

Laser Safety Bulletin OPV Series, VCSEL



Application Bulletin 221

This bulletin is intended to clarify issues relating to laser safety requirements for products, manufacturers and users of Optek OPV Series VCSEL lasers.

Laser Safety Classification

- General Classifications — Products may be classified under the **IEC 60825-1** laser safety standard¹ as *Class 1, Class 1M, Class 2, Class 2M, Class 3R, Class 3B, and Class 4*, where the higher number indicates increasing hazard. The following descriptions of the applicable hazards for those classes are extracted from this IEC standard.
- *Class 1* products are safe under reasonable foreseeable conditions of operation, including the use of optical instruments (e.g., eye loupes or magnifiers) to view the beam
- *Class 1M* products are safe under reasonably foreseeable conditions of operation, but may be hazardous if the user employs an eye loupe or magnifier to view the emitted beam within a distance of 100 mm. The limits for Class 1M are the same as for Class 1 – the difference is that Class 1 products are safe even when viewed with optical instruments.
- *Classes 2 and 2M* apply only to energy in the visible range (400-700 nm), and thus they cannot be considered for the VCSEL products that emit at 780 nm. They rely on the aversion response to the visible beam to provide adequate protection.
- *Class 3R* products have beams that are potentially hazardous if viewed directly, but the risk is lower than for Class 3B and few engineering features or control measures are required. The limit is 5X that for Class 1.
- *Class 3B* products have beams that are normally hazardous when a direct exposure occurs within Nominal Ocular Hazard Distance (NOHD). See discussion below.
- *Class 4* products have beams that may be hazardous, even for diffuse reflections. They may cause skin injuries and could also constitute a fire hazard. No Optek products are Class 4.

Other Laser Safety Standards

- *The European Norm*² EN 60825-1 is essentially identical to the IEC standard and is used for evaluation of CE conformance
- *The Laser Product Performance Standard* is published by the U.S. Center for Devices and Radiological Health (CDRH) within the FDA. These **CDRH regulations**³ are mandatory for any company who sells products to end users within the U.S. Certification of products sold only to OEMs is not required, however, for convenience of our OEM customers, Optek products have been certified to the CDRH regulations. The CDRH is in the process of adopting the classification procedures in the IEC 60825-1 standard, as they recognize that their own requirements are not up to date. Since the amendment process will take several years, the CDRH has published⁴ Laser Notice No. 50 to allow manufacturers to use the IEC classification scheme in certifying their products for sale in the U.S. in the interim.
- User requirements in the U.S. are found in the **ANSI Z136.1 standard**⁵. The criteria used are the Maximum Permissible Exposure (MPE) limits, where the MPE is defined as “the level of laser radiation to which a person may be exposed without hazardous effect or adverse biological changes in the eye or skin”. While the MPE is a specific value for a given time duration and wavelength, an exposure somewhat above the MPE is not necessarily hazardous as there is a significant safety margin in the limits. The MPE has essentially the same limits as Classes 1 and 1M, and it is expressed as the Threshold Limit Values (TLV) in some other standards. Requirements similar to those in the ANSI Z136.1 document can also be found in **Section 3 of IEC 60825-1**.

May 2003
Issue 1.0

Laser Safety Bulletin

OPV Series, VCSEL



Application Bulletin 221

- Other user requirements are found in the IEC 60825-2 **fiber optics communications standard**⁶ that applies primarily to a complete fiber communication system. This document does not currently include Class 1M and Class 3R, but a revision to include those new classes should be available in 2004. In the interim, a document⁷ has been issued by the IEC indicating that the requirements specified for Class 3A in that standard are applicable for these classes.

NOHD Determination

- While the standards for product classification specify a distance that must be used to determine the class, the user standards account for the fact that most laser beams become less hazardous at a distance from the source. This concept is expressed as the Nominal Ocular Hazard Distance (NOHD) or Nominal Hazard Zone (NHZ). Those are distances (or areas) beyond which an exposure to the emitted laser energy is below the MPE limits. They will depend on the beam divergence as well as the output power and wavelength.
- A product that is Class 1M would normally have an NOHD of 100 mm or less when viewed with an eye loupe, and it would have an NOHD of zero distance if viewed without any optical aides. A product that is Class 3R may have an NOHD of many cm, while the NOHD for a Class 3B product may be several meters or more.

Output Power Vs Drive Current

- The IEC 60825-1 standard requires that products be classified with consideration of any reasonably foreseeable, single fault condition. Thus the Optek OPV products are classified assuming the maximum allowable drive current of 30 ma, a value far above the nominal operating current of 12 ma.
- There are OPV models that are classified as Class 3B when the high current level are assumed. However, the outputs of these devices could be considered Class 3R or **1M** if the drive current is limited. This information has been provided to the CDRH in our certification report.

CDRH Requirements on Product Suppliers

- As discussed above, manufacturers of products sold to end users for delivery in the U.S. must certify their models to the CDRH regulations. This requires that labels be applied to the products, a quality control program be used to verify compliance, manuals and sales literature include specified information, and a report be filed with the CDRH in accordance with their guideline. Measurements of output power levels would not be needed if the Optek-certified classes are used, however, they would be required if a reduced drive current level is being used to obtain a lower class. The CDRH regulations and reporting guidelines for laser products can be found at their website:

www.fda.gov/cdrh/comp/rad_nonion_products.html.

References

1. IEC 60825-1/A2:2001, Safety of Laser Products - Part 1: Equipment classification, requirements, and user's guide, International Electrotechnical Commission, Geneva, 1993, with Amendment 2, 01/2001.
2. EN 60825-1/A2:2001, Safety of Laser Products - Part 1: Equipment classification, requirements, and user's guide, European Committee for Electrotechnical Standardization, Brussels, 1994, with Amendment 2, 01/2001.
3. 21 CFR 1040, CDRH Laser Performance Standard, Center for Devices and Radiological Health, as published in the Federal Register, August 20, 1985. Also administrative requirements in 21 CFR 1000.
4. CDRH Laser Notice No. 50, Laser Products – Conformance with IEC 60825-1, Am.2 and IEC 60601-2-22; Final Guidance for Industry and FDA, as published in the Federal Register, July 26, 2001.
5. ANSI Z136.1-2000, ANSI Standard for the Safe Use of Lasers, American National Standards Institute, New York, 2000.
6. IEC 60825-2, Safety of Laser Products – Part 2: Safety of Optical Fibre Communication Systems, International Electrotechnical Commission, Geneva, second edition, May 2000.
7. IEC 60825-2 IS 01, Interpretation Sheet 1, International Electrotechnical Commission, Geneva, August 2001.

May 2003
Issue 1.0