

# Requirements for Commercial Laser Products

# Requirements for Laser Products

- Laser products sold in the United States.
  - Product classification
  - Labeling
  - Safety features like protective covers
  - Verification program
  - Filing of the product with the FDA.
- Requirements are different for
  - Laser Products
    - FDA – Center for Devices and Radiological Health (CDRH)
  - Laser Safety within an Organization
    - ANSI / OSHA

# Why should I Develop a Safe Product?

It is the right thing to do.

- Coworkers
  - Our boss said so.
- Marketing Department
  - Nothing dampens repeat business like blinding the customer.
- Finance Department
  - The extra components are cheaper than the lawsuit.
- Service Technicians
  - It is most likely your eyes that will be saved.

# Challenges

- Ease of Use
  - Should be simple for the customer to use and understand.
- Reliable
- May affect on the performance of the system.
- Filling takes time.
  - Plan ahead.
- Added Cost

# Procedure for Developing a Laser Product

- Reduce access to any unnecessary laser radiation.
  - Add protective housing.
  - Reduce output power.
- Classify of your product during operation.
  - Calculations and Measurements
- Label the product and add warnings to manuals
- Develop a laser testing plan for all safety features
- File with the FDA

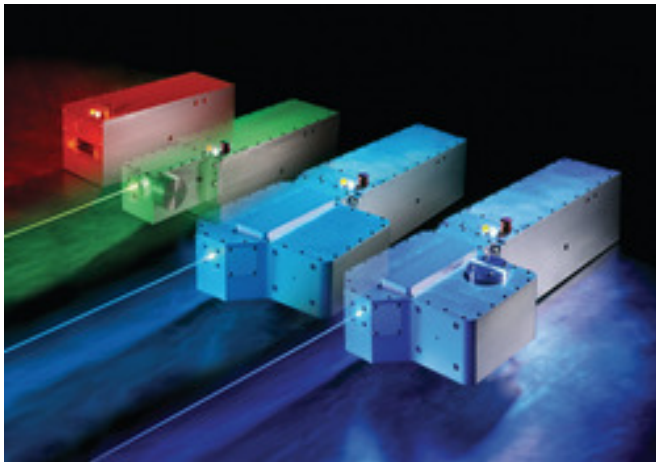
# Standards

- United States
  - Filing required before part is shipped.
  - Food and Drug Administration (FDA)
    - Center for Devices and Radiological Health (CDRH)
      - [21 CFR 1040.10](#)
      - 21 CFR 1040.11
      - [Laser Notice No. 50 \(July 2001\)](#)
        - » FDA will allow European classifications for Laser Classes and Labels.
- Europe
  - IEC 60825-1, AM2
  - IEC 60620-2-22

# Definitions

- **Laser System**
  - A laser in conjunction with its power supply
- **Laser Product**
  - Any device that constitutes, incorporates, or is intended to incorporate a laser or laser system.

# Laser System vs. Laser Product



## Laser System

Laser



## Laser Product

Laser Welder

# More Definitions

- **Operation**

- functions by which the product accomplishes its intended purpose.
  - loading work-pieces or documents
  - setting and manipulating external controls.

- **Maintenance**

- functions performed by the user to assure performance.
  - cleaning and replenishment of expendables.

- **Service**

- usually means repair.
- may be performed by
  - specially trained service personnel
  - sophisticated users following instructions specifically indicated as service instructions.
- Certain maintenance procedures will be considered service if they are infrequent, complex, or highly specialized.

# Laser Classifications

- Based on maximum accessible laser radiation during operation.
- Classifications are listed in the 21 CFR 1040.11
  - Class I – no hazard
  - Class II – direct long duration exposure eye hazard
  - Class IIIa – visible, does not exceed 5mW
  - Class IIIb – direct exposure eye hazard
  - Class IV – diffuse reflection eye hazard
- *Laser Safety Notice 52* allows for the use of European laser classifications

