Laser Safety Requirements in Manufacturing for the United States

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US Laser Safety Requirements

Overview

- Lasers: What?
- Safety: Why?
- What to Do?

Regulation and Quasi-Regulation

- FDA / CDRH- Product
- ANSI (OSHA)- Workplace / Users
- Special Purpose Standards

What’s New?

- Policy 50 (re-issue)
- ANSI

Wrap
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What

Laser Acronym

Light

Amplification by

Stimulated

Emission of

Radiation
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What

Wave Nature of Light

- Wavelength
- Time
- Period
- Amplitude
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What

The combination of these three properties makes laser light focus 100 times better than ordinary light.
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What

White Light
- (Many Wavelengths)
- Increasing Wavelength
  - Red
  - Yellow
  - Green
  - Blue
  - Violet
  - Decreasing Wavelength

Laser Beam
- (One Wavelength)
- One Single Wavelength
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What Coherence Properties of a Laser Beam
(Waves Shown Frozen In Time)
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### What

<table>
<thead>
<tr>
<th>Region</th>
<th>Wavelength Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ultraviolet (UV)</strong></td>
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</tr>
<tr>
<td>UV - C</td>
<td>0.100 to 0.280 μm</td>
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<tr>
<td>UV - B</td>
<td>0.280 to 0.320 μm</td>
</tr>
<tr>
<td>UV - A</td>
<td>0.320 to 0.400 μm</td>
</tr>
<tr>
<td><strong>Visible (Light)</strong></td>
<td></td>
</tr>
<tr>
<td>Visible (Light)</td>
<td>0.400 to 0.700 μm</td>
</tr>
<tr>
<td><strong>Infrared (IR)</strong></td>
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</tr>
<tr>
<td>IR - A</td>
<td>0.700 to 1.4 μm</td>
</tr>
<tr>
<td>IR - B</td>
<td>1.4 - 3.0 μm</td>
</tr>
<tr>
<td>IR - C</td>
<td>3.0 to 1,000 μm</td>
</tr>
</tbody>
</table>
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#### What

**Types of Lasers**

- **Gas** lasers use gas atoms, molecules, or ions in a tube. A mixture of gasses is sometimes used. They are excited by electric current passing through the gas. Metal vapor lasers are gas lasers that use thermally evaporated metal atoms in a carrier gas.

- **Solid State** lasers employ metal ions embedded in a transparent crystal and are excited by an arc lamp, a flashlamp, or another laser.

- **Diode** lasers use electrons passing across the boundary between two layers of semiconductor material and are excited by an electric current.

- **Dye** lasers use complex organic dye molecules in solution and are excited by a flashlamp or another laser.

- **Fiber Laser** - A version of solid state, where the fiber is the cavity.
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What

Army says weapon could change how battles will be fought.

The U.S. Army used this high-energy laser to shoot down an artillery shell in mid-flight on November 5, 2002.
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**Why:** Laser Tissue Interactions

**THERMAL:**
- Caused by elevated temperature after absorption of laser energy.
- Occurs at nearly all wavelengths and exposure durations.

**PHOTOCHEMICAL:**
- Caused by chemical reactions within body tissue after absorption of laser energy.
- Occurs only with wavelengths less than about 0.600 μm.
- Dominant effect for shorter wavelengths for exposures greater than 10 seconds.

**SHOCKWAVE (ACOUSTIC):**
- An explosive effect when short pulses are absorbed in the retina.
- Occurs when pulse duration is less than 50 microseconds.

**ULTRASHORT PULSES:**
- Self-focusing increases retinal irradiance & minimizes energy needed for damage.
- Laser induced breakdown absorbs energy and shields retina.
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Why:

- CILIARY BODY
- CORNEA
- AQUEOUS HUMOR
- IRIS
- PUPIL
- CRYSTALLINE LENS
- OPTIC NERVE
- NASAL SIDE
- TEMPORAL SIDE
- SCLERA
- CHOROID
- VITREOUS HUMOR
- FOVEA
- OPTIC NERVE HEAD
- CILIARY MUSCLES
- RETINA
- BIO-STRUCTURE ON-BOARD OPTICAL DETECTOR
- AND IMAGE PROCESSOR
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**Why:**

**Absorption of Laser Light by the Eye**

Visible (400 – 700 nm) and Near-Infrared wavelengths (700 – 1400 nm) are focused by the cornea and lens and are absorbed by the retina.

Far Infrared (1400 nm – 1 mm) and Short Ultraviolet (100 – 300 nm) wavelengths are absorbed by water on the surface of the eye.

