Laser Pointer Safety Testing Service
Checking Compliance to CDRH Requirements

Laser pointers have widespread uses in a variety of applications such as presentations, alignment, and entertainment. However, along with the usefulness of these devices, there also come some concerns about safety, due to the potential levels of laser radiation emitted, and the variety of intended users.

Background

U.S. FDA’s Center for Devices and Radiological Health (CDRH) regulates laser products marketed, sold, or imported into the United States. Laser product manufacturers must ensure that their products comply with the CDRH’s regulations. Compliance with the regulations usually involves:

- Laser power testing
- Determining the laser classification (how hazardous the radiation is) typically ranging from Class I (least hazardous) to Class IV (most hazardous)
- Manufacturers can rely on CDRH Laser Notice 50, which allows the IEC laser designations of numerals 1-4 instead of Roman Numerals I-IV, and the CDRH will accept IEC generated test data as a basis of the product report submitted to the CDRH
- Ensuring the product complies with the applicable performance requirements (for example: labeling, construction features, user manual statements, etc.)
- Generation of the appropriate CDRH report to send to the CDRH

The laser product manufacturer does not need the CDRH to review and approve the report prior to marketing, selling, or importing the product into the United States (submitting the report and receiving a CDRH acknowledgment letter is sufficient to put a laser-based product into commerce). Therefore, the determination of CDRH compliance for laser products sold in the U.S. is typically based on the manufacturer’s own self-certification without a 3rd party check. However, based upon the complexity of laser testing – sophisticated instrumentation, equipment and competency to carry out the laser product evaluation – many manufacturers turn to UL to conduct the appropriate testing and completion of the CDRH Product Report on their behalf. This service results in accuracy of reporting and faster turnaround time for product to market.
CDRH Position on Laser Pointers

Laser pointers fall under Surveying, Leveling, and Alignment (SLA) laser products per the CDRH’s regulations in 21CFR Part 1040.11(b). The CDRH laser class limit for SLA laser products, including laser pointers, is Class IIIa. The CDRH also accepts IEC 60825-1 Class 3R as equivalent to CDRH Class IIIa. Both of these CDRH and IEC 60825-1 laser classes would equate to a laser power that does not exceed 5mW. Laser powers over 5mW can be hazardous, causing potential issues such as temporary visual problems or eye injuries. Therefore, any laser pointer emitting radiation over Class IIIa/3R are not allowed to be imported into, sold or promoted in the United States.

Laser Pointer Compliance

Due to the variety of applications, the stated CDRH restrictions, and vast list of potential users (anyone from children to business professionals) of laser pointers, there is a growing need to have a 3rd party confirm a laser pointer manufacturer’s CDRH self-certification. This need for 3rd party confirmation is further boosted by recent NIST findings that show inaccuracies in the stated laser powers/classifications on sample laser pointers tested. The NIST findings indicated that nearly 90% of green pointers and approximately 44% of red pointers were not in compliance with federal safety regulations.

How UL Can Help Laser Pointer Manufacturers and Retailers

- **Full Laser Testing Service:** UL has full service laser testing laboratories in the United States and Japan where all types of laser products are tested to both CDRH and IEC laser safety requirements. This full laser testing service can result in a complete CDRH Report ready to file with the FDA or an IEC 60825-1 CB Test Report with CB Certificate.

- **Informative Laser Pointer Report:** In addition to being able to generate complete CDRH and IEC 60825-1 Reports for laser product manufacturers, UL also has a tailor-made laser pointer service where we can perform only the needed 3rd party confirmation of a manufacturer’s CDRH self-certification.

  - **The report** summarizes
    - the measurement results of the laser testing
    - confirmation of the laser class
    - confirmation that the laser pointer complies with the applicable CDRH requirements.

  - **This service** could be used in a number of ways by laser pointer manufacturers who wish to further support their own CDRH self-certification. Or it could be used by retailers who sell laser pointers (manufactured by other companies), to better ensure they are selling a product that meets the U.S. CDRH or other global requirements for laser safety.

Links:
1. See FDA/CDRH Web site [www.fda.gov](http://www.fda.gov)

More information on UL’s Laser Safety Testing Services, visit [www.ul.com/lasers](http://www.ul.com/lasers) or contact our technical experts below:

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