LIPA
Laser
Illuminated
Projector Association

Understanding
Laser Illuminated Projector Safety Regulations

An Informational Webinar

Presented by:
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MissionRock DIGITAL

October 17, 2019

A Word from our sponsor…

About the Laser Illuminated Projector Association

MISSION: *LIPA will speed the adoption of laser illuminated projectors through cooperative industry activity*

- Education
- Regulatory Affairs
- Safety

A Word from our sponsor…

About the Laser Illuminated Projector Association

GOAL: Advocate for a positive regulatory environment that will facilitate commercial adoption of laser illuminated projectors.

- Represent the leading projector manufacturers and supply chain companies
  - Projector manufacturers (both laser- and lamp-based)
  - Component manufacturers (laser & micro-displays)
  - Integrators / Installers
  - End Users (Theater-owners, film studios, and theme parks)

LIPA Membership

Join us!

www.LIPAinfo.org

- Newsletters
- Events
- Meetings
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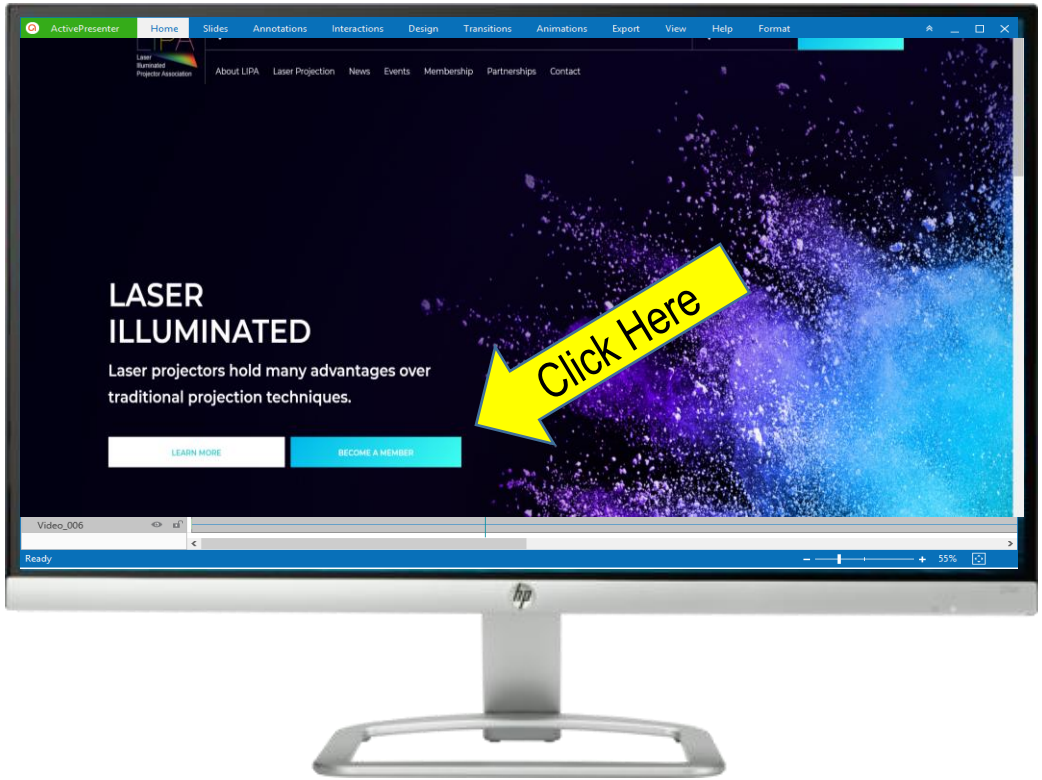

Today's agenda

- About Laser Illuminated Projectors
- Understanding Brightness Measurements
- Regulatory Background
- The new FDA Laser Notice 57
- About "Variances"
- Installation Considerations
- Summary and Q&A

For Avixa Members:

- By completing this webinar course, participants can earn the following AVIXA Renewal Units for each designation level:

Certification Level	Renewal Units
CTS	**1**
CTS-D	**1**
CTS-I	**1**

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https://www.avixa.org/training-certification

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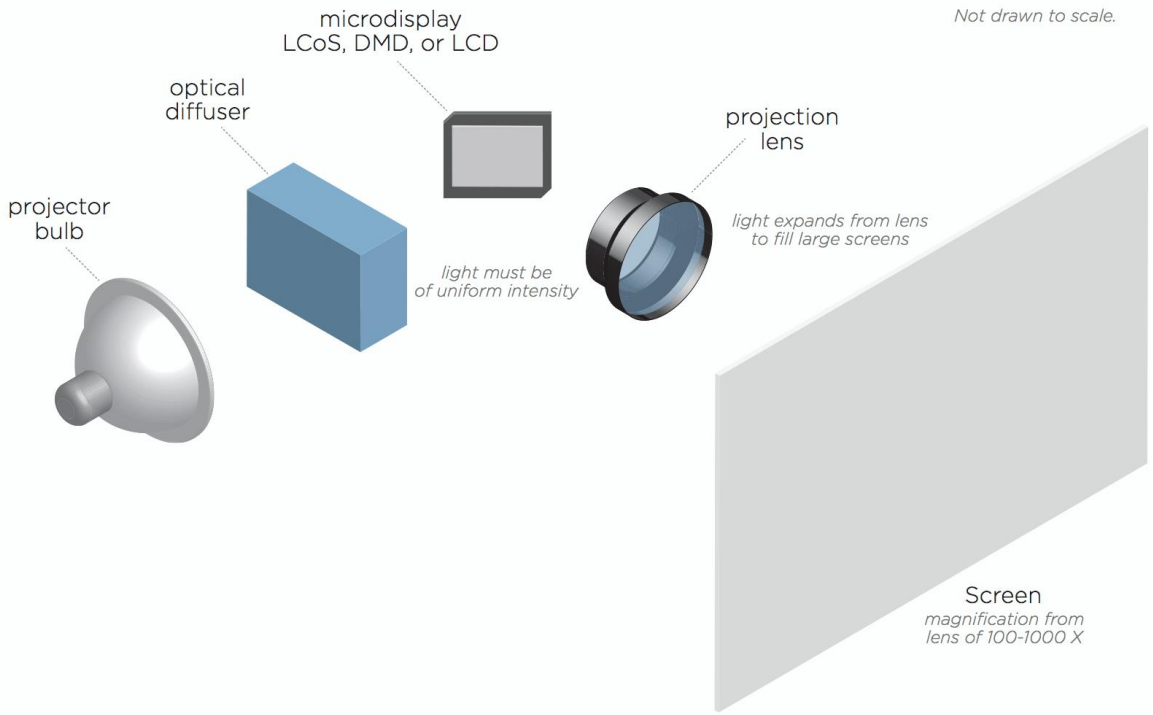
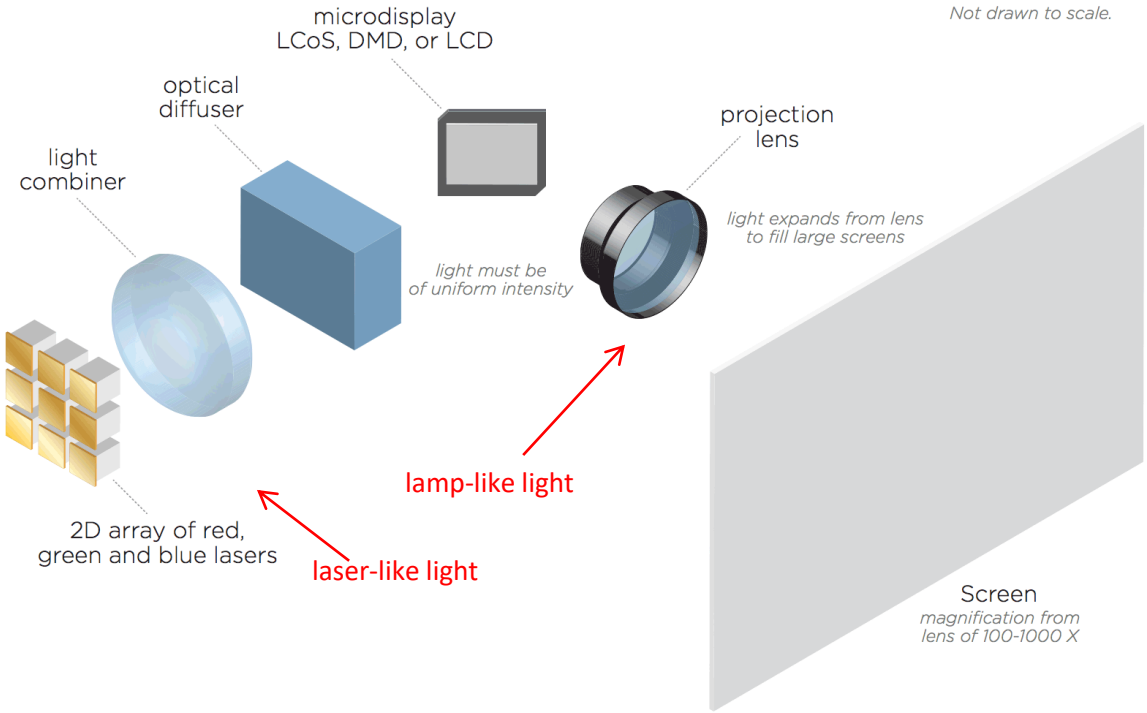
Laser Illuminated Projector (LIP) Basics

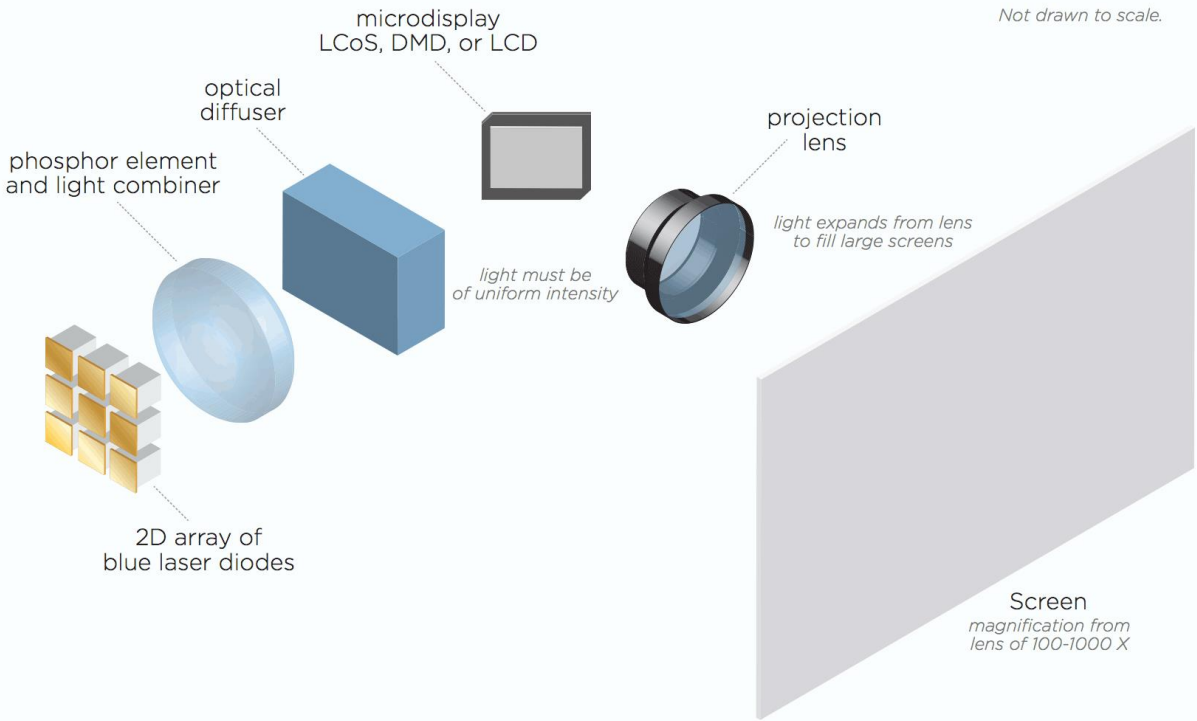
Lamp based Optical Architecture



RGB Laser Projector Optical Architecture

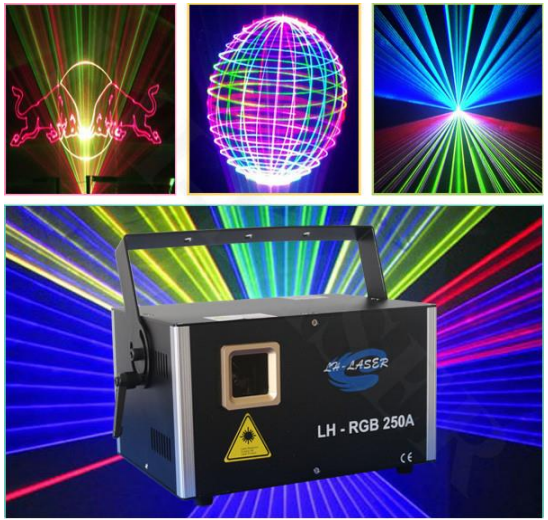


Laser-pumped Phosphor Optical Architecture



Why Laser *Illuminated*?