Long Ultraviolet (300 - 400 nm) wavelengths are absorbed in the cornea, vitreous humor and lens structures, producing photo-chemical effects.
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Why: Self-Focusing in the Eye

Normal Beam Propagation

Beam Self-Focuses In Eye
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Why:

• Lasers Bright, Unidirectional, Coherent
• Focusable
  ◆ Human Eye Most Vulnerable
  ◆ Visible and near visible effects
    • Green, Blue retinal absorption
    • Near infra-red
• Oh yeah, and regulations!
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What to Do?:

Purpose of LASER Standards

Standards assist in the accomplishment: Safety
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Manufacturers

- FAA 7400.2
- SAE-G10 Laser
- ACGIH
- Z136.1 Main
- Z136.2 Fiber
- Z136.3 Medical
- Z136.4 Measure Draft
- Z136.5 Schools
- Z136.6 Outdoors
- Z136.7 Eyewear Draft
- Z136.8 Lab
- Z136.9 Mfg.
- Z136.10 Demo

ANSI

- ANSI B11.21
- 21 CFR
- 7400.2
- FDA

NFPA

- NFPA
- National Electric Code
- 115 Fire

STATES

- CRCPD Model State
- Z136.10 Demo

I EC/EN

- 60825-1
- 60825-14

I EC/EN TR

OSHA

- Pub. 8-1.7 Ch. 17
- ANSI

USER S
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What to Do?:

- Product Requirements

  21 CFR
  - 1000-1005, 1010
  - 1040
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- **Part 1000**: Pertains to General Provisions, Applicability and Definitions
- **Part 1002**: Describes required Reports and requirements for Recordkeeping, including initial Product Reports, Annual Reports; Reports of Accidents; and manufacturers’ and dealers records
- **Part 1003**: Deals with the protocol incumbent on Manufacturers upon discovery of product non-compliance, including the format and content of Notification to customers, product repair and recall.
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- Part 1004: Proscribes the manufacturers responsibility to repair, replace, or refund, at no cost to the user, parts or assemblies involved in non-compliance issues, including the publishing of the manufacturers plans in this regard to FDA for review and approval.

- Part 1005: Regulations on the importation of listed products, including sampling for compliance, dealing with non-compliant products, etc.

- Part 1010: Outlines requirements to Identify and Certify electronic products, application and approval of Variances, and protocol for obtaining exemption from compliance for products intended for United States Government use.

- Part 1020: Performance standards for ionizing radiation products
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- **Part 1030**: Performance standards for microwave and radio frequency emitting products.
- **Part 1040**: Describes the Applicability, definitions and the requirements of the Federal Laser Product Performance Standard (FLPPS) including the abbreviated requirements for manufacturers of stand-alone components (parts which are not capable of being a laser device when removed from the incorporating system, and for which the manufacturers’ intent is to offer a component.)
- **Part 1050**: Performance standards for sonic, infrasonic, and ultrasonic radiation-emitting products.
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Are You a Laser Manufacturer?

Any electronic product that incorporates or is intended to incorporate a laser is a laser product
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- frequently misunderstood by those who import products, or who are third party integrators
  (Last to add, must Certify)

- AS a USER, test your suppliers
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- Basic cornerstone of all standards, for both user and laser products, is the concept of classification of hazards.
- Classifying hazards is a convenience adopted for universal understanding of degree of harmful potential of a given transmitted laser energy.
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Requirements of Manufacturers’ Standard

**Protective Housing**

*Each laser product shall have a protective housing.*

*Protective Housing must be Class I except where access to radiation is necessary for the function of the product*
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...in the protective housing of the product.

Class 3B or 4 Laser Source

Single Surface Reflector

Gaps in housing must be closed

Protective Housing

Radiation needed for Product Function, here.
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- **Considering Class I Protective housings.**
  
  For Class IIIb and IV "Human Access", is two Part

No part of Human body (in IEC 12 X 80 mm probe)

No reflection from (hypothetical mirror) thru any hole.
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Requirements of Manufacturers’ Standard

Master Key Control
All Class IIIb (3B)and Class IV (4) lasers

Emission Indicator
Visible or audible signal during emission required for Class II, IIIa, IIIb and IV. (IEC = Class 3R and above)

Class 3 and 4, must indicate before laser is emitted.
**Beam Attenuator**
Class II, III (a or b), and IV (IEC Class 3B and 4, only) lasers must have a permanent attached means of preventing access to the laser and collateral radiation.

**Location of Controls**
The controls must be located so that exposure to the beam is not necessary for normal operating functions.
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**Viewing Optics**

All viewing optics, view ports and display screens shall at all times limit the levels of the laser and collateral radiation to less than Class I limits.