TABLE I  
CLASS I ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration (seconds)	Class I-Accessible emission limits		
		(value)	(unit)	(quantity)**
>180 but <400	≤3.0 X 10 <sup>4</sup> -----	2.4 X 10 <sup>-5</sup> k <sub>1</sub> k <sub>2</sub> *	Joules(J)*	radiant energy
	>3.0 X 10 <sup>4</sup> -----	8.0 X 10 <sup>-10</sup> k <sub>1</sub> k <sub>2</sub> *	Watts(W)*	radiant power
>400 but <1400	>1.0 X 10 <sup>-9</sup> to 2.0 X 10 <sup>-5</sup> ---	2.0 X 10 <sup>-7</sup> k <sub>1</sub> k <sub>2</sub>	J	radiant energy
	>2.0 X 10 <sup>-5</sup> to 1.0 X 10 <sup>1</sup> ---	7.0 X 10 <sup>-4</sup> k <sub>1</sub> k <sub>2</sub> t <sup>3/4</sup>	J	radiant energy
	>1.0 X 10 <sup>1</sup> to 1.0 X 10 <sup>4</sup> ---	3.9 X 10 <sup>-3</sup> k <sub>1</sub> k <sub>2</sub>	J	radiant energy
	>1.0 X 10 <sup>4</sup> -----	3.9 X 10 <sup>-7</sup> k <sub>1</sub> k <sub>2</sub>	W	radiant power
	and also (See paragraph (d)(4) of this section)			
	>1.0 X 10 <sup>-9</sup> to 1.0 X 10 <sup>1</sup> ---	10k <sub>1</sub> k <sub>2</sub> t <sup>1/3</sup>	Jcm <sup>-2</sup> sr <sup>-1</sup>	integrated radiance
>1.0 X 10 <sup>1</sup> to 1.0 X 10 <sup>4</sup> ---	20k <sub>1</sub> k <sub>2</sub>	Jcm <sup>-2</sup> sr <sup>-1</sup>	integrated radiance	
>1.0 X 10 <sup>4</sup> -----	2.0 X 10 <sup>-3</sup> k <sub>1</sub> k <sub>2</sub>	Wcm <sup>-2</sup> sr <sup>-1</sup>	radiance	
>1400 but <2500	>1.0 X 10 <sup>-9</sup> to 1.0 X 10 <sup>-7</sup> ---	7.9 X 10 <sup>-5</sup> k <sub>1</sub> k <sub>2</sub>	J	radiant energy
	>1.0 X 10 <sup>-7</sup> to 1.0 X 10 <sup>1</sup> ---	4.4 X 10 <sup>-3</sup> k <sub>1</sub> k <sub>2</sub> t <sup>1/4</sup>	J	radiant energy
	>1.0 X 10 <sup>1</sup> -----	7.9 X 10 <sup>-4</sup> k <sub>1</sub> k <sub>2</sub>	W	radiant power
>2500 but <1.0 X 10 <sup>6</sup>	>1.0 X 10 <sup>-9</sup> to 1.0 X 10 <sup>-7</sup> ---	1.0 X 10 <sup>-2</sup> k <sub>1</sub> k <sub>2</sub>	Jcm <sup>-2</sup>	radiant exposure
	>1.0 X 10 <sup>-7</sup> to 1.0 X 10 <sup>1</sup> ---	5.6 X 10 <sup>-1</sup> k <sub>1</sub> k <sub>2</sub> t <sup>1/4</sup>	Jcm <sup>-2</sup>	radiant exposure
	>1.0 X 10 <sup>1</sup> -----	1.0 X 10 <sup>-1</sup> k <sub>1</sub> k <sub>2</sub> t	Jcm <sup>-2</sup>	radiant exposure

\*Class I accessible emission limits for wavelengths equal to or greater than 180 nm but less than or equal to 400 nm shall not exceed the Class I accessible emission limits for the wavelengths greater than 1400 nm but less than or equal to 1.0 X 10<sup>6</sup> nm with a k<sub>1</sub> and k<sub>2</sub> of 1.0 for comparable sampling intervals.

\*\*Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE II-A

## CLASS IIa ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

CLASS IIa ACCESSIBLE EMISSION LIMITS ARE IDENTICAL TO CLASS I ACCESSIBLE EMISSION LIMITS EXCEPT WITHIN THE FOLLOWING RANGE OF WAVELENGTHS AND EMISSION DURATIONS:				
Wavelength (nanometers)	Emission duration (seconds)	Class IIa-Accessible emission limits		
		(value)	(unit)	(quantity)*
>400 but ≤710	$>1.0 \times 10^3$	$3.9 \times 10^{-6}$	W	radiant power

\*Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE II

## CLASS II ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

CLASS II ACCESSIBLE EMISSION LIMITS ARE IDENTICAL TO CLASS I ACCESSIBLE EMISSION LIMITS EXCEPT WITHIN THE FOLLOWING RANGE OF WAVELENGTHS AND EMISSION DURATIONS:				
Wavelength (nanometers)	Emission duration (seconds)	Class II-Accessible emission limits		
		(value)	(unit)	(quantity)*
>400 but ≤710	$>2.5 \times 10^{-1}$	$1.0 \times 10^{-3}$	W	radiant power

\*Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE III-A  
CLASS IIIa ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

