

Laser Standard – Revised Proposed Amendments

| Present regulation | Proposed 3/24/1999 | Revision from 3/24/1999 |
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| <p>..21 CFR Part 1010.2 Certification.</p> <p>(a) Every manufacturer of an electronic product for which an applicable standard is in effect under this subchapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under this subchapter.</p> <p>(b) The certification shall be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use, unless the applicable standard prescribes some other manner of certification. All such labels or tags shall be in the English language.</p> <p>(c) Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Director, Center for Devices and Radiological Health may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this subchapter.</p> <p>(d) In the case of products for which it is not feasible to certify in accordance with paragraph (b) of this section, upon application by the manufacturer, the Director, Center for Devices and Radiological Health may approve an alternate means by which such certification may be provided.</p> <p>38 FR 28631, Oct. 15, 1973, as amended at 40 FR 32257, July 31, 1975; 42 FR 18063, Apr. 5, 1977; 53 FR 11254, Apr. 6, 1988</p> | <p>(d) In the case of products for which it is not feasible to certify in accordance with paragraph (b) of this section, upon application by the manufacturer or upon his or her initiative, the Director, Office of Compliance, Center for Devices and Radiological Health, may approve an alternate means by which such certification may be provided.</p> | |

..21 CFR Part 1010.3 Identification.

(a) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall set forth the information specified in paragraphs (a)(1) and (2) of this section. This information shall be provided in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the applicable standard. Except for foreign equivalent abbreviations as authorized in paragraph (a)(1) of this section all such labels or tags shall be in the English language.

(1) The full name and address of the manufacturer of the product; abbreviations such as "Co.," "Inc.," or their foreign equivalents and the first and middle initials of individuals may be used. Where products are sold under a name other than that of the manufacturer of the product, the full name and address of the individual or company under whose name the product was sold may be set forth, provided such individual or company has previously supplied the Director, Center for Devices and Radiological Health with sufficient information to identify the manufacturer of the product.

(2) The place and month and year of manufacture:

(i) The place of manufacture may be expressed in code provided the manufacturer has previously supplied the Director, Center for Devices and Radiological Health with the key to such code.

(ii) The month and year of manufacture shall be provided clearly and legibly, without abbreviation, and with the year shown as a four-digit number as follows:

Manufactured: (Insert Month and Year of Manufacture.)

(b) In the case of products for which it is not feasible to affix identification labeling in accordance with paragraph (a) of this section, upon application by the

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manufacturer, the Director, Center for Devices and Radiological Health may approve an alternate means by which such identification may be provided.

(c) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall provide to the Director, Center for Devices and Radiological Health a list identifying each brand name which is applied to the product together with the full name and address of the individual or company for whom each product so branded is manufactured.

40 FR 32257, July 31, 1975, as amended at 42 FR 18063, Apr. 5, 1977; 53 FR 11254, Apr. 6, 1988

..21 CFR Part 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:

application by the manufacturer or upon his or her initiative, the Director, Office of Compliance, Center for Devices and Radiological Health, may approve an alternate means by which such identification may be provided.

Applicability.

The provisions of this section and Sec. 1040.11, as amended, are applicable as specified to all laser products manufactured or assembled after (date 1 year after date of publication in the Federal Register of any final rule that issues based on this proposed rule), except when:

- (1) Such a laser cannot under any conditions of operation, maintenance, service, or single failure emit radiation in excess of the accessible emission limits of a Class 1 laser product, or
- (2) Such a laser is sold to a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, or
- (3) Such a laser is 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:

..21 CFR Part 1040.10 Laser products.

Applicability.

The provisions of this section and Sec. 1040.11, as amended, are applicable as specified to all laser products manufactured or assembled after (date 1 year after date of publication in the Federal Register of any final rule that issues based on this proposed rule), except when:

- (1) Such a laser cannot under any conditions of operation, maintenance, service, or single failure emit or allow human access to radiation in excess of the accessible emission limits of a Class 1 laser product, or
- (2) Such a laser is sold to a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, or
- (3) Such a laser is 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:

