# LASER PRODUCT SAFETY FAQ

## What are the laser product safety requirements?

A: The Center for Devices and Radiological Health, part of the The Food and Drug Administration (FDA) agency, is charged with overseeing the safety of medical devices and radiation-emitting products. The CDRH requirements for laser product safety are contained in 21 Code of Federal Regulations (CFR), Parts 1010 and 1040. Outside the U.S., laser product safety requirements are contained in the IEC 60825 series of standards. Both of these standards contain requirements for classifying the laser radiation, labeling, construction features, and user manual statements.

## How is a potential laser hazard from a product conveyed?

A: When evaluated to the laser safety standards, the laser is Classified by assigning a number to the radiation. The FDA / CDRH laser Classifications use Roman Numerals I through IV, with some sub-classes in between. Class I is the least hazardous laser class and Class IV is the most hazardous. In the IEC 60825-1, laser Classifications use Arabic Numerals 1 through 4, with some sub-classes in between. Similar to the FDA/CDRH, Class 1 is the least hazardous laser Class and Class 4 is the most hazardous. The higher the laser Class, the more safeguards you should expect to see on the product. FDA/CDRH and IEC 60825-1 laser Classifications are not interchangeable, so an FDA Class I is not the same as an IEC 60825-1 Class 1. However, the FDA/CDRH will accept IEC 60825-1 laser Class designations in certain circumstances, as allowed by their Laser Notice No. 50 – see the FDA's web site for more details (https://www.fda.gov/Radiation-EmittingProducts/default.htm).

## How is the Class of a laser determined?

A: The Class of a laser is generally determined with a series of laser power or energy measurements. These measurements are performed at various distances from the laser source through certain limiting apertures. The distances and limiting aperture diameters are specified in the laser product safety standards, and are designed to represent real-world exposure scenarios. Depending on the specific circumstance, there could be other measurements required in order to determine the laser Class.

## If I incorporate an FDA/CDRH and/or IEC 60825-1 certified component into my end-product, do I need to do anything additional to address laser safety requirements?

A: In most cases, yes. The FDA/CDRH and IEC 60825-1 standards are end-product standards, with end-product requirements for labeling, construction features, and user manual statements. A certified component will not always address these end-product requirements. In addition, the end-product's laser drive circuit could have an effect on the laser power emitted by the component. There could be exceptions to this general rule, depending on the specific circumstance. For example, please see the FDA/CDRH Laser Notice No. 42 on the FDA's web site for more details.

## How do I know if the laser radiation emitted from a product is hazardous?

A: The laser product safety standards FDA/CDRH 21CFR and IEC 60825-1 require products to be labelled with their laser Class, as well as specific cautions/warnings based on that laser Class. The following table summarizes the IEC 60825-1 Laser Classes (the FDA/CDRH 21CFR Laser Classes would be similar, and it should be noted that the FDA/CDRH will accept the IEC 60825-1 laser Class designations in certain circumstances):

| LASER CLASS | GENERAL DESCRIPTION |
|---|---|
| Class 1 | Generally safe during use, including when viewed with optical viewing instruments |
| Class 1M | Generally safe during use, but may be hazardous when viewed with optical viewing instruments such as eye loupes and binoculars |
| Class 2 | Safe for momentary exposures but can be hazardous for deliberate staring into the laser beam |
| Class 2M | Safe for short time exposures; potentially more hazardous when viewed with optical viewing instruments such as eye loupes and binoculars |
| Class 3R | Direct viewing of the beam is potentially hazardous |
| Class 3B | Normally hazardous when directly viewing the beam, including accidental short time exposure |
| Class 4 | Hazardous for viewing and skin exposure; Can also be a fire hazard |

## I have an Accession Letter from the FDA/CDRH for a laser product – does this mean the FDA/CDRH has confirmed the product complies with the FDA/CDRH laser safety requirements?

A: No. The Accession Letter is sent by the FDA/CDRH to the laser product manufacturer when they receive a CDRH Report. The letter is an acknowledgement of the Report receipt, and the letter states it does not convey approval of the Report. Generally, FDA/CDRH compliance is self-certified by the laser product manufacturer.

## Does UL offer any services to help laser product manufacturers prepare the CDRH Report for submittal to the FDA/CDRH?

A: Yes. UL can help laser product manufacturers with the FDA/CDRH process with services tailor-made for the manufacturer, depending on the specific scenario. For example, a manufacturer may just need UL to perform the laser testing and they will then generate the Report. Or, a manufacturer may need a ready-to-file Report. UL can help with any and all of these possible needs.

## How are projectors incorporating lasers evaluated for radiation safety?

A: Generally, the laser radiation from laser based projectors is evaluated using FDA/CDRH and/or IEC 60825-1. However, the 2014 Edition of IEC 60825-1 (Ed. 3) provides an exception allowing a laser designed to function as a conventional lamp (including laser illuminated projectors) to be evaluated to the IEC 62471 series of standards normally reserved for LED and lamp radiation – primarily IEC 62471-5 "Photobiological safety of lamps and lamp systems – Part 5: Image projectors". This exception can be used if certain parameters in the IEC 60825-1 (Ed. 3) are met. However, this assessment to the IEC 62471-5 parameters is typically only for the accessible radiation emitted from the product during normal operation – the product itself typically also needs to be evaluated to IEC 60825-1 – for instance to address laser related hazards from the laser component(s) during maintenance or service.

The FDA/CDRH has also issued a similar guidance specifically for laser projectors – see the FDA web site for more information.

## Can UL issue a Certified Body (CB) Test Certificate to IEC 60825?

A: Yes. As a National Certification Body (NCB), UL has IEC 60825 in its IECEE CB Scope, and has global locations that are Certified Body Testing Laboratories (CBTLs) for IEC 60825. This means that UL has been authorized by the IECEE to perform IEC 60825 testing, generate a CB Test Report, and issue a CB Test Certificate. A CB Test Certificate means that a CBTL has confirmed complete compliance with the Standard.