A “Laser Projector”



A “Laser Illuminated Projector”

Laser Safety

- In normal operation, LIPs are fundamentally as safe as lamp projectors
  - Assuming radiance and beam geometry are equivalent
  - LIPs are designed to emit light nearly identical to a lamp projector
- But – “raw”, collimated laser beams can be harmful
  - Since laser sources are inside the projector, care must be taken
  - Particular considerations during maintenance access
- Since laser sources are used, special safety regulations apply

Consult your manufacturer for specific safety requirements, and to answer any questions about your particular situation

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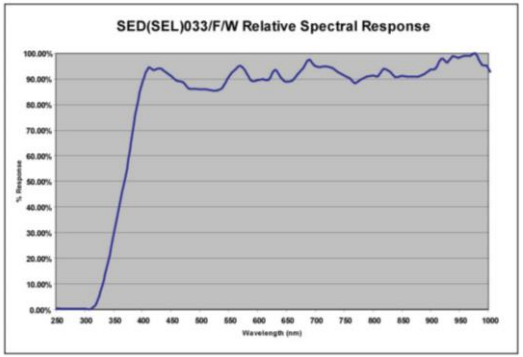
Understanding Brightness Measurements

“How many lumens does a projector need to be before stricter regulations kick in? “

Understanding Brightness measurements

Radiometry

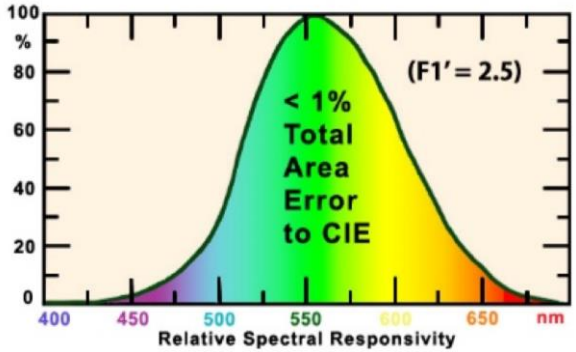
The measurement of light waves in the optical portion of the electromagnetic spectrum (including UV, visible and IR light).



Example of typical Radiometer

Photometry

A special subset of radiometry weighted for a typical human eye response



Example of typical Photometer

Source:http://depts.washington.edu/mictech/optics/me557/Radiometry.pdf

Understanding Brightness measurements

Radiometry

The measurement of light waves in the optical portion of the electromagnetic spectrum (including UV, visible and IR light).

Photometry

A special subset of radiometry weighted for a typical human eye response

Units of Measure

- Radiant power (Watts)
- Irradiance (W/m^2)
- Radiance (W/m^2/steradian)

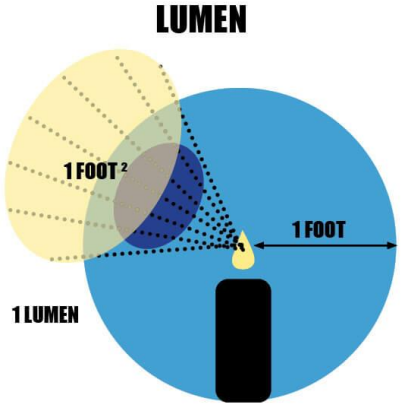
Units of Measure

- Luminous flux (lumens)
- Illumination (lux = $lumen/m^2$)
- Luminance (cd/m^2 = $lumen/m^2$/steradian)

Understanding Brightness measurements

Luminance Flux

In photometry, luminance flux is a measure of the total quantity of visible light emitted by a source,



Source: https://www.standardpro.com/how-to-measure-light/

Measured in:

The lumen (symbol: lm)

1 lm = 1 cd · sr

1 lux = 1 lumen/m^2

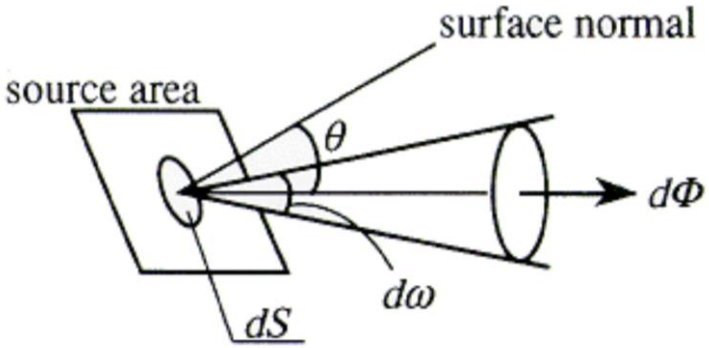
For Projectors: **"ANSI Lumens"**

Defined in IEC 61947-1:2002

Understanding Brightness measurements

Radiance

In radiometry, radiance is the radiant flux emitted, reflected, transmitted or received by a given surface, per unit solid angle per unit projected area.



Measured in:

Watts per steradian per square meter ($W \cdot sr^{-1} \cdot m^{-2}$)

Source: http://wtlab.iis.u-tokyo.ac.jp/wataru/lecture/rsgis/rsnote/cp1/cp1-6.htm

Understanding Brightness measurements

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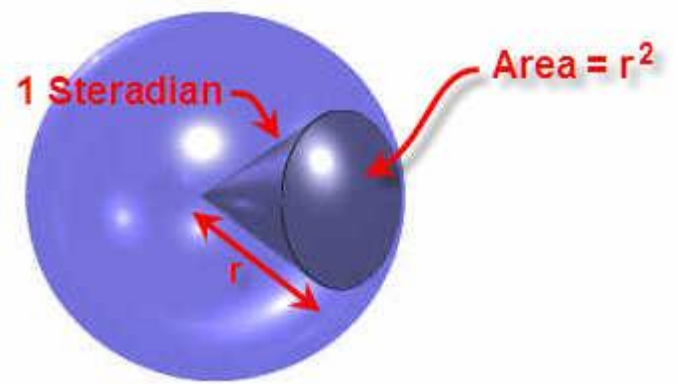

Source: Coles Physics II Website
https://sites.google.com/site/colesphysicsiiwebsite/light-and-color

Measured in:

Watts per steradian per square meter ($W \cdot sr^{-1} \cdot m^{-2}$)

The **steradian** (symbol: **sr**) or **square radian** is the SI unit of a solid angle

Understanding Brightness measurements

In Summary

- Hazard assessment doesn't directly relate to Lumens because:
  1) Color spectrum measured
     - "Brightness" is characterized by human-visible wavelengths
     - Safety is evaluated by *all* wavelengths of light
  2) Geometry of light rays
     - Radiance consider apparent source size
     - Luminance flux does not

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Regulatory Background

US Laser Regulations

- Federal Laser Product Performance Standard (FLPPS)
- 21CFR subchapter parts 1040.10 and 1040.11
- Administered by the Center for Devices and Radiological Health (CDRH)

US Laser Regulations

- ANSI Z136.1 – 2014
  Safe Use of Lasers

- Part of a Suite of Standards
  - ANSI Z136.2 - Fiber Optic
  - ANSI Z136.3 - Healthcare
  - ANSI Z136.4 - Safety Measurements
  - ANSI Z136.5 - Educational Institutions
  - ANSI Z136.6 - Outdoor
  - ANSI Z136.7 - Test/Label Equipment
  - ANSI Z136.8 - R&D/Testing
  - ANSI Z136.9 – Manufacturing

- Referenced by
  - CDRH Variances
  - State Regulations
  - OSHA
  - Others

US Laser Regulations

- Referenced by
  - FDA Regulations
  - Worldwide regulators

- IEC 60825-1:2014

  Safety of laser products

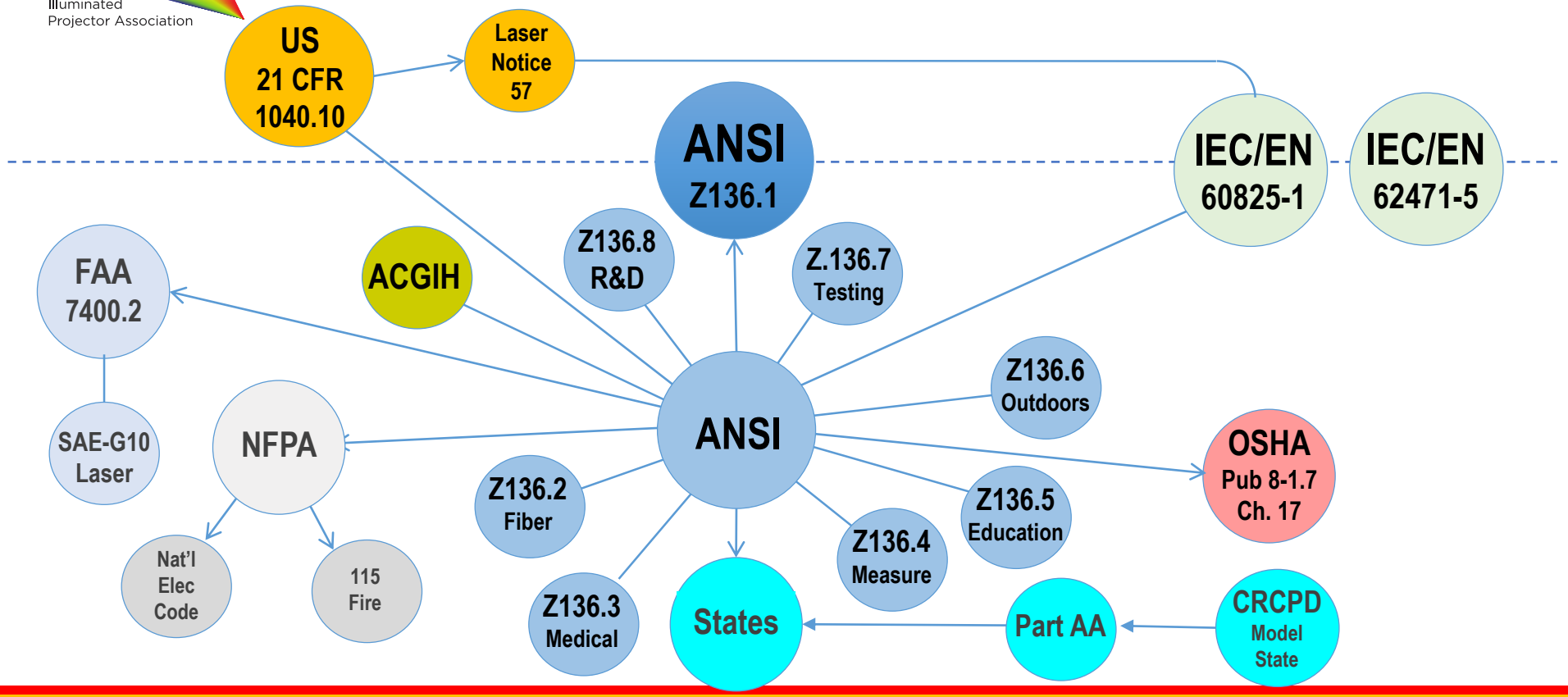
  Part 1: Equipment classification and requirements

