LDI Laser Safety Requirements

INTRODUCTION

LDI's laser safety requirements help ensure a safe and professional trade show for exhibitors and visitors. **All exhibitors using lasers must understand and follow these requirements.** They were developed with guidance from the International Laser Display Association (ILDA) and from industry experts working on national standards for laser usage at trade shows.

Exhibitors bringing in laser equipment from outside the United States should also be aware of U.S. regulations governing the importation of laser equipment, and possible U.S. restrictions on the laser usage based on the importation declaration.

Laser equipment, as well as laser displays and shows, are regulated at the U.S. federal level by the **Food and Drug Administration (FDA)**. Most of this document assumes you are familiar with FDA regulatory compliance requirements. If these requirements are new to you, at the end of this document is an appendix with a summary of FDA requirements, plus the address of a web page with more details and links to FDA forms.

> *Be aware that complying with FDA laser requirements may require weeks or months of preparation, especially for Class 3B and 4 laser products and shows. Be sure you are FDA-compliant well in advance of the LDI trade show.*

LDI's Laser Safety Officer will be reviewing laser exhibits

LDI's designated Laser Safety Officer (LSO) will be present before and during LDI's trade show to review exhibits, answer questions, offer assistance, and confirm compliance with requirements.

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 us well before the trade show if you have any questions.

LASER CLASSIFICATIONS

Laser Classes are used throughout this document. The following is a quick review of the major Classes (not including 1M and 2M). Some additional details about all visible light Classes is at www.lasersafetyfacts.com/laserclasses.html.

> *After each Class, we have listed the power levels for the kind of lasers typically used in laser display devices and projectors: 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, with a highly divergent beam, or with a pulsed beam -- consult a laser safety expert to determine the proper Class.*

- **Class 1:** Not considered hazardous. For typical display devices/projectors, 0 – 0.39 milliwatts (mW)
- **Class 2:** Not considered hazardous for momentary viewing. Do not stare into beam. For typical display devices/projectors, 0.4 – 0.99 mW.

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- **Class 3R:** 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:** Can be hazardous when directly viewed by the eye. Avoid exposure to beam. For typical display devices/projectors, 5 – 499.9 mW.
- **Class 4:** Can be hazardous to the eye from viewing direct or scattered light. 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.

LDI REQUIREMENTS

Companies that exhibit, demonstrate, present, or use any lasers at LDI must comply with LDI's requirements for various Classes and types of lasers. These requirements are in sections R0 – R8 below. **Note that more than one section may apply to your laser products or laser usage.**

R0: Requirements for ALL laser display devices and projectors that will be powered on at LDI

Certification required: Manufacturers must certify all laser display devices and projectors ("demonstration laser products") that will be powered on at LDI, regardless of Class. This means that the LSO will check that the laser device/projector has 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 power limit for its stated or labeled Class. If it does exceed the power 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, so that vibration or accidental movement will not misalign the system, possibly causing exposure or reflection above Class 2.

Beams outside the booth will be reviewed: If laser light is emitted outside of the exhibitor's booth, the usage is subject to approval by LDI and/or the LSO. The laser light must not interfere with other exhibitors' displays.

Control stray light: Stray laser light -- either diffuse or direct beams -- that is not a necessary and intended part of the display must be controlled or eliminated. Diffuse reflections 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 audience scanning effect permitted by a relevant FDA display/show variance.

Caution with fiber optic laser cables: Fiber optic cables carrying high power laser beams must be routed to prevent ignition of flammable materials in the event of failure of the cable.

R1: Requirements for Class 1 laser display devices/projectors that will be powered on at LDI

All requirements from section R0 above, plus the following:

Not restricted: Class 1 laser light and effects are not restricted at LDI, except that they should not be directed into other exhibitors' spaces.

As a reminder, Class 1 laser display devices or projectors do not require a FDA variance. Similarly, displays or shows using Class 1 laser products also do not require a FDA variance.

R2: Requirements for Class 2 laser display devices/projectors that will be powered on at LDI

All requirements from section R0 above, plus the following:

Class 2 human exposure to laser light generally allowed: Class 2 laser effects 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 2 lasers should not be used at LDI where purposeful staring into the beam or prolonged exposure to the eye is intended 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."

As a reminder, Class 2 laser display devices or projectors do not require a FDA variance. Similarly, displays or shows using Class 2 laser products also do not require a FDA variance.

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

All requirements from section R0 above, plus the following:

Class 3R allowed where persons are not expected: Class 3R laser effects 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 lasers 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 Class 3R laser effects in an area where persons are expected to be located, such as aiming beams down into accessable areas of your booth, 1) no part of the effect 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 Class 3R laser light that, in his or her determination, exceeds or may exceed the applicable MPE. (For a small source, continuous wave laser beam, the MPE for an unintentional exposure of less than 0.25 seconds would generally apply; this MPE is 2.54 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, unless it can be demonstrated that the exposure is below the MPE applicable to the expected exposure duration."

As a reminder, Class 3R laser display devices or projectors do not require a FDA variance. Similarly, displays or shows using Class 3R laser products also do not require a FDA variance.

