# 2025
# LDI Laser and LILI Safety Requirements

## OVERVIEW

LDI's Laser and LILI Safety Requirements in this document ensure a safe and professional trade show for exhibitors and visitors. **These LDI Requirements apply to all exhibitors showing or using lasers, including those showing or using Laser Illuminated Lighting Instruments (LILIs).**

> *LILIs modify laser light so the resulting light emission is incoherent. They can be used essentially the same as conventional lighting fixtures. In the U.S., LILIs are regulated like conventional light show laser projectors.*

**Throughout this document, any references to "lasers" also includes LILIs unless stated otherwise.**

### LDI's Laser Safety Officer will review laser and LILI exhibits

LDI's Laser Safety Officer (LSO) will review exhibits before and during the trade show, provide guidance, and ensure compliance. **LDI and/or its LSO reserves the right to limit or stop any unsafe laser activity at its sole discretion**. Exhibitors with questions should contact LDI well in advance of the trade show date.

### In addition to LDI review, there are U.S. legal regulations

The U.S. Food and Drug Administration (FDA) regulates laser products and shows in the U.S., including importation, manufacturing, and marketing. Exhibitors should comply with FDA regulations, summarized in Appendix C. Compliance can take weeks or months, particularly for Class 3B and 4 lasers, so start well before the LDI exhibition dates.

While LDI aligns with many FDA rules, it is not a government agency. If the FDA inspects exhibits, it may enforce stricter actions than LDI's requirements.

### Summary

**In summary, laser and LILI exhibitors *must* follow the LDI Requirements R0-R5 that begin on page 3. They *should* also follow FDA regulations for importing, making, selling, and marketing laser products and displays, as detailed in Appendix C that begins on page 13.**

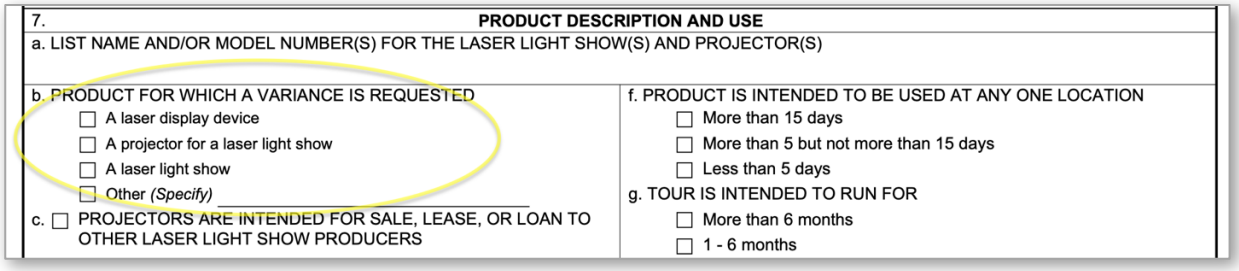
# LDI 2025
# LDI Laser and LILI Safety Requirements

## CHANGES TO THIS DOCUMENT FOR 2025

If you will be exhibiting Class 3B or 4 lasers or Risk Group 3 LILIs that are turned on, please note the following changes made this year (2025) to the LDI Requirements.

### Only manufacturer variance needed for most Class 3B/4/RG3 exhibitors

In 2024, exhibitors of Class 3B/4/RG3 devices needed both a manufacturer variance and a show variance (both using FDA Form 3147). However, we have since learned that an FDA-approved manufacturer variance automatically includes a show variance. (A "manufacturer variance" is when item 7b in Form 3147 has either the device or projector boxes checked. A "show variance" is when item 7b has only the show box checked.)



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

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

Starting in 2025, LDI manufacturers or distributors of Class 3B/4/RGB laser and LILI devices that are turned on must have:

1) the manufacturer variance form (Form 3147, with the device or projector boxes in 7b checked) submitted to FDA,
2) the resulting variance approval letter sent from FDA, **AND**
3) the most recent annual report (Form 3636) submitted to FDA, and the resulting acknowledgment letter sent from FDA. This report and letter must confirm the variance remains valid from when it was first issued, through the date of the LDI show (e.g., through Dec. 2025).

Exhibitors who **do not** manufacture or distribute lasers/LILIs but are using Class 3B/4/RG3 devices (for example, to attract people to their booth) must have a show variance and meet the same documentation requirements in #2 and #3 above.

More information on variances is in Appendix C.

### Annual form acknowledgement letters needed to show that variance is current

LDI now explicitly requires FDA variances to be current.

As stated above, if LDI requires you to have a variance (either manufacturer or show), you must have 1) the original variance form submitted to FDA, 2) the resulting variance approval letter sent from FDA, and 3) the most recent annual report submitted to FDA and the resulting acknowledgement letter sent from FDA. The annual report and acknowledgement letter must confirm the variance remains valid from when it was first issued, through the date of the LSI show.

# LDI 2025
# LDI Laser and LILI Safety Requirements

## LDI REQUIREMENTS R0-R5

> ***Before you begin:*** *The LDI Requirements below assume that you know the Class of your laser (Class 1, 2, 3R, 3B or 4) and for LILIs, the lamp Risk Group (Exempt, RG1, RG2 or RG3). If you do not, review the information in Appendix B that begins on page 11.*

Companies that exhibit, demonstrate, present, or use any lasers or LILIs at LDI must comply with the LDI Requirements listed below in sections R0 through R5. The sections differ depending on what type or use of lasers are involved.

