## OSHA / FDA / ANSI Requirements

## <u>OSHA</u>

Federal OSHA has no specific requirement for Laser "Interlocks", but they require companies falling under their jurisdiction to follow industry standard "best practices" for laser safety. They will enforce this through the "General Duty Clause" of 29 CFR 1910. State OSHA may or may not specifically address Laser Interlocks, it depends on the state.

Q: What document do they reference for enforcement?

A: They look at the guidelines set forth in ANSI Z136.1-2014 and related specific ANSI Z136 subchapters. If they find a problem with a laser that does not appear to meet normal safety codes, they will refer to the FDA enforcement codes under 21 CFR 1040

## **FDA**

The U.S. Food & Drug Administration's Center for Devices and Radiological Health (CDRH) mandates are released as federal code in Title 21 of the Code of Federal Regulations (21CFR). The subsections of this title list the required elements to which manufacturers must comply if they are offering a product for sale in the United States.

A summary of 21CFR chapters related to laser products:

**21CFR1000-1005** - Broad scope list of devices regulated the records and reports that must be produced and retained by a manufacturer, and the import / export requirements.

21CFR1010 - General performance standards, certifications and variances.

**21CFR1040.10** - Performance standards for manufacture of laser products. This is where one will find the information pertaining to the laser housing interlocks, remote electrical interlocks, labeling, and power classification. In addition to providing the required information for manufacturers, this standard is a useful reference for the end user in situations where the user is building their own class 1 enclosure around class 3B or class 4 laser systems.

**21CFR1040.11** - Performance standards for specific use laser products. Medical, survey, leveling, alignment, and demonstration laser products must meet criteria listed in this chapter as well as all criteria listed in 21CFR1040.10

# The chapters above are collectively known by the acronym FLPPS, which stands for <u>F</u>ederal <u>Laser Product Performance Standards</u>.

#### FLPPS requirements specific to the remote laser interlock:

Every commercial Class 3b and Class 4 laser sold in the United States shall include a remote electrical interlock connection. The connection will have two terminals that need to be electrically shorted to each other. If the circuit opens, the laser will not emit a laser radiation hazard above the MPE threshold. The manufacturer is given leeway in choosing the method to be employed to accomplish this task. The manufacturer may use an electro-mechanical shutter or electro-optic modulator behind the laser housing, or they may choose to electrically shut down the power supply to the laser. The only real constraint is the fact that the device must be fail-safe and the voltage used for this remote interlock circuit shall be less than 130 volts RMS. Although it is unlikely that a modern manufacturer would use this voltage, one needs to be aware of the potential shock hazard that may be present at this connector. If you are unsure of the potential on a particular laser, consult the manufacturer. The fail safe requirement is an important feature. When a safety circuit has tripped the laser off, the laser must remain off until it has been restarted by an operator even if the safety circuit trip was momentary.

#### Lasers or laser systems manufactured for "in-house" use:

Every effort should be made to meet the intent of FLPPS when a facility is constructing a laser or laser enclosure for its own use. FLPPS is intended for the safety of the end user. With the increased availability of high power laser diodes, any person with a basic understanding of electronics can construct class 3B or class 4 lasers without any knowledge of laser physics or laser safety. This places an increased emphasis on the laser safety officer to monitor and enforce laser safety issues.

A facility that fully adopts the ANSI Z136.1 standard is effectively adopting FLPPS. A majority of the FLPPS requirements are repeated (almost verbatim) in section 4.3 of the ANSI Z136.1 standard. This repeat of the FLPPS requirements within the ANSI standard provides beneficial safety information, but can lead to confusion when trying to implement end user engineered safety controls. ANSI Z136.1-2014 sections 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5.1, 4.3.7, 4.3.8, and 4.3.14 are FLPPS specifications that are expected to already exist as a performance feature in a commercially certified product. These items should be verified to exist upon receipt of a laser and should be checked periodically to verify their functionality. If the laser or laser system is built inhouse, full compliance is an expectation.

#### End user interlocking requirements:

We noted earlier that there was a legal mandate in FLPPS to provide an external interlock on all commercial class 3B and class 4 lasers. It is somewhat interesting that there is not a federal legal mandate for the end client to actually use it. In fact, the interlock connector will most likely come from the manufacturer in an electrically shorted state. This is unfortunate because the lasers are often placed into service without consideration of a proper interlock system configuration.

Q: Why isn't use of the remote interlock mandated?

A: There are thousands of possible laser applications. Many applications would not require the connection to an external interlock control system. Instead of mandating the use of the interlock, the ANSI Z136 series of standards provides several methods of instituting an engineered laser safety program.

## **ANSI Z136**

ANSI Z136.1 is the American National Standard for Safe Use of Lasers. Z136.1 is the parent document referenced by all other Z136 standards. The standards are developed by the ANSI Accredited Standards Committee (ASC) Z136, a collaboration of the leading experts in the field, and are considered to be the authoritative standard in the United States for safe laser operation and practices. Although the standards are not "law," compliance with the standard is often mandated by federal entities.\*

\* 10CFR851.23(11) requires all Dept. of Energy contractors to comply with ANSI Z136.1 see: https://www.govinfo.gov/app/details/CFR-2012-title10-vol4/CFR-2012-title10-vol4-part851

The ANSI Z136.1-2014 standard is a copyrighted publication available for purchase from several commercial sources. The ANSI Z136 secretariat and publisher is the Laser Institute of America (LIA), whose web address is: <u>http://www.laserinstitute.org/</u>