Laser Projections & Regulations: An Update

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Jan Daem

January 14, 2014
About the **Laser Illuminated Projector Association**

» **Mission:** To facilitate the adoption of laser illuminated projectors through cooperative industry activity
  - Education
  - Regulatory Affairs
  - Safety

- Represent the leading projector manufacturers and supply chain companies
  - Projector manufacturers (both laser- and lamp-based)
  - Component manufacturers (laser & micro-displays)
  - End Users (Theater-owners, film studios, and theme parks)
LIPA Membership
Explanation of Laser Illuminated Projectors
Lamp based Optical Architecture

- Projector bulb
- Optical diffuser
- Microdisplay: LCoS, DMD, or LCD
- Projection lens
- Light must be of uniform intensity
- Screen
  - Magnification from lens of 100-1000X

Not drawn to scale.
Full Laser based Optical Architecture

- Microdisplay (LCoS, DMD, or LCD)
- Optical combiner
- Light diffuser
- Light must be of uniform intensity
- Lamp-like light
- Laser-like light
- 2D array of red, green, and blue lasers
- Projection lens
- Light expands from lens to fill large screens
- Screen
  - Magnification from lens of 100-1000 X

Not drawn to scale.
Laser/Phosphor based Optical Architecture

- Laser output
- Phosphor element and light combiner
- 2D array of blue laser diodes
- Microdisplay: LCoS, DMD, or LCD
- Optical diffuser
- Projection lens
- Light expands from lens to fill large screens

“Collateral Emissions”
Current Regulatory Environment
Current FDA & State Requirements

21 CFR §1040.10 - 1040.11
» Not harmonized with current IEC standards
» No distinction for laser devices with “non-laser” (low radiance) emissions
» LIPA recently commented on FDA Proposed Amendment to Performance Standard (Docket No. FDA-2011-N-0070)
» Trigger end user requirements from other regulatory bodies

Laser Notice 50 (2007)
» Guidance for conformance with 2007 IEC standards in lieu of certain sections of 21 CFR §1040 (enforcement discretion)

Demonstration Laser Products
» Appropriate for Laser Light Shows and other uses that do not comply with 21 CFR § 1040
» Not suitable for low-radiance projectors
APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW, DISPLAY, OR DEVICE

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 Division of C Rodgers Management (HFA-305), Food and Drug Administration, Rm 1041, 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 street address and box.

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

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

9. PRODUCT FOR WHICH A VARIANCE IS REQUESTED
   □ A laser display device
   □ A projector for a laser light show
   □ A laser light show
   □ Other (Specify)

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

11. 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)

12. 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

13. TOUR IS INTENDED TO RUN FOR
   □ More than 6 months
   □ 1-5 months
   □ Less than one month
   □ Not applicable (Not a tour)
   □ Other (Specify)

14. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS
   □ Print 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 Metrics)
   □ Stationary irradiation of rotating mirror balls, etc.

15. DOCKET NUMBER

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

17. 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 the application in accordance with 21 CFR 1010.12, 1010.11(c).

18. Inappropriate for LIPs
   □ Safety equivalent to current lamp projectors

19. Burdensome
   □ Expected market demand: 10’s of thousands of projectors/year, starting in 2014
US State Laser Regulations

January 15, 2014 Pete Ludé
US Professional & Cinema Projector Landscape

- ~90,000 shipments per year
- 1st LIPs introduced in 1Q13 with very favorable adoption
- LIPs End User Benefits are
  - Lower Total Cost of Ownership at existing brightness level
  - And the ability to match brightness of 3D Movies to 2D Movies

PMA Research Data
US Professional & Cinema Projector Landscape

Likely Class 3B or 4

Likely Class 3R or less

Classification varies based on architecture

PMA Research Data

Units shipped – trailing 12 months

0 5,000 10,000 15,000 20,000 25,000 30,000

3000-3999 4000-4999 5000-5999 6000-6999 7000-9999 10,000+

would likely require a Laser Light Show Variance

some lower percentage would require a Laser Light Show Variance
US Professional Projector Market – 12-36 months

- Assume LIP adoption of 50%
- In yellow band assume 25% will require a variance
- In red band assume 50% will require a variance

- Expected outcome: 10,000+ projectors requiring variances per year

- Result: Significantly reducing US market adoption and burdening FDA with variance requests
A new Scientific Study
New Study conducted