Here is a summary of which of the below LDI Requirements may apply to you:

**If your laser or LILI will NOT be powered on**, apply section R0 only.

**If your laser or LILI WILL be powered on:**

For **laser Class 1 or Class 2, or a Risk Group 2 LILI**, apply sections R1 and R2.

For **laser Class 3R**, apply sections R1 and R3.

For **laser Class 3B or 4**, apply sections R1 and R4. **If your laser is emitting light that is on humans ("audience scanning") or is accessible to humans**, also apply section R5a.

For **a Risk Group 3 LILI,** apply sections R1 and R4. **If your LILI is emitting light that is on humans, or is accessible to humans**, also apply section R5b.

## R0: Requirements for lasers of any Class or type, including LILIs, that will NOT be powered on

**Certification not required:** If a laser or laser product (including devices/projectors) will not be powered on at LDI, it does not have to be certified or reported to FDA. However, each non-certified laser product at LDI must carry a clearly visible label stating "This laser product sample is not yet certified to U.S. FDA safety standards and cannot be activated".

**Must be disabled:** In addition to the above requirement, LDI also requires that non-certified laser products be disabled so they cannot be easily activated at the trade show. For example, a key could be removed from a keyswitch, or the power cord or supply could be removed and stored. If deemed necessary by the LSO, LDI personnel will hold onto the key, power cord/supply, etc. until the end of the show.

## R1: Requirements for ALL laser display devices and projectors, including LILIs, that WILL be powered on at LDI

**Certification required:** All laser display devices and projectors that will be powered on at LDI should be certified to FDA, regardless of Class. The LSO at their discretion may prohibit use of laser devices/projectors that do not have a valid FDA-required certification label.

**No output over the Class limit.** The LSO may measure the laser output to check that it does not exceed the limits for its stated/labeled Class. If it does exceed the Class limit, the laser will be regulated using requirements of what its proper Class should be.

**Secure mounting:** All projectors and other optical components must be rigidly secured if vibration or accidental movement could misalign the system such that exposure to a direct beam or its reflection could exceed the Class 2 limit of 4.99 milliwatts.

**Beams outside the booth:** If laser or LILI light is emitted outside of the exhibitor's booth, the usage is subject to approval by LDI and/or the LSO. The light must not interfere with other exhibitors' displays or pose any safety risks to people or materials (for example, drapes). In general, avoid directing light into other exhibitors' spaces.

**Control stray light**: Stray light – either direct or diffuse beams -- that is not a necessary and intended part of the display must be controlled or eliminated.

*This paragraph applies only to lasers, not LILIs:* Diffuse reflections from lasers shall produce no more than 5 microwatts/$cm^2$ in aisles or neighboring trade show booths, except where preapproved by the LSO as part of an effect permitted by a relevant FDA display/show variance.

**Caution with fiber optic laser cables**: Any fiber optic cables carrying high power laser beams must be routed, armored and protected to prevent ignition of flammable materials in the event of failure of the cable.

**Laser and LILI light of any Class or Risk Group** may be directed onto walls or into the ceiling.

For walls, Class 3B or 4 laser light and RG3 LILI light shall not go onto any window on the wall.

For the ceiling, be aware that Las Vegas Convention Center employees may be walking on the catwalks at times. However, you do NOT have to cease or modify light going into the ceiling area. (By agreement with LDI and LVCC, access is restricted to LVCC employees who have been warned via signage to avoid and not look at the lasers below.)

## R2: Requirements for Class 1 and Class 2 laser display devices/projectors, and Risk Group 2 LILIs, that will be powered on at LDI

### All requirements from section R1 above, plus the following:

**Human exposure to Class 1/Class 2/RG2 light is generally allowed:** Effects from these can be human-accessible, as long as eye exposure is unlikely (for example, do not aim beams towards eyes) and the effects are not directed into other exhibitors' spaces.

More specifically, Class 1 & 2 lasers and RG2 light should not be used at LDI if purposeful staring into the beam or prolonged exposure to the eye is intended or expected, unless it can be demonstrated that persons will not be exposed to levels of laser light above the Maximum Permissible Exposure (MPE) applicable to the expected exposure duration.

**Human exposure to RG2 light from LILIs:** These may be used at LDI in the same manner as a conventional lighting instrument. Note however that RG2 light may be so intense as to be uncomfortably bright or hot, even if it is not technically unsafe for accidental or incidental eye exposure.

## R3: Requirements for Class 3R laser display devices/projectors that will be powered on at LDI

### All requirements from section R1 above, plus the following:

**Class 3R light can be used in locations where a person's eyes would not normally be expected to be located,** such as having the effects behind a table or barrier. In such a case, the laser effects can be unattended. More specifically, Class 3R devices can be left operating unattended provided their beams are directed into locations where a person's eyes are not expected to be located, even though access is possible.

**Deliberate human exposure to Class 3R laser light below the MPE:** If you wish to use effects produced by a Class 3R laser in an area where persons are expected to be located, such as aiming beams down into accessible areas of your booth, 1) no part of the exposure can exceed the applicable Maximum Permissible Exposure (MPE), and 2) the laser effects must be continuously monitored.

For example, if a beam is kept continuously moving, this generally would not exceed the MPE, but if the beam were to stop deliberately or accidentally, the MPE could be exceeded.

The LSO will not allow operation of any laser where the exposure, in his or her determination, could exceed the applicable MPE. (For a small source, continuous wave laser beam, the MPE for an unintentional exposure of less than ¼ second would generally apply; this MPE is 2.5 milliwatts per square cm. Other more uncommon types of lasers or effects may have different MPE requirements.)