- IEC 62471-5:2015

  Photobiological safety of lamps and lamp systems

  Part 5: Image projectors

US Laser Regulatory Landscape



Laser classifications according to FDA and IEC

Intended for "raw" (collimated) laser beams

Laser Class

FDA	IEC	Description	Notes	Example Products
I	1 1M	**Considered non-hazardous in normal operation**	Hazard increases if viewed with optical aids, including magnifiers, binoculars, or telescopes.	• Laser printers • CD / DVD players
II IIa	2 2M	**Eye protection normally through aversion response**	Hazard increases when viewed directly for long periods of time, or if viewed with optical aids.	• Bar code scanners
IIIa	3R	**May be momentarily hazardous when viewed directly or with specular reflection.**	Depending on power and beam area. Risk of injury increases when viewed with optical aids.	• Laser Pointers
IIIb	3B	**Immediate skin hazard from direct beam and immediate eye hazard when viewed directly.**		• laser light show projectors • industrial lasers • research lasers
IV	4	**Immediate skin hazard and eye hazard from exposure to either the direct or reflected beam; Potential a fire hazard.**	May also produce laser-generated air contaminates and hazardous plasma radiation	• laser light show projectors • industrial / research lasers • surgical lasers

Definitions (General to laser safety regulations)

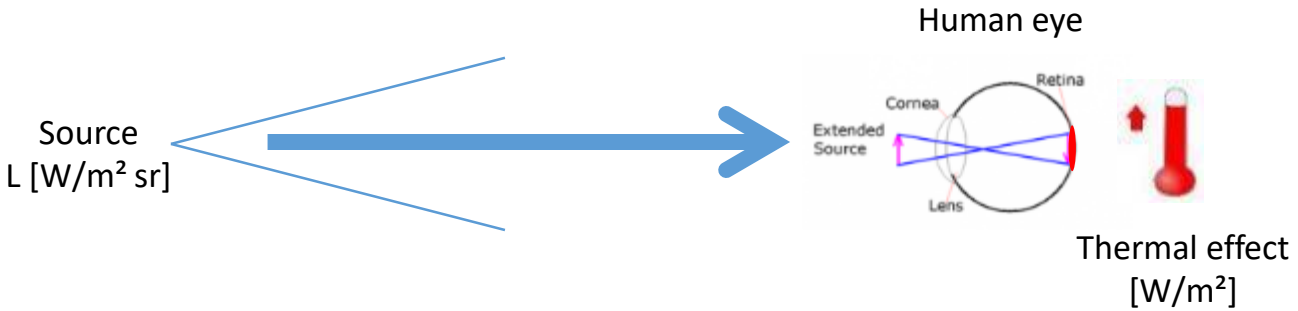
- MPE Maximum Permissible Exposure
  - the maximum limit to which a person may be exposed without suffering adverse effects
- NOHD Nominal Ocular Hazard Distance
  - The distance from the projector where the light exceeds the MPE
- SNHZ Skin Nominal Hazard Zone
  - The area where skin burns are possible

Definitions (Used in LIP Regulations)

- AEL Accessible Emission Limit
  - maximum accessible emission permitted within a particular risk group
- HD Hazard Distance
  - distance from the projector's nearest point of human access, where the beam radiance or irradiance exceeds the applicable exposure limit
- HZ Hazard Zone
  - the 3-dimensional space encompassing the region that is considered RG-3 based on the Hazard Distance

LIPS vs Lamp based projectors

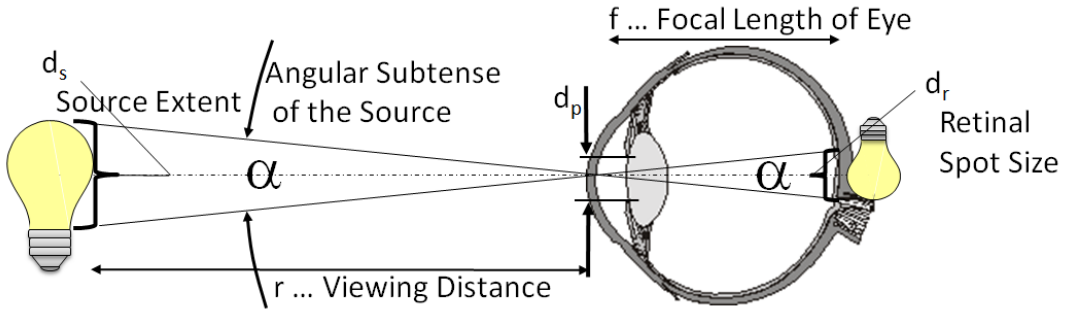
- The **eye injury** mechanism is identical for laser or lamp projectors
  - **Thermal** induced retinal injury model = 0.25s **accidental exposure** through 7mm eye pupil



- **Risk** Lamp projector = Risk Laser projector
  - For *identical radiance and lens exit pupil geometry*

How are LIPs different than laser beams?

LIPs have an extended source, not a collimated beam



A source that emits broadband incoherent radiation represents an extended source, producing a correspondingly large image on the retina.

Projector Safety Regulations

Risk Factors

- “Brightness” [lumens]
- Throw Ratio
- Angular subtense α [Rad]
- **Radiance** L [W/m²sr]
  ≈ effect on the human eye

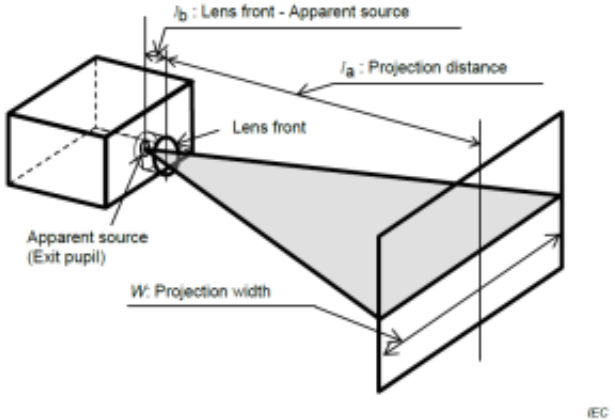


Figure 3 – Definition of throw ratio

IEC Laser Regulations

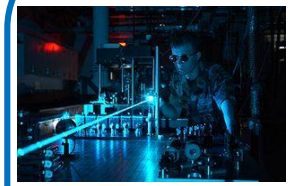
IEC **60825-1** Ed 2 (2007)

Safety of Laser Products

Part 1: Equipment classification & Requirements

- Previously, *all* laser product requirements were defined in IEC 60825-1
  - Medical
  - Industrial
  - Laboratory use
  - Laser Welding
  - Laser Illuminated Projectors

IEC Laser Regulations






But under the latest revision (Edition 3), laser products intended to behave as lamp devices may be carved out…

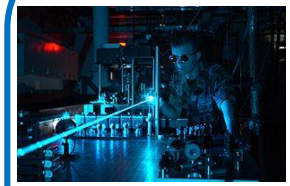
IEC **60825-1** Ed **3** (2014)

Safety of Laser Products

Part 1: Equipment classification & Requirements

Carve-out for devices with irradiance < $\frac{1\text{MW}\cdot\text{sr}^{-1}\cdot\text{m}^{-2}}{\alpha}$

IEC Laser Regulations





IEC **60825-1** Ed **3** (2014)

Safety of Laser Products

Part 1: Equipment classification & Requirements





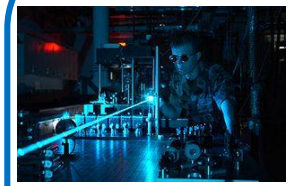

IEC **62471** Ed [illegible] (2006)

Photobiological safety of lamps a[illegible] systems

Carve-out for devices with irradiance < $\frac{1\text{MW}\cdot\text{sr}^{-1}\cdot\text{m}^{-2}}{\alpha}$

…and regulated under Lamp standards

IEC Laser Regulations





IEC 6082[illegible]
Safety
Part 1: Equipment

..and this new standard was created *specifically* for projectors






IEC **62471-5** Ed 1 (2015)
Photobiological safety of Lamp Systems for Image Projectors

Evolution of LIP regulations

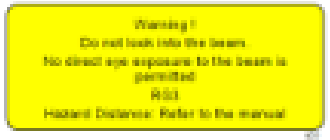
- The international community TC 76 optical radiation **safety experts** created a specific classification path for Laser products *which are designed to function as* ***conventional lamps****.*

- Risk from a Lamp projector **is the same** as from a Laser projector
  - *Assuming identical radiance and lens exit pupil geometry*

- **SOLUTION**: **Dual classification**
  - Laser based Class *and*
  - Lamp based Risk Group
  - **Example: "Class 1 – Risk Group (RG) 3"**

Why was IEC 62471-5:2015 created?

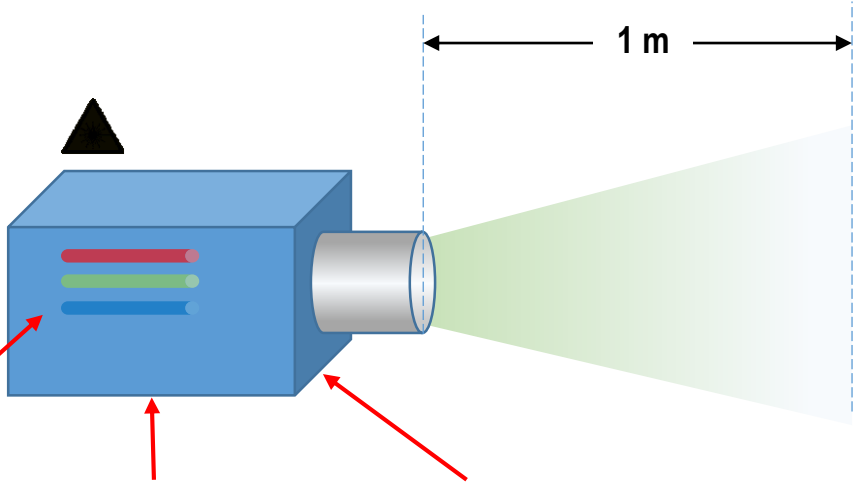
- **Lower classification power to consider**, new ICNIRP limits
- Clear line **what is considered safe** for consumer use or not
- **Guidance** in **what separation height** to maintain for RG 3 Projectors:
  - **Cinema:** Hazard Zone to be 2m above floor
  - **Non Cinema**: Hazard Zone to be 3m above floor
- **Clear labels** and **user information** instructions **generic for projectors**



Evolution of LIP regulations

Example: "Class 1 – Risk Group (RG) 3"

IEC 60825-1:2014
section 4.4



Emission evaluated under
IEC 62471-5: 2015
Photobiological safety of Lamp Systems for Image Projectors

Embedded lasers *inside* enclosure may be Class 3B or 4

But enclosure is protected by light-stops and interlock switches

So product is rated as Class 1 Laser Product

Risk Group Classifications

RISK GROUP	Safety Implication
Risk Group 0	Inherently safe
Risk Group 1	Safe, for intended use
Risk Group 2	Safe, based on aversion response (eye blink)
Risk Group 3	Potential hazardous for eye and skin exposure at close distance

