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NEW EUROPEAN LASER PRODUCT SAFETY STANDARDS: AMENDMENT FOR EN 60825-1 AND EN 50689

Paper #L0602

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Abstract

At ILSC 2019, a paper reported on the progress of two European standardisation projects for laser products. These two standardisation documents have been both published in 2021. One is amendment A11 for EN 60825-1. Up to this amendment, the European version EN 60825-1 was identical with the international version IEC 60825-1, both published in 2014. For most laser products, the new European amendment A11 does not contain requirements that go beyond those of EN and IEC 60825-1:2014, other than the compliance statement on the label and/or in the manual. The only exception applies to the wavelength range of 1250 nm to 1400 nm, where amendment A11 defines an additional limit to protect the cornea. The reason for this is that in some cases, the Class 3B limitation which is a dual limit also in IEC 60825-1:2014 is not sufficient to protect the cornea. For consumer products, A11 requires compliance with EN 50689:2021. Amendment A11 also includes the IEC interpretation sheets in an annex.

EN 50689:2021 pertains to laser consumer products brought onto the market in Europe. It is harmonised under the Low Voltage Directive but will also be harmonised under the General Product Safety Directive. The main content of EN 50689 is to define which classes are permitted for consumer products. Child appealing laser products are distinguished from non-child appealing products. Some Class 3R lasers are permitted as consumer products, however, only when a number of specific requirements are fulfilled. For most Class 1 laser products (as long as they are not emitting in the UV wavelength range) as well as for Class 2 laser products (as long as they are not child appealing) there are no additional requirements defined in EN 50689, other than a statement of compliance with EN 50689 (which for Class 1 laser products can be in the manual).

Since the details of both documents are discussed in White Papers, in this paper the multi-fold limits that apply in the wavelength range of 1250 nm to 1400 nm are discussed.

Introduction

This paper discusses some aspects of two Europe-only standardization documents in relationship to requirements of IEC 60825-1.

The document references are:

[1] Amendment A11:2021 to EN 60825-1 Safety of laser products – Equipment classification and requirements

[2] EN 50689:2021 Safety of laser products. Particular requirements for laser consumer products.

While A11:2021 with EN 60825-1 has the same scope as IEC 60825-1 [3] and therefore applies to all laser products, EN 50689 only applies to laser consumer products, but also listing some categories of consumer products where EN 50689 does not apply.

The standard EN 60825-1:2014 amended by A11:2021 is referred to here as EN 60825-1+A11 in short, although formally this is not fully correct.

Both EN 50689 as well as EN 60825-1+A11 require that products that fall in the respective scope of the given standard complies with the mutual other.

The details of the two documents are discussed in respective White Papers [4,5] which can be freely downloaded from our website:

<https://laser-led-lamp-safety.seibersdorf-laboratories.at/downloads/e-books-white-papers>

In this proceedings paper limits that apply to the wavelength range of 1250 nm to 1400 nm are discussed.

A summary in tabular form should help to gain an overview of the various requirements.

The requirements of IEC 60825-1:2014 will be included in the discussion.

Various Restrictions for 1250 nm to 1400 nm

IEC Class 1 retinal thermal AEL

In the wavelength range of 1250 nm to 1400 nm, the 2014 update of IEC 60825-1 introduced a steeply increasing wavelength correction factor C_7 . The respective limits of Class 1 and Class 1M (Table 3 and 4 of IEC 60825-1) were derived to protect against injury of the retina. The factor C_7 might have to be reduced in future editions of the standard for some conditions, or other limits lowered, as discussed in another ILSC 2023 paper [6].

The factor C_7 also applies to Class 3R AEL values, which are a factor of 5 higher than the Class 1 AEL.

For measurement Condition 3 (unaided eye, see Table 10 of IEC 60825-1:2014), the usual aperture stop of 7 mm applies, with a classification distance of 100 mm from the reference point, and including further distances for an analysis as extended source. For measurement Condition 1, a 50 mm aperture stop at a distance of 2 m or further applies.

We note that Table 3 and Table 4 of IEC 60825-1:2014 refer to the Class 1 and Class 1M limit. For simplicity in the following, we refer to Class 1 only but imply also Class 1M.

