Laser Safety in a Manufacturing Environment

Corporate & Employer Responsibilities

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Select regulatory compliance agencies & consensus standards for review:

- Federal Laser Product Performance Standards (FLPPS) 1040.10 & 1040.11
- International Electrotechnical Commission (IEC 60825-1)
- American National Standard ANSI Z136.1 for Safe Use of Lasers (series)
- Laser Institute of America (LIA)
- Occupational Safety & Health Administration (OSHA)
- State & local regulations may also apply
Food & Drug Administration (FDA)
Center for Devices & Radiological Health (CDRH)

**Federal Laser Product Performance Standards (FLPPS)**
21 CFR (Code of Federal Regulations) Part 1040.10
Laser Products

**Applicability**

...provisions of this section and 1040.11, as amended, are applicable as specified to all laser products manufactured or assembled after August 1, 1976, except when....
CDRH Subjects

SUBCHAPTER J-RADIOLOGICAL HEALTH
PART 1010 PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS:
GENERAL

..21 CFR Part 1010.2 Certification
..21 CFR Part 1010.3 Identification
..21 CFR Part 1040.10 Laser Products
  - Classification Of Laser Products
  - Accessible Emission Limits
  - Tests For Determination Of Compliance
  - Performance Requirements
  - Labeling Requirements
  - Informational Requirements
  - Modification Of A Certified Product

..21 CFR Part 1040.11 Specific Purpose Laser Products
  - (A) Medical Laser Products
Food and Drug Administration, Center for Devices and Radiological Health (CDRH):

.....intends to amend its standard for laser products (Federal Laser Product Performance Standards [FLPPS] CFR 1040.10 & 1040.11) to harmonize with those of IEC 60825-1 and 60601-2-22*.....

* Per Laser Notice No. 50, Document issued on July 26, 2001
International Electrotechnical Commission IEC 60825 – 1 Safety of laser products Part 1: Equipment classification, requirements and user’s guide

...is the definitive guide on laser safety in Europe and in parts of the rest of the world [ROW] except in the USA...
CDRH ~ Warning letter*

“…..This letter is written to advise you of items of noncompliance with the Federal laser product performance standard encountered during review to advise you of items of…. Laser Operator’s manual lacks the calibration procedures and schedule, which are required to be supplied with each Class III and IV medical laser product under 21 CFR 1040.11(a)(2) ….. the requirement is clear that the instructions must be supplied to the purchaser. You will note that the IEC 60825 standard has a similar requirement…. You have not filed the 2001 annual report with the FDA for the Lpulsa, LightLas, and any other laser products, as required under 21 CFR 1002.13 …. Office of Compliance…Center for Devices and Radiological Health...”

*Per http://www.fda.gov/foi/warning_letters/g3974d.htm
ANSI Z136 (series) for Safe Use of Lasers

An American National Standard

“…..implies a consensus of those substantially concerned with its scope and provisions…..is intended as a guide to aid the manufacturer, the consumer and the general public….is subject to periodic review…..”
ANSI Z136 (series) for Safe Use of Lasers

Serves as a user guide in the US and generally referenced in Canada and Australia
Laser Institute of America (LIA) is the secretariat and publisher of the ANSI Z136 series:

- **Z136.1 Safe Use of Lasers (parent document)**
- **Z136.2** Safe Use of Lasers and LED’s in Telecommunications Applications
- **Z136.3** Safe Use of Lasers in Health Care Facilities
- **Z136.4** Measurements and Instrumentation
- **Z136.5** Safe Use of Lasers in Educational Institutions
- **Z136.6** Safe Use of Lasers Outdoors
- **Z136.7** Eyewear and Protective Barriers
- **Z136.8** Safe Use of Lasers in Research, Development and Testing
- **Z136.9** Safe Use of Lasers in Manufacturing Environments
- **Z136.10** Safe Use of Lasers in Entertainment, Displays and Exhibitions
U.S. Department of Labor
Occupational Safety & Health Administration
OSHA

What standards apply?
Occupational Safety & Health Administration
Section 5(a)(1) of the OSH Act, often referred to as the **General Duty Clause**, requires:

“…..employers to furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees...."
General Industry (29 CFR 1910)

Directives


Guidelines For Robotics Safety. STD 01-12-002 [PUB 8-1.3], (1987, September 21). Identifies controls that can be used on robotic laser systems.
Regulations (Standards - 29 CFR)
Nonionizing radiation. - 1926.54
Safety and Health Regulations for Construction