Regulations define “exit pupil”

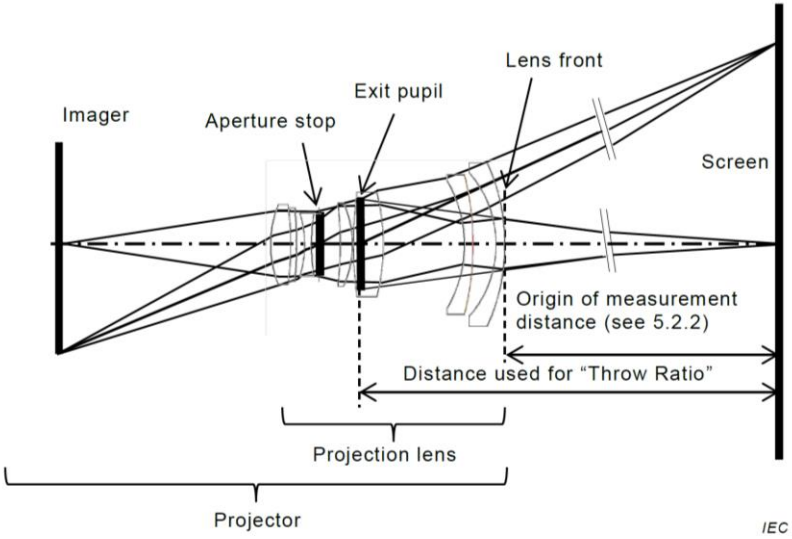
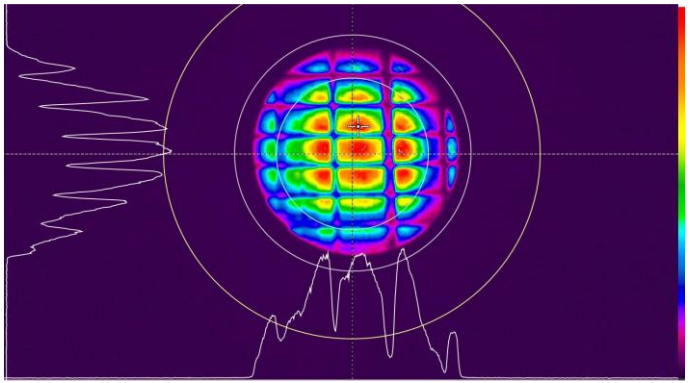


Figure 1 – Exit pupil in projector

From IEC 62471-5: Photobiological safety of lamps and lamp systems – Part 5: Image projectors

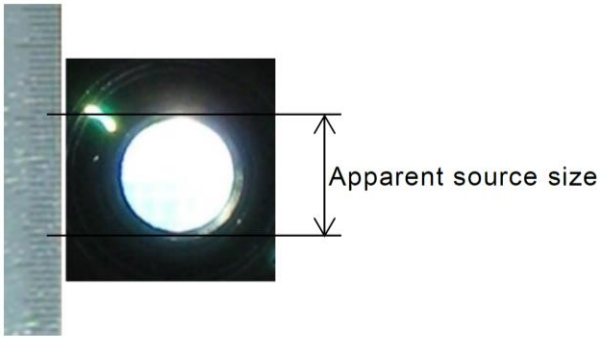


Irradiance distribution of the image of the exit pupil (taken as the apparent source).

LIPA Report: *Risk Analysis Data Base and Case Study, Karl Schulmeister, PhD*

Apparent Source Size

Used in the calculation of Radiance (and therefore Risk Group)



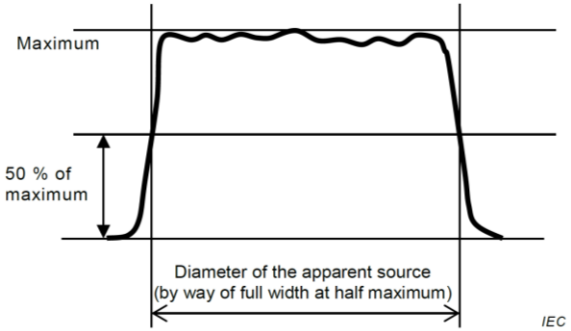
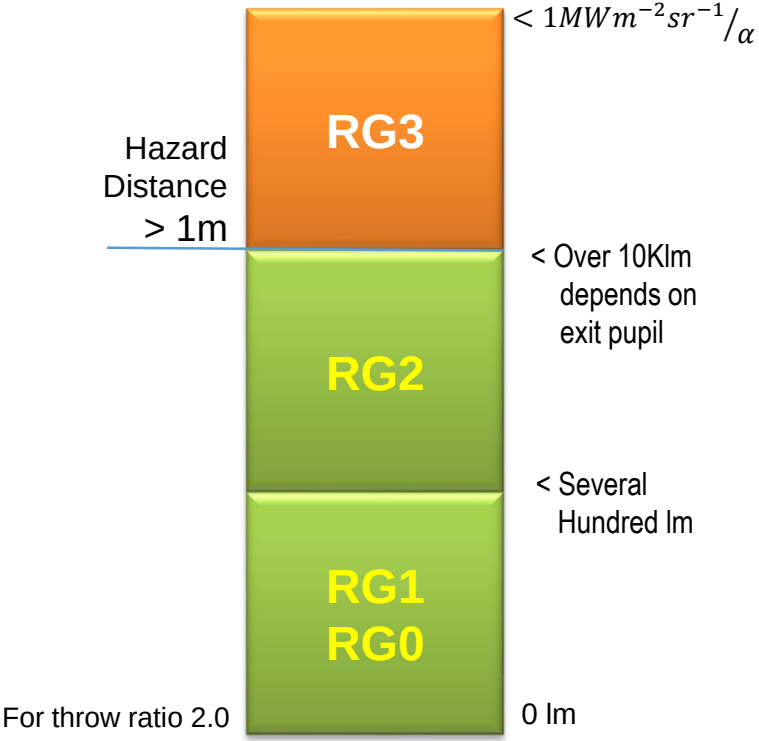


Figure 4 – Diameter of the apparent source

From IEC 62471-5: Photobiological safety of lamps and lamp systems – Part 5: Image projectors

Risk Group Classifications



RG 3 – **Potentially hazardous** at close distance

Professional Use Projectors – with FDA Variance

IEC 62471-5:2015 requires:

- Sold only to professionals. Warning labels
- No access to beam within hazard distance
- Use & installation requirements, Soft start

RG 2 - Safe based on aversion response *(blink reflex)*

Home/office use projectors

IEC 62471-5:2015 requires:

- Caution labels, Soft start, User information and instruction

RG 0/1 - Inherently Safe

Pico Projectors

IEC 62471-5:2015 requires:

- User information

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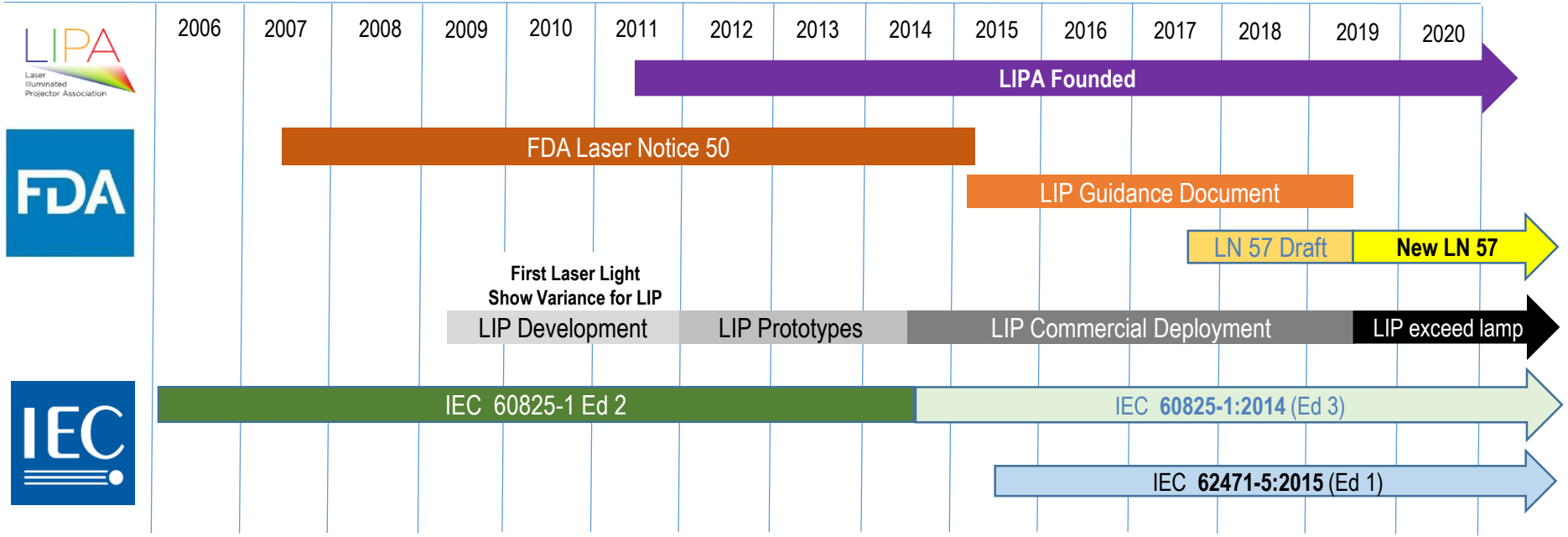
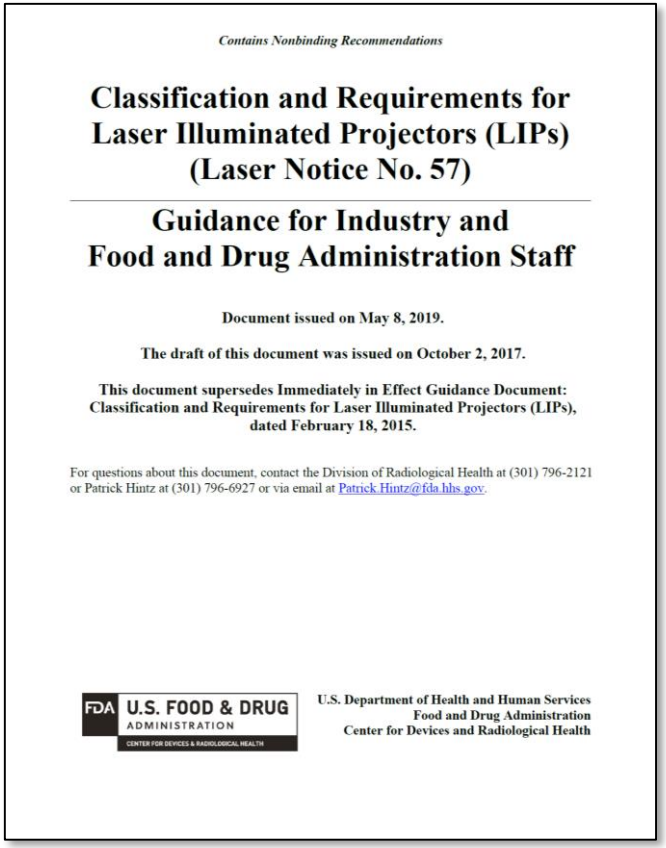
Introducing: Laser Notice 57!

