

# LASER SAFETY REQUIREMENTS

The following summarizes laser safety requirements and their impact on integrators and users of Synrad CO<sub>2</sub> lasers, and it provides sources for obtaining additional information and assistance.

The first section describes the legal requirements on **product manufacturers** (OEMs and system integrators) who purchase Synrad CO<sub>2</sub> lasers and include them in a product for resale. These regulations, published by the U.S. government, are mandatory for laser products.

The second section discusses standards for **laser users** in the U.S. who purchase Synrad CO<sub>2</sub> lasers or products that contain Synrad lasers for use in their facilities. These requirements are adopted by the individual states, and at this time only a few have such regulations. User laser safety standards from ANSI and the guidelines published for OSHA inspectors are also described.

The third section includes **references** and sources for documents and assistance. Information on **international** laser safety requirements that apply outside of the United States is also available upon request.

## Laser Safety Standards for OEMs/System Integrators

The U.S. Federal Government has requirements that impact the manufacture or import of any products containing lasers that are sold in the United States. 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.

The regulations exempt lasers shipped to Original Equipment Manufacturers (OEMs) for resale (requirements described herein for OEMs apply equally to System Integrators). However, to help reduce the effort required by OEMs and System Integrators in certifying their end products, the Synrad line includes "keyswitch" versions of CO<sub>2</sub> lasers that have been certified to the CDRH regulations. Please note that end-use products sold to users must still be certified, even if they include a certified Synrad laser.

**Product Classification** - 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 would 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 CO<sub>2</sub> laser energy are Class IV (the other classes would not apply for these products since the output of Synrad lasers is Class IV). CO<sub>2</sub> laser energy is considered "accessible" by the safety standards if a finger or a very thin, straight probe can contact a beam.

**Product Housing** - During normal operation, the housing of the end product that contains a Synrad 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 usually must be enclosed during operation.

On systems with marking heads, for example, the beam tube supplied must be installed to seal the beam path between the laser head and the marking head. Also, if part handling precludes full enclosure of the marking area, blockage of laser energy beyond the part and other shields should be used to the extent feasible.

In addition to sheet metals, polycarbonate and acrylic (eg., Lexan and Plexiglas) and most other plastic materials are typically acceptable for a product enclosure. The material thickness must be selected to provide mechanical stability as well as the ability to withstand diffuse reflections of the CO<sub>2</sub> 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 at the CO<sub>2</sub> laser wavelength most of the laser energy can be reflected from bare aluminum or other metals even though they do not have polished surfaces. Plastic curtains can be used if the mechanical characteristics are adequate and if a hazard evaluation shows that the incident energy under the worst case conditions would not cause the material to degrade.

If a product housing has panels or doors that are openable 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 a procedure is considered "service" to be performed only by trained personnel.

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

Class IV lasers and systems must include the following accessible features: a keyswitch to prevent unauthorized access (a computer password would 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. Most Synrad lasers can be ordered with these features ("keyswitch" models); however, the system housing may require additional interlocks and labels.

Viewing windows, microscopes, and protective eyewear must prevent access above Class I. That is not normally a problem for CO<sub>2</sub> 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 U.S. 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 should be part of that report. A reference to the report that Synrad has provided to the CDRH on a certified laser may reduce the documentation that is needed.

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 specified. Wording for these labels is provided in the regulations. If a warning logotype is required on the product, it must also appear on the sales literature.

## **Laser Safety Standards for End Users**

The above materials describes the requirements on OEMs and system integrators. This section discusses the requirements that apply to companies who purchase a Synrad Class IV laser or a Class I or Class IV system that contains a Synrad laser for use in their facility. Recommendations for users are provided in the ANSI laser safety standard as discussed below, but in most states there are no legal regulations on laser safety installations. Please note, however, that OSHA inspectors can be called in and can cite facilities as part of their overall regulations 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 energy during maintenance or service.

**Class IV installations** - Control measures for Class IV 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 the hazard from a CO<sub>2</sub> laser. 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, or welding, 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. State Requirements** - In the U.S., user safety regulations are up to the individual states, and they are primarily based on the ANSI Z136.1 safety standard. Those states with active laser safety control programs (and the telephone numbers for contact) are: Arizona (602) 255-4845, Florida (904) 487-1004, Illinois (217) 785-9975, Massachusetts (617) 727-6214, New York State (718) 797-7641, and Texas (512) 834-6688. Most of those state user regulations exempt facilities with Class I systems, but they 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 usually charge annual registration fees.

**OSHA** - The Occupational Safety & Health Administration does not have specific laser safety requirements. However, if they are called into 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.

## **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, Fax (407) 380-5588.

## **Assistance with Requirements**

For assistance with the CDRH and international laser safety requirements or for a copy of the Laser Safety Update newsletter, OEMs and system integrators can contact Weiner Associates, 544-23rd Street, Manhattan Beach, CA 90266; Telephone (310) 545-1190, Fax (310) 546-7490, E-mail Bob@WeinerAssociates.com.

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