- **LIPA Commissioned Study:** Tested optical characteristics of
  - 35mm film projector
  - Current Xenon short-arc digital cinema projectors
  - Prototype laser projectors

- **Lead Researcher:** Dr. David Sliney
  - Casey Stack, Laser Compliance
  - Jay Parkinson, Phoenix Laser Safety
  - David Schnuelle, Dolby Laboratories

- Eight projectors tested in various locations over 7 months.
Dr. David Sliney, Consulting Health Physicist

- Former manager of the Laser/Optical Radiation Program, US Army Center for Health Promotion and Preventive Medicine (retired in 2007)
- Research interests: UV effects upon the eye, laser-tissue interactions, laser hazards and laser applications in medicine and surgery, safety standards for protection against non-ionizing radiation in particular from lasers and other high-intensity optical sources
- Serves as member, advisor and chairman of numerous committees and institutions for the following organizations:
  - LIA, ANSI, ISO, ACGIH, IEC, WHO, NCRP, and ICNIRP
- Co-author of over 100 technical papers and the 1000-page handbook, "Safety with Lasers and Other Optical Sources,"
- Education
  - B.S. in physics from Virginia Polytechnic Institute
  - M.S. in physics and radiological health from Emory University
  - Ph.D. in biophysics and medical physics from the University of London, Institute of Ophthalmology.
- Multiple awards
  - Fulbright Scholar to Yugoslavia in 1977
  - Received the Schawlow Award from the Laser Institute of America in 2005
  - Received the Wilkening Award in 2004.
Scheduled for publication

- Accepted for publication in *Health Physics*
  - Radiation Safety Journal
  - Official Journal of the Health Physics Society
- Peer review complete
- Publication scheduled in March, 2014

Additional analysis presented at *Society of Motion Picture & Television Engineers* Conference – October 22, 2013.
Laser Brightness (Radiance)

LARGE FOCAL SPOT (FILAMENT IMAGE)

MICROSCOPIC FOCAL SPOT (“DIFFRACTION LIMITED”)

From Sliney DH and Trokel, S, 1993
Analysis of the apparent source

Intra-beam viewing of representative optical sources

By contrast, a direct, collimated laser beam appears as a point source, a thousand-fold higher radiance.
Comparing Radiance: **Lamp** vs. **Laser**

<table>
<thead>
<tr>
<th>Proj</th>
<th>Actual Luminance Power (Lumens)</th>
<th>Normalized Luminance Pwr (Lumens)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proj 6</td>
<td>Laser</td>
<td>5,000</td>
</tr>
<tr>
<td>Proj 2</td>
<td>Xenon</td>
<td>17,000</td>
</tr>
<tr>
<td>Proj 1</td>
<td>Xenon</td>
<td>30,000</td>
</tr>
<tr>
<td>Proj 4</td>
<td>Laser</td>
<td>55,000</td>
</tr>
<tr>
<td>Proj 5</td>
<td>Laser</td>
<td>2,000</td>
</tr>
</tbody>
</table>
Conclusion

Traditional lamp projectors and new laser-illuminated projectors, when of equal luminance power, emit almost identical radiance.
IEC Regulatory Changes
Laser Projector Regulation under IEC

- All laser product requirements are defined in 60825
  - Medical
  - Industrial
  - Laboratory use
  - Laser Welding
  - Laser Illuminated Projectors

IEC 60825-1 Ed 2 (2007)
Safety of Laser Products
Part 1: Equipment classification & Requirements
Updates to IEC standards

• IEC TC-76 carefully considered appropriate requirements for devices such as laser projectors
  • 60825-1 Safety of Laser Products Part 1: Equipment classification & requirements
  • Radiance of projector emission equivalent to conventional lamp devices
• Two year discussion / consideration within global due-process committee
• New Final Draft International Standard (FDIS) now written – will be updated 60825-1 Edition 3
  • Expected to be approved for publication within the next few months

Result: LIPs Emissions treated under lamp - not laser - standards
Laser Projector Regulation under IEC

IEC 60825-1 Ed 3 (2014)
Safety of Laser Products
Part 1: Equipment classification & Requirements