Timeline for Regulatory Reform





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
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

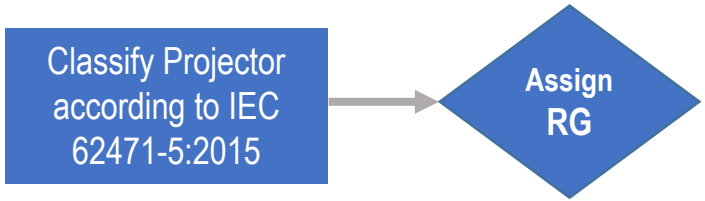
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Laser Notice 57

- US Standards (finally!) harmonize with IEC Risk Groups!
- Applies to:
  - Laser Illuminated Projectors (LIPs)
    - A type of Demonstration Laser Product*
    - That comply with IEC Standards during laser product classification
    - Not a children's toy laser product or medical device
  - Designed to display an image without use of raster-scanned collimated laser beams

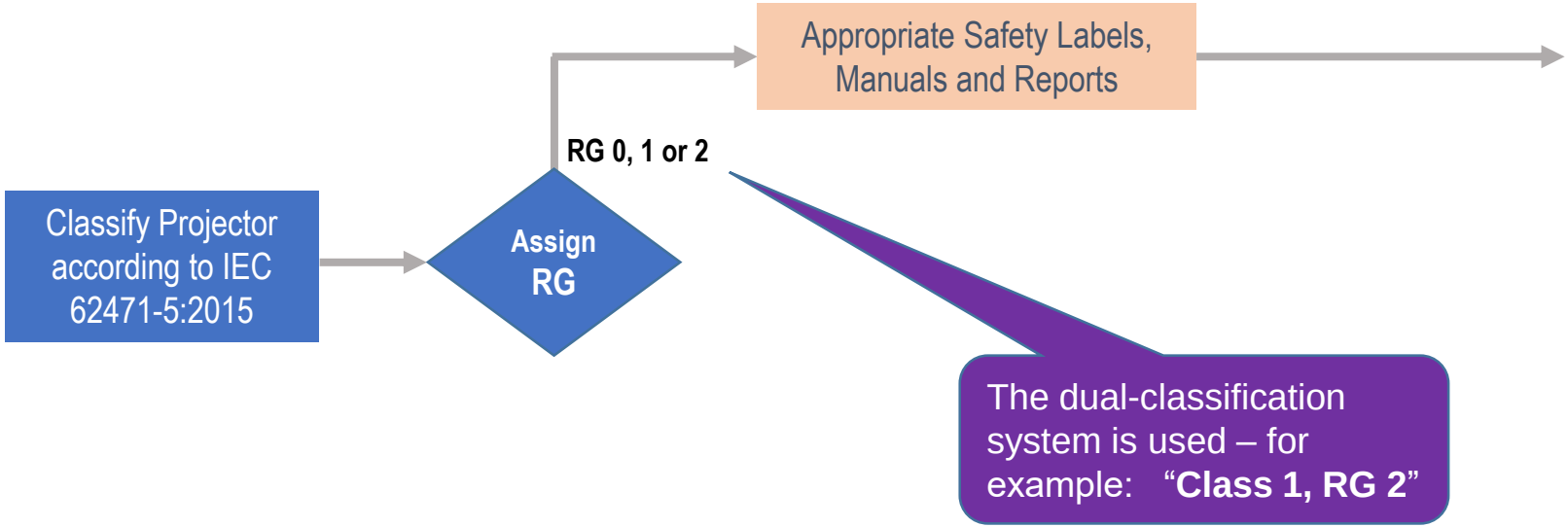
*Demonstration Laser Product: "Any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display or artistic composition." - 21 CFR 1040.10(b)(13)

Summary of LN 57 Guidance



AEL - Accessible Emission Limit
RG - Risk Group

Summary of LN 57 Guidance



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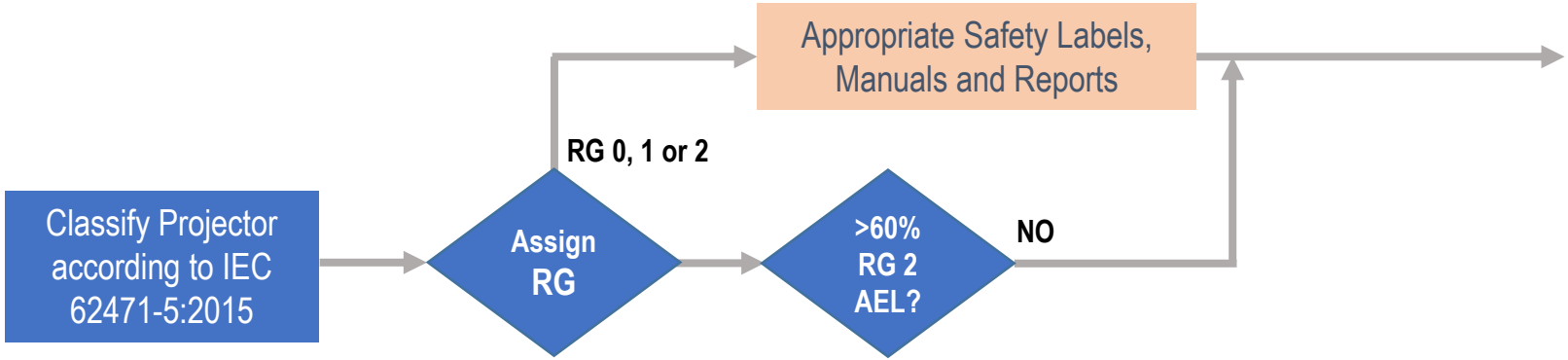

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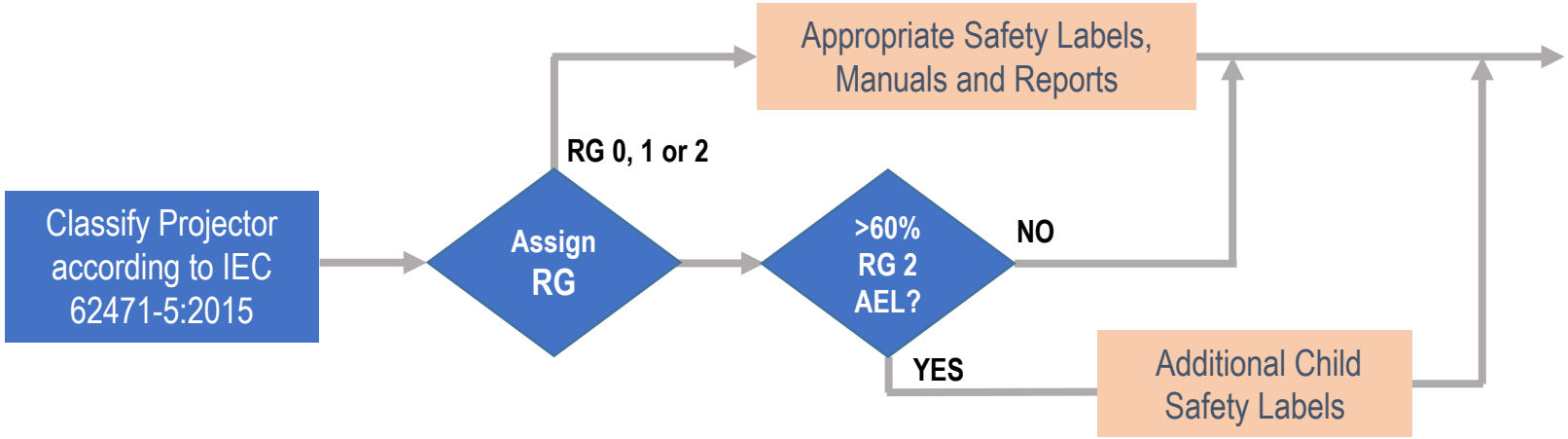
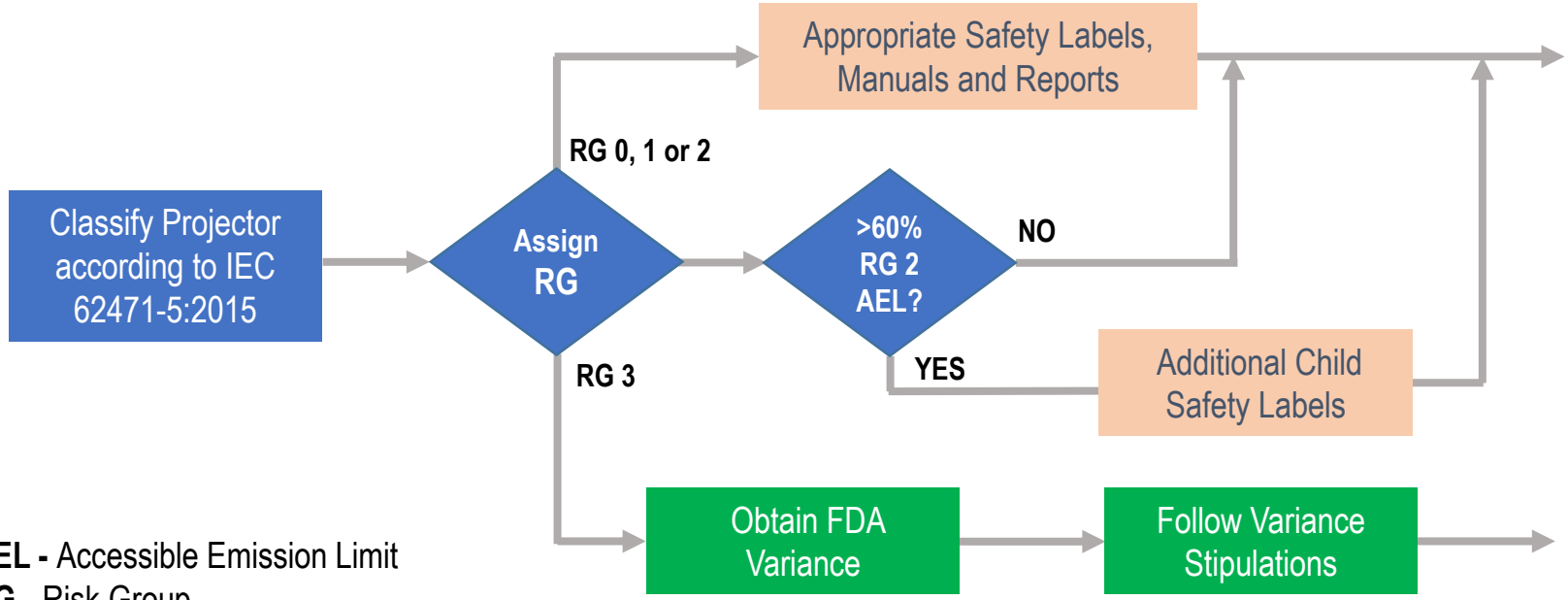


AEL - Accessible Emission Limit
RG - Risk Group

WARNING
Mount Above the Heads of Children

Summary of LN 57 Guidance



AEL - Accessible Emission Limit
RG - Risk Group

As explained by Laser Notice 57…

"CDRH considers LIPS that are in RG3 to be… equivalent to Laser Classes IIIb or IV (IEC Class 3B or 4)"

"When… laser products are Class IIIb or IV, a **variance approval** by FDA is required… that permits the laser product to exceed the… limit"

LIPA
Laser
Illuminated
Projector Association

Variances

First, a brief history…


Coke adds life to...
1978


TONY RUFFINO & LARRY VAUGHN WITH CEDRIC KUSHNER PRESENT:
Blue Oyster Cult
WITH ALL NEW FANTASTIC LASER LIGHT SHOW
THIS FRIDAY
GOOD SEATS AVAILABLE
AND
RUSH
FRIDAY, JANUARY 13 AT 8:00 P.M. TICKETS ARE $6.50 and $7.50
ALL SEATS RESERVED TICKETS AVAILABLE AT THE COLISEUM BOX OFFICE (516) 794-9100 AND ALL TICKETRON OUTLETS (212) 977-9020
Nassau Coliseum


BLUE ÖYSTER CULT
FALL TOUR '77

"It was the coolest show I've ever seen! Unbelievable. They had those glitter balls you'd see later in discos hung all over the place and ***they'd shoot a laser*** *into one in the center which was spinning and the* ***laser would ricochet*** *to the other balls that were spinning and you felt like you were in a* ***war zone.*** *They seemed to be coming from all directions. They had* ***rings with lasers, guns with lasers*** *and those strobe light laser guns!"*

Pittsburgh Press

August 8, 1978

U.S. Pulling Plug On Laser Shows

By DON KIRKMAN
Scripps-Howard Science Writer

WASHINGTON – The U.S. Food and Drug Administration is cracking down on rock groups and art shows that are using powerful laser beams to stage colorful light shows that may be dangerous to the eyes of those watching and participating.

