2024
LDI Laser and LILI Safety Requirements

INTRODUCTION

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

> *A LILI is a fixture used for lighting in entertainment, architecture and other professional applications where an original laser light source is made incoherent, is widened, and is otherwise modified so the resulting light can be used in a manner essentially identical to conventional lighting fixtures.*

In the U.S., LILIs are regulated in essentially the same manner as conventional light show laser projectors. **Therefore, throughout this document any reference to "lasers", "laser products" and similar terms also includes LILIs unless otherwise noted.**

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

LDI's Laser Safety Officer (LSO) will be present before and during LDI's trade show to review exhibits, answer questions, offer assistance, and look for potential LDI Requirements compliance issues. **LDI and/or its LSO reserves the right to limit or stop laser activity that it deems to be unsafe or in violation of LDI Requirements, at any time, at LDI's sole discretion.**

We want all exhibitors to have a successful experience at LDI. Therefore, we urge you to contact the LDI office well before the trade show if you have any questions.

In addition, there are U.S. legal requirements

In the United States, the Food and Drug Administration (FDA) is the federal agency that regulates the importation, manufacturing, distribution and marketing of laser products, shows and displays. The exhibitor should be familiar with and should comply with all applicable FDA legal requirements. To help exhibitors, Appendix C (page 12) has a summary of common FDA laser requirements.

> *Be aware that complying with FDA laser requirements may require weeks or months of preparation; especially for Class 3B and 4 laser products and displays.*

Many of the LDI Requirements are the same as or similar to FDA legal requirements. However, LDI is not a government enforcement agency. LDI's primary concern is with the safe use of lasers at its trade shows.

FDA prohibits non-compliant products or displays from being used at trade shows. 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.

Summary

In summary, laser and LILI exhibitors *must* follow the LDI Requirements R0-R5. They *should* also follow FDA rules for importing, making, selling, and marketing laser products and displays, as detailed in Appendix C on page 12.

LDI 2024
LDI Laser and LILI Safety Requirements

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 10.

LDI REQUIREMENTS R0-R5

Companies that exhibit, demonstrate, present, or use any lasers or LILIs at LDI must comply with the following LDI Requirements listed in sections R0 through R5.

The sections differ depending on what type or use of lasers are involved. **Note that more than one section may apply to your laser products or laser usage.** Be sure to review all applicable sections.

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 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 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.

Display/show variance required: All Class 3B or 4 laser display devices or projectors, and all RG3 LILIs, that will be powered on **must be operated under an *approved* FDA variance** describing how the display/show will be presented. This applies even if the device/projector is only powered on and is not otherwise used to make a laser show.

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.

> *Note: Usually, the manufacturer applies for a variance for the device/projector. Then, another party such as a dealer, distributor, laser show producer, or end user applies for a separate variance for the display/show. If the manufacturer is also exhibiting (e.g., demonstrating their laser equipment), they may have separate device/projector and display/show variances, or they may have a single combined device/projector/display/show variance.*

> *Note: FDA considers even a simple demonstration of a laser projector to be "manufacturing" a light show. For example, **when a dealer, distributor or exhibitor turns on a Class 3B or 4 laser display device or projector ("demonstration laser product") at LDI, they become a light show manufacturer** and are subject to FDA requirements including having an approved variance for a laser display/show. Even if you just buy or rent laser equipment to draw attention to your trade show booth, **the operator of the laser display/show – the LDI exhibitor, or a person or company hired by the exhibitor – must have a display/show variance approval letter in-hand** before the laser can be used for a public demonstration.*

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 or confidently 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 would be reviewed by the LSO to determine if they are sufficient for the potential hazard.

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 requirements.*

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

Prior to the opening of exhibits, LDI's designated Laser Safety Officer will walk the trade show floor. As the LSO visits each booth with lasers or LILIs, **the exhibitor will be required to demonstrate their equipment, and to provide their documentation to the LSO.**

> *The LSO requests that **all documentation be in readily-available, easily readable form.** For example, a binder with paper copies of the documents, tabbed for ready access, or digital documents readily accessible on a computer or tablet. Having haphazard or hard-to-find documents wastes the exhibitor's and LSO's time, and negatively reflects on the exhibitor's safety attitude.*

Laser equipment: The LSO may measure laser emission levels to determine compliance. The LSO will pay special attention to any exhibit booths where audience scanning is in use. If audience scanning is being done, the exhibitor must have appropriate and calibrated test equipment available on-site.

Required documentation

- **For any laser or laser product including LILIs that are being displayed at LDI but have not yet been certified to FDA,** the LSO will look for 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.

