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Drug Administration, may grant an exemption from one or more of the statements (radiation safety warnings) specified in paragraph (c)(6)(i) of this section. Such exemption shall be based upon a determination by the Director that the microwave oven model for which the exemption is sought should continue to comply with paragraphs (c) (1), (2), and (3) of this section under the adverse condition of use addressed by such precautionary statement(s). An original and two copies of applications shall be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Copies of the written portion of the application, including supporting data and information, and the Director's action on the application will be maintained by the Branch for public review. The application shall include:

(a) The specific microwave oven model(s) for which the exemption is sought.

(b) The specific radiation safety warning(s) from which exemption is sought.

(c) Data and information which clearly establish that one or more of the radiation safety warnings in paragraph (c)(6)(i) of this section is not necessary for the specified microwave oven model(s).

(d) Such other information and a sample of the applicable product if required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application.

[38 FR 28640, Oct. 15, 1973, as amended at 40 FR 14752, Apr. 4, 1975; 40 FR 52007, Nov. 7, 1975; 46 FR 8461, Jan. 27, 1981; 48 FR 57482, Dec. 30, 1983; 50 FR 13566, Apr. 5, 1985; 53 FR 11254, Apr. 6, 1988; 59 FR 14365, Mar. 28, 1994]

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

Sec.

1040.10 Laser products.

1040.11 Specific purpose laser products.

1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

1040.30 High-intensity mercury vapor discharge lamps.

AUTHORITY: Secs. 501, 502, 510, 515-520, 701, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360e-360j, 371, 381); secs. 354-360F of the Public Health Service Act (42 U.S.C. 263b-263n).

§ 1040.10 Laser products.

(a) *Applicability.* The 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:

(1) Such a laser product is either sold to a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, or

(2) Sold by or for a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, provided that such laser product:

(i) Is accompanied by a general warning notice that adequate instructions for the safe installation of the laser product are provided in servicing information available from the complete laser product manufacturer under paragraph (h)(2)(ii) of this section, and should be followed,

(ii) Is labeled with a statement that it is designated for use solely as a component of such electronic product and therefore does not comply with the appropriate requirements of this section and § 1040.11 for complete laser products, and

(iii) Is not a removable laser system as described in paragraph (c)(2) of this section; and

(3) The manufacturer of such a laser product, if manufactured after August 20, 1986:

(i) Registers, and provides a listing by type of such laser products manufactured that includes the product name, model number and laser medium or emitted wavelength(s). The registration and listing shall include the name and address of the manufacturer and shall be submitted to the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857.

(ii) Maintains and allows access to any sales, shipping, or distribution records that identify the purchaser of such a laser product by name and address, the product by type, the number

of units sold, and the date of sale (shipment). These records shall be maintained and made available as specified in § 1002.31.

(b) *Definitions.* As used in this section and § 1040.11, the following definitions apply:

(1) *Accessible emission level* means the magnitude of accessible laser or collateral radiation of a specific wavelength and emission duration at a particular point as measured according to paragraph (e) of this section. Accessible laser or collateral radiation is radiation to which human access is possible, as defined in paragraphs (b) (12), (15), and (22) of this section.

(2) *Accessible emission limit* means the maximum accessible emission level permitted within a particular class as set forth in paragraphs (c), (d), and (e) of this section.

(3) *Aperture* means any opening in the protective housing or other enclosure of a laser product through which laser or collateral radiation is emitted, thereby allowing human access to such radiation.

(4) *Aperture stop* means an opening serving to limit the size and to define the shape of the area over which radiation is measured.

(5) *Class I laser product* means any laser product that does not permit access during the operation to levels of laser radiation in excess of the accessible emission limits contained in Table I of paragraph (d) of this section.¹

(6) *Class IIa laser product* means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table I, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table II-A of paragraph (d) of this section.²

(7) *Class II laser product* means any laser product that permits human ac-

cess during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table II-A, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table II of paragraph (d) of this section.³

(8) *Class IIIa laser product* means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table II, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table III-A of paragraph (d) of this section.⁴

(9) *Class IIIb laser product* means any laser product that permits human access during operation to levels of laser radiation in excess of the accessible emission limits of Table III-A, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table III-B of paragraph (d) of this section.⁵

(10) *Class III laser product* means any Class IIIa or Class IIIb laser product.

(11) *Class IV laser product* means any laser that permits human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table III-B of paragraph (d) of this section.⁶

(12) *Collateral radiation* means any electronic product radiation, except laser radiation, emitted by a laser product as a result of the operation of the laser(s) or any component of the laser product that is physically necessary for the operation of the laser(s).

³Class II levels of laser radiation are considered to be a chronic viewing hazard.

⁴Class IIIa levels of laser radiation are considered to be, depending upon the irradiance, either an acute intrabeam viewing hazard or chronic viewing hazard, and an acute viewing hazard if viewed directly with optical instruments.

⁵Class IIIb levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct radiation.

⁶Class IV levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct and scattered radiation.

¹Class I levels of laser radiation are not considered to be hazardous.

²Class IIa levels of laser radiation are not considered to be hazardous if viewed for any period of time less than or equal to 1×10^3 seconds but are considered to be a chronic viewing hazard for any period of time greater than 1×10^3 seconds.

(13) *Demonstration laser product* means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition. The term “demonstration laser product” does not apply to laser products which are not manufactured, designed, intended, or promoted for such purposes, even though they may be used for those purposes or are intended to demonstrate other applications.

(14) *Emission duration* means the temporal duration of a pulse, a series of pulses, or continuous operation, expressed in seconds, during which human access to laser or collateral radiation could be permitted as a result of operation, maintenance, or service of a laser product.

(15) *Human access* means the capacity to intercept laser or collateral radiation by any part of the human body. For laser products that contain Class IIb or IV levels of laser radiation, “human access” also means access to laser radiation that can be reflected directly by any single introduced flat surface from the interior of the product through any opening in the protective housing of the product.

(16) *Integrated radiance* means radiant energy per unit area of a radiating surface per unit solid angle of emission, expressed in joules per square centimeter per steradian ($\text{Jcm}^{-2} \text{sr}^{-1}$).

