

ANSI Z136.3
SAFE USE OF LASERS IN HEALTH CARE FACILITIES
Changes only - from 2011 to 2018

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A Synopsis of the sections and changes in the 2018 standards from the previous 2011 version.

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

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. This "Cliff Notes" summary will help you to better read and understand the standards once you acquire them.

ANSI Z136.3 SAFE USE OF LASERS IN HEALTH CARE FACILITIES

The following is a synopsis and summary of the 2018 ANSI Z136.3 guidelines for the safe use of lasers in health care facilities. The 2018 version is available for distribution as of August 2018, per the LIA email announcements. Readers are encouraged to purchase current copies of the ANSI standards (Z136.1 and Z136.3). Hospitals need a copy of both sets of standards, but from a practical point of view follow primarily the Z136.3. Any facility involved with health care lasers (including aesthetic laser spas and salons) require a copy of these standards.

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 it in a nutshell. This highlights some of the points which the author judges appropriate, and discusses the pertinent changes from its previous 2011 edition. The interpretation of the ANSI standards is based on the professional opinion and experiences of the author, Gregory Absten, from over 40 years experience in the medical laser field, who also sits on this ANSI committee, and is not represented as formally portraying the opinions (if any) of the ANSI committee. ANSI section and paragraph numbers are noted in parenthesis for reference when

appropriate. You MUST have a copy of the pertinent ANSI standards if you are a health care facility utilizing lasers. This would include Hospitals, medical offices, clinics and outpatient surgery facilities, dental offices, veterinarian offices, medi-spas or laser hair removal clinics, and Low Level Light Therapy (LLLT - Now called PhotoBiomodulation or PBM) clinics.

It is important to note the nomenclature used in the ANSI document. Where the word **SHOULD** is used, the standard is recommended but not required to be in compliance with the standards. Where the word **SHALL** is used, adherence to the standard is required.

In this review we have highlighted changes from the previous versions of Z136.3 by indicating a "*CHANGE" in bold letters outside the margin, and/or *italicized* the wording which has changed.

Several abbreviations are useful to note up front. These include:

- HCLS - Health Care Laser System
- HCF - Health Care Facility
- LSO - Laser Safety Officer
- DLSO - Deputy Laser Safety Officer
- LEV - Local Exhaust Ventilation (i.e. smoke evacuator)
- LSS - Laser Safety Specialist (same as the LSCC)
- LSSC - Laser Safety Site Contact
- MPE - Maximum Permissible Exposure
- NHZ - Nominal Hazard Zone
- OSHA - Occupational Safety and Health Administration
- PAC - Plume and Airborne Contaminants
- SOP - Standard Operating Procedure(s)

ANSI Z136.3 - 2018:

American National Standard for the Safe Use of Lasers in Health Care Facilities.

Summary of Changes / Additions

WHAT HAS BEEN CHANGED? Short Version:

- LSO training recommendations and National LSO Certification recommendation.

- LSO, DLSO, LSSC duties & job descriptions moved to "Normative" Appendix A
- Laser Signs changed - but 2005 and later versions grandfathered
- New Laser Class of 1C
- Confirmation that biomedical engineers and service agents are entitled to complete service information and manuals as required by CMS requirements for the providers, and by Federal Law for the manufacturers
- Medical Surveillance verbiage (eye exams) replaced by Laser "Accidents"
- Further clarification that Control Measures based on Risk Analysis
- others.....

Before we summarize each of the sections of the 2018 ANSI, let's first just list some of the these changes from 2011 so that those making the transition from 2011 to 2018 versions may distill this more easily. These will be expanded upon some in the summary. Here we've listed only changes in real content, and not included minor changes in wording or omissions of non-essential items. Remember that you still need to buy a copy of the standards. This will just help you read them more easily.

Section 1 Changes:

1.1 - Adds clarification that standard applies to all wavelengths between 180nm and 1000um.

