and clarified requirements in order to address concerns by the European Commission as well as by a German representative of the LVD working party):

- With respect to laser products falling under the LVD and the GPSD (products referred to as "general laser products" in A11), compliance with the amended EN 60825-1 can be assumed[8] to result in a sufficiently safe product (with respect to laser related hazards to the eye and skin), i.e. EN 60825-1 is justified to be a harmonised standard under the LVD and the GPSD.
- With respect to laser products falling under a New Approach directive other than the LVD, EN 60825-1 is not harmonised under the respective directive. Standards that are

[7] Standards listed in the OJ in support of the GPSD are not „harmonised" standards, since this term is reserved for „New Approach" („CE-Marking") directives, but they also provide presumption of conformity equivalent to harmonised standards.

[8] The manufacturer still needs to check, as part of a generally required risk assessment, if the standard sufficiently covers the risk of the given product; for special cases this might not be the case.

harmonised under these directives, for products containing lasers, require compliance with EN 60825-1 and usually also adapt requirements or state additional requirements.

In the discussions during the development of the amendment, the following graphical representation (Figure 1) for these two different functions of EN 60825-1 has been used.

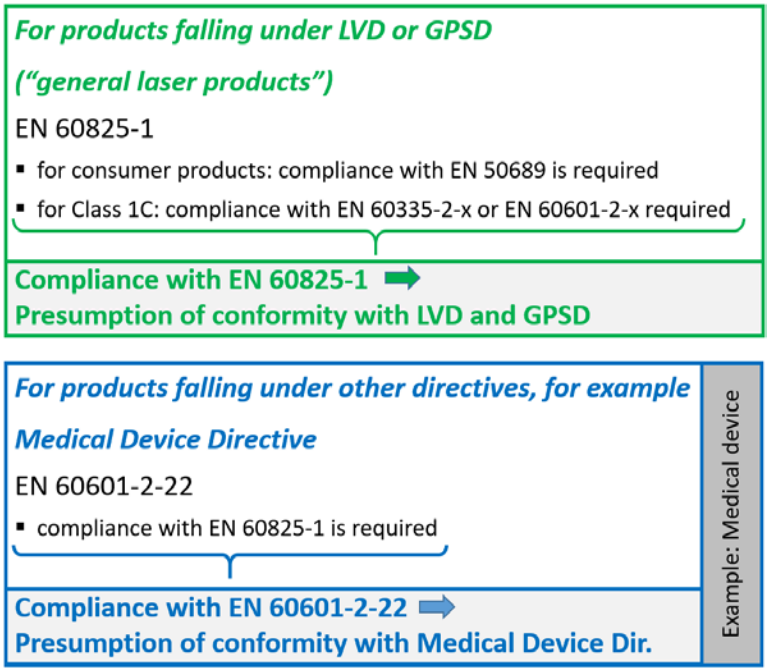

Figure 1 Schematic presentations of the two functions of EN 60825-1, depending on the applicable product safety directive.

5 ADDITIONAL LIMIT TO PROTECT THE CORNEA

The wavelength range of 1250 nm to 1400 nm is associated with the transition from the hazard to the retina to the hazard to the cornea [7, 8, 9]. In this wavelength range, water starts to absorb significantly, showing a very strong dependence on wavelength: at 1250 nm, the absorption depth (the depth where the irradiance is reduced to 1/e of the irradiance that is present at the surface) is equal to 9 mm and a significant portion of the radiation that is incident on the eye reaches the retina, where it is absorbed by the melanin particles in the retinal pigment epithelium and the choroid. At a wavelength of 1310 nm, the absorption depth is decreased to 6 mm and at 1390 nm, the penetration depth is only 1 mm so that virtually all of the radiation is absorbed in the cornea and aqueous, and almost no radiation is transmitted through to the retina (the transmittance to the retina decreases exponentially between 1250 nm and 1400 nm). In that sense, in the wavelength range that approaches 1400 nm, the pre-retinal media of the eye "protect" the retina. Since the MPEs are defined at the surface of the eye, the correction factor C_7 for the retinal limits, that was amended in the 2014 edition of IEC 60825-1 (based on ICNIRP 2013 [8]; with EN 60825-1:2014 being identical) increases exponentially [5]. It is evident that when the limit that pertains to the retina permits such high levels to be incident on the surface of the eye, the concern shifts to the cornea. Thus it was necessary, when the correction factor C_7 was increased, to define additional limits to protect the cornea. In IEC 60825-1:2014, in the MPE section it was recommended to apply the skin MPEs to protect the cornea, while for the classification as Class 1, 1M, and 3R, the respective AEL tables required to limit the accessible emission to the AEL of Class 3B.