(17) *Invisible radiation* means laser or collateral radiation having wavelengths of equal to or greater than 180 nm but less than or equal to 400 nm or greater than 710 nm but less than or equal to 1.0×10^6 nm (1 millimeter).

(18) *Irradiance* means the time-averaged radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimeter (W cm^{-2}).

(19) *Laser* means any device that can be made to produce or amplify electromagnetic radiation at wavelengths greater than 250 nm but less than or equal to 13,000 nm or, after August 20, 1986, at wavelengths equal to or greater than 180 nm but less than or equal to 1.0×10^6 nm primarily by the process of controlled stimulated emission.

(20) *Laser energy source* means any device intended for use in conjunction

with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries shall not be considered to constitute laser energy sources.

(21) *Laser product* means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system that is intended for use as a component of an electronic product shall itself be considered a laser product.

(22) *Laser radiation* means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph (b)(19) of this section that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop and within the appropriate solid angle of acceptance, as specified in paragraph (e) of this section.

(23) *Laser system* means a laser in combination with an appropriate laser energy source with or without additional incorporated components. See paragraph (c)(2) of this section for an explanation of the term “removable laser system.”

(24) *Maintenance* means performance of those adjustments or procedures specified in user information provided by the manufacturer with the laser product which are to be performed by the user for the purpose of assuring the intended performance of the product. It does not include operation or service as defined in paragraph (b) (27) and (38) of this section.

(25) *Maximum output* means the maximum radiant power and, where applicable, the maximum radiant energy per pulse of accessible laser radiation emitted by a laser product during operation, as determined under paragraph (e) of this section.

(26) *Medical laser product* means any laser product which is a medical device as defined in 21 U.S.C. 321(h) and is manufactured, designed, intended or promoted for in vivo laser irradiation of any part of the human body for the purpose of: (i) Diagnosis, surgery, or therapy; or (ii) relative positioning of the human body.

(27) *Operation* means the performance of the laser product over the full range of its functions. It does not include maintenance or service as defined in paragraphs (b) (24) and (38) of this section.

(28) *Protective housing* means those portions of a laser product which are designed to prevent human access to laser or collateral radiation in excess of the prescribed accessible emission limits under conditions specified in this section and in §1040.11.

(29) *Pulse duration* means the time increment measured between the half-peak-power points at the leading and trailing edges of a pulse.

(30) *Radiance* means time-averaged radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian ($\text{W cm}^{-2} \text{sr}^{-1}$).

(31) *Radiant energy* means energy emitted, transferred or received in the form of radiation, expressed in joules (J).

(32) *Radiant exposure* means the radiant energy incident on an element of a surface divided by the area of the element, expressed in joules per square centimeter (Jcm^{-2}).

(33) *Radiant power* means time-averaged power emitted, transferred or received in the form of radiation, expressed in watts (W).

(34) *Remote interlock connector* means an electrical connector which permits the connection of external remote interlocks.

(35) *Safety interlock* means a device associated with the protective housing of a laser product to prevent human access to excessive radiation in accordance with paragraph (f)(2) of this section.

(36) *Sampling interval* means the time interval during which the level of accessible laser or collateral radiation is sampled by a measurement process. The magnitude of the sampling interval in units of seconds is represented by the symbol (*t*).

(37) *Scanned laser radiation* means laser radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference.

(38) *Service* means the performance of those procedures or adjustments de-

scribed in the manufacturer's service instructions which may affect any aspect of the product's performance for which this section and §1040.11 have applicable requirements. It does not include maintenance or operation as defined in paragraphs (b) (24) and (27) of this section.

(39) *Surveying, leveling, or alignment laser product* means a laser product manufactured, designed, intended or promoted for one or more of the following uses:

(i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement.

(ii) Positioning or adjusting parts in proper relation to one another.

(iii) Defining a plane, level, elevation, or straight line.

(40) *Visible radiation* means laser or collateral radiation having wavelengths of greater than 400 nm but less than or equal to 710 nm.

(41) *Warning logotype* means a logotype as illustrated in either Figure 1 or Figure 2 of paragraph (g) of this section.

(42) *Wavelength* means the propagation wavelength in air of electromagnetic radiation.

(c) *Classification of laser products*— (1) *All laser products.* Each laser product shall be classified in Class I, IIa, II, IIIa, IIIb, or IV in accordance with definitions set forth in paragraphs (b) (5) through (11) of this section. The product classification shall be based on the highest accessible emission level(s) of laser radiation to which human access is possible during operation in accordance with paragraphs (d), (e), and (f)(1) of this section.

(2) *Removable laser systems.* Any laser system that is incorporated into a laser product subject to the requirements of this section and that is capable, without modification, of producing laser radiation when removed from such laser product, shall itself be considered a laser product and shall be separately subject to the applicable requirements in this subchapter for laser products of its class. It shall be classified on the basis of accessible emission of laser radiation when so removed.

(d) *Accessible emission limits.* Accessible emission limits for laser radiation

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in each class are specified in Tables I, II-A, II, III-A, and III-B of this paragraph. The factors, k_1 and k_2 vary with wavelength and emission duration. These factors are given in Table IV of this paragraph, with selected numerical values in Table V of this paragraph. Accessible emission limits for collateral radiation are specified in Table VI of this paragraph.

NOTES APPLICABLE TO TABLES I, II-A, II, III-A AND III-B:

- (1) The factors k_1 and k_2 are wavelength-dependent correction factors determined from Table IV.
- (2) The variable t in the expressions of emission limits is the magnitude of the sampling interval in units of seconds.