CLASS IIIa ACCESSIBLE EMISSION LIMITS ARE IDENTICAL TO CLASS I ACCESSIBLE EMISSION LIMITS EXCEPT WITHIN THE FOLLOWING RANGE OF WAVELENGTHS AND EMISSION DURATIONS:				
Wavelength (nanometers)	Emission duration (seconds)	Class IIIa-Accessible emission limits		
		(value)	(unit)	(quantity)*
>400 but <710	$>3.8 \times 10^{-4}$	$5.0 \times 10^{-3}$	W	radiant power

\*Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE III-B  
CLASS IIIb ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration (seconds)	Class IIIb-Accessible emission limits		
		(value)	(unit)	(quantity)*
$\geq 180$ but $\leq 400$	$\leq 2.5 \times 10^{-1}$	$3.8 \times 10^{-4} k_1 k_2$	J	radiant energy
	$> 2.5 \times 10^{-1}$	$1.5 \times 10^{-3} k_1 k_2$	W	radiant power
>400 but	$> 1.0 \times 10^{-9}$ to $2.5 \times 10^{-1}$	$10 k_1 k_2 t^{1/3}$	$Jcm^{-2}$	radiant exposure
		to a maximum value of 10	$Jcm^{-2}$	radiant exposure
$\leq 1400$	$> 2.5 \times 10^{-1}$	$5.0 \times 10^{-1}$	W	radiant power
>1400 but $\leq 1.0 \times 10^6$	$> 1.0 \times 10^{-9}$ to $1.0 \times 10^1$	10	$Jcm^{-2}$	radiant exposure
	$> 1.0 \times 10^1$	$5.0 \times 10^{-1}$	W	radiant power

\*Measurement parameter and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE IV

VALUES OF WAVELENGTH DEPENDENT CORRECTION FACTORS  $k_1$  AND  $k_2$

Wavelength (nanometers)	$k_1$	$k_2$		
180 to 302.4	1.0	1.0		
> 302.4 to 315	$10^{\left[\frac{\lambda - 302.4}{5}\right]}$	1.0		
> 315 to 400	330.0	1.0		
> 400 to 700	1.0	1.0		
> 700 to 800	$10^{\left[\frac{\lambda - 700}{515}\right]}$	if: $t \leq \frac{10100}{\lambda - 699}$ then: $k_2 = 1.0$	if: $\frac{10100}{\lambda - 699} < t \leq 10^4$ then: $k_2 = \frac{t(\lambda - 699)}{10100}$	if: $t > 10^4$ then: $k_2 = \frac{\lambda - 699}{1.01}$
> 800 to 1060	$10^{\left[\frac{\lambda - 700}{515}\right]}$	if: $t \leq 100$ then: $k_2 = 1.0$	if: $100 < t \leq 10^4$ then: $k_2 = \frac{t}{100}$	if: $t > 10^4$ then: $k_2 = 100$
> 1060 to 1400	5.0			
> 1400 to 1535	1.0	1.0		
> 1535 to 1545	$t \leq 10^{-7}$ $k_1 = 100.0$	1.0		
	$t > 10^{-7}$ $k_1 = 1.0$			
> 1545 to $1.0 \times 10^6$	1.0	1.0		

Note: The variables in the expressions are the magnitudes of the sampling interval(t), in units of seconds, and the wavelength ( $\lambda$ ), in units of nanometers.

TABLE V  
 SELECTED NUMERICAL SOLUTIONS FOR  $k_1$  AND  $k_2$

Wavelength (nanometers)	$k_1$	$k_2$				
		$t \leq 100$	$t=300$	$t=1000$	$t=3000$	$t \geq 10,000$
180	1.0	1.0				
300	1.0					
302	1.0					
303	1.32					
304	2.09					
305	3.31					
306	5.25					
307	8.32					
308	13.2					
309	20.9					
310	33.1					
311	52.5					
312	83.2					
313	132.0					
314	209.0					
315	330.0					
400	330.0					
401	1.0					
500	1.0					
600	1.0					
700	1.0					
710	1.05	1	1	1.1	3.3	11.0
720	1.09	1	1	2.1	6.3	21.0
730	1.14	1	1	3.1	9.3	31.0
740	1.20	1	1.2	4.1	12.0	41.0
750	1.25	1	1.5	5.0	15.0	50.0
760	1.31	1	1.8	6.0	18.0	60.0
770	1.37	1	2.1	7.0	21.0	70.0
780	1.43	1	2.4	8.0	24.0	80.0
790	1.50	1	2.7	9.0	27.0	90.0
800	1.56	1	3.0	10.0	30.0	100.0
850	1.95	1	3.0	10.0	30.0	100.0
900	2.44	1	3.0	10.0	30.0	100.0
950	3.05	1	3.0	10.0	30.0	100.0
1000	3.82	1	3.0	10.0	30.0	100.0
1050	4.78	1	3.0	10.0	30.0	100.0
1060	5.00	1	3.0	10.0	30.0	100.0
1100	5.00	1	3.0	10.0	30.0	100.0
1400	5.00	1	3.0	10.0	30.0	100.0
1500	1.0	1.0				
1540	100.0*					
1600	1.0					
$1.0 \times 10^6$	1.0					