**Scanning Safeguards**

A scan failure cannot allow the laser to increase its classification.
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- FDA Laser Policy Notices
  - These notices (54 since 1976) are incorporated as interpretations of the FLPPS. They have the *de facto* force of law, in this context.
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- Walk-in Workstations.
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Walk-in Workstations

US Requirement is Laser Policy Notice # 37, approximately the same requirement as the IEC 60825-1 clause 4.12, except as follows:

a) enclosure is safety interlocked and labeled as required by the FLPPS.

b) a means is provided as part of the overall safety interlock scheme to detect the presence of persons within the enclosure, and/or to prevent operation of the laser when a person is inside the enclosure,

AND The user information clearly instructs operators to avoid procedures that could give access to hazardous levels of laser radiation.
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- Laser Policy Notice No. 50, permits manufacturers to comply with the US FLPPS, using specific paragraphs of IEC 60825 (more later)

- Reduces the burden of manufacturers from making two separate product lines
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Users standards or Laser workplace safety

- **Laser workplace safety**, in the United States, OSHA has adopted a practice of enforcement under the General Duty Clause (Clause 5 (a)(1) of Public Law 91-596)
Accepted standard for workplace safety of lasers (in the US) is American National Standards Institute (ANSI) Z 136 series.


This concept is endorsed (making *de facto* law) by OSHA publication of OSHA Instructional Publication 8-1.7 (5 Aug'91), essentially an endorsement and paraphrased duplication of ANSI Z 136.1, *Safe Use of Lasers*. 


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- **product “make” vs. product “use”**.

- Product standards are based on the ACCESS
User (workplace) standards also identify hazard levels (classes), but the control perspective is one of limiting, reducing or eliminating human EXPOSURE.
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- The difference between ACCESS and EXPOSURE is an important concept when applying the respective standards.
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- Preventing or limiting EXPOSURE, may use administrative controls such as barricades and personal protective equipt. (PPE) but the control of human ACCESS requires engineering features.
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Common Elements of User Standards

- Establishing Laser Hazard Classification
  - 4 base hazard Classes
- Evaluation of Hazards, by determining
  - MPE
  - NHZ
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Define Control Measures

● Engineering Controls
  - Enclosures
  - Interlocks
  - Warning Systems

● Administrative and Procedural Control
  - Authorized Personnel
  - SOP: Alignment and Maintenance
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- Administrative and Procedural Control
  - Training
  - Protective Equipment
    - Eyewear
    - Barriers
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SPECIAL PURPOSE USER STANDARDS

- **ANSI Z 136 Series**
  - In addition to ANSI Z.136.1 there are a number of special purpose or environment versions or edition of the Z 1236 series. Some examples:
    - Z136.2 Safe Use of Optical Fiber Communications Systems
    - Z136.3 Safe Use of Lasers In Health Care Facilities
    - Z136.4 Safe Use of Lasers \: Measurement Methods
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SPECIAL PURPOSE STANDARDS

- **ANSI Z 136 Series**
  - **Z136.5** Safe Use of Lasers In Educational Institutions
  - **Z136.6** Safe Use of Lasers Outdoors
  - **Z136.7** Laser protective Eyewear and Barriers
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SPECIAL PURPOSE USER STANDARDS

● FAA 7400.2: For installations in proximity to aviation. Must get FAA approval before installation / operation.
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• ANSI B11.21 Safety Requirements for Laser Machine Tools (Materials Processing)
  ◦ Laser Guards and Barriers Standard
    IEC 60825-4
  ◦ Laser Processing Machines (Machine Directive) ISO / IEC 11553-1, 2, & 3
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- **US States**: Within the various States of the United States there are several laws and regulations pertaining to lasers and laser use. Most are directed at nuisance or consumer products (e.g. laser pointers used outdoors),

- Eight (8) States have comprehensive standards for workplace safety
  - Some of these require registration and licensing fees
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What’s New?

- Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22; Guidance for Industry and FDA Staff (Laser Notice No. 50, Originally May 2001, re-issued in June 2007)
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**ANSI Z 136.1 – 2007**

- With a view to harmonization of the Product Standard, this edition is updated to reflect compatibility with international standards
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#### Comparison of Classification Schemes between the various major standards

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<td>I</td>
<td>1</td>
<td>1 - 1</td>
</tr>
<tr>
<td>IIa</td>
<td>1M</td>
<td>- 1M</td>
</tr>
<tr>
<td>II</td>
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<td>IIIa</td>
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<tr>
<td>IIIb</td>
<td>3R</td>
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</tr>
<tr>
<td>IV</td>
<td>3B</td>
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What’s Next?

- Publishing Three New ANSI standards
  - Laboratory
  - Manufacturing
  - Light Shows and demonstrations

Goal is to publish within 2 years (about 14 months remaining)
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**What’s it all about**

- Education . . . Education . . . Education

- Lasers are just light, but powerful
- Eye is most vulnerable, least healable
- Product manufacturers must certify FDA
- Users comply with General Duty Clause

USE ANSI Z 136