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 ⁴	2.4 X 10 ⁻⁵ k ₁ k ₂ *	Joules(J)*	radiant energy
	>3.0 X 10 ⁴	8.0 X 10 ⁻¹⁰ k ₁ k ₂ *	Watts(W)*	radiant power
>400 but ≤1400	>1.0 X 10 ⁻⁹ to 2.0 X 10 ⁻⁵	2.0 X 10 ⁻⁷ k ₁ k ₂	J	radiant energy
	>2.0 X 10 ⁻⁵ to 1.0 X 10 ¹	7.0 X 10 ⁻⁴ k ₁ k ₂ ^{3/4}	J	radiant energy
	>1.0 X 10 ¹ to 1.0 X 10 ⁴	3.9 X 10 ⁻³ k ₁ k ₂	J	radiant energy
	>1.0 X 10 ⁴	3.9 X 10 ⁻⁷ k ₁ k ₂	W	radiant power
and also (See paragraph (d)(4) of this section)				
>1400 but ≤2500	>1.0 X 10 ⁻⁹ to 1.0 X 10 ¹	10k ₁ k ₂ t ^{1/3}	Jcm ⁻² sr ⁻¹	integrated radiance
	>1.0 X 10 ¹ to 1.0 X 10 ⁴	20k ₁ k ₂	Jcm ⁻² sr ⁻¹	integrated radiance
	>1.0 X 10 ⁴	2.0 X 10 ⁻³ k ₁ k ₂	Wcm ⁻² sr ⁻¹	radiance
	>1.0 X 10 ⁻⁹ to 1.0 X 10 ⁻⁷	7.9 X 10 ⁻⁵ k ₁ k ₂	J	radiant energy
>2500 but ≤1.0 X 10 ⁶	>1.0 X 10 ⁻⁷ to 1.0 X 10 ¹	4.4 X 10 ⁻³ k ₁ k ₂ t ^{1/4}	J	radiant energy
	>1.0 X 10 ¹	7.9 X 10 ⁻⁴ k ₁ k ₂	W	radiant power
>2500 but ≤1.0 X 10 ⁶	>1.0 X 10 ⁻⁹ to 1.0 X 10 ⁻⁷	1.0 X 10 ⁻² k ₁ k ₂	Jcm ⁻²	radiant exposure
	>1.0 X 10 ⁻⁷ to 1.0 X 10 ¹	5.6 X 10 ⁻¹ k ₁ k ₂ t ^{1/4}	Jcm ⁻²	radiant exposure
	>1.0 X 10 ¹	1.0 X 10 ⁻¹ k ₁ k ₂ t	Jcm ⁻²	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 10⁶ nm with a k₁ and k₂ 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 X 10 ³	3.9 X 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 X 10 ⁻¹	1.0 X 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

Wavelength (nanometers)	Emission duration (seconds)	Class IIIa-Accessible emission limits		
		(value)	(unit)	(quantity)*
>400 but ≤710	>3.8 X 10 ⁻⁴	5.0 X 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)*
≥180 but ≤400	≤2.5 X 10 ⁻¹ but >2.5 X 10 ⁻¹	3.8 X 10 ⁻⁴ k ₁ k ₂	J	radiant energy
>400 but ≤1400	>1.0 X 10 ⁻⁹ to 2.5 X 10 ⁻¹ to a maximum value of 10	1.5 X 10 ⁻² k ₁ k ₂	W	radiant power
>1400 but ≤1.0 X 10 ⁶	>2.5 X 10 ⁻¹ to 1.0 X 10 ⁻¹ to 1.0 X 10 ¹	10k ₁ k ₂ t ^{1/3}	Jcm ⁻²	radiant exposure
		5.0 X 10 ⁻¹	W	radiant power
		10	Jcm ⁻²	radiant exposure
		5.0 X 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: $\frac{10100}{\lambda - 699} < t \leq 10^4$ then: $k_2 = \frac{10100}{t}$
> 800 to 1060	$10^{\left[\frac{\lambda - 700}{515}\right]}$	if: $t \leq 10^4$ then: $k_2 = 1.0$
> 1060 to 1400	5.0	if: $100 < t \leq 10^4$ then: $k_2 = \frac{t}{100}$
> 1400 to 1535	1.0	1.0
> 1535 to 1545	$t \leq 10^{-7}$ $k_1 = 100.0$ $t > 10^{-7}$ $k_1 = 1.0$	1.0
> 1545 to 1.0×10^6	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 (λ), 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	2.1	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					
1.0×10^6	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.

TABLE VI

ACCESSIBLE EMISSION LIMITS FOR COLLATERAL
RADIATION FROM LASER PRODUCTS

<p>1. <u>Accessible emission limits</u> for collateral radiation having wave-⁶lengths greater than 180 nanometers but less than or equal to 1.0×10^6 nanometers are identical to the accessible emission limits of Class I laser radiation, as determined from Tables I and IV in this paragraph.</p> <p style="margin-left: 40px;">i. In the wavelength range of less than or equal to 400 nanometers, for all emission durations;</p> <p style="margin-left: 40px;">ii. In the wavelength range of greater than 400 nanometers, for all emission durations less than or equal to 1×10^3 seconds and, when applicable under paragraph (f)(8) of this section, for all emission durations.</p> <p>2. <u>Accessible emission limit</u> for collateral radiation within the x-ray range of wavelengths is 0.5 milliroentgen in an hour, averaged over a cross-section parallel to the external surface of the product, having an area of 10 square centimeters with no dimension greater than 5 centimeters.</p>

(1) *Beam of a single wavelength.* Laser or collateral radiation of a single wavelength exceeds the accessible emission limits of a class if its accessible emission level is greater than the accessible emission limit of that class within any of the ranges of emission duration specified in Tables I, II-A, II, III-A, and III-B of this paragraph.

(2) *Beam of multiple wavelengths in same range.* Laser or collateral radiation having two or more wavelengths within any one of the wavelength ranges specified in Tables I, II-A, II, III-A, and III-B of this paragraph exceeds the accessible emission limits of a class if the sum of the ratios of the accessible emission level to the cor-

responding accessible emission limit at each such wavelength is greater than unity for that combination of emission duration and wavelength distribution which results in the maximum sum.

(3) *Beam with multiple wavelengths in different ranges.* Laser or collateral radiation having wavelengths within two or more of the wavelength ranges specified in Tables I, II-A, II, III-A, and III-B of this paragraph exceeds the accessible emission limits of a class if it exceeds the applicable limits within any one of those wavelength ranges. This determination is made for each wavelength range in accordance with paragraph (d) (1) or (2) of this section.