More specifically, Class 3R lasers should not be used at LDI where direct exposure of the eye is intended or expected, unless it can be demonstrated that the exposure is below the MPE for the expected exposure duration.

## R4: Requirements for Class 3B or 4 laser display devices/projectors, and Risk Group 3 LILIs, that will be powered on at LDI

### All requirements from section R1 above, plus the following:

**Device/projector variance required:** All Class 3B or 4 laser display devices or projectors, and all RG3 LILIs, that will be powered on **must be manufactured and certified under an *approved* FDA variance** describing the device/projector. Both the variance form submitted to FDA, and the resulting FDA variance approval letter, must be shown to the LDI Laser Safety Officer.

**Only FDA-approved variances will be valid:** Merely *applying* to FDA for a variance is not sufficient – the applicant must have *received* a variance approval letter from FDA before the device/projector can be operated in public, or before the display/show can be performed in public.

*If you are exhibiting Class 3B or 4 lasers, or RG3 LILIs that you manufacture or distribute, then having an FDA approved manufacturer variance for your device or projector is sufficient. However, if you are using Class 3B or 4 lasers, or RG3 LILIs, as part of a general show or display – you are not the manufacturer or distributor – then you must have an FDA approved show variance for your show/display. See Appendix C for a description of the difference between manufacturer and show variances.*

**The variance must be current:** After a variance is issued, the variance holder must submit an annual report to FDA each year (FDA Form 3636). FDA will review this and send an acknowledgement letter stating that the report was received, and the variance is renewed. If this is not done – if even one year is missed – the variance expires and is no longer current.

LDI laser and LILI exhibitors with variances must have the most recent annual report submitted to FDA, and the resulting acknowledgement letter sent from FDA. The annual report and acknowledgement letter must confirm the variance remains valid from when it was first issued, through the date of the LSI show.

**Operate under terms of the variance:** All variance holders must abide by the terms and conditions stated in their variance. Only those effects specifically allowed in the variance shall be performed.

**Set up using low power:** Setup and alignment procedures should be conducted at the lowest practical power. Prior to laser emission, all persons in the area should be made aware that the laser will be coming on. This is particularly important when multiple laser systems are being set up by different exhibitors.

**Continuous operator control:** All varianced shows shall be under the direct, continuous control of an operator, at all times when laser emissions are possible. The only exception is when automated show playback is specifically allowed in the variance, and adequate control measures described in the variance are implemented.

**"Laser operator" definition**: The laser operator is directly operating the laser display/show, as prescribed in the variance. They must be trained in how to safely operate the laser and perform the show or display. They must be an employee of the variance holder, or otherwise reliably follow all instructions from the variance holder.

**Operator must see all beams**: The operator must be able to see all beam paths at any time, from the laser source to the termination point. This is to help ensure that no one accidentally or deliberately is able to access the beam.

Remote viewing (CCTV) can be used for paths not visible from the operator's console or position. Spotters can be used in cases of short shows where a spotter is specifically assigned to assist the operator during the short duration of the show. **The LSO may require changes to non-compliant or poorly-compliant situations where beams are not always monitored.**

**Use an emergency stop button or similar:** There must be an easily accessible device or method to immediately terminate (end) the laser or LILI light in case of any unsafe condition. Usually this is done using one or more hardware e-stop buttons.

Other methods, such as an always-onscreen software e-stop or turning off a power strip, may be allowed; these will reviewed by the LSO to determine if they are sufficient to protect against potential hazards. Whatever the device or method, **test it each day** during pre-show setup to ensure it is working.

**Scan-fail beam block:** Laser projectors incorporating scanners, and oriented such that an errant signal or scanner failure could allow laser light above Class 3R to be directed into human accessible areas, shall incorporate a permanent or temporary physical beam block to prevent this.

**Restricted beam areas:** There can be no human access to Class 3B or 4 beams or other laser radiation, unless permitted by an FDA "audience scanning" variance as per LDI Requirements section R5a below. There can be no human access to light from an RG3 LILI within the fixture's hazard distance as per LDI Requirements section R5b below.

At LDI, vertical beams overhead must be at least 8 feet above the floor or surface where persons are permitted to stand. Lateral beams must be kept far enough from where a person stands or could lean so

that no person could touch the beams. These distances may be relaxed for laser operators, performers and employees at the discretion of LDI's LSO.

*Note: FDA has more restrictive access distances of 3 meters (9′ 10″) above the floor or surface where persons are reasonably expected to stand, and 2.5 meters (8′ 2″) to the side or below from where persons are permitted to be. If FDA were to inspect the LDI show and enforce their limits, the exhibitor is responsible for meeting FDA's regulations.*

**How to restrict access:** Restricting access is done by measures including sturdy physical structures (tables, rails, drapery) or flexible/removable barriers (ropes, stanchions). The exhibitor's staff must regularly monitor that the barriers have not been moved or breached.

**No access behind non-solid screens:** Do not project laser light onto scrims, water screens, nitrogen clouds, or other materials that do not attenuate or diffuse the laser energy to levels below the MPE, if there is human access behind the material.

**Do not burn materials:** Class 3B and 4 laser light, and possibly RG3 LILI light, can burn materials, especially dark-colored materials, and substances that can easily ignite such as cloth or paper. Ensure that the laser irradiance is low enough that illuminated surfaces do not smolder or ignite. For example, do not aim a stationary collimated Class 4 laser beam at a black drape.

