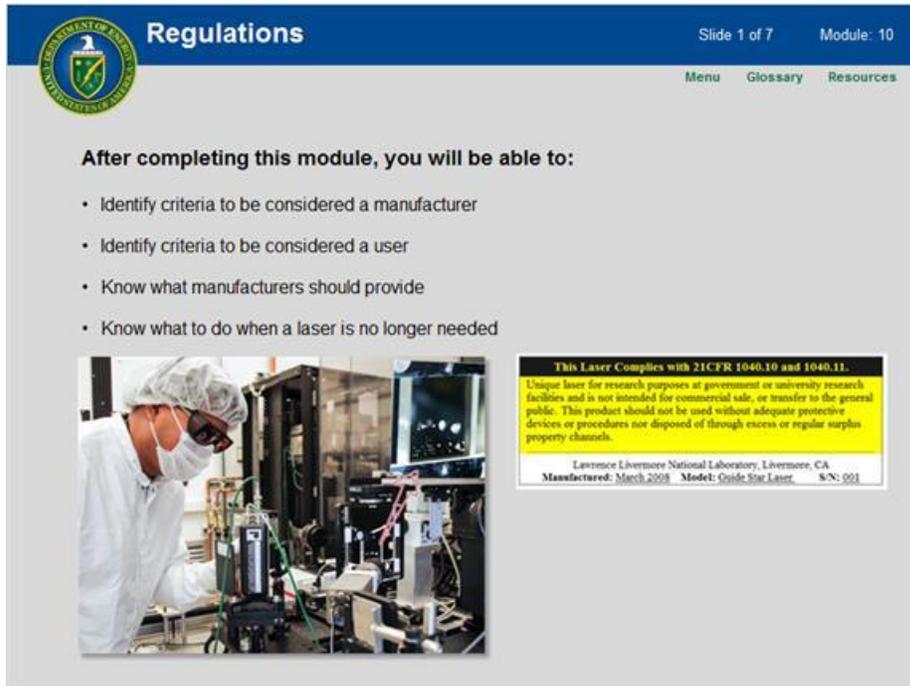


Slide 1 Regulations



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After completing this module, you will be able to:

- Identify criteria to be considered a manufacturer
- Identify criteria to be considered a user
- Know what manufacturers should provide
- Know what to do when a laser is no longer needed



This Laser Complies with 21CFR 1040.10 and 1040.11.
Unique laser for research purposes at government or university research facilities and is not intended for commercial sale, or transfer to the general public. This product should not be used without adequate protective devices or procedures nor disposed of through excess or regular surplus property channels.

Lawrence Livermore National Laboratory, Livermore, CA
Manufactured: March 2008 Model: Guide Star Laser S/N: 001

After completing this module, you will be able to identify the criteria by which you may be considered a laser manufacturer, identify the criteria by which you are considered a laser user, know what safety controls manufacturers should provide, and know what to do when a laser is no longer needed.

Slide 2 Regulations

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Laser Operation Categories

Manufacturer

User

Laser operation can fall into two regulatory categories: laser manufacturer and laser user. Those that manufacture laser products for others must comply with the regulations of the Federal Food and Drug Administration. The role of the FDA is to ensure that anyone buying or using a laser system in the U.S. is getting a safe product. In general, a laser needs to conform to basic electrical and laser safety standards. The majority of laser work at DOE labs does NOT fall under FDA regulations for manufacturers, but rather under the ANSI standards for laser users. This is because we use commercial certified laser products or we build lasers solely for use at DOE facilities.

Slide 3 Regulations



Regulations

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Laser Manufacturer

Must comply with government regulations when sending lasers offsite to a non-DOE site within the US.



Contact your LSO!

Sometimes a laser product is sent to a non-DOE site in the U.S. In this situation, you may be considered a manufacturer and, if so, must comply with FDA regulations. If you are building or modifying a laser and it will be shipped offsite, it is important to work with your LSO to address proper compliance with manufacturer requirements! Note that laser hazard classification (Class 1, 2, etc.) is not taken into consideration when determining if you are a manufacturer.

Slide 4 Regulations



Regulations

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Manufacturer Examples

Compliance with FDA regulations is required if *YOU* do any of the following and then send the laser product to a non-DOE facility in the US:

- Build or assemble the laser
- Modify a commercial laser
- Incorporate a commercial laser into a DOE-built laser system



Situations that require meeting FDA regulations for manufacturers include when DOE lab personnel do any of the following and then send the laser product to a non-DOE facility in the US: Assemble a laser from parts, modify a commercial laser product so that the output or safety characteristics have been changed, or embed or incorporate any laser into a DOE-built or designed laser system.