Concern over the danger has risen sharply as an increasing number of rock groups and art shows have turned to bouncing laser light off mirrors, ceilings and imaginative bracelets worn by rock musicians.

According to the FDA's Bureau of Radiological Health, there is fear some people may suffer serious eye damage, or even be blinded.

The bureau doesn't know exactly how dangerous the shows are, but is concerned that someone catching a beam in the exact center of the eye could be permanently blinded and persons hit in other areas of the eye could suffer irreversible vision damage.

To prevent such injuries, the FDA has instituted a nationwide program to check the strength of the lasers used in the light shows, agency director Dr. Norman C. Telles said.

One rock group, "The Blue Oyster Cult," has been prohibited from using an overly strong laser during the past couple of months, Telles said.

The FDA said it's particularly concerned about rock groups' use of bracelets that spray laser light in all directions. The bracelets are connected to a laser which produces exotic colors that usually are directed toward the ceiling.

However, sometimes the laser light is splashed over the audience and may be hitting the performers in the eyes, Telles warned.

Similarly, the FDA is worried about the use of many-prismed mirrors that rotate above audiences and splash reflected laser light in all directions.

Not as dangerous are the laser art shows which forbid viewers to look directly into a laser beam, Telles said. However, people should be aware that these shows are a hazard, he added.

"The best advice we can give," Telles said, "is never look directly at a laser. And if you're going to attend a rock show that's using lasers, be aware of the danger."

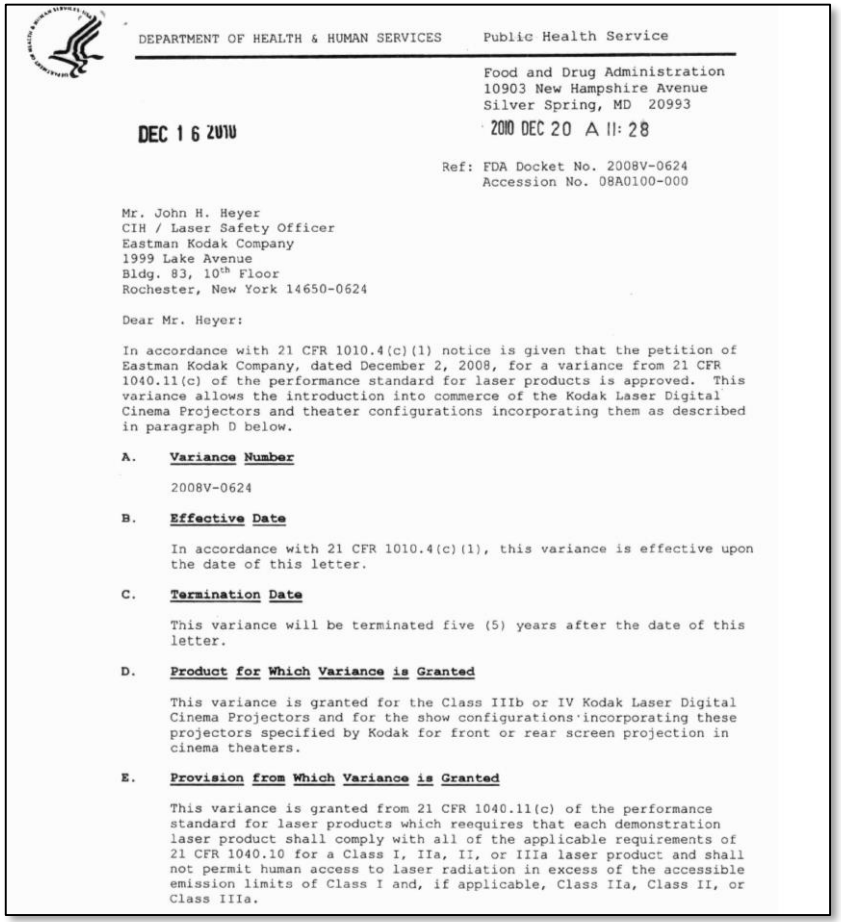
Additionally, Telles said the bureau has asked eye doctors to be on the lookout for laser-caused eye damage cases and report them to the FDA.

Original Laser Light Show Variance

- Requirements, circa 1978 (Partial list)
  - File specifications on laser equipment prior to use
  - Prior Reporting of every show
  - Annual Reporting of prior shows
  - Safety Checks before every show
  - Regular Variance Renewal, extensive paperwork and logging
  - Subject to Federal Show Inspection, each set-up
  - 3 to 6 meters minimum vertical separation distance

Variances for LIPs

FDA began issuing Laser Light Show Variances for Laser Illuminated Projectors in ***December 2010***



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

DEC 16 2010

2010 DEC 20 A 11:28

Ref: FDA Docket No. 2008V-0624
Accession No. 08A0100-000

Mr. John H. Heyer
CIH / Laser Safety Officer
Eastman Kodak Company
1999 Lake Avenue
Bldg. 83, 10th Floor
Rochester, New York 14650-0624

Dear Mr. Heyer:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Eastman Kodak Company, dated December 2, 2008, for a variance from 21 CFR 1040.11(c) of the performance standard for laser products is approved. This variance allows the introduction into commerce of the Kodak Laser Digital Cinema Projectors and theater configurations incorporating them as described in paragraph D below.

A. **Variance Number**

2008V-0624

B. **Effective Date**

In accordance with 21 CFR 1010.4(c)(1), this variance is effective upon the date of this letter.

C. **Termination Date**

This variance will be terminated five (5) years after the date of this letter.

D. **Product for Which Variance is Granted**

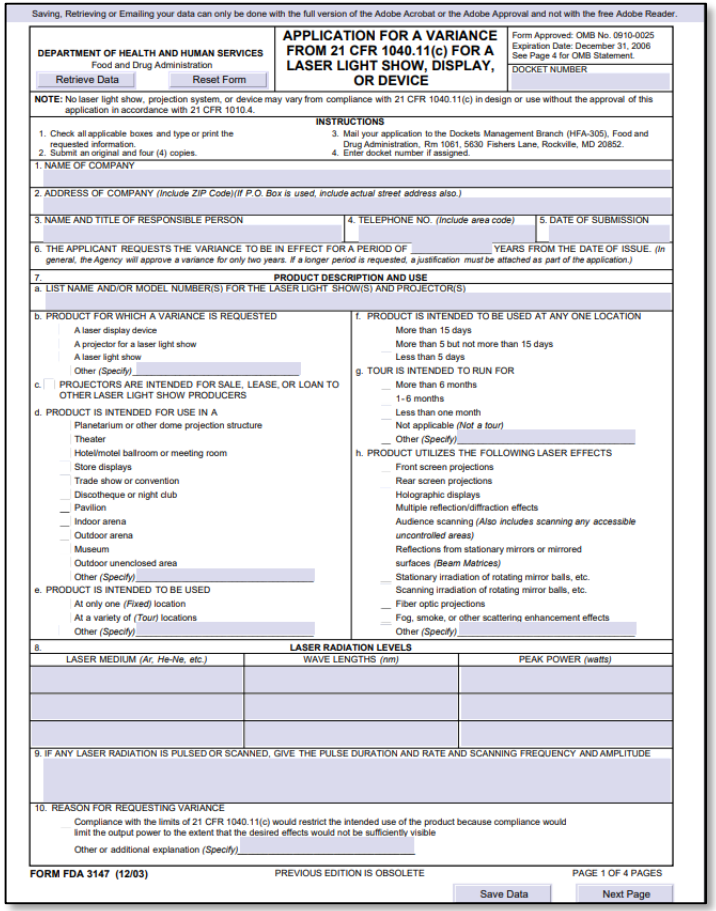
This variance is granted for the Class IIIb or IV Kodak Laser Digital Cinema Projectors and for the show configurations incorporating these projectors specified by Kodak for front or rear screen projection in cinema theaters.

E. **Provision from Which Variance is Granted**

This variance is granted from 21 CFR 1040.11(c) of the performance standard for laser products which reequires that each demonstration laser product shall comply with all of the applicable requirements of 21 CFR 1040.10 for a Class I, IIa, II, or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.

Laser Illuminated Projector Association

FDA Laser Light Show Variance Application



Saving, Retrieving or Emailing your data can only be done with the full version of the Adobe Acrobat or the Adobe Approval and not with the free Adobe Reader.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Retrieve Data | Reset Form

APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW, DISPLAY, OR DEVICE

Form Approved: OMB No. 0910-0025
Expiration Date: December 31, 2006
See Page 4 for OMB Statement.

DOCKET NUMBER

NOTE: No laser light show, projection system, or device may vary from compliance with 21 CFR 1040.11(c) in design or use without the approval of this application in accordance with 21 CFR 1010.4.

INSTRUCTIONS

1. Check all applicable boxes and type or print the requested information.
2. Submit an original and four (4) copies.
3. Mail your application to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm 1061, 5630 Fishers Lane, Rockville, MD 20852.
4. Enter docket number if assigned.

1. NAME OF COMPANY

2. ADDRESS OF COMPANY *(Include ZIP Code)(If P.O. Box is used, include actual street address also.)*

3. NAME AND TITLE OF RESPONSIBLE PERSON | 4. TELEPHONE NO. *(Include area code)* | 5. DATE OF SUBMISSION

6. THE APPLICANT REQUESTS THE VARIANCE TO BE IN EFFECT FOR A PERIOD OF _____ YEARS FROM THE DATE OF ISSUE. *(In general, the Agency will approve a variance for only two years. If a longer period is requested, a justification must be attached as part of the application.)*

7. **PRODUCT DESCRIPTION AND USE**

a. LIST NAME AND/OR MODEL NUMBER(S) FOR THE LASER LIGHT SHOW(S) AND PROJECTOR(S)

b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED
- A laser display device
- A projector for a laser light show
- A laser light show
- Other *(Specify)* _____

c. PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS

d. PRODUCT IS INTENDED FOR USE IN A
- Planetarium or other dome projection structure
- Theater
- Hotel/motel ballroom or meeting room
- Store displays
- Trade show or convention
- Discotheque or night club
- Pavilion
- Indoor arena
- Outdoor arena
- Museum
- Outdoor unenclosed area
- Other *(Specify)* _____

e. PRODUCT IS INTENDED TO BE USED
- At only one *(Fixed)* location
- At a variety of *(Tour)* locations
- Other *(Specify)* _____

f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION
- More than 15 days
- More than 5 but not more than 15 days
- Less than 5 days

g. TOUR IS INTENDED TO RUN FOR
- More than 6 months
- 1-6 months
- Less than one month
- Not applicable *(Not a tour)*
- Other *(Specify)* _____

h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS
- Front screen projections
- Rear screen projections
- Holographic displays
- Multiple reflection/diffraction effects
- Audience scanning *(Also includes scanning any accessible uncontrolled areas)*
- Reflections from stationary mirrors or mirrored surfaces *(Beam Matrices)*
- Stationary irradiation of rotating mirror balls, etc.
- Scanning irradiation of rotating mirror balls, etc.
- Fiber optic projections
- Fog, smoke, or other scattering enhancement effects
- Other *(Specify)* _____

8. **LASER RADIATION LEVELS**

LASER MEDIUM *(Ar, He-Ne, etc.)*	WAVE LENGTHS *(nm)*	PEAK POWER *(watts)*

9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE

10. REASON FOR REQUESTING VARIANCE
- Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible
- Other or additional explanation *(Specify)* _____

FORM FDA 3147 (12/03) PREVIOUS EDITION IS OBSOLETE PAGE 1 OF 4 PAGES

Save Data | Next Page

Variance Conditions

Temporary Installation

- Rental and Staging
- Trade Shows

Permanent Installation

- Non-cinema
  - Presentation rooms
  - House of Worship

- Cinema
  - Movie theater
  - Premium Large Format

Example of Variance Application…

13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. *(Check as many boxes as apply. In item 14 "Remarks," justify any boxes not checked, using additional sheets as necessary. State any other means of radiation protection that will be used.)*

a. ☒ All laser products, systems, shows, and projectors will be certified to comply with 21 CFR 1040.10 and the conditions of this variance and will be reported as required by 21 CFR 1002.10 AND 1002.11 using the reporting guides provided for such purpose. These actions will be accomplished prior to any introduction into commerce.

b. ☒ Effects not specifically indicated in this variance application will not be performed. No other effects will be added until an amendment to the variance has been obtained and the required reports or supplements, as applicable, have been submitted.

c. ☒ Scanning, projection, or reflection of laser and collateral radiation *(Light show radiation)* into audience or other accessible uncontrolled areas will not be permitted except for diffuse reflections produced by the atmosphere, added atmospheric scattering media, and target screens.