## R5a: Requirements for Class 3B or 4 laser displays/shows using audience scanning at LDI (does not include LILIs – see next section for LILIs)

**All applicable requirements from sections R1 and R4 above, plus the following:**

**Audience scanning:** Using Class 3B or 4 lasers to deliberately scan or expose an audience to laser light may only be performed with devices/projectors approved by FDA for audience scanning, and with an FDA display/show variance specifically allowing such audience scanning effects. Power, energy or irradiance levels in the audience-scanned areas must not exceed those levels permitted in the display/show variance.

**Audience scanning definition**: For LDI, the term "audience scanning" includes scanning or otherwise exposing laser light onto *any* person: audience, exhibitor, employee, performer, etc. The only exception is if a display/show variance specifically describes or permits laser light effects on persons identified in the variance by a special role (exhibitor, employee, performer, etc.). LDI will allow the display/show to be operated as per the variance.

**LDI review of audience scanning**: Exhibitors presenting audience scanning must be prepared to walk LDI's Laser Safety Officer through setup and testing procedures as outlined in their audience scanning variance**. Appropriate and calibrated test equipment must be available on-site by the exhibitor. If the exhibitor cannot demonstrate and measure safe levels as described in their variance, to the satisfaction of the LSO, audience scanning will not be allowed**.

## R5b: Requirements for Risk Group 3 LILIs with light on or accessible by humans at LDI

**All applicable requirements from sections R1 and R4 above, plus the following:**

**In general, any LILIs that are Risk Group 3 should not have the light beam on or near any person.** The light beam may be aimed upwards, at a wall, etc. as long as there is no potential human access to the beam at any distance.

However, human exposure to RG3 LILI light is permitted if 1) any actual or potential human access is beyond the LILI's hazard distance and 2) the LSO is provided with satisfactory hazard distance documentation (such as in an FDA certification or variance). **Regardless of any documentation, the LSO may require an increased distance, or may not permit any human access, at the sole discretion of the LSO.**

## LASER SAFETY OFFICER REVIEW OF EXHIBITS

Before the trade show opens, LDI's Laser Safety Officer will inspect all booths with lasers or LILIs. **Exhibitors must demonstrate their equipment and provide organized, easily accessible documentation (binder with tabs, or digital files on a computer/tablet – not on a hard-to-read phone).**

Disorganized documents waste time and reflect poorly on safety compliance. The LSO may measure laser emission levels to determine compliance. The LSO will closely inspect booths using audience scanning; any such booths require the exhibitor to have calibrated test equipment on-site.

### Documents required by LDI

- **Uncertified lasers and LILIs**: Products not yet certified to the FDA must have a label stating "This laser product sample is not yet certified to U.S. FDA safety standards and cannot be activated". The laser or laser product will not be allowed to be turned on. To ensure this, LDI will also require that the laser or laser product be disabled so it cannot easily be turned on. The LSO will check that this has been done.
- **Certified lasers and LILIs**: All operational lasers must have a valid FDA certification label. If missing, LDI may require disabling the device.
    - In addition, **for Class 3B/4 & RG3 LILIs**, the LSO will check for FDA Form 3147, the FDA approval letter, and all annual reports and FDA acknowledgment letters. Any required safety signage must be posted. Failure to provide documents or signage may result in device disablement or confiscation.

### Contacting LDI for guidance

For questions or early inspections, exhibitors should contact LDI in advance. The LSO will also be available the day before the show; visit or call the LDI show office for assistance.

### Documents NOT required by LDI

**State & Local Forms:** LDI is unaware of any Nevada or Clark County laser regulations for trade shows. Meeting LDI Requirements is sufficient. However, where there are any state, county or other laser regulations, the exhibitor is responsible for compliance with those regulations.

**FDA Importation Form:** LDI does not require FDA Form 2877 on-site, but exhibitors should comply with FDA import regulations. The FDA may inspect exhibits and enforce stricter rules than LDI. To avoid issues, exhibitors should ensure compliance with both LDI and FDA regulations.

## LDI AND LSO AUTHORITY

LDI and its agents, including the Laser Safety Officer, have sole discretion over how lasers may be used at the trade show. Decisions are based on safety, compliance, attendee impact, or improper use outside the exhibitor's space.

**This determination is solely at the discretion of LDI. If a violation occurs, LDI/LSO may restrict usage, disable, or confiscate the laser product until the exhibition ends.**

### Laser safety responsibility

Exhibitors are solely responsible for ensuring their laser use is safe (per LDI Requirements and ANSI Z136.1) and compliant with all regulations. While LDI promotes safety and enforces rules as practical, it only provides exhibition space and is not responsible for exhibitors' compliance. **The exhibitor is responsible for the safe and compliant operation of their lasers at LDI.**

### Liability disclaimer

LDI and the LSO are not liable for any consequences resulting from actions or inactions regarding an exhibitor's laser presentation, demonstration or use of lasers.

## APPENDIX A: PLAN AHEAD FOR A SAFE SHOW

Beyond basic safety measures like barriers and emergency stops, also plan for accidents or intentional misuse. **All the laser incidents that ILDA knows about, could have been avoided with foresight.**

Consider not just how equipment should work, but also what to do if it fails—like a misaligned laser projecting onto the exhibit floor – or if someone deliberately decides to go into a hazard area.

### Examples from Past LDI Shows

- **Barrier violations**: Attendees may bypass barriers for a closer look. **Regularly monitor restricted areas**. Immediately remove anyone not authorized. Use emergency stops if necessary to prevent any hazardous exposure.