Slide 5 Regulations

Laser Worker Training test



Regulations

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Manufacturer Requirements



The collage illustrates various manufacturer requirements for Class 3B and Class 4 lasers. It includes a white laser unit with yellow 'CAUTION' and 'AVOID EXPOSURE' labels. A blue panel labeled 'TO USER' features an 'INTERLOCK' port (System Interlock) and a 'REF IN' port (Timing Stabilizer). A manufacturer's label from Continuum Electro-Optics, Inc. provides model, PIN, date, and serial information. A yellow 'CAUTION' label with a laser symbol and text is also shown. A 'LASER ON' key switch and a manual are also depicted.

If you are receiving a Class 3B or Class 4 laser from a manufacturer, or are yourself delivering a Class 3B or Class 4 laser to a non-DOE agency in the US, the following is required to be included as part of the laser product: key control, remote interlock, labels, protective housing, and a manual.

Slide 6 Regulations



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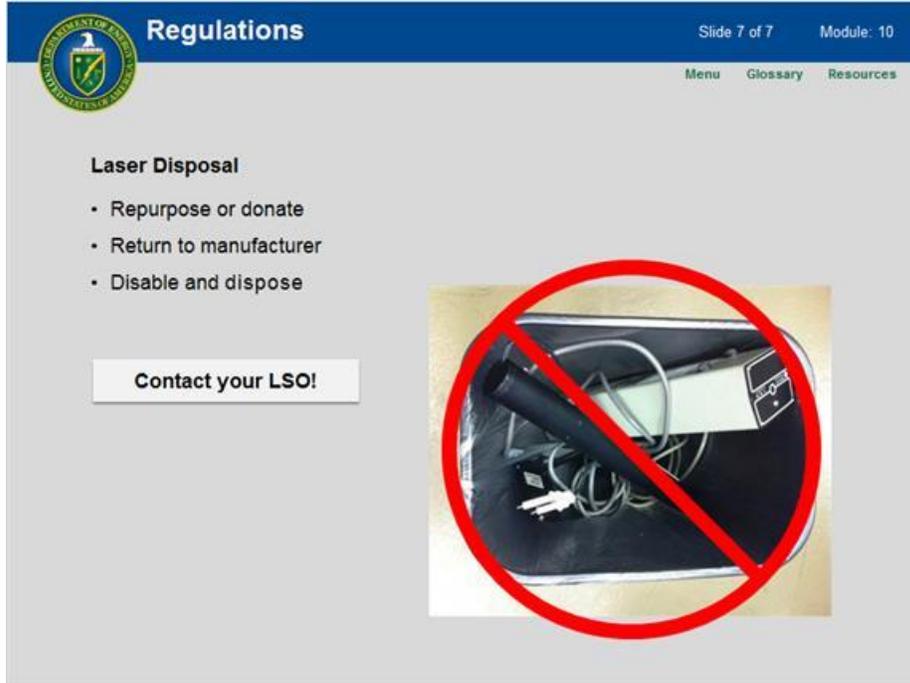
Laser User

Laser safety program at each DOE Facility is based on ANSI Standard Z136.1 and other applicable safety standards and regulations:

ANSI Z136.1	Safe Use of Lasers
ANSI Z136.2	Safe Use of Optical Fiber Communications Systems Utilizing Laser Diode and LED Sources
ANSI Z136.4	Recommended Practice for Laser Safety Measurements for Hazard Evaluations
ANSI Z136.6	Safe Use of Lasers Outdoors
ANSI Z136.7	Testing and Labeling of Laser Protective Equipment
ANSI Z136.8	Safe Use of Lasers in Research, Development or Testing
ANSI C7.2	Recommended Practices for Laser Beam Welding, Cutting, and Drilling
ANSI B11.21	Machine Tools Using lasers for Processing Materials
NFPA CODE 115	Laser Fire Safety
10 CFR 851	DOE Worker Safety and Health Program

Most DOE laser work falls under laser use and not laser manufacturing. Each DOE facility must provide a laser safety program to protect its workforce from laser hazards. This program includes requirements found in the American National Standards Institute document Z136.1: Safe Use of Lasers, and other applicable safety standards and regulations. By completing this web-based laser safety course, you have learned about many of the laser safety program components and requirements at your facility.

Slide 7 Regulations



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Laser Disposal

- Repurpose or donate
- Return to manufacturer
- Disable and dispose

Contact your LSO!



Lastly, if you are disposing of a laser that is no longer needed, you have several options.

Proper disposal methods for lasers include: repurposing or donating (you must comply with all applicable product safety standards, have the user manual, and ensure that the receiving organization has a viable laser safety program); returning to the original manufacturer; or disabling the laser and disposing of the parts according to the federal, state and local regulations. Contact your LSO when you have a laser that is no longer needed.