(4) *Class I dual limits.* Laser or collateral radiation in the wavelength range of greater than 400 nm but less than or equal to 1,400 nm exceeds the accessible emission limits of Class I if it exceeds both:

(i) The Class I accessible emission limits for radiant energy within any range of emission duration specified in Table I of this paragraph, and

(ii) The Class I accessible emission limits for integrated radiance within any range of emission duration specified in Table I of this paragraph.

(e) *Tests for determination of compliance—(1) Tests for certification.* Tests on which certification under §1010.2 is based shall account for all errors and statistical uncertainties in the measurement process. Because compliance with the standard is required for the useful life of a product such tests shall also account for increases in emission and degradation in radiation safety with age.

(2) *Test conditions.* Except as provided in §1010.13, tests for compliance with each of the applicable requirements of this section and §1040.11 shall be made during operation, maintenance, or service as appropriate:

(i) Under those conditions and procedures which maximize the accessible emission levels, including start-up, stabilized emission, and shut-down of the laser product; and

(ii) With all controls and adjustments listed in the operation, maintenance, and service instructions adjusted in combination to result in the maximum accessible emission level of radiation; and

(iii) At points in space to which human access is possible in the product configuration which is necessary to determine compliance with each requirement, e.g., if operation may require removal of portions of the protective housing and defeat of safety interlocks, measurements shall be made at points accessible in that product configuration; and

(iv) With the measuring instrument detector so positioned and so oriented with respect to the laser product as to result in the maximum detection of radiation by the instrument; and

(v) For a laser product other than a laser system, with the laser coupled to

that type of laser energy source which is specified as compatible by the laser product manufacturer and which produces the maximum emission level of accessible radiation from that product.

(3) *Measurement parameters.* Accessible emission levels of laser and collateral radiation shall be based upon the following measurements as appropriate, or their equivalent:

(i) For laser products intended to be used in a locale where the emitted laser radiation is unlikely to be viewed with optical instruments, the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1×10^{-3} steradian with collimating optics of 5 diopters or less. For scanned laser radiation, the direction of the solid angle of acceptance shall change as needed to maximize detectable radiation, with an angular speed of up to 5 radians/second. A 50 millimeter diameter aperture stop with the same collimating optics and acceptance angle stated above shall be used for all other laser products (except that a 7 millimeter diameter aperture stop shall be used in the measurement of scanned laser radiation emitted by laser products manufactured on or before August 20, 1986).

(ii) The irradiance ($W\text{ cm}^{-2}$) or radiant exposure ($J\text{ cm}^{-2}$ equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and, for irradiance, within a circular solid angle of acceptance of 1×10^{-3} steradian with collimating optics of 5 diopters or less, divided by the area of the aperture stop (cm^{-2}).

(iii) The radiance ($W\text{ cm}^{-2}\text{ sr}^{-1}$) or integrated radiance ($J\text{ cm}^{-2}\text{ sr}^{-1}$) equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1×10^{-5} steradian with collimating optics of 5 diopters or less, divided by that solid angle (sr) and by the area of the aperture stop (cm^{-2}).

(f) *Performance requirements—(1) Protective housing.* Each laser product shall have a protective housing that prevents human access during operation

to laser and collateral radiation that exceed the limits of Class I and Table VI, respectively, wherever and whenever such human access is not necessary for the product to perform its intended function. Wherever and whenever human access to laser radiation levels that exceed the limits of Class I is necessary, these levels shall not exceed the limits of the lowest class necessary to perform the intended function(s) of the product.

(2) *Safety interlocks.* (i) Each laser product, regardless of its class, shall be provided with at least one safety interlock for each portion of the protective housing which is designed to be removed or displaced during operation or maintenance, if removal or displacement of the protective housing could permit, in the absence of such interlock(s), human access to laser or collateral radiation in excess of the accessible emission limit applicable under paragraph (f)(1) of this section.

(ii) Each required safety interlock, unless defeated, shall prevent such human access to laser and collateral radiation upon removal or displacement of such portion of the protective housing

(iii) Either multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing shall be provided, if failure of a single interlock would allow;

(a) Human access to a level of laser radiation in excess of the accessible emission limits of Class IIIa; or

(b) Laser radiation in excess of the accessible emission limits of Class II to be emitted directly through the opening created by removal or displacement of the interlocked portion of the protective housing.

(iv) Laser products that incorporate safety interlocks designed to allow safety interlock defeat shall incorporate a means of visual or aural indication of interlock defeat. During interlock defeat, such indication shall be visible or audible whenever the laser product is energized, with and without the associated portion of the protective housing removed or displaced.

(v) Replacement of a removed or displaced portion of the protective hous-

ing shall not be possible while required safety interlocks are defeated.

(3) *Remote interlock connector.* Each laser system classified as a Class IIIb or IV laser product shall incorporate a readily available remote interlock connector having an electrical potential difference of no greater than 130 root-mean-square volts between terminals. When the terminals of the connector are not electrically joined, human access to all laser and collateral radiation from the laser product in excess of the accessible emission limits of Class I and Table VI shall be prevented.

(4) *Key control.* Each laser system classified as a Class IIIb or IV laser product shall incorporate a key-actuated master control. The key shall be removable and the laser shall not be operable when the key is removed.

(5) *Laser radiation emission indicator.* (i) Each laser system classified as a Class II or IIIa laser product shall incorporate an emission indicator that provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I.

(ii) Each laser system classified as a Class IIIb or IV laser product shall incorporate an emission indicator which provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I, and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to the laser radiation.

(iii) For laser systems manufactured on or before August 20, 1986, if the laser and laser energy source are housed separately and can be operated at a separation distance of greater than 2 meters, both laser and laser energy source shall incorporate an emission indicator as required in accordance with paragraph (f)(5) (i) or (ii) of this section. For laser systems manufactured after August 20, 1986, each separately housed laser and operation control of a laser system that regulates the laser or collateral radiation emitted by a product during operation shall incorporate an emission indicator as required in accordance with paragraph (f)(5) (i) or (ii) of this section, if the laser or operation control can be operated at a separation distance greater than 2 meters from

any other separately housed portion of the laser product incorporating an emission indicator.

(iv) Any visible signal required by paragraph (f)(5) (i) or (ii) of this section shall be clearly visible through protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation.