\* The factor  $k_1 = 100.0$  when  $t \leq 10^{-7}$ , and  $k_1 = 1.0$  when  $t > 10^{-7}$

Note: The variable (t) is the magnitude of the sampling interval in units of seconds.

# Laser Safety Components

- Laser Products
  - All Classes
    - **Protective Housing**
    - **Safety interlocks** for access to radiation in excess of Class I
      - Redundant interlock for access to Class IIIb or higher
- Laser Systems
  - Class II and higher
    - **Emission Indicator** (warning light or sound)
    - **Beam Attenuator** (beam block)
  - Class IIIb and IV
    - **Remote Interlock**
    - **Key Control**
  - Class IV
    - **Manual Reset**

# Labeling Requirements

IEC labeling can be used.

- Warning label required on Class II and higher laser products.
  - Class of the laser
  - Warning statement
  - Maximum output
  - Wavelength range
  - Statement of compliance.
    - Manufacture Name and Date
- Also Required on
  - Removable or displaceable housings.
  - Apertures
  - All brochures and manuals

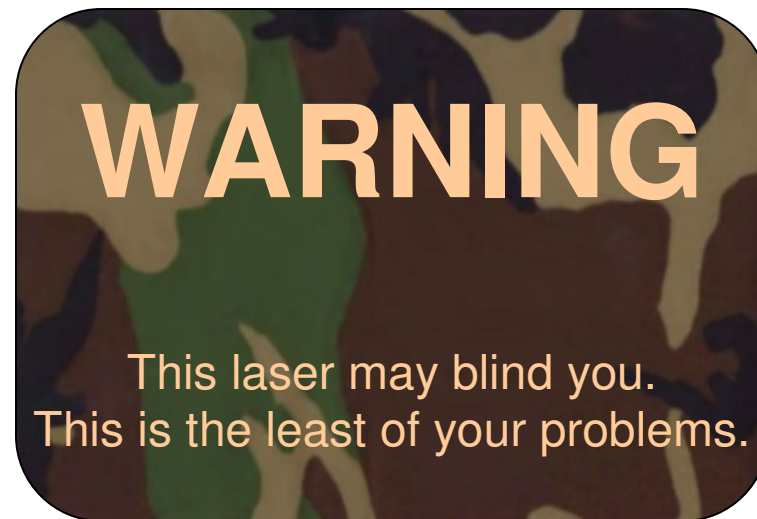


VISIBLE LASER RADIATION  
AVOID EXPOSURE TO BEAM  
CLASS 3a LASER PRODUCT  
< 5 mW AT 633 nm

Complies with 21 CFR 1040.10  
except for deviations pursuant to  
Laser Notice No. 50 (July 2001)

# Department of Defense Exemption

According to [Laser Safety Notice 52](#) the Department of Defense is exempt from the labeling and reporting requirements of the FDA



# Recordkeeping and Filing

- Recordkeeping
  - Develop a testing program to ensure compliance
  - Maintain records of compliance
  - Maintain distribution records in the event of a recall.
- Filing
  - Electric Filing
    - [Cesub software](#)

# Links

- 21 CFR 1040.10
  - [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=1040.10](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=1040.10)
- Compliance Guide
  - [www.fda.gov/cdrh/radh1th/pdf/lasgde01.pdf](http://www.fda.gov/cdrh/radh1th/pdf/lasgde01.pdf)
- Electronic Filing Link
  - [www.fda.gov/cdrh/cesub](http://www.fda.gov/cdrh/cesub)
- Laser Notice No. 50 (harmonization with European Standards)
  - [www.fda.gov/cdrh/comp/guidance/1346.pdf](http://www.fda.gov/cdrh/comp/guidance/1346.pdf)
- IEC website
  - [www.iec.ch](http://www.iec.ch)
- Laser Notice No. 52 (exemption for military applications)
  - [www.fda.gov/cdrh/comp/guidance/1412.pdf](http://www.fda.gov/cdrh/comp/guidance/1412.pdf)