

ANSI Z136.3, 2018

Sections Relevant to Biomedical Engineering and Service:

Professional Medical Education Assn
The Laser Training Institute
www.LaserTraining.org
August 2018

DISCLAIMER: Please note that this is NOT a reproduction of the Z136.3 standards, and each user will need to obtain a copy for their facility. Each facility only needs one copy to use as a reference. Each individual user or operator does NOT require a copy themselves. These standards are used by the facility Laser Safety Officer as a reference when developing written policies for their own formal laser safety program. This is an editorial summarization and clarification of these standards, rather than a reproduction of them. You still need a copy.

ANSI Z136.3 2018 LASER SAFETY STANDARDS

Safe Use of Lasers in Health Care Facilities

“Cliff Notes” version of section summaries- Here as applicable to Service / Biomed

To purchase these 136.3 Standards , contact us at 800-342-2704, or contact the LIA directly. They are available at the standard pricing plus shipping. Not every individual requires a standard. One standard is used per facility as a reference for administering their safety program, not as a day to day working document for staff or operators.

The following is a synopsis and summary of the 2018 ANSI Z136.3 guidelines for the safe use of lasers in health care facilities as it applies to servicing laser systems. The content included here is in the form of **editorial comment and synopsis** and does not purport to review or reproduce this ANSI document in any detail. It summarizes the service related issues in a nutshell.

1.4.2 - ADDED a section under Third Party Use that discusses intake testing at levels exceeding that of biomed normal leakage checks, and to include condition of laser and all accessories, credentials of the technician and provider, documentation forms and staffing assignments for personnel while in room.

1.4.3 Under Diagnostic Health Care Laser Systems. Clarifies that the LSO is not responsible for controlling hazards of embedded laser systems, and instead manufacturers and service agents assume full responsibility for controlling the hazards of these embedded lasers.

4.2.1 Policies & Procedures. Adds wording that the LSO shall REQUIRE approved written procedures on maintenance, which now INCLUDES service information for any Class 3B or Class 4 laser. This section also states that it is the manufacturer or service agent that assumes responsibility for safety when doing service (not the LSO).

4.2.2 Manufacturer's Procedures - Added an entire section that clarifies the requirement of CMS (Medicare-Medicaid) Services that facility biomed engineers and service agents are required to obtain written service, calibration and schedule of maintenance instructions from the manufacturer and that Federal law requires these procedures to be made available by the mfg to anyone upon request at the reasonable cost of reproduction of the service manuals, and it references the actual Federal Law at

(21CFR 1040.10 H2II, and 21CFR 1040.11 A2). This is an important addition to the ANSI standards because it now draws this Federal Law to the attention of hospital administrators and LSO's that they are supposed to have this service information and that manufacturers are required by law to provide it. Previously this was more vague because not all medical laser owners were actually aware of the legal requirement.

NOTE: An explanation of the mechanics of requesting these service manuals, and/or having it enforced by the CDRH of the FDA, is explained on the www.LaserTraining.org website at the specific URL of: <https://www.lasertraining.org/CFRs-Service.html>.

4.2.4 - Maintenance & Service - Eliminates the requirement that servicing of the lasers shall follow the requirements of ANSI 136.1 (measurements and calculations to determine the NHZ). ADDS wording that the service shall be only be performed by technicians "certified" by the manufacturer, **OR** have "other" specific qualifications for medical devices. (Note - those engineers attending the laser repair training of Professional Medical Education Assn, or having attained an NCLC Laser Certification of "Certified Laser Repair Technician", also show specific qualifications for laser service to meet this requirement. Having both is better).

4.3.4 Service and Repair of Laser Systems (all classes)

Laser Maintenance & Repair: The LSO will determine whether any changes in the control measures are required after servicing of the equipment. Under ordinary circumstances no change will be required -- if the laser was simply repaired or serviced back to its original configuration and operation. Service calls are typically accompanied by a service report and acceptance back into service, which should satisfy the documentation requirements to show that no change in control measures are required. If the laser must be temporarily modified or altered (sometimes this is done to make a laser functional while waiting on a special part or repair), then the LSO should confer with the service technician to determine what, if any, changes in control measures may be required to ensure the safe operation of the unit.

4.3.5 Equipment Modifications

Generally discusses that modifications of the laser (including mfg recommended upgrades such as software) may require changes in safe operating procedures or "recertification" by the FDA. LSO shall ensure that any changes that affect "labeled claims" shall be accompanied by a hazard evaluation. (changing paint color on panels, or replacing worn optics with the new of the same type would not change its labeled claims)

***Note** - as discussed previously - the "Certification" of the equipment is between the Mfg and the FDA and normally is only done once at the time of Mfg. It does "Certify" it as to its Laser Class, but it is also "Certified" for approval by the FDA based upon the configuration and operation as submitted to the FDA initially. If that configuration or operation would substantially change (which does not happen when you buy used equipment), then it might have to be "recertified" by the FDA. That's up to the Mfg.

4.4.1 Nominal Hazard Zone (NHZ) - Adds wording at the end that discusses the fact that service personnel involved with alignments and service should recognize that service (i.e. covers removed or looking more closely at the outputs) may increase the NHZ, etc..