- **For all lasers and LILIs that will be or could be turned on,** the LSO will check for a valid FDA-required certification label. If a valid certification label is not on the laser or laser product, LDI may 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.

  In addition, **for Class 3B and 4 laser displays/shows, and RG3 LILIs,** the complete FDA display/show variance paperwork, and any other documents required by the display/show variance, must be available for review. Any FDA-required safety signage must also be available and properly posted. If the exhibitor does not provide documentation or required signage by show opening, LDI reserves the right to disable or confiscate the laser projector or device for the remainder of the trade show.

Questions and guidance: If any aspect of the exhibitor's display is in question, the exhibitor should contact LDI in advance and ask for the LSO inspection to be done earlier. This allows time for corrective actions to be taken.

Contact information: The LSO will also be available the day before the show to offer assistance. Call or visit the LDI show office to contact the LSO. Also, if you have any questions about who is the official, designated LSO, call or visit the LDI show office.

Documents that are not required by LDI

State, local forms are not required by LDI: Neither LDI nor ILDA is aware of any current state (Nevada) or county (Clark County) laser show inspections or other laser requirements for trade shows. Therefore**, meeting the LDI Requirements outlined in this document shall be sufficient for LDI's review of exhibitors' laser safety compliance.**

However, where there are any state, county or other laser requirements, the exhibitor is responsible for compliance with those requirements.

Importation form is not required by LDI: Exhibitors should ensure their importation complies with FDA requirements and is done under FDA Form 2877. **LDI does not require Form 2877 to be available or onsite.**

However, this form is required by FDA for U.S. Customs importation clearance. FDA has the right to inspect exhibits at LDI. Some of FDA's requirements may be different or more stringent than LDI Requirements. **To avoid any potential issues, exhibitors should therefore ensure they meet both LDI Requirements, and any applicable FDA requirements including proper importation.**

LDI AND LSO AUTHORITY

LDI and its designated agents (such as a Laser Safety Officer) have the right to determine whether and how a laser product may be presented, demonstrated or otherwise used within LDI's trade show. This determination may be based on factors including laser safety, regulatory compliance, adverse effect on attendees or other exhibitors, or laser use outside of the exhibitor's trade show space. **This determination is solely at the discretion of LDI.**

If LDI sees or learns that a laser product was utilized in violation of these requirements, then LDI/LSO reserves the right to take actions including but not limited to: setting limits on how the laser product or display/show may be used, disabling the laser product, and/or confiscating the laser product until the conclusion of the exhibition.

Laser safety responsibility

Each exhibitor is ultimately responsible for their laser use …

1. … being **safe**, as per LDI Requirements and generally recognized standards such as ANSI Z136.1, and
2. … being **compliant** with federal, state and local regulations.

While LDI wishes to have a safe and compliant show, and will assist and enforce as practical, LDI is providing exhibition space. Neither LDI nor the LSO are responsible for ensuring exhibitors' safety and/or regulatory compliance. **The exhibitor is responsible for the safe and compliant operation of their lasers at LDI.**

Liability disclaimer

LDI and the LSO disclaim liability from any exhibitor or other party, resulting from LDI or the LSO taking or not taking action against an exhibitor's presentation, demonstration or use of lasers.

APPENDIX A: PLAN AHEAD FOR A SAFE SHOW

As you plan for your LDI exhibition, keep in mind unusual or unlikely situations that may arise. It is not enough to plan obvious safety measures such as barriers/stanchions, unplugging lasers, using emergency stops. **You should also plan ahead for accidents, deliberate actions, etc. that could happen.**

In all laser show accidents and incidents that ILDA knows about, laser exposure could have been prevented if the show producer or operator "thought ahead." **Think not only about how the equipment, show and safety measures are *supposed* to work. Think about what to do if they *actually* don't work,** such as if a laser slips on its truss so the beam now points onto the exhibit floor.

Some examples:

- A person might want to get a closer look at equipment, or might want to video a booth from a different angle. So they deliberately go past a barrier or stanchion. **To ensure safety, regularly monitor such limited-access areas.**
  If a person does get into a laser/LILI restricted area, you must immediately ensure that they are not exposed to unsafe laser or LILI light. E-stop the light or otherwise get the person safely out of the area. Then fix the problem so it does not happen again.

- The LSO will require each exhibit with lasers to have one or more e-stops which will immediately turn off the lasers. **Test your e-stops as part of the setup procedure before each show day.**
  At a past LDI show, there were two laser exhibits where the LSO asked to see the e-stop work, but nothing happened when it was pressed. The exhibitors were required to stop all lasers until the e-stop was fixed, and the fix was demonstrated to the LSO's satisfaction.