- **E-Stop failures**: Every laser exhibit must have tested, functional e-stops. At a past LDI, two exhibits failed e-stop tests and had to disable lasers until fixes were verified. **Test your e-stops as part of the setup procedure before each show day.**

- **Power cords**: **Simply removing a power cord might not prevent access.** At a past LDI, an exhibitor removed the power cord from a RG3 LILI. An attendee found it nearby. He plugged it into the LILI which activated the fixture. Fortunately, there was a password needed before light could be emitted. Unfortunately, he figured out the password as described in the next paragraph.

- **Keys and passwords**: In the example above, the attendee tried common passwords such as "12345" or "admin". It turned out that "admin" worked. The LILI turned on and began emitting unsafe light. (To fix this, the exhibitor moved the LILI so they could better see if anyone was fiddling with it, and they changed the password.) **The lesson here is that you must think two or three steps ahead.**
  Similarly, many laser keyswitches are simple in shape or are keyed to all lasers of the same type. A person might already have a key, or take a key from a nearby matching laser, and thus may be able to turn on your laser.

- **File well in advance with FDA.** At one LDI, an exhibitor was showing a RG3 LILI. However, due to time pressures this had not yet been certified to FDA. The LSO permitted a turned-off LILI fixture to be exhibited on the show floor as per LDI Requirement R0. The LSO permitted another fixture of the same model to be turned on, but only for demonstrations to potential buyers/distributors if 1) the demo was done off the show floor, 2) in a closed room, 3) by invitation only, 4) with a static beam (no panning, tilting or moving), and 5) with the light dimmed to RG2 levels. **If the fixture had been certified and varianced, these restrictions would not have been imposed.**

# APPENDIX B: ABOUT LASER AND LILI HAZARDS

## Laser hazard information

Laser Hazard Classifications (Classes) are used throughout this document. The following is a quick review of the major Classes for lasers.

Power levels in the list below apply to small-source, continuous wave (CW) visible lasers typically used in display devices. For other types of lasers such as non-visible, pulsed, highly divergent, or scanning beams, consult a laser safety expert to determine the correct Class

- **IEC Class 1** (FDA Class I): Not considered hazardous. For typical display devices/projectors, 0 – 0.39 milliwatts (mW).
- **IEC Class 2** (FDA Class II): Not considered hazardous for momentary viewing. Do not stare into beam. For typical display devices/projectors, 0.4 – 0.99 mW.
- **IEC Class 3R** (FDA Class IIIa): Exceeds the exposure limits for momentary viewing, but is considered low risk. Avoid direct eye exposure. For typical display devices/projectors, 1 – 4.99 mW.
- **IEC Class 3B** (FDA Class IIIb): Can be very hazardous when directly viewed by the eye. Avoid exposure to beam. For typical display devices/projectors, 5 – 499.9 mW.
- **IEC Class 4** (FDA Class IV): Can be very hazardous to the eye from viewing direct or scattered light, and can be hazardous to skin. Avoid eye or skin exposure. Can be a fire hazard. Avoid exposing surfaces which could smolder or burn. For typical display devices/projectors, 500 mW and above.

Additional details about Classes can be found at www.lasersafetyfacts.com/laserclasses.html

### MPE definition

An important concept in laser safety is the **Maximum Permissible Exposure (MPE)**. This is defined as the level of laser light or energy to which an unprotected person may be exposed without adverse biological changes in the eye or skin.

MPE varies based on factors like wavelength, exposure time, and target (eye or skin).

For visible lasers at trade shows, the applicable MPE is **2.5 mW/cm²** for a **¼ second eye exposure**, since people typically blink or turn away in that time. Federal law and LDI enforce this limit unless prolonged direct viewing is expected, in which case a lower MPE applies. Consult a Laser Safety Officer for details.

See Appendix C for more information about U.S. federal regulations for laser and LILI exhibitors, manufacturers, distributors and users.

## Lamp hazard information (for LILIs only)

Laser Illuminated Lighting Instruments are classified according to both their laser hazard and their light-emitting hazard as a bright lamp.

- **Laser hazard:** When classified as a laser, most LILIs fall into the Class 1 category.
- **Lamp hazard:** Classification as a lamp source is done using the IEC 62471-5 standard. There are four categories: Exempt (no hazard), Risk Group 1 (no risk for a <10 sec exposure), Risk Group 2 (no risk for a <1/4 sec exposure due to the bright-light aversion response or heat discomfort) and Risk Group 3 (may be a hazard for momentary or brief exposure). Most LILIs used in entertainment lighting are in Risk Group 2 or 3.

### Summary of LILI Requirements at LDI

- At LDI, any LILIs that are Exempt may be used without restriction.
- At LDI, any LILIs that are Risk Group 1 or 2 in general may be used in the same manner as a conventional lighting instrument. Note however that for RG2 LILIs, the light may be so intense as to be uncomfortably bright or hot, even if it is not technically unsafe.
- **At LDI, any LILIs that are Risk Group 3 cannot have the light beam onto or near any person. The light beam may be aimed upwards, at a wall, etc. as long as there is no potential human access to the beam.** (This may be relaxed for long distance human exposures, but the exhibitor should be prepared to prove to the LSO's satisfaction that any exposure at LDI is beyond the hazard distance of the LILI.)

LILIs also will be required to have FDA certification and variance documents, and to comply with all other LILI conditions stated in the LDI Requirements R0-R5 beginning on page 3.