IEC 62471 Ed 1 (2006)
Photobiological safety of lamps and lamp systems

Carve-out for devices with radiance < \((1 \text{ MW}\cdot m^{-2}\cdot sr^{-1})/\alpha\)
Laser Projector Regulation under IEC

IEC 60825-1 Ed 3 (2014)
Safety of Laser Products
Part 1: Equipment classification & Requirements

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

» June 2013  - FDA Submitted NPRM regarding updated laser regs
» Sept 2013  - 37 Respondents advised FDA against NPRM
» Dec 2013  - LIPA meeting with FDA – positive response
» Jan 2014  - New IEC 60825-1 Edition 3 FDIS (Draft) published
» May 2014  - IEC 60825-2 Edition 3 expected to be published
» Sept 2014?? - IEC 62471-5 FDIS expected to be published

» NEXT:  FDA Regulatory updates (new “Laser Notice”?)
US State and other Federal regulation updates
EU Workplace safety standard updates
European Landscape

Jan Daem, Barco
Laser sources – brightness

- Relates to source size
- $W/m^2sr \rightarrow$ over solid angle
- Sun: $\pm 7.2 \text{ MW}/m^2sr$
- Projector 60 klm: $\pm 3.5 \text{ MW}/m^2sr$
- Pointer 5mW: $\pm 70 \text{ MW}/m^2sr$
Legal Landscape:

- Z136 series
- ANSI
- FAA
- NFPA
- OSHA
- NFPA 115
- National Electric Code
- Local states
- FDA
- CFR T 21
- Variance

IEC

IEC 60825 series
IEC 62471 series
CENELEC

Member states

Work Place directive
2006/25/EC AOR
Minimum Social directive

EN 60825 series
EN 62471 series

Transposition
eg: NBN 60825-1:2007
National law

FDA
Laser notice 50
ANSI
CFR T 21
OSHA

Z136 series

Export Controls (Local)

? Other
China
Russia
Japan
Korea
...

Local
states

IEC

IEC 60825 series
IEC 62471 series

CENELEC

GPSD

EN 60950 series
EN 60825 series
EN 62471 series

Member states

ICNIRP
MPE’s

LVD

EMC

Harmonised standard

Minimum Social directive

Event Safety

Exposure limits (user related) exposure limiting values

Emission limits (product related) accessible emission limits

IEC 60950 series
CIE S009
EN 60950 series

Variance

Export
Controls
(Local)

China
Russia
Japan
Korea
...

ICNIRP
MPE’s
Pillars in the EU:

1. **Product safety**
   - Manufacture related
   - CE mark
   - Laser standard
   - Market surveillance authority's

2. **Workplace safety**
   - Employer related
   - Artificial optical radiation directive AORD (covers both XIP and LIP)
   - Workplace safety authorities EU-OHS

3. **Event safety**

4. **Country specifics (France, Germany ...)**
Current burden – regulatory EU

- **Laser Light Show** requirements (3 – 6m separation height)
- **Event Safety** regulation (un-harmonized)
- **Import restriction** (in France > Class 2M devices are restricted = violation against single market philosophy?)
- Strict and old **engineering requirements** (remote interlock, key control, manual reset …)
- Considered to be **High Risk products** for consumers
- >6000 lm **Pro use only** (LSO, training requirements and restricted area, installation requirements)
- Typically 40% of the products exceeds the ELVs **Artificial Optical Radiation Directive** = Workplace safety
Reaction LIPA

- Starting to inform proactively the relevant regulatory body's within the EU

- Supporting the adoption of the EN 60825-1 ed3 laser standard and EN 62471-5 image projector standards.

- Lobby to get the AORD updated

- Funding of Risk Assessment project

- Seek support with other partners
NEW IEC 62471-5: Photobiological Safety of Lamp Systems interpretation = clear situation

Hazard Distance in function of modifying optics:

- **Consumer**
- **Clear situation**
- **PRO**

Radiance $W/m^2sr$ vs. Throw Ratio in Meters [m]:

- L 100 limit
- L 10000 lumens
- HD
Practical installation DC - EU

- **Restricted** area (e.g. separate room, ceiling mount ...)
- **Training** requirements (user, LSO ...)
- **Separation height** (2,5m)
- Additional **AORD control measures** (e.g. barrier)
Thank You

For More Information:

www.LIPAinfo.org