For temporary venues

…vels in excess of the limits of Class I will not be permitted at any point less than 3.0 meters above any surface upon which …n operators, performers, or employees are permitted to stand or 2.5 meters below or in lateral separation from any place …ns are permitted to be. Operators, performers, and employees will not be required or allowed to view radiation above the limits …xposed to radiation above the limits specified in 21 CFR 1040.11(c).

e. … Any product which relies on scanning to meet access, exposure, or product class limits will incorporate a scanning safeguard system which directly senses scanner motion and which will react fast enough to preclude exceeding the applicable limit.

f. ☐ All laser light shows shall be under the direct and personal control of trained, competent operator(s). The operator(s) will:

(1) Be an employee of the variance holder who will be responsible for the training and the conduct of the operator;

(2) Be located where all beam paths can be directly observed at all times; and

(3) Immediately terminate the emission of light show radiation in the event of any unsafe condition; or, for outdoor shows, upon request by any air traffic control officials.

g. ☒ The maximum laser projector output power will not exceed the level required to obtain the intended effects.

…and a Variance issued

8. All laser light shows shall be under the direct and personal control of a trained, competent operator(s). The operator(s) shall:

(a) be an employee of the variance holder who shall be responsible for the training and conduct of the operator; and
(b) be located where all propagating beam paths, their terminations, and the audience can be directly observed at all times; and
(c) be in communication with personnel assisting in surveillance of the laser display; and
(d) immediately terminate (or designate the termination) of the emission of light show radiation in the event of any unsafe condition and, for open air shows, at the request of any air traffic control officials; and
(e) ensure one or more readily accessible controls are provided to immediately terminate laser radiation.

Variance requirements: Temporary Installs

- Temporary Show Installations containing RG3 LIPS
  - May be installed by LIP (Branded) Manufacturer
  - Or may be sold or leased to valid laser show FDA Variance holders
  - Also applies to Dealers and Distributors
- Examples of Appropriate Operational Practice:
  - Locate projectors so that all beam paths within Hazard Zone, and the audience, can be observed at all times
  - Maintain communications with personnel observing operations
  - Terminate projection immediately upon any unsafe condition
  - Provide readily accessible controls for termination

Variance requirements: Fixed Installs

- Permanent Installations
  - Typical Variance specifies the Hazard zone not lower than:
    - 3m for non-cinema
    - 2m for cinema
  - Horizontal clearance to Hazard Zone should be 2.5m
  - Any human access to Hazard Zone restricted by barriers
  - Installation by trained and authorized installers

Always check with your manufacturer or variance-holder
FDA variances may differ!

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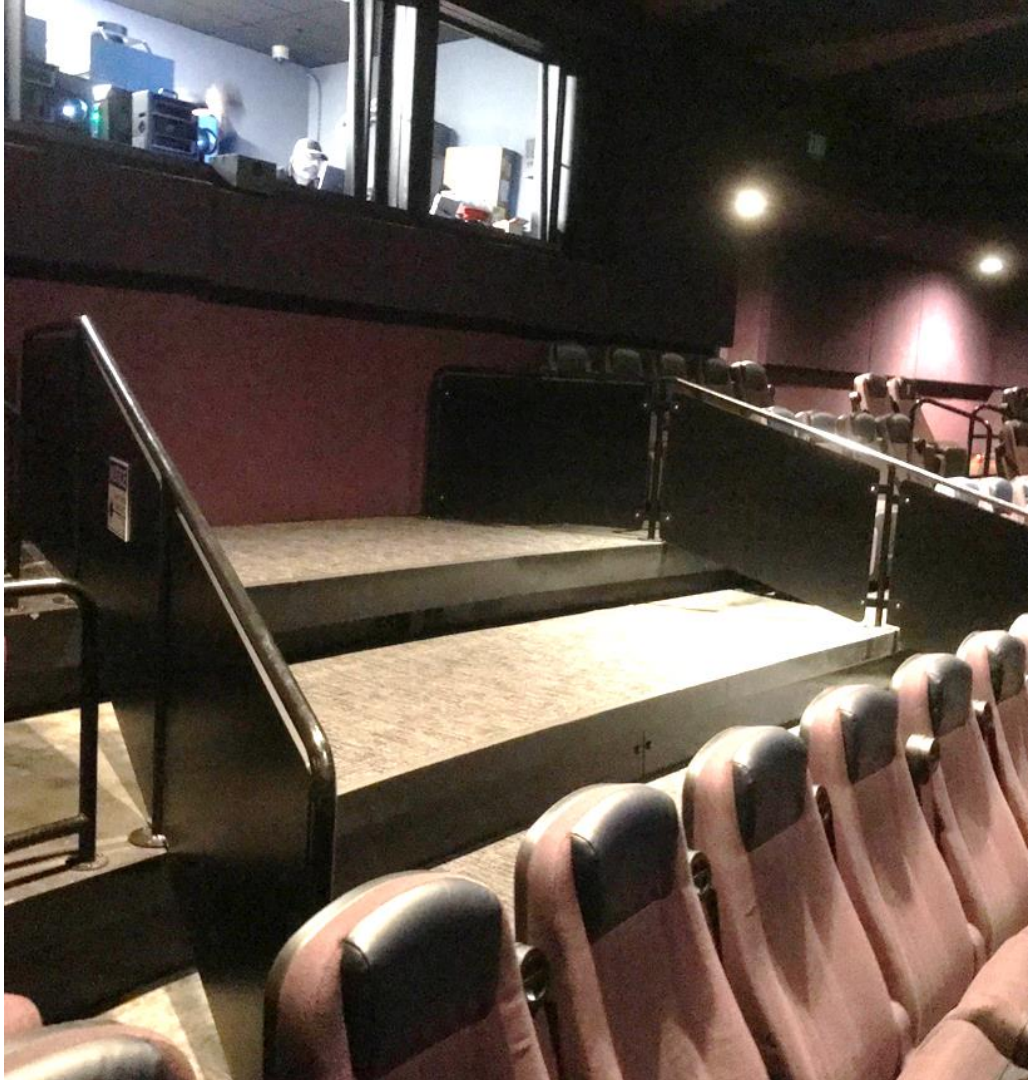
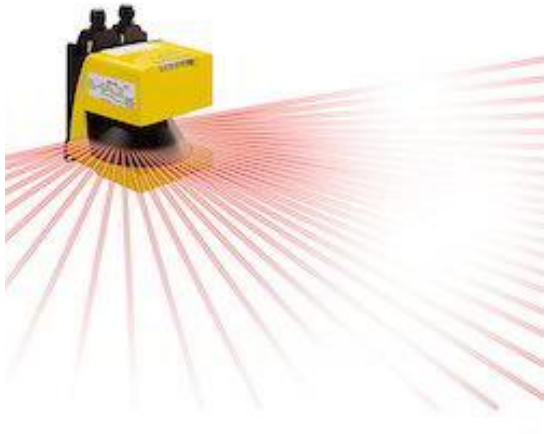


FDA Variance Exception

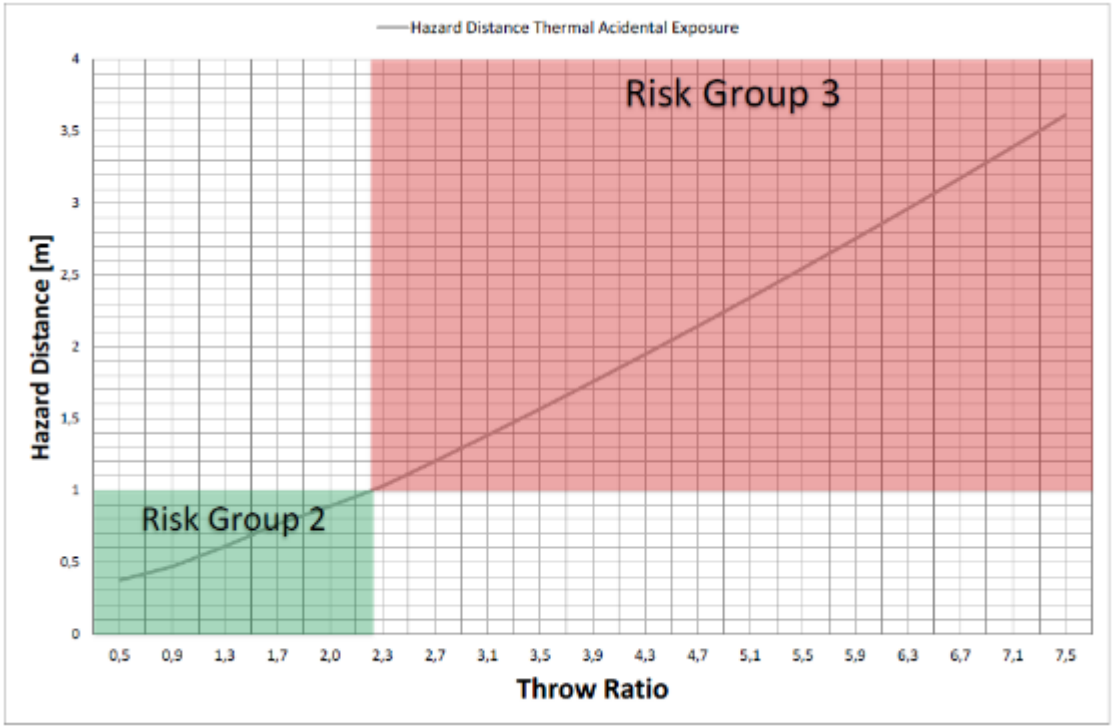


- RG 3 LIPS that **prevent human access** to the Hazard Zone by use of **engineering controls** will not require a Variance application
  - Sensors which detect the location of the human body or objects within hazardous areas
  - Output power is reduced automatically when personnel or reflective objects are detected entering the enter the HZ

Installation Considerations & Requirements

Hazard distance RG2 to RG3

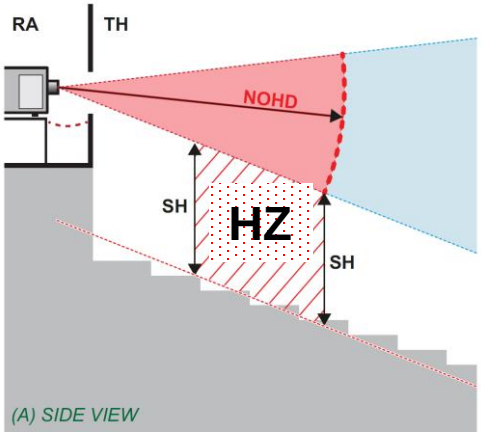
- For RG3 products, the HD is determined under *maximum emission power* at each throw ratio.
- For interchangeable lenses, the *maximum foreseeable HD* should be provided