R4: Requirements for Class 3B or 4 laser display devices/projectors that will be powered on at LDI

All requirements from section R0 above, plus the following:

Device/projector variance required: All Class 3B or 4 laser display devices or projectors 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 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.

Approval for variances is required: 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: Exhibitors of Class 3B and 4 laser displays/shows must abide by the terms and conditions stated in their variance. Only those effects specifically allowed in the variance shall be performed.

Continuous operator control: All Class 3B and Class 4 laser displays/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 additional control measures described in the variance are implemented.

"Operator" definition: The laser operator must be a fully trained, legal employee of the variance holder who is responsible for the presentation of the laser display/show, as prescribed in the variance.

No access behind non-solid screens: Laser light projected on scrims, water screens, nitrogen clouds, or other materials that do not completely diffuse the beam are not acceptable, if there is access to areas behind these screens that would allow an exposure above the Maximum Permissible Exposure (MPE).

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.

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 shall be made aware that laser light will be coming on. This is particularly important when multiple laser systems are being set up by different exhibitors.

Restricted beam areas: LDI will enforce the following: There can be no access to Class 3B or 4 beams or other laser radiation. Vertically, beams overhead must be at least 8 feet above the floor or surface where a person could reasonably stand. Laterally, beams should be kept far enough from where a person stands or could lean over, so that no person can touch the beams. Restricting access can be done by measures including sturdy physical structures (tables, rails, drapery), or flexible/removable barriers (ropes, stanchions) where the exhibitor's staff monitors that the barriers are not moved or breached.

Note: If federal, state or local regulations regarding access are more restrictive, the exhibitor is responsible for meeting those requirements.

Note: The "Restricted beam areas" paragraph does not apply to displays/shows where audience scanning onto persons is allowed by FDA variance. See the next section for more requirements regarding audience scanning.

R5: Requirements for Class 3B or 4 laser displays/shows using audience scanning at LDI

All applicable requirements from sections R0 and R4 above, plus the following:

Audience scanning: Class 3B or 4 audience scanning may only be performed with devices/projectors preapproved 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 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, audience scanning will not be allowed**.

R6: Requirements for Class 4 lasers that will be powered on at LDI

Class 4 laser display devices/projectors must meet all requirements from sections R0, R4 and (if applicable) R5 above, plus the following. Class 4 non-display lasers -- for example, a general purpose laser -- must meet all requirements from section R7 below, plus the following.

Do not burn materials: Class 4 laser 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.

R7: Requirements for lasers that will be powered on; but are NOT laser display devices or projectors, and are NOT used for displays or shows

FDA requirements are less stringent for general purpose lasers (e.g., just a laser emitting a beam) and for lasers that are not "demonstration" light show lasers as defined by FDA (for example, an industrial laser).

These non-demonstration lasers must be certified, and a Laser Product Report (FDA Form 3632) must be submitted to FDA. Variances are not required.

Because LDI is a trade show featuring entertainment lighting products**, it is probable that any laser-emitting product at LDI falls under the FDA definition of a demonstration laser product** in 21 CFR 1040.10(b)(13) as follows:

> *"Demonstration Laser Product means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition. The term 'demonstration laser product' does not apply to laser products which are not manufactured, designed, intended, or promoted for such purposes, even though they may be used for those purposes or are intended to demonstrate other applications."*

This FDA definition means that merely demonstrating a laser product at a trade show does not necessarily turn the product into a "demonstration laser product".

Only if the laser product's purpose is "demonstration, entertainment, advertising display or artistic composition" as defined above, then the laser product is a "demonstration laser product." Class 3B and 4 demonstration laser products are required by FDA to have an approved variance for the product (the device/projector) and an approved variance for the display/show (how it is used), prior to any public use such as exhibiting at LDI. These may be separate variances, or a single variance obtained by a manufacturer to cover both their device/projector and how it is displayed/showed.

R8: Requirements for lasers of any Class or type that will NOT be powered on

Certification not required: Lasers and laser products (including devices/projectors) that will not be powered on do not have to be certified or reported to FDA. However, each non-certified laser product must carry a clearly visible label indicating "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 FDA requirement, LDI also requires that non-certified laser products be disabled so they cannot be activated at the trade show. For example, a key could be removed from a keyswitch, or the power cord could be removed and stored.

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LASER SAFETY OFFICER REVIEW

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

> **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.
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> **Documentation:** For Class 3B and 4 laser displays/shows, the complete display/show variance paperwork, and any other documents required by the display/show variance, must be present on. Any FDA-required safety signage must also be available and properly posted. The LSO will review the documents and signage. 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.

LDI DOCUMENT CHECK

Certification label check:

1) **Label required if laser could be turned on:** For any laser or laser product (including display devices/projectors) that will be or could be turned on, LDI will check for a valid FDA-required certification label. If a valid certification label is not on the laser or laser product, LDI will 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.

2) **For non-certified lasers:** For any laser or laser product being displayed at LDI that has not yet been certified, LDI 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.