See Appendix C for more information about U.S. federal regulations for laser and LILI exhibitors, manufacturers, distributors and users.

# APPENDIX C: SUMMARY OF U.S. FEDERAL REGULATIONS FOR LASERS AND LASER ILLUMINATED LIGHTING INSTRUMENTS (LILIs)

## LDI Requirements vs. FDA legal regulations

As stated at the bottom of page 1, LDI's Requirements R0-R5 **must** be followed at the LDI show.

The U.S. Food and Drug Administration (FDA) also has legal regulations which **should** be followed at LDI. If FDA were to visit or inspect LDI exhibitor booths, FDA may take enforcement actions that are different from or more severe than those in LDI's Requirements.

To help exhibitors understand FDA's regulations, this Appendix lists the most important FDA requirements for laser light show devices/projectors, displays/shows, and LILIs as they apply to a trade show such as LDI. The information is NOT necessarily valid for other laser types and uses such as medical, surveying, industrial, research, etc.

This Appendix is a summary of complex regulations. If there is any conflict between this Appendix and federal/state/local regulations, the federal/state/local regulations will apply.

## FDA and CDRH – the same thing

Laser products manufactured or imported into the U.S. are regulated at the federal level by the Food and Drug Administration (FDA), in a division known as the Center for Devices and Radiological Health (CDRH).

In regulatory discussions you may see "FDA" or "CDRH" used interchangeably. For laser regulation purposes they refer to the same agency or division of the agency.

## What is a laser product?

The term "laser product" can refer to both the laser device/projector, and to a laser display/show. Information and links about FDA laser light show requirements is here: http://tinyurl.com/ycp7qe74

In the U.S., "laser product" also refers to devices that modify laser light to produce wide, incoherent beams. In the fields of entertainment, display and lighting, these modified laser products are known by the following terms:

- **LILI** – Laser Illuminated Lighting Instrument
- **LIP** - Laser Illuminated Projector
- **LPL** - Laser Pumped Lighting
- **LEP** - Laser-Excited Phosphor

We will use the term "LILI" in this document to refer to any of the above.

Throughout this document, references to "laser", "laser product" and similar also includes LILIs unless otherwise specifically noted.

## Summary of FDA regulations

At the U.S. federal government level, the Food and Drug Administration (FDA) has strict regulations and requirements for the design, manufacture, importation, distribution, sale, and use of laser products. Because LILIs use a laser as a source, FDA is legally required to treat all LILIs in a similar manner as traditional lasers and laser products.

Here is a summary of FDA regulations:

- All laser products — including all LILIs — must comply with U.S. laser import laws. The manufacturer or distributor must submit to FDA a **laser product report** (FDA Form 3632).

- **"Variances"** are required for laser Class 3B or 4, or Risk Group 3 LILIs uses in entertainment, light shows and displays. Essentially all laser show projectors and LILI products bright enough for commercial or professional use will require a manufacturer variance. All shows using Class 3B/4/RG3 devices also require a show variance. Neither the projectors nor the show may be used in public ("in commerce") until the variance applicant receives a letter from FDA that approves their variance application. There are two types of variances, both submitted using the same FDA Form 3147:

  -- Manufacturers or distributors of laser products that are Class 3B or 4, or Risk Group 3 LILIs, and are used for entertainment or display purposes will check the boxes in section 7b for "a laser display device" and/or "a laser light show projector." This is a so-called "manufacturer variance."

  -- Persons using Class 3B/4/RG3 products in any type of show or display must apply for a variance will check the box in section 7b for "a laser light show." This is a so-called "show variance."

- To legally operate a light show using Class 3B or 4 laser projectors, or Risk Group 3 LILIs, the user must file a **laser light show report** (FDA Form 3640). This describes the laser show setup (the equipment, power and effects), safety measures, operating procedures, and diagrams showing beam paths and protective measures.

- Finally, if a show or display requiring an FDA variance emits **laser light outdoors** that goes into navigable airspace, the show producer must also apply to the Federal Aviation Administration (FAA) for review. The light usage must receive a "letter of determination" from FAA stating that they do not object to the show or display, before FDA will allow the show or display's light to enter navigable airspace.

## Details of FDA regulations

### FDA imported laser products regulations and form

All laser products coming from outside the United States must be accompanied during shipping, and must be **declared upon import**, by FDA Form 2877. This applies whether the laser product is functional or is non-functional.

**FDA Form 2877, "Declaration for Imported Electronic Products Subject to Radiation Control Standards"**

In the U.S., it is illegal to import, manufacture, distribute or use laser products which do not comply with federal laser product regulations. This form tells FDA and U.S. Customs the safety and legal status of the laser product.

- If the product has been certified and an Accession Number has been received from FDA, the FDA Accession Number is entered on this form allowing passage of the product into the U.S.

- If the product has NOT been certified, it typically will enter under a temporary import bond (TIB) or similar, which ensures the product will be promptly re-exported; see Declaration C2. Products imported on a TIB cannot be powered on.

Always declare laser products on the shipping documents when importing to the U.S. The word "laser" must appear; do not use only a general term such as "lighting instrument" or "lamps". A false declaration is a felony for both the shipper (sender outside the U.S.) and the consignee (recipient in the U.S.). Violations can result in recalls, in seizing and destruction of the laser products as well as large fines. Thousands of non-compliant laser products are impounded by U.S. Customs and are destroyed annually.