4.5.1.1 Operation Alignment and Calibration

You're required to check the alignment of the aiming beam with the surgical laser on systems like with a CO2 laser where they can separate. You're also required to "Verify" the power meter and calibration.

4.5.1.2 Safety During Alignment Procedures.

This section talks about the hazards of alignments, requires that the manufacturer provide detailed alignment methods (3B & 4) and that the LSO approve them.

4.5.1.3 Temporary Laser Controlled Area (All Classes)

This section does require that a temporary laser controlled area be established whenever (or training, or demos) is performed, and that all personnel including the service technicians will adhere to control measures (eyeglasses, etc.) and post warning signs. This provision makes it inappropriate to perform laser service in open areas where personnel come wandering by. This also applies to circumstances such as training labs, demonstrations, etc. Discusses use of the "NOTICE" sign.

4.5.2 Service Personnel.

This section requires that all service technicians shall have documented "education and training commensurate with the class of the . . . laser" on which they are working. Refers to section 5 for training

4.7.1 Area Warning Signs and Equipment Labels.

- Laser warning signs must be conspicuously posted to warn personnel of laser use. They should not be left posted on a permanent basis, since personnel will become accustomed to seeing the signs all the time and become complacent when the laser is actually in use. They shall be covered or removed when the laser is not in use.

4.7.2 Signal Words

Discusses the key words of "Danger", "Warning", and "Caution" in laser signs.

* **Change** - CHANGE IN LASER SIGNS SIGNAL WORDS - "Danger" will be used for Class 4 lasers with high kilowatt output powers or energies when used as open beams. "Warning" will be used for most Class 4 and all Class 3b lasers. "Caution" shall be used for Class 2 lasers that exceed the MPE (not many).

4.7.4 Temporary Laser Controlled Area Signs (3B and 4)

This discusses the blue "Notice" sign for service, and that it "shall" be used, but the appropriate "Danger" warning sign is still required in the room - so most service people just use the "Danger" sign to begin with.

5.2 Training

General discussion that says ALL who work in the presence of 3b or 4 lasers shall have laser safety training, and they specifically identify technical support staff. This is general laser safety, not technical training.

7.2 Electric Hazards

Says that personnel should remain diligent and take appropriate measures to prevent potential electrical-related hazards if encountered:

This section on Electric Controls point out seven common potential hazards in HCF.

Electrical hazards in this section are really not unique to lasers, and can occur with any other type of hospital/medical electrical/electronic equipment.

7.7 Electromagnetic Interference and Susceptibility

This section discusses possible interference with devices such as pacemakers, or interference from electrosurgical Units. Electromagnetic Interference (EMI) safety hazards are normally designated in the manufacturer's labeling. If they are not, then they shall be established by the LSO or consultant.

In the author's experience, this has not been a common practical problem for medical laser systems, but is certainly possible. It is a far outlier. One of the reasons that laser is used in cardiac procedures such as pacemaker lead extraction, is that the laser does NOT interfere with either the pacemaker nor the EKG.

7.10 Laser Gases and Dyes.

This section points out that some of the gases and dyes used with many lasers are hazardous substances and refers back to ANSI 136.1.

Author's note - this is not a practical problem for laser users, but of some consideration in manufacturing or servicing of the equipment in some situations.

9.1 Beam Shape, Alignment and Testing

Says lasers *should* not be used if there is a "faulty" aiming system - alignment or beam shape.

Says that I.R. lasers require verification of the proper alignment with the aiming beam prior to use, and that beam mode and shape are correct.

v. August 2018.

LASER TRAINING INFORMATION:

Professional Medical Education Association, inc - est. 1978

"The Laser Training Institute"

3142 Broadway, Suite 201

Grove City, OH 43123

www.LaserTraining.org, Email: Info@LaserTraining.org

Tel: 800.342.2704, 614.883.1739 Fax: 305.946.0232.

Medical Laser Safety Officers (MLSO) should consider attending the 2 day MLSO seminars of our Laser Training Institute for more complete information. www.LaserTraining.org. Those that have attended our LSO courses since 2018 are welcome to a more complete review of these new ANSI standards, available for free by emailing us at info@LaserTraining.org. You'll still need to buy a set of the Standards however. Attendees at any of our current Laser Safety Officer seminars will also receive a copy of the full "Cliff Notes" synopsis of these standards, and have the option to buy a set of standards during the seminar. In addition you'll be able to take an NCLC Laser Certification exam for the MLSO at the end of the seminar at no additional charge. Go to www.LaserTraining.org and check the seminars page.

Those interested in Laser Repair training should review the page on our website at

https://www.lasertraining.org/Laser_Repair.html.

LASER CERTIFICATION INFORMATION:

National Council on Laser Certification, inc - est. 2000

3142 Broadway, Ste 200

Grove City, OH 43123

www.LaserCertification.org, Email: Info@LaserCertification.org

Tel: 305.407.8901, Fax: 305.946.0232

Training is a separate process from Certification. The NCLC manages laser certifications, not training. Among the other Laser Certifications available for Laser Operators, the NCLC offers the original MLSO Certification for Medical Laser Safety Officers. An MLSO Certification is now recommended by the ANSI standards.

Certification is also available for Certified Laser Repair Technicians (CLRT), which helps establish credentials in support of the CMS services requirement for "qualified" service personnel.

www.LaserCertification.org