IEC Class 3B dual limit

Due to the very high accessible emission levels permitted by the Class 1 retinal limit, a dual limit was introduced in IEC 60825-1:2014, stated in a footnote in Table 3 and 4 for the AEL of Class 1 and in Table 6 and 7 for the AEL of Class 3R.

This dual limit applies to the wavelength range of 1250 nm to 1400 nm and is defined as the Class 3B AEL. The measurement distances and aperture stops are the same as for the Class 1 and Class 3R assessment. In other words, the accessible emission AE determined through the aperture stop (7 mm for Condition 3) at the distance where the Class 1 and Class 3R AEL is assessed, needs to be also below the AEL of Class 3B. For the comparison against Class 3B limits, an open field of view is implied for the determination of the accessible emission. For the cw limit and $C_6 = 1$, for a wavelength of 1310 nm, the Class 1 AEL equals 505 mW. Thus, for this condition as an example, the Class 3B AEL of 500 mW limits the permitted emission.

Note that the Class 3B limit applies the same way for Class 1, 1M and Class 3R. That is, for Class 3R classification, the dual limit is not 5 times Class 3B. This means that when a product exceeds the Class 3B dual limit, it “jumps” from Class 1 to Class 4.

IEC Class 3B warning label criterion

Subclause 7.13 of IEC 60825-1:2014 requires a warning label when the level of radiation determined with an aperture stop with 3.5 mm diameter positioned at the closest point of human access exceeds the AEL of Class 3B.

This criterion does not impact the class of the product, but it determines whether or not a warning label is necessary on the product. The warning label pertains to potential hazards for exposures at very close distance, such as touching of the laser aperture with a finger or placing the eye extremely close to the product.

This warning label criterion applies to all wavelengths.

For consumer products it is questionable if a warning label is sufficient to make this a safe product. See subsequent requirements of EN 50689.

For this labelling criterion, while the AEL as such is the same as the Class 3B limit for classification discussed above, the aperture to be used to determine the accessible emission is only 3.5 mm in diameter. However, this aperture is positioned at the closest point of human access, i.e. at the housing of the product on top of the laser emission aperture. Due to the potentially shorter distance to the reference point as compared to the 100 mm for the Class 3B dual limit for classification, this label criterion can be more restrictive and can overall be the limiting condition for the permitted emission, in case the manufacturer wants to avoid such a label.

It also should be noted that the level permitted by Class 3B limits without a warning label is relatively high, with 500 mW permitted for the cw case, or for the average power. When a power level of 500 mW is concentrated within a small beam diameter, the resulting local irradiance is sufficiently high to cause a thermal burn within a few seconds. It is only when the exposure duration is short (moving out of the beam due to heat pain) that a thermal burn is avoided. In case a burn occurs, the diameter would be correspondingly small. See the subsection on EN 50689 and child-appealing products.

A11 triple limit skin-cornea

The above two limits were not amended in EN 60825-1+A11 and apply in the same way as per IEC 60825-1:2014. Scientific studies showed that, in the wavelength range of 1250 nm to 1400 nm, in some cases (particularly for small beam diameters at the cornea), the Class 3B limit is not sufficiently protective for the cornea [7,8].

Therefore, the European standardization organization CENELEC has included an additional limit (additional to the Class 3B AEL) in Amendment A11:2021. This limit was derived from the skin MPE but has the function to protect the cornea as well as the eyelids. Correspondingly, the limiting apertures are used, that are in IEC 60825-1 defined to protect the cornea for wavelengths above 1400 nm, namely a diameter of 1 mm for emission durations less than 0.35 s and a diameter of 3.5 mm for emission durations of 10 s and above (details are discussed in [4,7,8]).

The limit has no formal name and is here called the “EN limit”.

For the cw case, the EN limit is equal to 100 mW where the accessible emission is determined with a 3.5 mm circular aperture stop at the same location as the other two limits are assessed (the Class 1 AEL and the Class 3B AEL). Note, however, that the AE of the other two limits are determined with the aperture stop given in Table 10 of the standard (7 mm for Condition 3), while the aperture stop for the EN limit has a diameter of 3.5 mm for the cw case and 1 mm in the pulsed regime. For the cw case (i.e. applicable to cw emission or to the average power for pulsed emission), the EN limit equals 100 mW that is permitted through a 3.5 mm aperture stop. When the beam is larger than 3.5 mm, a higher power level is permitted in the beam based on the EN limit. When the beam irradiance profile is top-hat and equal to or larger than 7 mm, then $(7/3.5)^2 \times 100 \text{ mW} = 400 \text{ mW}$ is permitted through a 7 mm aperture stop. Therefore, for the cw case, the EN limit is in all cases more restrictive than the Class 3B limit.