1.1 - Adds that the principal laser hazard control rests with the user

1.1 - Eliminates discussion of the Federal Laser Product Performance Standard (FLPPS) under the CFR's. (but those CFR's still apply to manufacturers)

1.1 - Eliminates the statement that nothing in the standards is intended to restrict or limit in any way the use of the laser intentionally administered ... by or under the direction of qualified licensed professionals (However this was moved over to section 4)

1.1 - Eliminates statement that control measures are intended to give reasonable assurances of laser safety to patient, public, employer and personnel (However this was moved over to section 4)

1.2.1 - Adds the new Class 1C Laser Classification - use such as home laser hair removal where the laser must be in contact with the target and prevents leakage in excess of class 1 levels. No controls, training nor LSO required.

1.2.3 - Adds the Assoc of Surgical Technologists (AST) to the list of non-governmental controls that reference ANSI standards and may have their own recommended guidelines.

1.3 - LSO and other personnel - expands LSO authority to suspend, restrict, or terminate the operation of a laser system if he/she deems that laser hazard controls are inadequate. Clarifies that the LSO may be a part time position.

1.3 - Introduces the idea now that the LSO may be a part-time position when the workload does not merit a full time position.

1.3 - Introduces Laser Safety Specialist (LSS) term to the LSO, DLSO and LSSC. (LSS is same as LSSC)

1.3 - Suggested responsibilities for the LSO and the others are now moved to the "Normative" Appendix A.

1.3.2.10 - Added a section on RECORDS just clarifying that the LSO must keep records required by applicable governmental regulations, and other records documenting maintenance of the safety program such as training records, SOP's approvals, audits, etc.

1.4 Environment - added clarification of three types of environments to consider when creating hazard controls - between unrestricted locations, restricted from public access, and controlled locations where access is tightly controlled (i.e. surgery).

1.4.2 Third Party Laser Use, paragraph 4 rewording that says the personnel in the room shall have adequate safety controls training on the laser and accessories (instead of saying training to operate the equipment in the absence of the third party employee) in order to ensure a laser safe environment.

- 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.

Section 2 Changes:

- Added definition for Laser Safety Specialist (same as LSSC)

Section 3 Changes:

3.1 - Adds remarks about the new 1C hazard class maintains a class 1 risk to eyes when used as intended on skin.

Section 4 Changes:

4.1.1 - Clarified use in RESEARCH - for non-FDA approved lasers used in research settings, the LSO shall devise control measures that comply with 136.1 requirements.

4.2.1 - Policies & Procedures - adds requirement for service policies & procedures: The LSO shall require approved written operating and maintenance (*including service*) P&Ps for Class 3B and Class 4 HCLSs.

- Added back to this section the wording they removed from section 1 - The guidelines contained herein are not intended to restrict or limit in any way the use of laser radiation, of any type, which may be intentionally administered to an individual for health care applications including diagnostic, aesthetic, preventative, therapeutic, or medical/dental research purposes, by or under the direction of qualified licensed professionals engaged in health care. - **In other words, medical and surgical clinical judgment still pre-empts the ANSI laser safety standards.**

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).

4.2.5 - Expands on the issue of using a dedicated laser operator, and what that actually means

4.3.2 - Accessory Equipment - ADDED wording regarding mechanical safety shutters on scopes, that it's proper functioning should be verified prior to each procedure.

4.3.5 - Equipment Modifications - simplified and reduced verbiage in this section

4.4.1 - NHZ. Adds wording that clarifies that the NHZ may be smaller than the entire room in situations such as endoscopic use, or when the lasers are outside the range of retinal hazards.

4.4.3 - Optical probes & fibers (i.e. hot tips) - expands on the fact that use of these tips may reduce or otherwise limit the NHZ for these types of probes.

4.5.1.3 - Adds a section on the Temporary Laser Controlled Area (TLCA). This would involve situations such as educational activities, service, demonstrations, etc. Just simplistically says that the TLCA shall be devised for safety of all involved. This is essentially just rewording and doesn't really change things from the previous versions of ANSI.

4.6.4 - ELIMINATED wording in personal protective equipment about shields, helmets and hearing protection (which is mostly industrial) but retained some wording on skin protection.

