FDA REQUIREMENTS FOR LASER PRODUCT SAFETY

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.

This process typically involves an evaluation to the CDRH's 21 Code of Federal Regulations (CFR) Parts 1010 and 1040, generating the appropriate CDRH Report, and submitting the Report to the CDRH. The following main steps to this process are listed here:

1. Determining the laser Class of the radiation that is accessible for the Operator, Maintenance, and Service personnel (usually by laser power/energy measurements per the CDRH's test methods);
2. Making sure the product employs the applicable labels, construction features (interlocks, key control, beam attenuator, emission indicator, etc.), user manual statements, etc. as required based on the laser Classes present;
3. Generating the appropriate CDRH Report documenting how the product complies;
4. Submitting the appropriate Report to the CDRH.

Once the CDRH receives the Report, they will send an acknowledgement letter back to the manufacturer – these letters are called Accession Letters. It is important to note that the Accession Letter does not constitute CDRH approval of the Report, rather, that the Report was received and is on file.

FDA/CDRH Requirements and UL Certification

When products are submitted to UL for UL certification (an evaluation of all potential hazards, not just laser hazards), generally, the laser safety aspect of that Certification process will use the FDA/CDRH laser safety requirements. Therefore, the CDRH compliance is not just relevant for meeting FDA obligations, but also potentially relevant to meet UL certification requirements for laser products.

How UL Can Help with the CDRH Process?

A: UL can perform any or all of the above steps in the FDA/CDRH process for laser product manufacturers, even without a concurrent evaluation for the UL Mark to address other non-laser safety requirements. Key services related to this FDA/CDRH process include:

- Conducting a preliminary evaluation on a product (or even the plans for a future product, if the actual product is not yet available) to provide guidance on what the CDRH regulations will require for labeling, construction requirements, user manual statements, etc.

- Performing only the laser testing and providing the results to the manufacturer for them to generate their own CDRH Report. This could also include the determination of the laser Classification by providing detailed classification calculations and results.
- Performing laser testing, determination of the laser Class, and a construction review of the product and providing the results in a letter report that can be used by the manufacturer to generate their own CDRH Report
- Performing all of the above and providing the manufacturer with a ready-to-file CDRH Report

These services can help manufacturers meet FDA laser safety obligations, as well as address laser safety requirements for a total UL Certification of the product.