(v) Emission indicators required by paragraph (f)(5) (i) or (ii) of this section shall be located so that viewing does not require human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI.

(6) *Beam attenuator.* (i) Each laser system classified as a Class II, III, or IV laser product shall be provided with one or more permanently attached means, other than laser energy source switch(es), electrical supply main connectors, or the key-actuated master control, capable of preventing access by any part of the human body to all laser and collateral radiation in excess of the accessible emission limits of Class I and Table VI.

(ii) If the configuration, design, or function of the laser product would make unnecessary compliance with the requirement in paragraph (f)(6)(i) of this section, the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, may, upon written application by the manufacturer, approve alternate means to accomplish the radiation protection provided by the beam attenuator.

(7) *Location of controls.* Each Class IIa, II, III, or IV laser product shall have operational and adjustment controls located so that human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI is unnecessary for operation or adjustment of such controls.

(8) *Viewing optics.* All viewing optics, viewports, and display screens incorporated into a laser product, regardless of its class, shall limit the levels of laser and collateral radiation accessible to the human eye by means of such viewing optics, viewports, or display screens during operation or maintenance to less than the accessible emission limits of Class I and Table VI. For any shutter or variable attenuator

incorporated into such viewing optics, viewports, or display screens, a means shall be provided:

(i) To prevent access by the human eye to laser and collateral radiation in excess of the accessible emission limits of Class I and Table VI whenever the shutter is opened or the attenuator varied.

(ii) To preclude, upon failure of such means as required in paragraph (f)(8)(i) of this section, opening the shutter or varying the attenuator when access by the human eye is possible to laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI.

(9) *Scanning safeguard.* Laser products that emit accessible scanned laser radiation shall not, as a result of any failure causing a change in either scan velocity or amplitude, permit human access to laser radiation in excess of:

(i) The accessible emission limits of the class of the product, or

(ii) The accessible emission limits of the class of the scanned laser radiation if the product is Class IIIb or IV and the accessible emission limits of Class IIIa would be exceeded solely as result of such failure.

(10) *Manual reset mechanism.* Each laser system manufactured after August 20, 1986, and classified as a Class IV laser product shall be provided with a manual reset to enable resumption of laser radiation emission after interruption of emission caused by the use of a remote interlock or after an interruption of emission in excess of 5 seconds duration due to the unexpected loss of main electrical power.

(g) *Labeling requirements.* In addition to the requirements of §§ 1010.2 and 1010.3, each laser product shall be subject to the applicable labeling requirements of this paragraph.

(1) *Class IIa and II designations and warnings.* (i) Each Class IIa laser product shall have affixed a label bearing the following wording: "Class IIa Laser Product—Avoid Long-Term Viewing of Direct Laser Radiation."

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(ii) Each Class II laser product shall have affixed a label bearing the warning logotype A (Figure 1 in this paragraph) and including the following wording:

[Position 1 on the logotype]

“LASER RADIATION—DO NOT STARE INTO BEAM”; and

[Position 3 on the logotype]

“CLASS II LASER PRODUCT”.

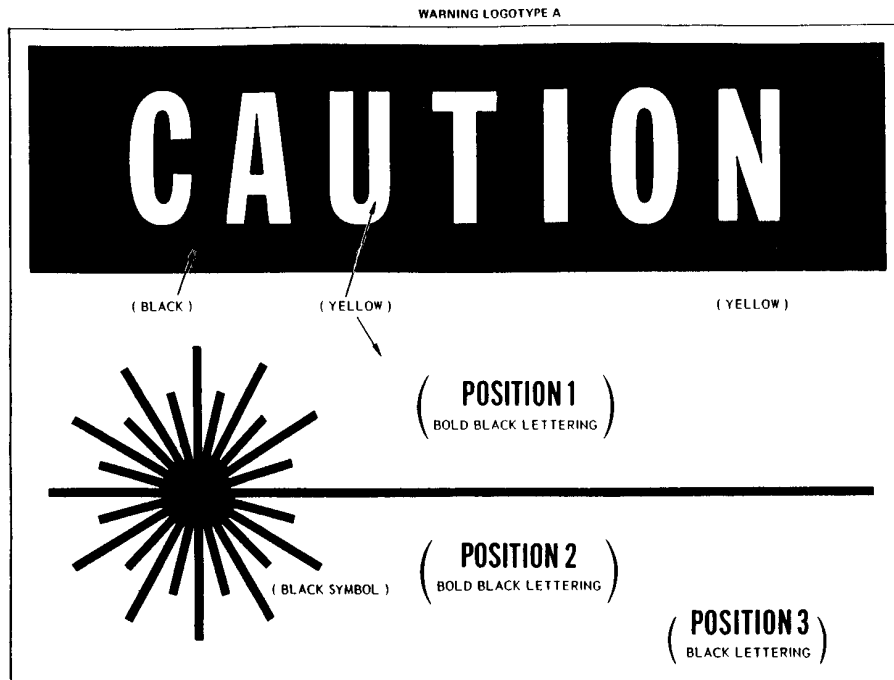


FIGURE 1

(2) *Class IIIa and IIIb designations and warnings.* (i) Each Class IIIa laser product with an irradiance less than or equal to $2.5 \times 10^{-3} \text{ W cm}^{-2}$ shall have affixed a label bearing the warning logotype A (Figure 1 of paragraph (g)(1)(ii) of this section) and including the following wording:

[Position 1 on the logotype]

“LASER RADIATION—DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS”; and,

[Position 3 on the logotype]

“CLASS IIIa LASER PRODUCT”.

(ii) Each Class IIIa laser product with an irradiance greater than $2.5 \times 10^{-3} \text{ W cm}^{-2}$ shall have affixed a label bearing the warning logotype B (Figure 2 in

this paragraph) and including the following wording:

[Position 1 on the logotype]
 "LASER RADIATION—AVOID
 DIRECT EYE EXPOSURE"; and,
 [Position 3 on the logotype]
 "CLASS IIIa LASER PRODUCT".