- **Removing and storing a laser or LILI's power cord may not restrict access.** At a past LDI, an exhibitor removed the power cord from a LILI. An attendee found it nearby. He plugged it into a RG3 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.

- **Removing a key, or having a password may not restrict access.** In the example above, the attendee tried a couple of common passwords such as "12345" or "admin". It turned out that "admin" worked. The LILI turned on and began emitting light at an unsafe distance.
  By adding a cord and entering the password, the attendee was able to get a supposedly impossible-to-operate hazardous device to run. The lesson here is that you have to think two or three steps ahead. (The exhibitor moved the LILI so they could better see if anyone was fiddling with it, and they changed the password.)
  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 which due to time pressures had not yet been certified to FDA. The LSO permitted a turned-off LILI to be exhibited on the show floor as per LDI Requirement R0. The LSO permitted it to be turned on, for demonstrations to potential buyers/distributors, only if 1) the demo was done off the show floor, 2) by invitation only, 3) in a closed room, 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.

> *This document uses the IEC class numbers which use Arabic numerals such as "Class 4". You might also see the classes using Roman numerals, such as "Class IV". These are essentially equivalent.*

After each Class, we have listed the power levels for the kind of lasers typically used in laser display devices and projectors (i.e., small source, continuous wave (CW) lasers emitting small diameter, collimated visible beams).

If you have some other type of laser product – for example, a laser with a non-visible beam, a laser using invisible beams to generate visible beams such as a doubled Nd:YAG, a laser with a highly divergent beam, a laser with a pulsed beam, or a display with scanning beams – consult a laser safety expert to determine the proper Class.

- **Class 1** (FDA Class I): Not considered hazardous. For typical display devices/projectors, 0 – 0.39 milliwatts (mW).
- **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.
- **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.
- **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.
- **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.

There are many different MPE levels, depending on the laser wavelength, time of exposure, whether the exposure is to eye or skin, and other factors.

For visible light at trade shows and laser shows, the ¼ second MPE is most often used for eye exposures. A person exposed to unwanted or unexpected visible laser light will blink, turn away or otherwise avoid the light within ¼ second. The MPE for visible light, for a ¼ second exposure limit, is 2.5 milliwatts per square centimeter (mW/cm^2).

Generally, this is the MPE that federal law and LDI will limit you to for eye exposures. (An exception would be a display where a person is intended or expected to stare directly into laser light for longer than ¼ second, in which case a lower MPE would be applied; consult a Laser Safety Officer for details.)

See Appendix C on page 12 for more information about U.S. federal requirements 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 2.

See Appendix C on page 12 for more information about U.S. federal requirements for laser and LILI exhibitors, manufacturers, distributors and users.

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

Note: 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.

If there is any conflict between this Appendix and federal/state/local requirements, the federal/state/local requirements will apply.

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 a laser display/show. Detailed information on 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. *(Note: 'LEP' is an incorrect and conflicting term not recognized by professional industry, regulators or standards, and should not be used to prevent delays in reporting, processing and importing.)*

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 very 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 requirements:

- All laser products — including all LILIs — must comply with U.S. laser import laws and must submit a laser product report to FDA.

- In addition, laser products that are Class 3B, Class 4, or LILIs that are Risk Group 3 (RG3) must apply for a variance for the product itself, and for the use of such products in any type of show or display. Essentially all lasers and LILIs bright enough 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.

- Finally, if a show or display requiring an FDA variance emits 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 requirements 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 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 requirements

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 requirements 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 also must be varianced using FDA Form 3147 as described below.

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.

[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 a 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.

FDA laser product requirements for Class 3B or 4 or RG3 laser products

The requirements 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 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 different types of variances required. Both are applied for using Form 3147.

- The first variance type is 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 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 other variance type is the "show variance." This 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. The applicant cannot take delivery of laser equipment 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 until the buyer has received an approved variance from FDA. See FDA Laser Notice No. 51.)

Performing a private sales demo, or exhibiting at a trade show is legally considered show production in the U.S. This can only be done by a person or company with an approved FDA show variance. As a condition of the show variance, the laser product — including LILIs — must also be manufactured under an FDA manufacturer's variance. Where a manufacturer's variance and a show production variance is granted at the same time, they may appear as the same variance, with the same variance number.

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. This is not necessary for every laser show performed, but for a tour would be for the general setup at each tour stop. Also use this form for fixed installations. 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)"
- **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.

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 the 60825-3 and/or ANSI Z136.1. Countries and regions also have non-LILI non-laser specific requirements that will 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 requirements 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 June 2024. 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 commensurate with traditional luminaire 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 new 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.
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