## Non-functional laser product regulations

Laser products which will be exhibited in a non-functional state (i.e., they will not be powered on at any time) may be exhibited at a trade show without being certified. FDA requires each non-certified laser product displayed in public to carry a **clearly visible label** indicating "This laser product sample is not yet certified to U.S. FDA safety standards and cannot be activated."

> *LDI is additionally requiring that non-certified laser products must be disabled so they cannot be easily activated at the trade show. This may involve removing power cords, power supplies or other parts. If deemed necessary by the LSO, LDI will hold onto the key, cords, etc. until the end of the show.*

## FDA laser product regulations for all lasers and LILIs

There are numerous FDA forms and documents that laser products must comply with. Here are the major ones:

### FDA Form 3632, "Guide for Preparing Product Reports on Lasers and Products Containing Lasers"

All U.S. laser products regardless of type, size or power — including LILIs — must be 'self-certified' by the manufacturer to be in compliance with U.S. law. This process involves:

- Designing the product for the proper laser safety Class, including all required engineered safety features, having the required safety labels, ensuring the label information is correct, and writing legally compliant manuals

- Legal requirements apply for providing information in all marketing and advertising, as well as providing compliant product service information

- Manufacturing the product under an accepted quality assurance program, and fully testing and individually certifying every unit assembled

- Filling out and submitting FDA Form 3632, the product report form.

After submission of Form 3632, FDA will review it. If approved, FDA will provide an "Accession Number." The product will then be legal to distribute and sell in the U.S. One exception is for Class 3B and 4 lasers and RG3 LILIs.[1] To be legally distributed and sold, these additionally must be varianced using Form 3147.

**FDA Form 3636, "Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products"**

FDA annual report Form 3636 must be filed by September 1 of each year. This provides FDA with details on the laser products sold, or shows produced, any quality control and safety issues, etc. This requirement applies to both laser product manufacturers as well as show producers.

Dealers and distributors also have a legal obligation when selling a laser product to maintain customer traceability to each unit sold. There are several more minor requirements beyond those described here.

## FDA laser product regulations for Class 3B or 4 or RG3 laser products

The regulations and forms discussed above apply in the U.S. to all laser product types and Classes, including LILIs

Additionally, laser products that are Class 3B, Class 4 or lamp Risk Group 3 ("RG3" or "Class 1 / RG3") which are used for entertainment, display or lighting have further requirements. These cannot be legally manufactured, imported, distributed or used in public ("in commerce") in the U.S. without a special U.S. FDA permit called a "variance."

As stated above, essentially all lasers and LILIs for any commercial or professional use will fall into one or more of these categories (Class 3B, Class 4, and/or RG3) and thus will require an FDA variance.

**FDA Form 3147, "Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display or Device"**

For Class 3B, Class 4 or RG3 laser products used in entertainment, display or lighting, there are two main types of variances required. Both are applied for using Form 3147. Section 7b of the form looks like this:

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)* _____

- Checking either of the top two products means you have a "manufacturer's variance." This is required for an entertainment, display or lighting laser product to be sold or used in the U.S. This

[1] To be more specific and precise: 21 CFR 1040.10(13) defines a demonstration laser product as "any laser product manufactured, designed, intended or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition." This will include laser light show equipment/projectors as well as the laser light show itself (how the lasers are used). 21 CFR 1040.11(c) limits demonstration laser products to be Class 3R or below (e.g., <5 milliwatts). However, to be sufficiently visible a public laser light show needs to use much more power than this. That is why laser shows 5 mW or more – Class 3B and 4 – as well as RG3 LILIs are required to obtain an FDA-approved variance for both the equipment/projectors as well as for the show itself. This is permission to "vary" from the 21 CFR 1040.11(c) limit.

U.S. variance must be granted and held by the manufacturer regardless of the country of manufacture. For non-U.S. manufacturers, FDA requires a U.S. resident to sign all reports.

- The third listed variance product is the laser light show – how the lasers are used, where the audience is, etc. Checking this item covers a laser light show production or usage. Note that FDA considers laser shows, displays or sales demonstrations to be "laser products" which require a variance. Said another way, anyone who owns or uses a Class 3B, Class 4, or RG3 laser product for entertainment, display or lighting purposes must apply for a variance using FDA Form 3147 AND must receive a variance approval letter from FDA.[2]

If a manufacturer submits a variance for a device or projector (top two boxes), and the variance is approved, the variance approval letter automatically also grants a variance for a laser light show so that they may demonstrate their device or projector in use. (The variance approval letter may also let the manufacturer use any other company's FDA-approved and varianced devices or projectors; check the exact language in the variance approval letter.)

Almost all LDI exhibitors with lasers or LILIs will be manufacturers or distributors. LDI will look for the form 3147 originally submitted to FDA, and for the resulting FDA variance approval letter. These are sufficient to allow the exhibitor to create a show or display with their lasers or LILIs.

**FDA Form 3640, "Reporting Guide for Laser Light Shows and Displays"**

As the name states, this is used to report the laser light show: what hardware is being used, how is it arranged relative to the audience, etc. For tours, the report will cover all the tour stops. For an installation, it will cover the particular setup and use at the location. Among the elements reported are the show manufacturer (you); your variance; projectors; venue(s); show locations, dates and times; laser effects being used; diagrams and drawings of the venue(s), laser levels; scanning safeguards; operator and projector controls; test procedures; and notification procedures.

Form 3640 has a sample checklist at the end of about 10 pages. As FDA states, it "shows the types of checks that should be performed during preparation for a laser light show. It is not intended that you adopt this sample without any modification."

