Laser Illuminated Projectors

Update to US Regulations

Pete Ludé
CTO, Mission Rock Digital LLC
San Francisco, CA
Pete @MissionRockDigital.com

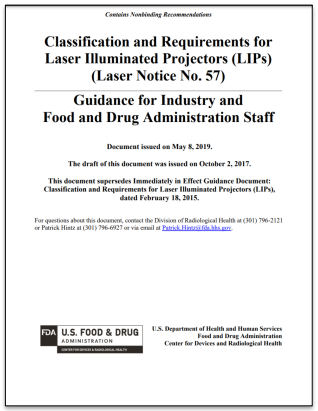
Disclaimer!

- Laser Safety requirements are important!
- …and they're complicated
- Refer to your manufacturer on specific requirements
- Read the original Regulations / Guidance documents yourself for clarity
- Summary here is for information only. No guarantees on accuracy or completeness

Laser Notice 57

- FDA released Guidance Document as of May 8, 2019:
- Laser Notice 57 *"Classification and Requirements for Laser Illuminated Projectors (LIPs)"*

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



Contains Nonbinding Recommendations

Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57)

Guidance for Industry and Food and Drug Administration Staff

Document issued on May 8, 2019.

The draft of this document was issued on October 2, 2017.

This document supersedes Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors (LIPs), dated February 18, 2015.

For questions about this document, contact the Division of Radiological Health at (301) 796-2121 or Patrick Hintz at (301) 796-6927 or via email at Patrick.Hintz@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

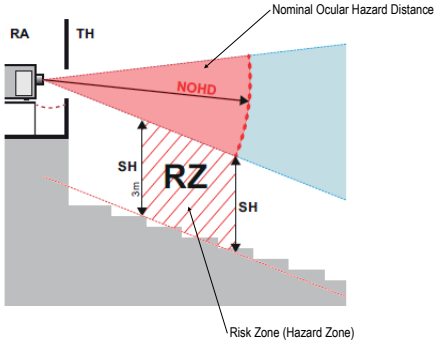
Laser Notice 57 – What does it say?

- Harmonizes nomenclature and device classification with International Standards
  - IEC 60825-1: Ed 3 Safety of Laser Products – Part 1: Equipment Classification and Requirements
  - IEC 62471-5: Ed 1.0 Photobiological safety of lamps and lamp systems – Part 5: Image projectors
- Eliminates need for Dual classifications (US and RoW) by Manufacturers
  - For example: a projector classified as Class 1, Risk Group 2 by IEC will be identically classified by FDA for US Market
- Simplified Deployments
  - Clarification on requirements for Variance Approvals

Basics

- IEC classifies LIPS by assigning Risk Group of 0, 1, 2 or 3
  - High Number = Higher optical radiation
- IEC 60825-1 contains an important exemption subclause (4.4) that qualifies laser products to use classification Risk Groups form the IEC Lamp Standards.
- FDA considers this classification acceptable, therefore, *"FDA does not intend to enforce"* the previous requirements 21 CFR 1040.10(c)(1) and 21 CFR 1040.11(c) for qualifying LIP's
- Risk Group 0, 1 and 2 have simple requirements
  - Labeling, Operations manual, Reports
- Risk Group 3 products require a Variance Approval from FDA
  - Installation requirements for clearance within Hazard Zone

Risk Group 3 – Hazard Zone clearance

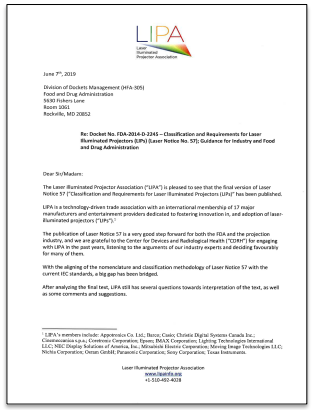


FDA Variance

- Variance Approvals "generally" issued by FDA:
  - Conditional on laser products being sold to Cinema Theater Operator
  - Or operators already holding a valid variance (i.e. for rental / staging rental)
- Labeling Requirements must be met
- Safety instructions must be included included
- Product reports and Annual Reports submitted by Manufacturer
- **Cinema operators do not need a variance**
  - Since manufacturers variance includes requirement for safe installation and training

LIPA Response to FDA

- Some technical questions on measurement geometry
- Seeking clarification of RG 2 emission classifications
- Seeking clarification on Pulsed laser sources
- Seeking clarification on Laser-pumped phosphor classification as Class 1 under IEC
- Yellow labels preferred over orange labels
- Request for vertical clearance of 2m rather than 3m to hazard zone, for fixed installations


LIPA

June 7th, 2019

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-D-2245 – Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57); Guidance for Industry and Food and Drug Administration

Dear Sir/Madam:

The Laser Illuminated Projector Association ("LIPA") is pleased to see that the final version of Laser Notice 57 ("Classification and Requirements for Laser Illuminated Projectors (LIPs)" has been published.

LIPA is a technology-driven trade association with an international membership of 17 major manufacturers and entertainment providers dedicated to fostering innovation in, and adoption of laser-illuminated projectors ("LIPs").[1]

The publication of Laser Notice 57 is a very good step forward for both the FDA and the projection industry, and we are grateful to the Center for Devices and Radiological Health ("CDRH") for engaging with LIPA in the past years, listening to the arguments of our industry experts and deciding favourably for many of them.

With the aligning of the nomenclature and classification methodology of Laser Notice 57 with the current IEC standards, a big gap has been bridged.

After analyzing the final text, LIPA still has several questions towards interpretation of the text, as well as some comments and suggestions.

[1] LIPA's members include: Appotronics Co. Ltd.; Barco; Casio; Christie Digital Systems Canada Inc.; Cinemascenics s.p.a.; Coretronic Corporation; Epson; IMAX Corporation; Lighting Technologies International LLC; NEC Display Solutions of America, Inc.; Mitsubishi Electric Corporation; Moving Image Technologies S.r.l.; Nichia Corporation; Osram GmbH; Panasonic Corporation; Sony Corporation; Texas Instruments.

Laser Illuminated Projector Association
www.lipainfo.org
+1-510-492-4028

https://www.regulations.gov/document?D=FDA-2014-D-2245-0022

Want to learn more?

LIPA
Laser
Illuminated
Projector Association

LIPA is planning:

- Further details on web site

  www.LipaInfo.org
- Webinar

Laser Illuminated Projectors

Update to US Regulations

Pete Ludé
CTO, Mission Rock Digital LLC
San Francisco, CA
Pete @MissionRockDigital.com