



Preco, Inc. 500 Laser Drive Somerset, Wisconsin 54025 USA
Toll-free: 800.775.2737 Phone: 715.247.3285 Fax: 715.247.5650 www.precoinc.com

LASER AND LASER SYSTEM SAFETY REQUIREMENTS

The following summarizes the USA laser safety requirements and their impact on laser system manufacturers and users. Sources for obtaining additional information, assistance or laser safety equipment are available by contacting Preco, Inc.

The first section describes the legal requirements of **product manufacturers** (OEMs or system integrators) who purchase or manufacture lasers and include them in products for sale. These regulations, published by the U.S. government, are mandatory for laser products.

The second section discusses standards for **laser users** in the USA who purchase lasers or products that contain lasers for use in their facilities. These requirements are adopted and enforced in the USA. At this time only a few individual states have their own regulations. User laser safety standards from ANSI and the guidelines published for OSHA inspectors are also described.

Laser Safety Standards for OEMs and System Integrators

The U.S. Federal Government has requirements for the manufacture or import of any products containing lasers that are sold in the United States. (Other countries may have their own laser safety requirements) These mandatory regulations are published and enforced by the FDA's Center for Devices and Radiological Health (CDRH). They specify product classification procedures, and they require a protective housing as well as engineering features and labels for each product class. The CDRH regulations also require manuals, test procedures, test and distribution records, and a certification report.

Product Classification – Laser products are classified in accordance with the laser energy that is accessible during normal operation. Energy that is accessible only during routine maintenance or during service will determine the need for interlocks, labels, shields, and protective eyewear, but it does not affect the product class.

The CDRH classification categories are Class I, IIa, II, IIIa, IIIb, and IV, in accordance with increasing hazard levels. In general, fully enclosed laser systems are Class I, while systems that allow access to the laser energy are Class IV (the other classes would not apply to industrial laser products since the output of the lasers in these products is Class IV). Laser energy is considered "accessible" by the safety standards if a finger, (or any body part) or a very thin, straight probe, can contact a beam, or if a single, flat, mirror like surface could reflect the beam of a Class IIIb or IV laser out of the product housing.

Product Housing - During normal operation, the housing of the end product that contains a laser must prevent access to laser energy, unless access to that energy is necessary for the product function. That is, systems should be Class I unless it is unreasonable to fully enclose the beams (e.g., due to loading and unloading procedures or the need to process different material configurations). Even if it is not feasible to prevent access to laser energy at the beam focus, the beam paths at other locations should be enclosed during operation.

In addition to metals, laser window materials, with the ability to withstand the laser's energy, are typically acceptable for a product enclosure. The material thickness and laser wavelength must be considered to provide mechanical stability as well as the ability to withstand reflections of the laser energy. Metals should be used for portions of the enclosure on which a collimated beam is likely to be incident, as well as for exposures of a focused beam within several feet of the beam focus. Reflected beams should be treated the same as the incident beam since most of the laser energy from many laser wavelengths can be reflected from bare aluminum or other metals even though they do not have polished surfaces.

If a product housing has panels or doors that can be opened during operation or routine maintenance by an operator and thus allow access to laser energy, interlocks are normally required. Such interlocks must be redundant or fail-safe, and they may be defeatable if specified requirements are met. If a panel or cover is to be removed only for service (e.g., repair by trained personnel), a warning label may be used for protection in lieu of an interlock. (While it is not stated in the CDRH regulations, the need for a tool to remove a non-interlocked cover is recommended.) The manual should clearly indicate if procedures are considered "service procedures" which are to be performed only by trained personnel.

Product Features - Once a system has been classified as Class I or Class IV by the manufacturer or system integrator, the required features can be determined. Other than the protective housing, labels, and (possibly) interlocks, no other safety features are needed for Class I systems.

Class IV lasers and systems must include the following features: a keyswitch to prevent unauthorized access (a computer password could be acceptable); an indicator (typically a light) to provide a warning of laser emission in advance of and during the emission time; a beam shutter to block the beam; a connector to facilitate the remote interlocking of room/cabinet doors by the customer; and the requirement for the operator to manually restart the product after a line voltage interruption.

Viewing windows, viewing optics, and protective eyewear must prevent access above Class I. That is not normally a problem for CO₂ laser energy since the 10.6 μm energy is absorbed by polycarbonate, acrylic, and most other plastic and glass window materials.