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| <p>(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,</p> <p>(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</p> <p>(iii) Is not a removable laser system as described in paragraph (c)(2) of this section; and</p> <p>(3) The manufacturer of such a laser product, if manufactured after August 20, 1986:</p> <p>(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.</p> <p>(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.</p> <p>(b) Definitions.</p> <p>As used in this section and 1040.11, the following definitions apply:</p> <p>(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.</p> | <p>(i) Is accompanied by a general warning notice that adequate instructions for the safe installation of the product are provided in servicing information available from the complete product manufacturer under paragraph (h)(2)(ii) of this section, and should be followed,</p> <p>(ii) Is labeled with a statement that it is designated for use solely as a component of such electronic product and therefore is not required to comply with the appropriate requirements of this section and Sec. 1040.11 for complete laser products, and</p> <p>(iii) Is not a removable laser system as described in paragraph (c)(2) of this section; and</p> <p>(4) The manufacturer of such a laser product, if manufactured after August 20, 1986,</p> <p>(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-342), Center for Devices and Radiological Health, 2098 Gaither Rd., Rockville, MD 20850; and</p> <p>(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 Sec. 1002.31 of this chapter.</p> <p>(b) Definitions.</p> <p>As used in this section and 1040.11, the following definitions apply:</p> <p>(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.</p> | <p>(i) Is accompanied by a general warning notice that adequate instructions for the safe installation of the product are provided in servicing information available from the complete product manufacturer under paragraph (h)(2)(ii) of this section, and should be followed,</p> <p>(ii) Is labeled with a statement that it is designated for use solely as a component of such electronic product and therefore is not required to comply with the appropriate requirements of this section and Sec. 1040.11 for complete laser products, and</p> <p>(iii) Is not a removable laser system as described in paragraph (c)(2) of this section; and</p> <p>(4) The manufacturer of such a laser product, if manufactured after August 20, 1986,</p> <p>(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-342), Center for Devices and Radiological Health, 2098 Gaither Rd., Rockville, MD 20850; and</p> <p>(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 Sec. 1002.31 of this chapter.</p> <p>(b) Definitions.</p> <p>As used in this section and 1040.11, the following definitions apply:</p> <p>(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.</p> |
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| <p>(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.</p> <p>(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.</p> <p>(4) "Aperture stop" means an opening serving to limit the size and to define the shape of the area over which radiation is measured.</p> <p>(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\</p> <p>\1\ Class I levels of laser radiation are not considered to be hazardous.]</p> <p>(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</p> | <p>(2) Accessible emission limit means the maximum accessible emission level permitted within a particular class as set forth in paragraphs (c) and (d) of this section when measured according to paragraph (e) of this section.</p> <p>(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.</p> <p>(4) Aperture stop means an opening serving to limit the size and to define the shape of the area over which radiation is measured.</p> <p>(5) Class 1 laser means any laser that does not permit access during the operation to levels of laser radiation in excess of the accessible emission limits contained in Table 1 of paragraph (d) of this section.\1\</p> <p>\1\ Class 1 levels of laser or radiation are not considered to be hazardous.</p> <p>NOTE: CLASS IIa - DELETED</p> | <p>(2) Accessible emission limit means the maximum accessible emission level permitted within a particular class as set forth in paragraphs (c) and (d) of this section when measured according to paragraph (e) of this section.</p> <p>(3) Angle of acceptance (γ) means the plane angle that includes the dimension of the apparent source as determined from an axial point in the plane of the measuring aperture.</p> <p>(4) Angular subtense (α) means the plane angle subtended by a source or apparent source determined at a point not less than 100 mm from the source or apparent source.</p> <p>(5) 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.</p> <p>(6) Aperture stop means an opening serving to limit the size and to define the shape of the area over which radiation is measured.</p> <p>(7) Beam means any laser radiation that may be characterized by direction, divergence, diameter or scan specifications. Scattered reflection from a non-specular surface is not considered to be a beam</p> <p>(8) Class 1 laser means any laser that does not permit access during operation to levels of laser radiation in excess of the accessible emission limits of Class 1 according to Conditions 1 and 2 of XXXX of this section.\1\</p> <p>\1\ Class 1 levels of laser or radiation are not considered to be hazardous.</p> <p>(9) Class 1M laser means any laser in the wavelength range from 302.5 nm to 4000 nm which does not permit human access to laser radiation in excess of the accessible emission limits</p> |
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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.

[Footnote: Class IIa levels of laser radiation are not considered to be hazardous if viewed for any period of time less than or equal to 1000 seconds, but are considered to be a chronic viewing hazard for any period of time greater than 1000 seconds.]

(7) "Class II 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 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.

[Footnote: Class II levels of laser radiation are considered to be a chronic viewing hazard.]

(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.

[Footnote: Class 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

(6) Class 2 laser means any laser that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table 1 in paragraph (d) of this section, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table 2 of paragraph (d) of this section.\2\

\2\ Class 2 levels of laser radiation are considered to be a chronic viewing hazard.

