Certifying Products that Incorporate a Laser

US, Canada, EU-CE, International

Lasers present a potential Radiation Hazard to the user. Consequently, products that include a laser also must meet additional laser product safety requirements – internal and external lasers, laser diodes built into a product, laser packages mounted to a product, etc. ALL products that integrate a laser in any way are considered a "Laser Product" and must meet the applicable laser safety requirements per the country of destination. Here is a brief summary of the laser product safety requirements and related design considerations:

Standards: In addition to the safety standard for the overall product, products that incorporate a laser must also comply with these requirements:

a) United States: The FDA's "Center for Devices & Radiological Health" (CDRH) Department specifies the requirements for Lasers within the United States. They can be found in 21 CFR parts 1010 and 1040. Part 1010 is the general marking and instruction requirements. Part 1040 contains the laser requirements. These requirements are available for free online. "UL" certification on products with a laser includes verification that the product complies with Parts 1010 and 1040.

b) Canada: Canada references both the US-FDA requirements as well as the International IEC60825 series. "CSA" certification on products with a laser includes verification that the product complies with these requirements. Many times the product is also being certified for US/UL and Parts 1010 and 1040 and this also satisfies the Canadian requirements (with bilingual English/French marking considerations).

c) European Union – CE: Laser product safety requirements fall under the Low Voltage Directive. The standards currently specified on the LVD standards list for laser products are:
   - EN60825-1: Equipment classification and requirements
   - EN60825-2: Additional requirements for laser fiber optics
   - EN60825-4: Additional requirements for laser guards
   - EN60825-12: Additional requirements for a laser that transmits information through the air

d) International: Countries outside of the US/CAN/EU typically use the IEC laser safety standards or a close variation. The current list of IEC laser safety standards for laser products are:
   - IEC60825-1: Equipment classification and requirements
   - IEC60825-2: Additional requirements for laser fiber optics
   - IEC60825-4: Additional requirements for laser guards
   - IEC60825-12: Additional requirements for a laser that transmits information through the air

Laser Class: The most important consideration in the scope of a laser safety review is the Laser Class. There are actually two laser class ratings for a product that incorporates a laser:

a) Laser Beam Class: What is the class rating of the laser beam?
   - Check the spec sheet for the laser or laser diode you are using.

b) Product Laser Class: What is the laser class rating for the overall product? This depends on your Laser Beam class and whether the user is exposed to the beam.

Laser Enclosure (Protective Housing): The laser requirements state that the user should never be exposed to a laser beam unless necessary for the purpose of the product. Also remember that if the user is exposed to a higher level beam (Class III or Class IV), the user must wear personal protective equipment including laser safety goggles. In addition, the equipment must be used in a specially protected room to prevent beam exposure to others in the facility. So it is strongly suggested that you enclose your laser beam if possible.

- Keep in mind that the beam can be scattered and reflected when striking an object - do not have any vents or openings in the laser enclosure for beams rated over Class I.

Classifying Your Laser Product:
   a) If the user is exposed to the beam, the Product Laser Class is the same as the Laser Beam Class.
   b) If the beam is completely enclosed such that the user has no access to the beam, the Product is Laser Class I.
   c) If the beam is enclosed but you have a viewing window or other laser filter such that the user can see but not access the beam, and the beam is above a Class I rating, you need to measure the exposure level to the user in order to determine the Product Laser Class.
   d) Keep in mind that depending on the wavelength, the beam may be either visible (light) or invisible (radiation).
   e) Products that have two lasers must be rated for both = products that have a Class III or Class IV invisible beam often include a Class I visible beam for sighting or alignment.

Laser Construction Requirements: Protective safety features must be incorporated in the product depending on the Product Laser Class.
   a) Emission Indicator: Audible or visible warning required on Class II and IIIA rated products while the beam is powered.
   b) Radiation Emission Warning: Audible or visible warning required on Class IIIB and IV rated products when the laser system is switched on and when the beam is powered.
   c) Beam Attenuator or Beam Stop: Class IIIB and IV laser products must have a means for the user to stop the beam (shutter) or attenuate the beam to a safe level (filter).
   d) Key Control: Class IIIB and IV laser products must have a removable key for control of the laser.
   e) Remote Interlock Connector: Class IIIB and IV laser products must have a connector for a remote interlock. This is for interconnection to an interlock on a laser protective room door = if the door is opened for the room where the laser is operating, the beam shuts off preventing hazardous laser light from hitting the intruder or exiting the door.

Laser Marking Requirements: In addition to the typical markings required for a certified product, laser products must also be marked to show the laser safety standards to which the product complies. Other laser specific markings are required including a "Warning Logotype" which provides critical laser rating information to the user.

Laser Reporting Requirements: In addition to "UL" certification in the USA, manufacturers of laser products must also file an initial "CDRH Report" with the CDRH. There are also annual filing requirements. The only exception is for Class I products using a Class I beam, where the device generating the Class I beam has also been verified to comply with the Class I requirements. See the FDA's CDRH information online.

Refer to the Laser Safety Standards for the full requirements

CertifiGroup has experts in the Certification of Laser Products
CertifiGroup operates a complete Product Test & Certification Lab
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On-site, at your facility, or in our lab!