Device/projector variance number for Class 3B or 4: For any Class 3B or Class 4 laser display device/projector that will be turned on, LDI will additionally check that the FDA-required certification label text includes a **valid variance number**. (Each laser device/projector must *receive* a variance approval letter from FDA before it can be publicly operated, sold, rented, or otherwise entered into commerce. The FDA variance approval letter will specify the text to be put into the certification label, part of this text includes the variance number. Under FDA requirements the variance number must be on the certification label affixed on the laser device/projector.)

Copies of the laser display/show variance letter and required documentation: Anyone presenting a Class 3B or Class 4 laser display/show must have on site at all times a copy of the full laser light show variance approval letter from FDA, under which the display/show is being presented. Additionally, any further documents as required

by FDA in the variance (such as setup procedures and safety checklists) must also be present and available for review by the LSO.

Required signage: The LSO will check for any FDA-required caution or warning signs. The laser display/show will not be allowed to proceed unless these signs are posted.

Documents that are not required by LDI

State, local forms 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. Therefore**, meeting the requirements outlined in this document shall be sufficient for LDI's review of exhibitors' laser safety and regulatory compliance.** However, where there are any state, county or other laser requirements, the exhibitor is responsible for compliance.

Importation form 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 for U.S. Customs importation clearance.

LDI/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: 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 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 any lasers at LDI.**

LDI disclaims liability from any third party, resulting from LDI taking or not taking action against an exhibitor's presentation, demonstration or use of lasers.

APPENDIX: SUMMARY OF U.S. FEDERAL REQUIREMENTS

Note: The following appendix is a brief summary of U.S. federal requirements. Additional laser safety information is at the web page http://lasershowsafety.info/LDIguide.html. The web page will have the most up-to-date laser safety information for LDI exhibitors. If there is any conflict between this printed document and the web page, the web page will apply.

Laser products manufactured or imported into the U.S. are regulated at the federal level by the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). The term "laser product" can refer to both the laser device/projector, and a laser display/show.

Detailed information on FDA requirements is here: http://tinyurl.com/ycp7qe74. The summary below lists the most important points as they relate to a trade show such as LDI, and to laser light show devices/projectors and displays/shows. (The information is NOT necessarily valid for medical, surveying, industrial, or some other laser types.)

FDA equipment (hardware) requirements

Lasers and laser products which will be exhibited in a functioning manner (i.e., they will be powered on) must be **certified** as per FDA requirements. Class 3B and 4 laser display devices/projectors also must be **varianced**.

For all laser products:

1. The manufacturer certifies that the laser product meets FDA requirements described in 21 CFR 1002 to 21 CFR 1040.11, and/or FDA Laser Notice 50. Additional information is available in FDA Publication 86-8260, "Compliance Guide for Laser Products."

2. The manufacturer then reports this product to FDA using Form 3632, "Guide for Preparing Product Reports on Lasers and Products Containing Lasers," commonly known as the "Laser Product Report."

3. After submitting the Laser Product Report, the manufacturer tests the product to confirm compliance. Upon confirmation, the manufacturer affixes a certification label to the laser product. This indicates to purchasers, regulators and others that the manufacturer has certified the product, and has reported the product to FDA.

For Class 3B and 4 laser display devices/projectors:

1. Follow step 1 above.

2. Follow step 2 above but do NOT follow step 3.

3. A "variance" is also required. (This gives "permission to vary" from FDA's requirement that only Class 1, 2 or 3R lasers be used for laser displays or shows.) All Class 3B or Class 4 laser devices/projectors intended for use in laser displays or shows must be manufactured and certified under the conditions of an approved FDA variance. Apply for the variance using FDA Form 3147, and submit this at the same time as the Laser Product Report in step 2 above.

4. FDA will review the documents. If FDA is satisfied, they will send a variance approval letter to the manufacturer. This letter specifies the certification label's verbatim text. The certification label shall be affixed onto the laser device/projector.

FDA display and show requirements

Laser displays and shows are also "demonstration laser products" under FDA regulations.

Displays/shows using Class 1, 2 and 3R do not require a variance.

Displays/shows using Class 3B and Class 4 laser devices/projectors must be presented only under the conditions of an approved FDA **variance**. Apply for a variance using FDA Form 3147.

> *Note that both the device/projector and the display/show (how the device/projector will be used) use Form 3147 to submit information to FDA. The difference is in item 7b, "Product for which a variance is requested". The product can be the device/projector (hardware), it can be the display/show (how it is used), or – for a device/projector manufacturer who also will be doing displays/shows – it can be both in the same variance application.*

FDA and LDI non-functional product requirements

Laser products which will be exhibited in a non-functional state (i.e., shall not be powered on at any time) may be exhibited 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."

Note that LDI is additionally requiring that **non-certified laser products must be disabled** so they cannot be activated at the trade show.

FDA importation requirements

All laser products coming from outside the United States must be **declared upon import**, and be accompanied during shipping by FDA Form 2877. Non-certified laser products imported into the U.S. under Declaration C2 in the form (temporary import bond for a trade show/demonstration) are allowed entry under the conditions of a bond. This is necessary to ensure they are not operated, and that they are promptly re-exported.