Other CDRH Requirements - A certification report must be filed by the OEM or system integrator with the CDRH before a product is delivered to customers or imported into the USA. The report must provide a description of the product that discusses how it complies with the regulations. Copies of the test procedure, manuals, labels, and sales literature will also be part of that report.

The test procedure must verify operation of each required laser safety feature, verify that there is no unnecessary access to laser energy, and verify the specified labels are affixed at the proper locations. Measurements of output power/energy levels are not normally required. The system manuals must include warnings and precautions for operation, maintenance, and service procedures.

Warning logotypes and aperture labels are required for Class IV systems. All products need warning labels for removable portions of the housings that are not interlocked, and an identification/certification label is necessary. Wording for these labels is provided in the regulations. If a warning logotype (label) is required on the product, a copy must also appear on the sales literature.

Laser Safety Standards for End Users

The above material describes the requirements on OEMs and system integrators. This section discusses the requirements that apply to companies who purchase a Class IV laser, a Class IV system or a Class I system that contains a Class IV laser for use in their facility. Recommendations for users are provided in the ANSI laser safety standard as discussed below. Most states do not have legal regulations on safety for laser installations. Please note, however, that OSHA inspectors can cite facilities as part of their overall inspections to provide a safe workplace.

Class I installations - Facilities with Class I systems are exempt from most of the laser safety control measures, unless there is access to Class IV laser energy during maintenance or service.

Class IV installations - Control measures for Class IV laser system include enclosing beam paths where feasible, establishing controlled access areas for trained personnel only, posting of warning signs, training and medical testing of operators, use of standard operating procedures (SOPs), protective eyewear and clothing, and protective barriers. These and other items are described in the ANSI laser safety standard that is discussed below. Class IV installations require that a trained Laser Safety Officer (LSO) be appointed to evaluate potential hazards and to ensure that appropriate control measures are implemented.

Laser Hazards - There are two main concerns when evaluating hazards from lasers. The collimated beam direct from the laser head or a mirror (without any focusing optics) contains sufficient heat energy to damage eyes, skin, or flammable materials for a considerable distance (100s of feet or more from the source). The focused beam contains much higher power density for marking, cutting, welding, etc., but it is present only in a very localized area near the beam focus. Past the focus, the beam pattern expands significantly, and there is a distance beyond which the power spreads over an area that is so large that the laser beam is no longer hazardous.

ANSI Standard - Most user laser safety documents are based on the ANSI Z136 series of standards, particularly ANSI Z136.1 Standard for the Safe Use of Lasers. That document includes: a discussion of laser hazard evaluation with limits for Maximum Permissible Exposures (MPEs); administrative, engineering, and procedural control measures; requirements for laser safety officers (LSOs); a discussion of non-beam hazards; and outlines for training and medical surveillance programs.

U.S. and State Requirements - In the USA user safety regulations are generally enforced by OSHA. Enforcement is primarily based on the ANSI Z136.1 safety standard. Some states have active laser safety programs and/or require registration of lasers and laser systems. Most of those state user regulations exempt facilities with Class I systems, but place registration and control requirements on facilities with Class IV systems or with Class I systems that allow access to Class IV energy during maintenance or service. States that require registration may charge annual registration fees.

OSHA - The Occupational Safety & Health Administration has few specific laser safety requirements. However, if they inspect a facility, the inspectors follow published guidelines (OSHA Instruction PUB 8-1.7 Guidelines for Laser Safety and Hazard Assessment) that are based on an earlier (1986) ANSI Z136.1 standard or they will use the General Duty Clause.

References and Sources

CDRH - Center for Devices and Radiological Health - An agency within the U.S. Food and Drug Administration which publishes and enforces legal requirements on laser product manufacturers. For copies of the CDRH regulations, contact: CDRH (HFZ-312), 2098 Gaither Road, Rockville, MD 20850, Telephone (301) 594-4654.

ANSI/OSHA - ANSI (American National Standards Institute) is a U.S. organization that publishes standards for laser users. Their laser safety standards are not laws, but they form the basis for state and OSHA requirements for the use of lasers. For copies contact ANSI in New York at (212) 642-4900 or the Laser Institute of America, at Telephone (407) 380-1553 or (800) 345-2737, Fax (407) 380-5588.

Assistance with Laser Safety Information, Training and Products

Please contact Preco, Inc., 500 Laser Drive, Somerset, WI, 54025 (phone 715-247-3285) for additional information and resources on laser safety, laser safety products and training.