4.7.2 - 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).

Section 5 Changes:

5.1 Administration

- paragraph 2 - Expands on the Laser Safety Committee and "should" meet at least quarterly, and the entire safety program "should" be reviewed at least annually.

5.2.1 - LSO Preparation and Training. ADDED several requirements, but "should" include formal Laser Safety Training, formal Laser Safety Officer Training, Certification as a Medical Laser Safety Officer, and previous laser operator work experience.

NOTE - This type of training is the way that the LSO training of our Laser Training Institute (www.LaserTraining.org) has been structured for many years. 1st Day for laser safety and laser operators (to include the LSO), 2nd Day for Laser Safety Officers only, then offering of the Medical Laser Safety Officer Certification exam (CLSO/M) through the National Council on Laser Certification (NCLC) www.LaserCertification.org.

Section 6 Changes:

- NAME CHANGE from "Medical Examination" to "Laser Accidents"

6.2 - recommendations for routine "medical surveillance" further limited for Class 1 through 3R lasers, and only recommended for 3b and 4 lasers for those "clearly known to be at risk".

Section 7 Changes:

7.4 - In LGAC section, introduce new terms of "Plume and Airborne Contaminants" (PAC)

7.4.2 Control Measures - further clarifies the use of LEV as near as practical, but then cautions about compromises to the procedure, patient safety, or adequate ventilation and oxygenation. (evacuating too near the airways in a compromised patient may result in excessive de-oxygenation). It has removed wording from the previous standard that suggested holding the smoke evacuator as near the airway as practical, in those cases.

7.4.2.1 Local Exhaust Ventilation (LEV) - Eliminates the discussion of recirculating systems. ADDS wording that all systems should have a filter change indicator of some type, and that mfg's should provide info on preventive maintenance, filter changes, etc..

7.4.2.3 - Half Mask Respirators as Respiratory Protection - drops all discussion of these masks. Discusses N95 or other high filtration masks, but be aware of mfg stated time limits, and continues to state that LEV shall be the first line of defense against PAC.

7.6.1 Fire hazards - expands on allowing time for alcohol preps to dry according to mfg recommendations prior to placing surgical drapes

7.6.2 Endotracheal Tube Fires

- Added wording to include Laryngeal Mask Airways (LMA)
- Added the anesthetic agent "Sevoflurane" to those that can support combustion
- NEW recommendation that if FIO2 >30% used, then oropharynx should be suctioned with metal cannula prior to using the laser.

7.6.4 Laser Ignition of Intestinal Gases

- Changed the wording from that of "insertion" of wet cotton into anal area, to that of "placement" of wet cotton that adequately "covers" the perianal region. This would reduce the chance of spreading viral warts from outside the anal sphincter to inside.

TABLE 4 Changes:

- Area warning signs. Note at bottom says that any signs conforming to previous revisions of this standard can still be used. (You can still use your old signs - at least the ones current as of the 2005 revision).

APPENDIX A (Normative) Changes: - LSO and other personnel

(Most of these duties were previously contained in section 1 of the 2011 standard. Now they've been moved to this normative Appendix A. Only the changes are noted here)

A1.1 - Verifies that the LSO may be a part time position

A1.2d - Hazard Response. Added wording that LSO shall have the authority to suspend, restrict or terminate the operation of a laser if they deem that the hazard controls are inadequate.

A1.4 - Suggested responsibilities of the LSSC or LSS expanded and defined here.

OTHER APPENDICES: The other Appendices in the ANSI Z136.3 standards are not considered to be part of the "Normative" standards, and are therefore not discussed here in this summary of changes, but you can review them yourself.

v. August 2018.

LASER TRAINING INFORMATION:

Professional Medical Education Association, inc - est. 1978

"The Laser Training Institute"

3142 Broadway, Suite 201

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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.

LASER CERTIFICATION INFORMATION:

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Among the other Laser Certifications available for Laser Operators, the NCLC offers the original MLSO Certification. An MLSO Certification is now recommended by the ANSI standards. www.LaserCertification.org