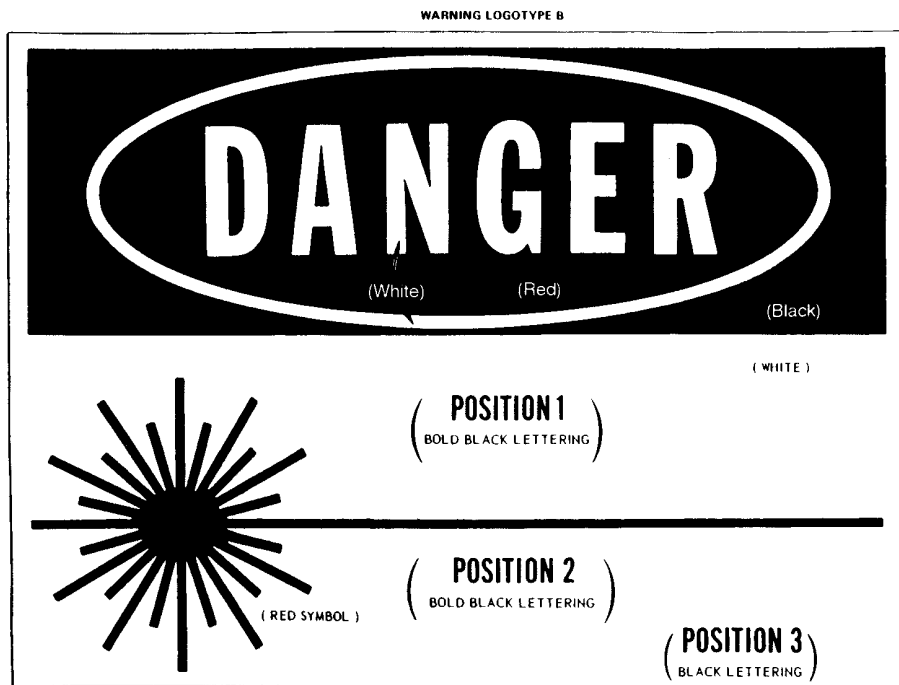


FIGURE 2

(iii) Each Class IIIb laser product shall have affixed a label bearing the warning logotype B (Figure 2 of paragraph (g)(2)(ii) of this section) and including the following wording:

[Position 1 on the logotype]
 "LASER RADIATION—AVOID
 DIRECT EXPOSURE TO BEAM"; and,
 [Position 3 on the logotype]
 "CLASS IIIb LASER PRODUCT".

(3) *Class IV designation and warning.* Each Class IV laser product shall have affixed a label bearing the warning logotype B (Figure 2 of paragraph (g)(2)(ii)

of this section), and including the following wording:

[Position 1 on the logotype]
 "LASER RADIATION—AVOID EYE OR
 SKIN EXPOSURE TO DIRECT OR
 SCATTERED RADIATION"; and,
 [Position 3 on the logotype]
 "CLASS IV LASER PRODUCT".

(4) *Radiation output information on warning logotype.* Each Class II, III, and IV laser product shall state in appropriate units, at position 2 on the required warning logotype, the maximum

output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength(s).

(5) *Aperture label.* Each laser product, except medical laser products and Class IIa laser products, shall have affixed, in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI of paragraph (d) of this section, a label(s) bearing the following wording as applicable.

(i) "AVOID EXPOSURE—Laser radiation is emitted from this aperture," if the radiation emitted through such aperture is laser radiation.

(ii) "AVOID EXPOSURE—Hazardous electromagnetic radiation is emitted from this aperture," if the radiation emitted through such aperture is collateral radiation described in Table VI, item 1.

(iii) "AVOID EXPOSURE—Hazardous x-rays are emitted from this aperture," if the radiation emitted through such aperture is collateral radiation described in Table VI, item 2.

(6) *Labels for noninterlocked protective housings.* For each laser product, labels shall be provided for each portion of the protective housing which has no safety interlock and which is designed to be displaced or removed during operation, maintenance, or service, and thereby could permit human access to laser or collateral radiation in excess of the limits of Class I and Table VI. Such labels shall be visible on the protective housing prior to displacement or removal of such portion of the protective housing and visible on the product in close proximity to the opening created by removal or displacement of such portion of the protective housing, and shall include the wording:

(i) "CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM." for Class II accessible laser radiation.

(ii) "CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS." for Class IIIa accessible laser radiation with an irradiance less than or equal to $2.5 \times 10^{-3} \text{ W cm}^{-2}$.

(iii) "DANGER—Laser radiation when open. AVOID DIRECT EYE EXPOSURE." for Class IIIa accessible

laser radiation with an irradiance greater than $2.5 \times 10^{-3} \text{ W cm}^{-2}$.

(iv) "DANGER—Laser radiation when open. AVOID DIRECT EXPOSURE TO BEAM." for Class IIIb accessible laser radiation.

(v) "DANGER—Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for Class IV accessible laser radiation.

(vi) "CAUTION—Hazardous electromagnetic radiation when open." for collateral radiation in excess of the accessible emission limits in Table VI, item 1 of paragraph (d) of this section.

(vii) "CAUTION—Hazardous x-rays when open." for collateral radiation in excess of the accessible emission limits in Table VI, item 2 of paragraph (d) of this section.

(7) *Labels for defeatably interlocked protective housings.* For each laser product, labels shall be provided for each defeatably interlocked (as described in paragraph (f)(2)(iv) of this section) portion of the protective housing which is designed to be displaced or removed during operation, maintenance, or service, and which upon interlock defeat could permit human access to laser or collateral radiation in excess of the limits of Class I or Table VI. Such labels shall be visible on the product prior to and during interlock defeat and in close proximity to the opening created by the removal or displacement of such portion of the protective housing, and shall include the wording:

(i) "CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM." for Class II accessible laser radiation.

(ii) "CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS." for Class IIIa accessible laser radiation with an irradiance less than or equal to $2.5 \times 10^{-3} \text{ W cm}^{-2}$.

(iii) "DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EYE EXPOSURE." for Class IIIa accessible laser radiation when an irradiance greater than $2.5 \times 10^{-3} \text{ W cm}^{-2}$.

(iv) "DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EXPOSURE TO

BEAM.” for Class IIIb accessible laser radiation.

(v) “DANGER—Laser radiation when open and interlock defeated. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.” for Class IV accessible laser radiation.