“…..Only qualified & trained employees shall be assigned to install, adjust, and operate laser equipment....Proof of qualification of the laser equipment operator shall be available and in possession of the operator at all times.....”
National Consensus (per/www.osha.gov)

Note: These are not OSHA regulations, however, they provide guidance from their originating organizations related to worker protection, and may be referenced by OSHA inspectors for informational purposes:

- Z136.1 Safe Use of Lasers
- Z136.2 Safe Use of Lasers and LED’s in Telecommunications Applications
- Z136.3 Safe Use of Lasers in Health Care Facilities
- Z136.4 Measurements and Instrumentation
- Z136.5 Safe Use of Lasers in Educational Institutions
- Z136.6 Safe Use of Lasers Outdoors
- Z136.7 Eyewear and Protective Barriers
- Z136.8 Safe Use of Lasers in Research, Development and Testing
- Z136.9 Safe Use of Lasers in Manufacturing Environments
- Z136.10 Safe Use of Lasers in Entertainment, Displays and Exhibitions
WASHINGTON -- The Occupational Safety and Health Administration (OSHA) and the Laser Institute of America have formed an Alliance that focuses on providing access to training resources to help protect worker safety and health particularly by reducing and preventing exposure to laser beam and non-beam hazards in industrial and medical workplaces....
General Duty Standard (applied ~ example)
Citation 304775331/01001

40.1-51.1. (a), Code of Virginia: The **employer did not furnish** employment and a place of employment which were free from recognized hazards that were causing or likely to cause death or serious physical harm to employees in that: Laser Room - The **employer did not establish an adequate program for the control of laser hazards** for a Class IV Furranti model # MF 400-550 watt continuous wave carbon dioxide laser which includes:

1) **Delegation of authority and responsibility** for the monitoring and enforcement of hazard evaluation and control to a designated employee that would serve as a Laser Safety Officer (LSO).
2) **Education and training of authorized personnel** (LSO, operators, service personnel and others) in the assessment and control of laser hazards.
3) Application of **adequate protective measures** for the control of laser hazards.
4) **Incident investigation**, including reporting of alleged accidents, and preparation of action plans for the future prevention of accidents following known or suspected incident.
5) An appropriate **medical surveillance** program. One feasible method of compliance is to conform to the requirements of the American National Standards Institute Publication ANSI Z136.1-1993, Section 5, Laser Safety and Training Programs.93
General Duty Clause

Michigan 2005: “The employer did not furnish employment and a place of employment which were free from recognized hazards that were causing or likely to cause death or serious physical harm to employees in that employees were exposed to the hazards of infrared non-ionizing radiation capable of causing severe burns of the eyes and skin. Specifically, class IV, metal cutting lasers (1800 watts, carbon dioxide, wavelength 10.6 mm)…”

“Facility using high powered CO2 laser for cutting metal products. Employees were using standard safety glasses and there was no guarding at and near where the laser was cutting metal. The company did not provide a laser safety program or have a laser safety officer at the time of investigation.”

NOTE: Source unknown, information provided by the Laser Institute of America
OSHA Web Resources

Safety and Health Topics
Laser Hazards

Laser Institute of America
- http://www.laserinstitute.org
Laser Safety Officer (LSO)

... an individual designated by the employer with the authority and responsibility to effect the knowledgeable evaluation and control of laser hazards, and to monitor and enforce the control of such hazards ... may be designated from among such personnel as the radiation safety officer, industrial hygienist, safety engineer, laser specialist, laser operator or user, etc. ... in any case, there shall be a designated LSO for all circumstances of operation, maintenance, and service of a Class 3B or Class 4 laser or laser system...
LSO Specific Duties and Responsibilities

- Safety Program
- Classification
- Hazard Evaluation
- Control Measures
- Procedure Approvals
- Protective Equipment
- Signs and Labels
- Facility and Equipment
- Training
- Medical Surveillance
- Records
- Audits, Surveys and Inspections
- Accidents
- Approval of Laser Systems Operations
Section 18 of the Occupational Safety and Health Act of 1970 (the Act) encourages States to develop and operate their own job safety and health programs. OSHA approves and monitors State plans. The following states have approved State Plans:

AK, AZ, CA, CT, HI, IN, IA, KY, MD, MI, MN, NV, NJ, NM, NY, NC, OR, PR, SC, TN, UT, VT, VI, VA, WA, WY
Check with radiation organizations as state & local regulatory oversight may apply in:

AL, AZ, AR, FL, GA, IL, MA, MT, NY, PA, TX, WA
“…it’s all fun and games until someone loses an eye…”

Mom