(7) Class 3A laser means any laser that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table 2 of paragraph (d) of this section, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table 3 of paragraph (d) of this section.\3\

\3\ Class 3A levels of laser radiation are considered to be either an acute viewing hazard at visible or near-infrared (700 to 1,400 nanometers (nm)) wavelengths if viewed directly with optical

of Class 1 for applicable wavelengths and emission durations, where the level of radiation is measured according to Condition 2 of XXXX. \2\

\2\ The output of a Class 1M product is therefore potentially hazardous when viewed using an optical instrument.

(10) Class 2 laser means any laser that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits of Class 1, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits of Class 2 according to Conditions 1 and 2 of XXXX of this section.\3\

\3\ Class 2 levels of laser radiation are considered to be a chronic viewing hazard.

(11) Class 2M laser means any laser which does not permit human access to laser radiation in excess of the accessible emission limits of Class 2 where the level of radiation is measured according to Condition 2 of XXXX. \4\

\4\ Class 2M levels of laser radiation are potentially hazardous when viewed using an optical instrument

(12) Class 3R laser means any laser which permits human access during operation to laser radiation exceeding the accessible emission limits of Class 1 or Class 2 but does not permit human access during operation to accessible emission levels in excess of the accessible emission limits of Class 3R. \5\

\5\ Class 3R levels, although recognised to be hazardous, are not believed to constitute a significant risk of injury because of the small amount by which they exceed the limits of the lower classes or their irradiance.

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| <p>viewed directly with optical instruments.]</p> <p>(9) "Class IIb 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.</p> <p>[Footnote: Class IIb levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct radiation.]</p> <p>(10) "Class III laser product" means any Class IIIa or Class IIIb laser product.</p> <p>(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.</p> <p>[Footnote: Class IV levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct and scattered radiation.]</p> <p>(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).</p> <p>(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</p> | <p>instruments, or a nominal hazard at wavelengths outside these ranges.</p> <p>(8) Class 3B 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 3 of paragraph (d) of this section, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table 4 of paragraph (d) of this section.\4\</p> <p>\4\ Class 3B levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct radiation.</p> <p>(9) Class 3 laser product means any Class 3A or Class 3B laser product.</p> <p>(10) Class 4 laser product means any laser product that permits human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table 4 of paragraph (d) of this section.\5\</p> <p>\5\ Class 4 levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct and scattered radiation.</p> <p>(11) 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).</p> <p>(12) 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</p> | <p>(13) Class 3B laser means any laser that permits human access during operation to laser radiation in excess of the accessible emission limits of the lower classes but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits of Class 3R.\6\</p> <p>\6\ Class 3B levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct radiation.</p> <p>(14) Class 3 laser product means any Class 3R or Class 3B laser product.</p> <p>(15) Class 4 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 Class 3B.\7\</p> <p>\7\ Class 4 levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct and scattered radiation.</p> <p>(16) 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).</p> <p>(17) 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</p> |
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| <p>those purposes or are intended to demonstrate other applications.</p> <p>(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.</p> <p>(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 IIIb 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.</p> <p>(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.</p> <p>(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 1,000,000 nm (1 millimeter).</p> <p>(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.</p> <p>(19) "Laser" means any device that can be made to produce or amplify electromagnetic radiation at</p> | <p>for those purposes or are intended to demonstrate other applications.</p> <p>(13) 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 possible as a result of operation, maintenance, or service of a laser product.</p> <p>(14) Human access means the capacity to intercept laser or collateral radiation by any part of the human body. For laser products that contain Class 3B or 4 levels of laser radiation, "human access" also means access to laser radiation that can be reflected directly onto any part of the human body by any single introduced flat surface from the interior of the product through any opening in the protective housing of the product.</p> <p>(15) 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 700 nm but less than or equal to 1,000,000 nm (1 millimeter).</p> <p>(16) 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.</p> <p>(17) Laser means any device that can be made to produce or amplify electromagnetic radiation at</p> | <p>for those purposes or are intended to demonstrate other applications.</p> <p>(18) 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 possible as a result of operation, maintenance, or service of a laser product.</p> <p>(19) Human access means the capacity of the human eye to intercept a direct (undeviated) Class 1, 1M, 2, 2M or 3R laser beam from a product. For laser products that contain Class 3B or 4 levels of laser radiation, "human access" also means access to laser radiation that can be reflected directly onto any part of the human body by any single introduced flat surface from the interior of the product through any opening in the protective housing of the product.</p> <p>(20) 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 700 nm but less than or equal to 1,000,000 nm (1 millimeter). \8\</p> <p>\8\ Note. Although vision scientists consider the wavelength ranges from about 380 to 400 nm and from 700 to about 780 nm to be visible, because of the reduced visual sensation in these ranges these ranges are treated as invisible in this standard.</p> <p>(21) 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.</p> <p>(22) Laser means any device that can be made to produce or amplify electromagnetic radiation at</p> |
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| <p>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 1,000,000 nm primarily by the process of controlled stimulated emission.</p> <p>(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.</p> <p>(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.</p> <p>(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.</p> <p>(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."</p> <p>(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.</p> | <p>wavelengths greater than 180 nm but less than or equal to 1,000,000 nm (1 millimeter) primarily by the process of controlled stimulated emission.</p> <p>(18) 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.</p> <p>(19) 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.</p> <p>(20) Laser radiation means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph (b)(17) 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 as specified in paragraph (e) of this section.</p> <p>(21) 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."</p> <p>(22) 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 paragraphs (b)(27) and (b)(37) of this section.</p> | <p>wavelengths greater than 180 nm but less than or equal to 1,000,000 nm (1 millimeter) primarily by the process of controlled stimulated emission.</p> <p>(23) 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.</p> <p>(24) 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.</p> <p>(25) Laser radiation means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph (b)(22) 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 as specified in paragraph (e) of this section.</p> <p>(26) 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."</p> <p>(27) 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 paragraphs (b)(31) and (b)(41) of this section.</p> |
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(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.