(vi) “CAUTION—Hazardous electromagnetic radiation when open and interlock defeated.” for collateral radiation in excess of the accessible emission limits in Table VI, item 1 of paragraph (d) of this section.

(vii) “CAUTION—Hazardous x-rays when open and interlock defeated.” for collateral radiation in excess of the accessible emission limits in Table VI, item 2 of paragraph (d) of this section.

(8) *Warning for visible and/or invisible radiation.* On the labels specified in this paragraph, if the laser or collateral radiation referred to is:

(i) Invisible radiation, the word “invisible” shall appropriately precede the word “radiation”; or

(ii) Visible and invisible radiation, the words “visible and invisible” or “visible and/or invisible” shall appropriately precede the word “radiation.”

(iii) Visible laser radiation only, the phrase “laser light” may replace the phrase “laser radiation.”

(9) *Positioning of labels.* All labels affixed to a laser product shall be positioned so as to make unnecessary, during reading, human exposure to laser radiation in excess of the accessible emission limits of Class I radiation or the limits of collateral radiation established to Table VI of paragraph (d) of this section.

(10) *Label specifications.* Labels required by this section and § 1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, or service, as appropriate. If the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, on the Director’s own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s)

or alternate wording for such label(s) as applicable.

(h) *Informational requirements—(1) User information.* Manufacturers of laser products shall provide as an integral part of any user instruction or operation manual which is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each laser product:

(i) Adequate instructions for assembly, operation, and maintenance, including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11.

(ii) A statement of the magnitude, in appropriate units, of the pulse durations(s), maximum radiant power and, where applicable, the maximum radiant energy per pulse of the accessible laser radiation detectable in each direction in excess of the accessible emission limits in Table I of paragraph (d) of this section determined under paragraph (e) of this section.

(iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and § 1040.11 to be affixed to the laser product or provided with the laser product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 of paragraph (g)(1)(ii) or Figure 2 or paragraph (g)(2)(ii) of this section). The corresponding position of each label affixed to the product shall be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in which they were supplied shall be provided.

(iv) A listing of all controls, adjustments, and procedures for operation and maintenance, including the warning “Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.”

(v) In the case of laser products other than laser systems, a statement of the

compatibility requirements for a laser energy source that will assure compliance of the laser product with this section and § 1040.11.

(vi) In the case of laser products classified with a 7 millimeter diameter aperture stop as provided in paragraph (e)(3)(i) of this section, if the use of a 50 millimeter diameter aperture stop would result in a higher classification of the product, the following warning shall be included in the user information: "CAUTION—The use of optical instruments with this product will increase eye hazard."

(2) *Purchasing and servicing information.* Manufacturers of laser products shall provide or cause to be provided:

(i) In all catalogs, specification sheets, and descriptive brochures pertaining to each laser product, a legible reproduction (color optional) of the class designation and warning required by paragraph (g) of this section to be affixed to that product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 of paragraph (g)(1)(ii) or Figure 2 of paragraph (g)(2)(ii) of this section).

(ii) To servicing dealers and distributors and to others upon request at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model, including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11; and in all such service instructions, a listing of those controls and procedures that could be utilized by persons other than the manufacturers or the manufacturer's agents to increase accessible emission levels of radiation and a clear description of the location of displaceable portions of the protective housing that could allow human access to laser or collateral radiation in excess of the accessible emission limits in Tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section. The instructions shall include protective procedures for service

personnel to avoid exposure to levels of laser and collateral radiation known to be hazardous for each procedure or sequence of procedures to be accomplished, and legible reproductions (color optional) of required labels and hazard warnings.

(i) *Modification of a certified product.* The modification of a laser product, previously certified under § 1010.2, by any person engaged in the business of manufacturing, assembling, or modifying laser products shall be construed as manufacturing under the act if the modification affects any aspect of the product's performance or intended function(s) for which this section and § 1040.11 have an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the product in accordance with the provisions of §§ 1010.2. and 1010.3.

[The information collection requirements contained in paragraph (a)(3)(ii) were approved by the Office of Management and Budget under control number 0910-0176]

[50 FR 33688, Aug. 20, 1985; 50 FR 42156, Oct. 18, 1985]

§ 1040.11 Specific purpose laser products.

(a) *Medical laser products.* Each medical laser product shall comply with all of the applicable requirements of § 1040.10 for laser products of its class. In addition, the manufacturer shall:

(1) Incorporate in each Class III or IV medical laser product a means for the measurement of the level of that laser radiation intended for irradiation of the human body. Such means may have an error in measurement of no more than 20 percent when calibrated in accordance with paragraph (a)(2) of this section. Indication of the measurement shall be in International System Units. The requirements of this paragraph do not apply to any laser radiation that is all of the following:

- (i) Of a level less than the accessible limits of Class IIIa; and
- (ii) Used for relative positioning of the human body; and
- (iii) Not used for irradiation of the human eye for ophthalmic purposes.

(2) Supply with each Class III or IV medical laser product instructions specifying a procedure and schedule for

Laser Products – Conformance with IEC 60825-1, Am. 2 and IEC 60601-2-22; Final Guidance for Industry and FDA (Laser Notice No. 50)

Document issued on: July 26, 2001



**U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Electronic Product Devices Branch
Division of Enforcement III
Office of Compliance**

Preface

Public Comment

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Such comments will be considered when determining whether to amend the current guidance.

After 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Jerome E. Dennis at (301) 594-4654, ext. 135, or by electronic mail at jxd@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at: <http://www.fda.gov/cdrh/comp/guidance/1346.pdf>, or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1346 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Guidance on Laser Products – Conformance with IEC 60825-1, Am. 2 and IEC 60601-2-22 (Laser Notice No. 50)

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Purpose

This guidance describes the conditions under which laser product manufacturers may introduce into United States commerce laser products that comply with the IEC standards 60825-1, as amended, and 60601-2-22. This guidance also describes additional requirements of the CDRH standard and alternate certification statements to be used with such products.