In the same way as for the dual Class 3B limit of IEC 60825-1, there is no “5 times” the EN limit permitted for Class 3R. This means that when the EN limit is exceeded, the product can be neither Class 1 nor Class 3R.

EN 50689 Class 3B limitation

As mentioned above, IEC 60825-1:2014 features a criterion based on Class 3B which is the basis for a warning label when the AEL of Class 3B is exceeded at the closest point of human access, where the AE is determined with a 3.5 mm aperture stop. When the Class 3B AEL is exceeded, the product still remains a Class 1 or a Class 3R laser product (provided that it complies with Class 1 or Class 3R limitations, respectively).

EN 50689 adopts this criterion for consumer products in a stricter way: according to EN 50689, what was referred to as a labelling condition above, and only affects the label according to IEC 60825-1, is now a

“hard limit” for compliance with EN 50689 for consumer products in Europe. In other words, when the emission determined through a 3.5 mm aperture at the closest point of human access or at the worst-case condition regarding the beam diameter exceeds the Class 3B AEL, the product is not considered as sufficiently safe to be brought onto the market in the European Union, even when it fulfils Class 1 classification.

Note that the criterion in EN 50689 is somewhat more restrictive than the warning label criterion of IEC 60825-1: the warning label criterion is based on the closest point of human access, while the criterion in EN 50689 is based on the closest point of human access as well as on further distances when the beam diameter is smaller and accessible (i.e. an external beam waist).

This criterion applies to all wavelengths, not just to 1250 nm to 1400 nm.

EN 50689 skin limit; 1 mm aperture

For child appealing consumer products, EN 50689 defines a restrictive limit to replace the Class 3B limit described in the previous subsection. The limit is defined as the skin MPE specified in terms of irradiance or radiant exposure in Annex A of EN 60825-1 (equal to Annex A of IEC 60825-1), but the limiting aperture to average the irradiance value that is compared against the skin MPE is only 1 mm. Considering the injury threshold data discussed in another 2023 ILSC paper [9] this seems to be a prudent cautious approach, even though it appears somewhat over-restrictive for some wavelengths, permitting only 1.6 mW through the 1 mm aperture for a cw beam in the visible wavelength range, and 4.0 mW for 905 nm.

Tabular overview

Designation of condition	Wavelength range	Clause and standard	Diameter of aperture stop	Location of aperture stop	Limitation for $t > 10$ s
Class 1 AEL based on C_7 (retinal limit)	1050 nm to 1400 nm	Table 3, 4, 6, 7 IEC 60825-1:2014 EN 60825-1:2014	Condition 3: 7 mm	Condition 3: 100 mm from reference point and further	505 mW for 1310 nm
Class 3B additional limit	1250 nm to 1400 nm	Tables as above, footnote IEC 60825-1:2014 EN 60825-1:2014	Condition 3: 7 mm	Condition 3: 100 mm from reference point	500 mW
Label condition, based on Class 3B AEL	All wavelengths	Subclause 7.13 IEC 60825-1:2014 EN 60825-1:2014	3,5 mm	Closest point of human access	500 mW for $\lambda > 315$ nm
Only in Europe: “EN condition” (to protect the cornea and eyelid)	1250 nm to 1400 nm	Amendment A11:2021 to EN 60825-1:2014	3,5 mm for $t > 10$ s 1 mm for $t < 0,35$ s	Condition 3: 100 mm from reference point	100 mW
For consumer products in Europe: Class 3B not to be exceeded	All wavelengths	EN 50689:2021	3,5 mm	Closest point of human access and smallest beam diameter	500 mW for $\lambda > 315$ nm
For child appealing consumer products in Europe: Skin MPE not to be exceeded	All wavelengths	EN 50689:2021	1 mm averaging aperture to determine irradiance	Closest point of human access and smallest beam diameter	7,9 mW through 1 mm aperture $\lambda > 1050$ nm

References

- [1] CENELEC (2021), Amendment A11 to EN 60825-1 Safety of laser products – Part 1: Equipment classification and requirements, Geneva.
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