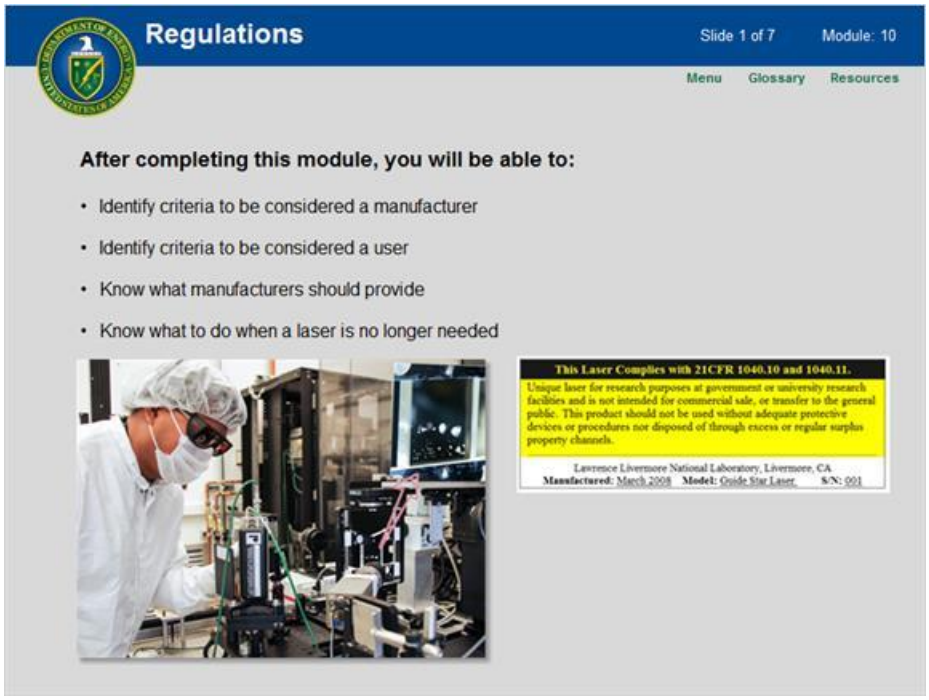
Slide 1 Regulations



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.

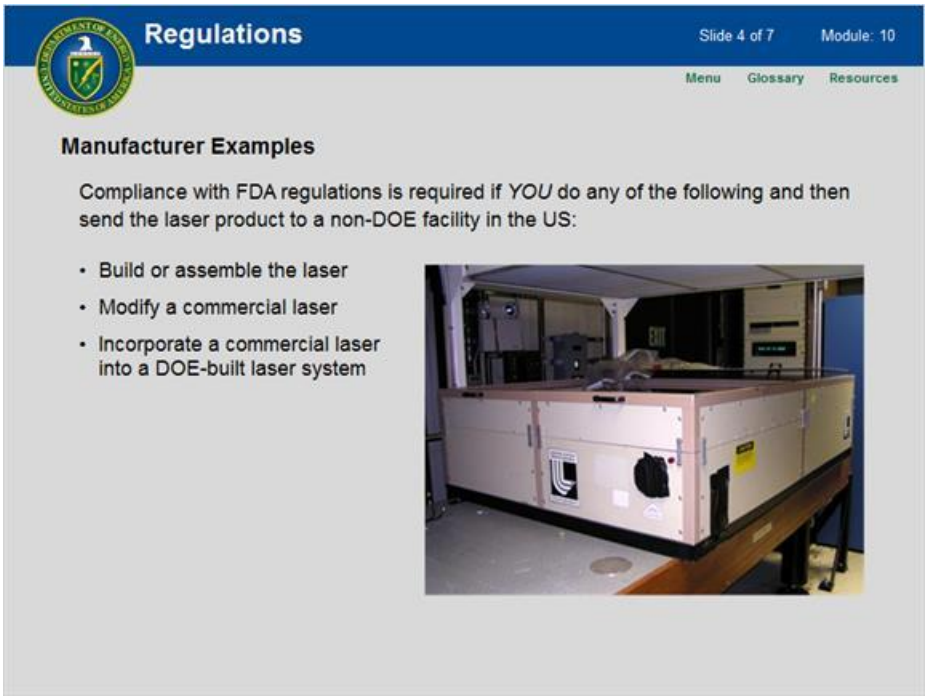
Slide 2 Regulations

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

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



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

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

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

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.