Issue

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) intends to amend its standards for laser products at 21 CFR §1040.10 and §1040.11 to harmonize many of its requirements with those of the IEC 60825-1 and 60601-2-22 standards. Although CDRH began its amendment process in anticipation of the amendment of IEC 60825-1, it is not yet ready to publish an amendment. CDRH has acknowledged the advantages of one set of criteria and requirements worldwide. Amendment 2 to IEC 60825-1 was published in January 2001. As a result, manufacturers distributing products in both the U.S. and countries that require conformance with, or that recognize IEC 60825-1, will have to evaluate the conformance of their products with this standard. This requires them to often change the hazard classification of their products. These manufacturers are requesting relief from CDRH so that they will have to comply with only one laser product radiation safety standard.

Background

Laser products for introduction into commerce in or imported into the United States must:

- Comply with 21 CFR §1040.10 and §1040.11 as applicable,
- Be certified and identified in accordance with 21 CFR §1010.2 and §1010.3, and
- Be reported in accordance with 21 CFR §1002.10.

CDRH has issued notices to laser product manufacturers and importers stating non-objection to:

- Lack of emission indicators or beam attenuators on Class II and Class IIIa systems, and
- Hazard warning labels as specified in IEC 60825-1.

These notices reduced the regulatory burden on both the industry and the agency.

CDRH will not object to conformance with many sections of IEC 60825-1, as amended, and IEC 60601-2-22 as alternatives to comparable sections of 21 CFR §1040.10 and §1040.11. CDRH plans to amend federal regulations for laser products to reflect those sections of the IEC standards. CDRH is also listing sections of its standard that contain requirements to which manufacturers must conform. This action is appropriate because of the numerous requests for relief, the amendment of IEC 60825-1, and the Center's intent to harmonize its requirements with many of those of the IEC standards.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of regulated products. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at <http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html>.

Guidance

Effective immediately, and until the effective date(s) of any amendments of the Federal regulations affecting laser products, CDRH will not object to conformance with the comparable sections of IEC 60825-1, as amended by Amendment 2 of January 2001 in lieu of conformance with the following sections of 21 CFR §1040:

1040.10(b)	Definitions
1040.10(c)(1)	Classification
1040.10(d)	Accessible emission limits
1040.10(e)	Tests for determination of compliance
1040.10(f)(1)	Protective housing
1040.10(f)(2)	Safety interlocks
1040.10(f)(3)	Remote Interlock connector
1040.10(f)(4)	Key control
1040.10(f)(5)	Laser radiation emission indicator
1040.10(f)(6)	Beam attenuator
1040.10(f)(7)	Location of controls
1040.10(f)(8)	Viewing optics
1040.10(f)(9)	Scanning safeguard
1040.10(g)	Labeling requirements
1040.10(h)(1)	User information

1040.11(a) Medical laser products

CDRH intends to harmonize the requirements of these sections with those of the IEC standards.

However, laser products must conform to the following sections of the CDRH standards:

1010.2	Certification
1010.3	Identification
1010.4	Variances
1040.10(a)	Applicability
1040.10(c)(2)	Removable laser systems
1040.10(f)(10)	Manual reset mechanism
1040.10(h)(2)	Purchasing and servicing information
1040.10(i)	Modification of a certified product
1040.11(b)	Surveying, leveling and alignment laser products
1040.11(c)	Demonstration laser products

CDRH intends to retain these requirements even if they differ from the IEC. They are either beyond the scope of the IEC standard, are sufficiently different, or are not normative and included as recommendations in the User's Guide section of the IEC standard.

In using this guidance, manufacturers should:

1. Use the following modified statement of compliance on the certification label:
"Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated (Insert date of this guidance.)"
or "Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated (Insert date of this guidance.);" and
2. Submit product reports or supplemental reports to describe changes to products in accordance with this guidance.

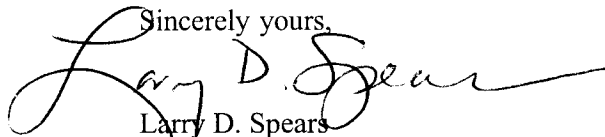
The effectiveness of this guidance will end on the effective date(s) of any amendments to the Federal regulations applicable to laser products under Chapter 1, Subchapter J of Title 21 of the Code of Federal Regulations.

Getting More Information

You can get more information about our requirements for lasers from our electronic product radiation control web page at <http://www.fda.gov/cdrh/radhlth/>.

If you have questions about this guidance, contact Jerome Dennis, CDRH, Office of Compliance (HFZ-342), 2094 Gaither Rd., Rockville, MD 20850, FAX 301-594-4672, or e-mail jxd@cdrh.fda.gov.

Sincerely yours,



Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health

IC 35-47-4.5

Chapter 4.5. Regulation of Laser Pointers

IC 35-47-4.5-1

Exceptions

Sec. 1. This chapter does not apply to the use of a laser pointer:

- (1) for educational purposes by individuals engaged in an organized meeting or training class; or
- (2) during the normal course of work or trade activities.

As added by P.L. 70-2000, SEC.1.

IC 35-47-4.5-2

"Laser pointer" defined

Sec. 2. As used in this chapter, "laser pointer" means a device that emits light amplified by the stimulated emission of radiation that is visible to the human eye.

As added by P.L. 70-2000, SEC.1.

IC 35-47-4.5-3

"Public safety officer" defined

Sec. 3. As used in this chapter, "public safety officer" means:

- (1) a state police officer;
- (2) a county sheriff;
- (3) a county police officer;
- (4) a correctional officer;
- (5) an excise police officer;
- (6) a county police reserve officer;
- (7) a city police officer;
- (8) a city police reserve officer;
- (9) a conservation enforcement officer;
- (10) a town marshal;
- (11) a deputy town marshal;
- (12) a state university police officer appointed under IC 20-12-3.5;
- (13) a probation officer;
- (14) a firefighter (as defined in IC 9-18-34-1);
- (15) an emergency medical technician; or
- (16) a paramedic.

As added by P.L. 70-2000, SEC.1.

IC 35-47-4.5-4

Directing laser pointer at public safety officer

Sec. 4. A person who knowingly or intentionally directs light amplified by the stimulated emission of radiation that is visible to the human eye or any other electromagnetic radiation from a laser pointer at a public safety officer without the consent of the public safety officer commits a Class B misdemeanor.

As added by P.L. 70-2000, SEC.1.