As a condition of a variance, FDA requires you to have a pre-show and post-show log and checklist. Each checklist item should have a procedure behind it – how the checklist item was done or performed. Keep these checklists indefinitely for possible FDA review during an inspection.

## FDA Laser Notices

There are additional regulations and information in FDA Laser Notices:

- **FDA Laser Notice 51**, "Responsibilities of Laser Light Show Projector Manufacturers, Dealers, and Distributors (Final Guidance for Industry and FDA)"

[2] The applicant cannot take delivery of laser equipment, and cannot use laser equipment in public ("in commerce"), until they have received a variance approval letter from FDA. It is not enough to APPLY for a variance. The laser product cannot technically be DELIVERED or USED IN PUBLIC until the buyer has received a variance approval letter from FDA. See FDA Laser Notice No. 51.

- **FDA Laser Notice 55**, "Procedures for Renewal and Amendment of Certain Laser Light Show Variances (Guidance for Industry and FDA Staff)"
- **FDA Laser Notice 56**, "Laser Products - Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1"
- **FDA Laser Notice 57**, "Classification and Requirements for Laser Illuminated Projectors (LIPs)." The LIP requirements also apply to LILIs and other laser-derived lighting sources. In addition, FDA also considers LIPs, LILIs and other laser-derived lighting sources to be "Laser Projectors" for some aspects of regulation.

Although the very old U.S. FDA CDRH regulation "21 CFR Part 1, Subchapter J" can still legally be used for laser product classification and certification in the U.S., there are great advantages of utilizing special allowances in the FDA's laser notices which allow conformance with the international IEC 60825-1 laser standards. Consult a laser safety compliance expert regarding these complexities.

## Requirements for laser and LILI light used outdoors

FDA requires a variance for entertainment, display and lighting uses. As one of the conditions of a variance, FDA also requires that outdoor laser light use — including LILIs— be reviewed and be non-objected to by FAA.

The only exception to FAA review of outdoor laser light use is if the light beam is terminated (ended) on a surface so that it never enters "navigable airspace." This can be defined generally as airspace where a crewed aircraft or helicopter could fly, land, or takeoff. If in doubt about whether laser light would be in navigable airspace, contact the appropriate Western, Central or Eastern FAA Service Center to determine if FAA Form 7140-1 needs to be filed. Service Center contact information can be found in FAA Advisory Circular 70-1B, Appendix E.

### FAA Form 7140-1 and FAA Advisory Circular AC 70-1B

For laser Class 3B or Class 4, or LILI RG3, laser products and uses that emit light which enters or could enter into navigable airspace, FDA requires the variance holder to submit their proposed usage to the U.S. Federal Aviation Administration (FAA). This should be done at least 30 days in advance of the display/show.

Submit information using FAA Form 7140-1. Instructions for this form are in a separate document, FAA Advisory Circular 70-1B.

FAA will review the request. They will reply with a "Letter of Determination." The letter will either state that FAA has no objections to the usage, or the letter will state that FAA objects to the usage and will give the reason for the objections. If there are FAA objections, FDA's variance requires either that the objectionable laser effect/product not be used, or the usage should be changed to fix FAA's objections.

## Laser product requirements for non-U.S. countries

Laser products sold in most non-U.S. countries must conform to the requirements of the IEC 60825-1 laser product standard. The standard's name or number may change somewhat from country to country.

Use of LILIs and similar laser products must comply with applicable user safety standards such as IEC 60825-3 and/or ANSI Z136.1. Countries and regions also have general product requirements that may apply such as the EU's CE mark, which encompasses many other non-laser requirements.

## Possible future LILI developments

In the future, it is possible that FDA and/or FAA will relax their regulations for LILIs. One industry standards group, SAE G10T, states that conventional lighting instruments such as stage lights, spotlights and searchlights usually have a radiance less than 10 MW $m^{-2}sr^{-1}$.

Therefore, SAE G10T proposes that LILIs which emit light with a radiance less than 10 MW $m^{-2}sr^{-1}$ should be treated the same way as conventional lighting instruments. This would mean they should not be subject to FDA variance requirements, and they could be used outdoors without FAA review. LILIs above this radiance would, in the SAE G10T proposal, continue to be regulated by FDA and FAA as lasers since their light is generally brighter than conventional lighting instruments.

The LILI proposal in the SAE G10T document, "ARP 5560", has not been adopted by FDA or FAA as of March 2025. All LILIs are still regulated as laser products, as described in this document you are reading.

SAE G10T's proposal is being monitored by the International Laser Display Association. Any LILI manufacturer, distributor, seller or user who is interested in having LILI regulations become more similar to traditional lighting fixture safety practices should contact ILDA.

## Laser safety regulation assistance

LILI product experts can help companies with U.S. and international LILI design and legal requirements. For example, here are two such LILI-knowledgeable firms:

**Laser Compliance**
www.lasercompliance.com
casey@lasercompliance.com

**Phoenix Laser Safety**
www.lasersafetyconsultant.com
jay@lasersafetyconsultant.com

The International Laser Display Association has a committee for ILDA Members who are primarily involved with LILIs, and who wish to help make U.S. LILI regulations more in line with other countries. For more information, contact ILDA:

**International Laser Display Association**
www.ilda.com
mail@ilda.com
407-797-7654

Source: This document was developed specifically for LDI with guidance from the International Laser Display Association (ILDA) and from industry experts working on standards for laser usage at trade shows.
Version 250412-05