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Guidelines on the Laser Light Show Variance Process for LIP Distributors and Dealers

Disclaimer: This document is for guidance purposes only. It does not contain legal advice and it is the responsibility of the Variance applicant to research and review the applicable national, state and local laws and regulations and adhere to them when installing and operating the covered equipment.

Introduction

Laser-Illuminated Projectors (abbreviated as "LIPs") are a new type of image / video projectors that use lasers instead of lamps as their internal light source. LIPs can have interchangeable projection lenses and they emit a diverging light beam towards the projection surface in the same way as lamp-based projectors. In almost every operational regard, LIPs are identical to their lamp-based counterparts with the exception of their new laser-based "light engines".

The US Food and Drug Administration ("FDA") has been regulating lasers and laser-based equipment introduced into the US market since the 1970s. Medical lasers, industrial lasers, and lasers for entertainment purposes ("scanning laser light-shows") are some of the product categories the FDA regulates.

Since these new LIPs are classified as "laser-based equipment", they fall under the jurisdiction of the FDA with its established regulatory requirements.

This document provides guidance for everyone involved in the manufacture, distribution, sales, installation and operation of LIPs, who may need to apply for an FDA "Laser Light Show" variance *before installation begins*.

We strongly advise you to read through this FDA link, that provides an overview of laser light shows, displays and reporting guides, and is the basis for this document.

What is a variance?

As demonstration laser products, LIPs and applications for LIPs cannot exceed Class IIIa emission limits as specified in 21 CFR 1040.11(c) (which is comparable to IEC 60825-1 Ed. 3 Class 3R) unless granted a variance by the FDA under 21 CFR 1010.4. Some LIPs and applications for LIPs will exceed the Class IIIa limits and therefore require a variance to exceed those emission limits. Such LIPs are classified as **Class 1, Risk Group 3** (RG3) according to Laser Notice 57. Therefore, Risk Group 3 LIPs need a **Laser Light Show Variance** that is approved by the FDA in order to be *sold, installed and operated* in the US market.

The variance can be considered as asking for an exception to the rule. The applicant requests a variance for a certain product, and if the CDRH (Center for Devices and Radiological Health within the FDA) approves, it also mandates certain restrictions (e.g. with respect to hazard distances and restriction zones) under which the product must be sold, installed and operated.

In practice, applying for a variance entails filling in a specific form (Form 3147), submitting it to the FDA by e-mail, and waiting for the approval. A detailed procedure is described further in the document. There is an obligation of annual reporting as well, of the number and type of LIP projectors sold and installed under the approved variance. This annual report, if submitted on time, acts as an automatic extension of the variance for another year.

Chain of custody – do you need a variance and when?*

The variance process starts with the manufacturers of LIPs. Prior to introducing a RG3 (or Class IIIb-IV) LIP product to the US market, manufacturers obtain a “product variance” from the FDA by submitting an Engineering Product Report, a Laser Light Show Report, and the actual Variance application.

The FDA requests a “chain of custody” which means that any party in the distribution chain (from the manufacturer, through distributors and dealers and in some cases end users of LIP equipment) also has **a legal obligation of having an approved variance**. According to the FDA document Laser Notice 51:

> *Dealers and distributors of laser light show projectors must have approved laser light show variances to purchase equipment from projector manufacturers. This requirement ensures that awareness of laser light show radiation safety and protection practices and regulatory requirements are transferred from one variance holder to the next.*

* Contact your manufacturer for more details regarding obtaining variances.

According to the FDA information on Laser Light Shows (https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/laser-light-shows), you will **need to obtain a variance** for RG3 LIPs if you are:

- A distributor, dealer, or end user of such LIPs (if you do not meet the exemptions noted below)

In addition to a variance application, you may also need to submit a **Laser Light Show report** (Form 3640) if:

- You are a laser light show producer or a LIP user for a temporary installation (e.g. a staging company). All temporary installations with RG3 LIPs count as laser light shows.

You are **exempt** from obtaining a variance if:

- Per 21 CFR 1040.11(c), if you resell or install only LIPs that are classified as Class I, II or IIIa (Class 1, 2 or 3R), or according to the new categorization method, as Risk Group 0, 1 or 2 only.
- Per Laser Notice 57, if you are the end user of a permanent installation in a cinema theater. The installation restrictions for the particular LIP must still be respected by the installer who needs to have an approved variance.
- As a result of the "chain of custody", if you are an end user of a permanent installation (for example a conference hall) and the installation has happened by the manufacturer, a manufacturer-authorized installer, or dealer or distributor that holds a variance. The installation must happen according to the variance requirements.
- If you are an A/V consultant or architect, proposing or designing a LIP in a certain installation. However, in this case please make yourself aware of the particular installation conditions (restrictions) of the LIP in question, because separation distances and restriction zones might be applicable. Obtain this information upfront from the manufacturer.

When in doubt, please contact your LIP projector manufacturer. Their variance may also have additional provisions for the particular LIP.

Step by Step Instructions on Variance Filing

For completeness, below we have copied the instructions on Variance Filling in their entirety from this link on the FDA website. Note that once approved, you will receive a variance-granting letter from CDRH that includes a variance number and the conditions of approval under which the variance is granted. These conditions need to be met for all LIPs installations under said variance.

The CDRH updated the application process to simplify the submission of Electronic Product Radiation Control (EPRC) variance applications. A variance is permission to vary from one or more requirements of a performance standard. A manufacturer whose products are subject to a performance standard but need a variance approval must follow certain procedures as prescribed in 21 CFR 1010.4, following the application process described here. This process was implemented on September 1, 2020, and includes updates to variance-related forms and the creation of an optional standardized cover sheet that applicants are encouraged to submit with all variance applications.

1. You can submit all variance applications and supporting materials to CDRH by completing the following steps:Email your application and related forms to CDRH's Document Control Center (DCC) at RadHealthCustomerService@fda.hhs.gov
2. Be sure each submission includes separate PDF attachments for the:
   - CDRH variance cover sheet
   - variance application (justification letter, or Form 3147 for Laser Light Show (LLS) or LLS equipment)
   - supporting materials, such as product or show reports, associated with these applications.

The variance application can be an original, renewal or an amendment. The CDRH variance cover sheet allows space for you to provide additional information about your package and includes a checklist to assist you in preparing a complete submission package.

CDRH's Document Control Center will process your variance application package and issue acknowledgement letters with Accession numbers for each variance application and report. Variance applications are forwarded by the Document Control Center to the FDA's Dockets Management Staff (DMS), who will also issue you an acknowledgement letter with your Docket number.

You no longer need to separately send applications to Dockets Management Staff (formerly the Division of Dockets Management).

If you have questions about variance applications, contact the Division of Industry and Consumer Education.

Useful links

Throughout this document, we use hyperlinks in the text to point to locations where you can find specific procedures, documents, and forms. Hereunder you can find the most useful links in full.

Information about laser light shows:
https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/laser-light-shows

Variance Application process:
https://www.fda.gov/radiation-emitting-products/records-and-reporting-radiation-emitting-products/electronic-product-radiation-control-eprc-variance-application-process-fda

Variance application form 3147:
https://www.fda.gov/media/72256/download

Laser Light Show Report 3640:
https://www.fda.gov/media/72658/download

Laser Notice 57:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-and-requirements-laser-illuminated-projectors-lips-laser-notice-no-57

Laser Notice 51:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/responsibilities-laser-light-show-projector-manufacturers-dealers-and-distributors-laser-notice-51