Since the publication of IEC 60825-1:2014, the application of a computer model to calculate injury thresholds of the cornea [7, 10] showed that for some special cases, the Class 3B

limitation is potentially not sufficiently restrictive to protect the cornea. The main reason is the application of the 7 mm aperture stop to determine the accessible emission to be compared against the Class 3B limit (equal to 500 mW for emission durations longer than 0,25 seconds). This means that 500 mW are permitted for beams with 1 mm diameter in the same way as for a beam with 7 mm diameter. However, the associated irradiance levels at the cornea is a factor of 49 higher for the 1 mm beam as compared to the 7 mm beam. Figure 2 shows the calculated injury thresholds for the cornea as function of wavelength, for an exposure duration of 1 second, for a beam diameter of 1 mm as well as 4 mm (top-hat irradiance profile). It can be seen that the injury threshold for the 4 mm beam is somewhat lower than that for the 1 mm beam, which is due to lack of heat flow for the larger beam. For beam diameters above 4 mm, for an exposure duration of 1 second, there is no longer a dependence of the injury threshold on beam diameter (equivalent in nature to the parameter α_{max} for the retinal limits), i.e. the injury threshold calculated for 4 mm beam diameter also applies to larger beam diameters. Also shown are irradiances permitted by the 500 mW Class 3B limit for beam diameters of 1 mm, 4 mm and 7 mm, respectively. We see that for the 1 mm beam, the predicted injury threshold is lower than the Class 3B limitation for wavelengths above 1360 nm so that in this case the Class 3B limitation is not sufficiently restrictive. For a 4 mm beam (and larger beams), and an exposure duration of 1 second, the 500 mW limitation is sufficiently low to protect the cornea even at 1400 nm.

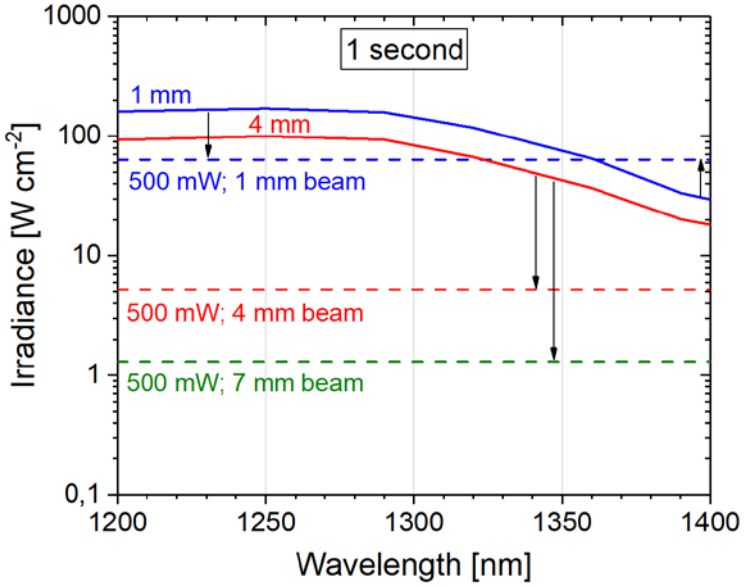

Figure 2 Comparison of calculated injury thresholds for the cornea (solid lines) with irradiances permitted by the 500 mW Class 3B limit for different beam diameters.

In order to limit permitted emissions to levels that are safe for the cornea including for small beam diameters in the wavelength range above about 1300 nm, amendment A11:2021 defines a third limit[9]. This third limit was directly derived, i.e. is basically equal to, the skin MPE. The difference to a skin MPE analysis is that for the A11:2021 limit, the aperture diameter depends on the emission duration in the same way as the aperture for corneal limits above 1400 nm, i.e. the aperture diameter equals 1 mm for emission durations up to 0,35 seconds and then increases to 3,5 mm at emission durations of 10 seconds and above. The Class 3B AEL was kept in A11:2011 as a limit to be applied for Class 1, 1M and 3R, as a prudent limitation also with respect to the safety of the retina. Therefore, for classification as Class 1, 1M or 3R in the wavelength range above 1250 nm, three limits need to be applied and complied with.