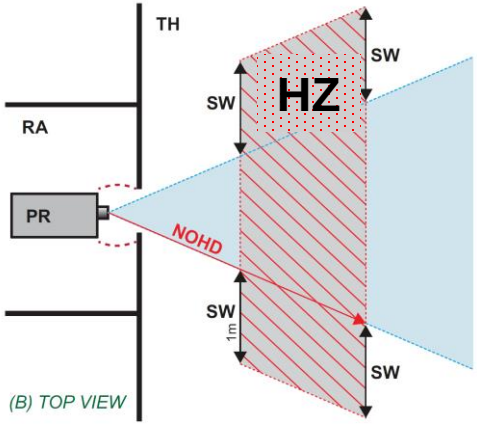


Hazard zone

- The region of space where the projection light is **greater than Emission Limits for RG2.**
- The ***Hazard Distance*** is defined* as collinear to the optical projection axis
- Therefore the Hazard Distance alone does not sufficiently describe a 3-dimensional **Hazard Zone**.
- The Hazard Zone encompasses the entire region of space that is considered RG3

*Defined in IEC 62471-5:Ed 1

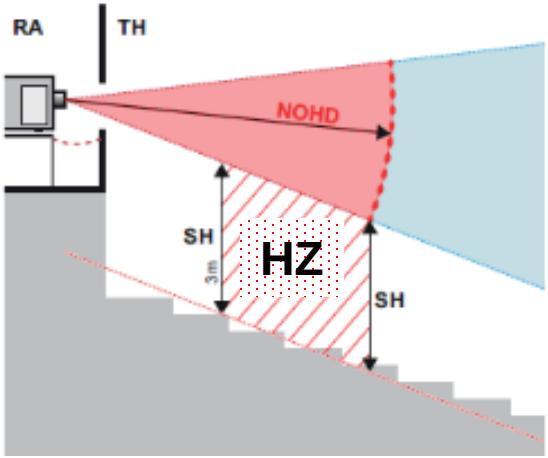




Responsibilities of Cinema Owners

PREVIOUS SITUATION

- Implement **local** government **safety regulation**
  - Laser light show **variance**
  - **Event safety** regulation
- Requirements based on **exposure** limits
  - LIP **operator**
    - Training requirements
    - Projection booth requirements (restricted area, protective barriers)
    - Risk based implementation
  - Cinema **visitor** (general public)
    - No exposure above safety limits is allowed in any case!
    - Physical barrier or sufficient separation height



Responsibilities of Cinema Owners

TYPICAL VARIANCE REQUIREMENTS (for Class 1 / RG 3)

- Cinema theaters do not need a variance approval
  - Because LIP Manufacturer has variance requiring them to provide adequate instruction
- Projector installed under restricted access location conditions
- Provide basic operator training
- Access to projector must be restricted by key or pass code lock
- Appropriate signage
- Installation test report to be provided to the theater manager
- No dedicated Laser Safety Operator required
  - Falls under general safety management
- Not retroactive except for any retrofit

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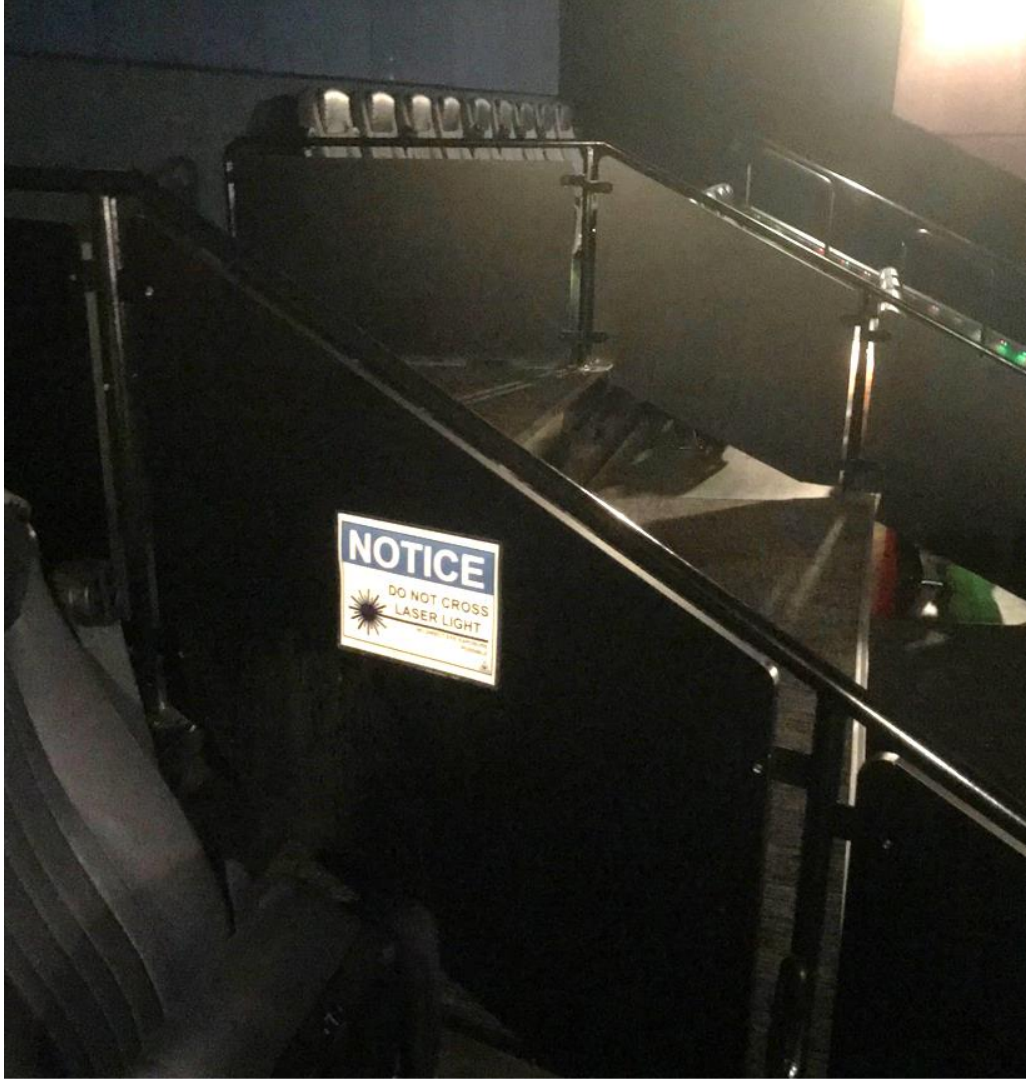
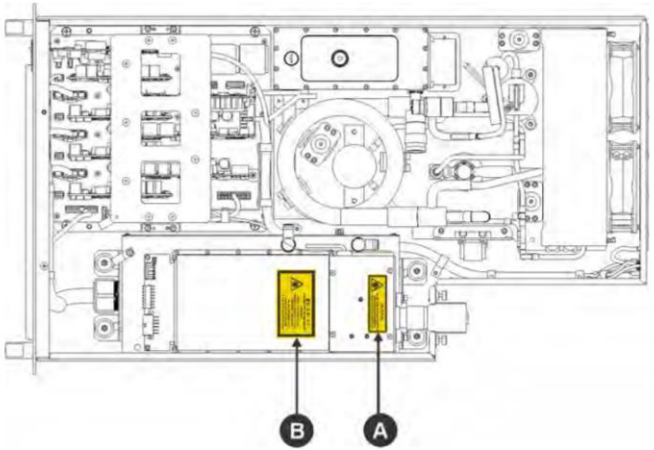


Servicing

- While servicing, Class 4 (collimated) laser sources could be exposed.
- Training required!
- Only qualified / certified personnel
- Safety features
  - Safety interlocks
  - Beamstop mechanism
  - Fibreoptic interlocks
- Labeling and signage required



A		CAUTION CLASS 4 LASER RADIATION WHEN OPEN AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION
B		Translation of label A in French, Chinese, Japanese, and Korean

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Summary and Q&A

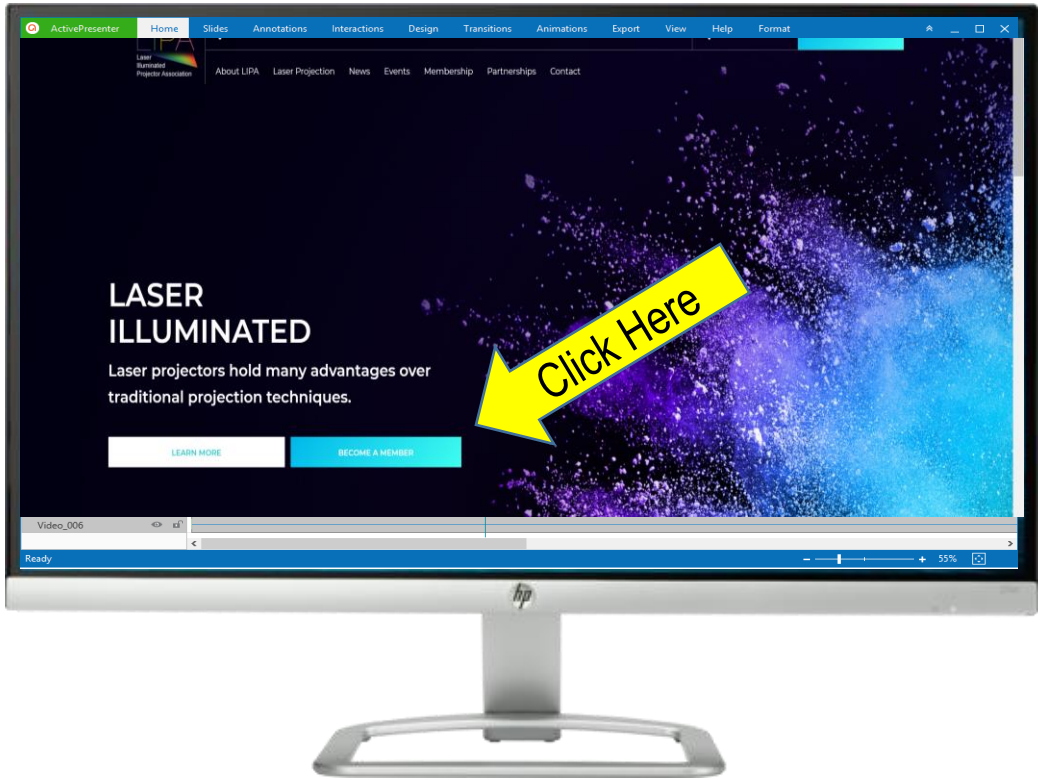
Summary

- LIPs present hazard similar to lamp projectors
  - Very unlike raw laser beams
- However, due to embedded laser, *laser regulations* apply
- US is now (nearly) harmonized to worldwide IEC standard
- Most high-power LIPs are RG3, and therefore require variance
- Variances are specific to a manufacturer & model family!
  - Work closely with your supplier to understand the specific requirements
- Review safety instructions / Hazard Zone constraints carefully
- Special care / training required for servicing LIPs

Join us!

www.LIPAinfo.org

- Newsletters
- Events
- Meetings
- Discounts



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Time for Questions

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Understanding
Laser Illuminated Projector Safety Regulations

An Informational Webinar

Presented by:
Pete Ludé, Mission Rock Digital LLC
Pete@MissionRockDigital.com

MissionRock DIGITAL

October 17, 2019