[9] The accessible emission values to be compared against the respective AEL are determined at the same location for all three criteria (i.e. the location of the aperture stop is the same), but for this third limit, the diameter of the aperture stop is different from the other two limits where the 7 mm aperture stop is defined.

The following table specifies this additional limit to be applied in the wavelength range of 1250 nm to 1400 nm and the respective requirement added to the AEL tables for Class 1, 1M and Class 3R. Since emission limits in this wavelength range are defined as power or energy, also the limit derived from the skin MPE was transformed to power and energy values. The nature of the limit is not an MPE but an AEL as requirement for the classification of the product. The limit as such did not receive a designation in A11:2021, but it is called “skin AEL” here.

For $t < 10^{-9}$ s:	$7{,}9 \times 10^{5}$ W	Aperture stop diameter: 1 mm
For 10^{-9} s ≤ $t < 10^{-7}$ s:	$7{,}9 \times 10^{-4}$ J	Aperture stop diameter: 1 mm
For 10^{-7} s ≤ $t <$ 0,35 s:	$4{,}3 \times 10^{-2}\ t^{0{,}25}$ J	Aperture stop diameter: 1 mm
For $t \geq$ 0,35 s:	0,1 W	Aperture stop diameter: 0,35 s ≤ $t <$ 10 s: 1,5 $t^{3/8}$ mm $t \geq$ 10 s: 3,5 mm

We see that the limits are given as power and energy to be compared against power and energy measured with the respective aperture stop. This is different from actual skin MPEs, which are specified as irradiance and radiant exposure and where the exposure level is averaged over the respective limiting aperture. The “skin AELs” presented in the table above were obtained by multiplication of the skin MPEs by the area of the respective aperture stop. For example, the skin MPE for an exposure durations of 10 seconds and above equals $2000 \cdot C_4$ W m^{-2}. C_4 for wavelengths above 1250 nm is equal to $C_4 = 5$, resulting in a skin MPE of 10 000 W m^{-2}. The area of a circular aperture with a diameter of 3,5 mm equals $9{,}62 \cdot 10^{-6}$ m^2. Multiplication of the MPE with that area results in a value of 0,096 Watt. This was rounded up for the definition of the skin AELs in A11:2011 to 0,1 Watt. This limit applies not only for emission durations above 10 seconds, but down to 0,35 seconds, because the dependence of the skin MPE on t is compensated by the dependence of the aperture diameter on t. The two versions of presenting limits and determining levels to compare against the limit are equivalent in the same way MPEs to protect the retina can be expressed either as irradiance (with the exposure level being averaged over 7 mm) or as power to be compared against the power measured with a 7 mm aperture (see for instance [9, 11]).

This additional limitation, called “skin AEL” here, is shown in Figure 3, where the data is plotted as function of exposure duration for a range of wavelengths.

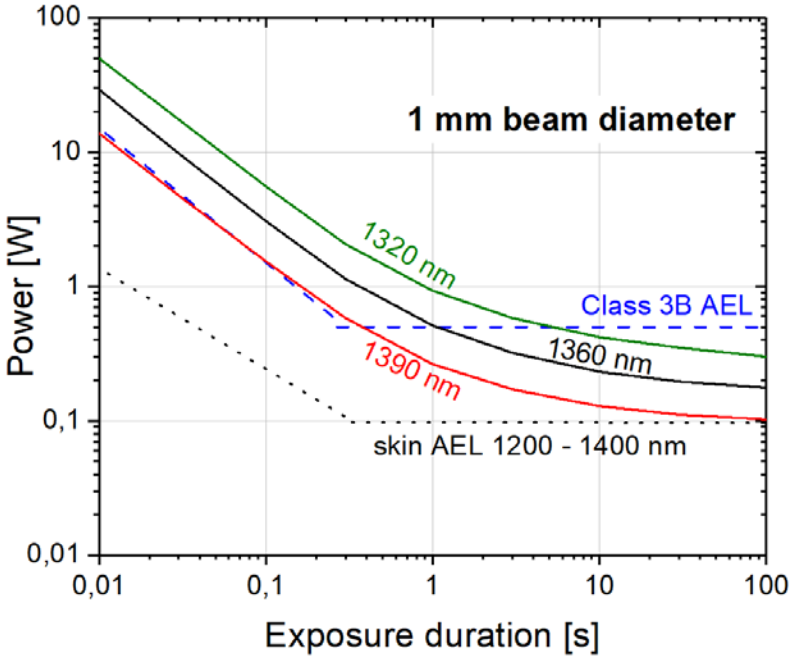

Figure 3 Calculated injury thresholds for the cornea, for a 1 mm beam and three selected wavelengths (solid lines) compared with the Class 3B AEL and the additional A11 limitation, here referred to as „skin AEL“.

6 REQUIREMENT FOR LOWEST CLASS

Amendment A11:2021 specifically requires that when access to radiation is necessary, it shall be of the lowest class that is commensurate with the function of the product. This was added to subclause 6.2.1, first paragraph, which now 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.

A subsequent note clarifies that the requirement for a protective housing means that the laser radiation shall be enclosed so that for normal operation conditions (unless necessary for the function of the product), either no radiation is emitted, or only levels below Class 1 AELs are emitted (the more technical term instead of emitted is “accessible”, because the criteria for the determination of the accessible emission are well defined including the criteria for “human access”, definition 3.40).

> 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 maintenance procedures.

A laser product other than Class 1 (particularly Class 3B and Class 4) where it is possible to enclose the beam as part of the product design (i.e. by the manufacturer - we are not referring to guards placed by the user), but does not feature such an enclosure, is not compliant with this requirement. When all requirements for an embedded laser product (definition 3.32) are met, then the product will actually be Class 1, or at least of a lower class than the laser source that is enclosed. However, it is not necessary that products are generally Class 1, which is also clarified by the above note.

In order to appreciate this point, it is necessary to consider the differences between a requirement that a product is classified as Class 1 according to the rules of EN 60825-1 (i.e. that the product is actually a Class 1 product that complies with all requirements, which are quite restrictive), from a requirement for an enclosure by a protective housing that prevents human access to radiation above the AEL of Class 1 where possible. The latter does not mean that the product actually has to be Class 1. Even for the case that the beam can be, and is, enclosed as design by the manufacturer, it might be the case that not all of the relatively strict requirements of EN 60825-1 for classification as a Class 1 laser product can be met, considering the function of the product. For instance, laser radiation that is accessible during maintenance performed by the user (as specified in the user manual) determines the class of the product when it is of a level of Class 3B or Class 4. In other words, it is not possible to classify a product based on the enclosure as Class 1, when the user manual specifies tasks for the user where the protective housing (an access panel) has to be opened and interlocks overridden so that the user then has access to laser radiation of Class 3B or Class 4. It is only permitted, according to subclause 6.2.1 third paragraph (which was not amended in A11:2021) that for maintenance of a Class 1 embedded laser product, radiation levels of Class 2 or Class 3R are accessible during maintenance (but of course not during operation). When radiation levels of Class 3B or Class 4 are accessible during maintenance, then the product

classification will be Class 3B or Class 4 even if during normal operation there is no radiation accessible. This is often the case for laser processing machines, where an enclosure is required by EN ISO 11553-1 as well as by the Machinery Directive. An example for a product falling under the LVD is a cell counter or cell sorter (used for biomedical research, such as the one shown in Figure 4) where the laser sources are fully enclosed in the housing and the sample compartment access panel is interlocked. When, however, it is specified in the user manual that laser sources can be replaced or changed which then have to be aligned, and these laser sources are Class 3B, the product is classified as Class 3B. The requirements discussed above for the amended subclause 6.2.1 are, however, satisfied.

Figure 4 Cell sorters have to be classified as Class 3B or Class 4 when user procedures make it necessary to open the protective housing and change laser sources and align laser beams. This can still be considered as „safe“ product that complies with the requirements of A11:2021 and the LVD.

In a number of cases it will not be possible to enclose the laser beam. For products that fall under the LVD, an example where the beam cannot be enclosed in the design of the product (i.e. by the manufacturer) are professional laser shows that are usually Class 3B or Class 4 and where the beam has to be emitted for the intended application. Also research lasers are examples where the manufacturer of the laser cannot enclose the laser radiation (however, it might be necessary for the user to place guards around the laser beam to avoid exposure of the user to laser radiation, in order to comply with work-place safety regulations). These are examples of products that, considering the warning labels and instructions for safe usage as required in EN 60825-1 are considered sufficiently safe for professional products to comply with the LVD. According to common policy, such products are, however, not considered sufficiently safe as consumer products, as will be reflected in the future EN 50689. The current draft of EN 50689 also does not permit access to levels of Class 3R during user maintenance of Class 1 or Class 2 products.

The amended requirements in A11:2021 should not affect many products with respect to existing designs and policy, because enclosure of the beam and achieving a lower class, where possible, is already common practice. This is motivated for professional products by reduced user requirements based on workplace safety legislation, so that the user of a lower class device, or a device with enclosed beams has less burden to assure safe usage of the product, and to comply with workplace safety legislation. For consumer products, the achievement of low safety classes is required in Europe based on the compliance policy of market surveillance authorities in support of the GPSD, and in some countries even by national legislation (such as in France) or at least formal Specifications (such as in Germany).

7 ANNEXES

7.1 Annex ZB with Interpretation Sheets

IEC TC 76 has developed two interpretation sheets for IEC 60825-1 which were published in 2017 [12, 13]. These interpretation sheets can be downloaded for free from the IEC website and are intended to clarify the application of requirements for complex cases. ISH1 concentrates on the analysis of extended sources and multiple pulses. ISH2 is related to Subclause 4.4 according to which the emission of laser products that replace lamps can be classified based on the lamp safety standard IEC 62471.

The content of the IEC interpretation sheets was included in the amendment A11:2021 as informative Annex ZB, because the document type “interpretation sheet” does not exist at CENELEC level. The extent of the IEC interpretation sheets were limited in terms of number of pages, which does not apply to annexes. Therefore it was possible to include a longer, earlier version of the interpretation sheets, which were considered as too long for an interpretation sheet at the IEC level.

The annex in A11:2021 received the designation “ZB” because Europe-only annexes generally start with “Z”, and the designation “Annex ZA” is reserved for an annex added to documents in the responsibility of CEN to state the relationship of requirements of the standard with safety objectives of European Commission decisions or European product safety directives under which the standard is to be listed as harmonised standard.

7.2 Annex ZZ

Amendment A11:2021 adds an informative Annex ZZ to EN 60825-1:2014 which describes the relationship of EN 60825-1 with the Low Voltage Directive. Table ZZ.1 provides information which clauses of EN 60825-1 address the safety objectives of the LVD.

Table ZZ.1 — Correspondence between this European standard and Annex I of Directive 2014/35/EU [2014 OJ L96]

Safety objectives of Directive 2014/35/EU	Clause(s) / subclause(s) of this EN	Remarks / Notes
1(a) (b)	Clause 7 (labelling) and Clause 8 (information for the user)	
1 (c)	Clause 5 (testing requirements) include intended use and maintenance	
2. (b) Protection against hazards arising from the electrical equipment with measures of a technical nature that ensure that radiation which would cause a danger is not produced.	Clauses 4–9	The scope of EN 60825-1 is limited to hazards from laser radiation to the eye or skin
3 (c)	Clause 5 (testing requirements) include single fault conditions	

8 MEET THE AUTHOR

Karl Schulmeister, Ph.D., is the senior consultant on laser and broadband radiation safety at the Seibersdorf Laboratories, where also a specialised accredited test house is operated. The research activities over the last fifteen years concentrated on thermally induced injury of the skin and eye, that also provided scientific input for amending the retinal image diameter dependence and multiple pulse rules of the retinal thermal limits. Dr. Schulmeister is a member of the ICNIRP Scientific Expert Group and served as the project leader for the development of IEC 60825-1 Edition 3.0. He also served as project leader for the development of the CENELEC amendment A11:2021 to EN 60825-1. He is associate director for CIE Division 6 “Photobiology”, member of the ANSI Z136 Technical Subcommittee “Laser Bioeffects” and Fellow of the Laser Institute of America. Karl is co-author of the book “Laser Safety” and has published more than 100 scientific papers.

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Research Gate

9 REFERENCES

Please note that most of the publications of the Seibersdorf Laboratories group can be downloaded from the website:
http://laser-led-lamp-safety.seibersdorf-laboratories.at

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[12] IEC 60825-1:2014/ISH2:2017 Interpretation Sheet 2 - Safety of laser products - Part 1: Equipment classification and requirements link to IEC info-website link for easy download