(23) 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.

(24) Maximum angular subtense means the value of angular subtense of the apparent source above which the AEL's are independent of the source size ($\alpha_{\max} = 0.1 \text{ rad (100 mrad)}$).

(25) Medical laser 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.

(26) Minimum angular subtense means the value of angular subtense of the apparent source above which the source is considered to be an extended source. Maximum permissible exposures (MPE's) and AEL's are independent of source size for angles less than the minimum angular subtense (α_{\min}).

$$\begin{aligned} \alpha_{\min} &= 0.0015 \text{ rad for } t \leq 0.7 \text{ s} \\ &0.002 t^{3/4} \text{ rad for } 0.7 \text{ s} \leq t \leq 10 \text{ s} \\ &0.01 \text{ rad for } t > 10 \text{ s.} \end{aligned}$$

(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)(22) and (b)(37) of this section.

(28) 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.

(29) Maximum angular subtense means the value of angular subtense of the apparent source above which the AEL's are independent of the source size ($\alpha_{\max} = 0.1 \text{ rad (100 mrad)}$).

(30) Medical laser 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.

(31) Minimum angular subtense means the value of angular subtense of the apparent source above which the source is considered to be an extended source. Maximum permissible exposures (MPE's) and AEL's are independent of source size for angles less than the minimum angular subtense (α_{\min}).

$$\begin{aligned} \alpha_{\min} &= 0.0015 \text{ rad for } t \leq 0.7 \text{ s} \\ &0.002 t^{3/4} \text{ rad for } 0.7 \text{ s} \leq t \leq 10 \text{ s} \\ &0.01 \text{ rad for } t > 10 \text{ s.} \end{aligned}$$

(32) Novelty or toy laser means a laser that is intended for sale or promoted to the general public for the purpose of amusement or as a game or toy. Examples may include "pointers" with pattern generating optics or that are promoted for use at parties, night clubs or sporting events, or for use as toys to amuse or exercise pets.

(33) 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)(25) and (b)(41) of this section.

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| <p>(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.</p> <p>(29) "Pulse duration" means the time increment measured between the half-peak-power points at the leading and trailing edges of a pulse.</p> <p>(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.</p> <p>(31) "Radiant energy" means energy emitted, transferred or received in the form of radiation, expressed in joules (J).</p> <p>(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.</p> <p>(33) "Radiant power" means time-averaged power emitted, transferred or received in the form of radiation, expressed in watts (W).</p> <p>(34) "Remote interlock connector" means an electrical connector which permits the connection of external remote interlocks.</p> <p>(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.</p> <p>(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).</p> <p>(37) "Scanned laser radiation" means laser</p> | <p>(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 Sec. 1040.11.</p> <p>(29) Pulse duration means the time increment measured between the half-peak-power points at the leading and trailing edges of a pulse.</p> <p>(30) Radiant energy means energy emitted, transferred or received in the form of radiation, expressed in joules (J).</p> <p>(31) 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 ($J \cdot cm^{-2}$).</p> <p>(32) Radiant power means time-averaged power emitted, transferred or received in the form of radiation, expressed in watts (W).</p> <p>(33) Remote interlock connector means an electrical connector which permits the connection of external remote interlocks.</p> <p>(34) 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.</p> <p>(35) 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).</p> <p>(36) Scanned laser radiation means laser</p> | <p>(34) 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 Sec. 1040.11.</p> <p>(35) Pulse duration means the time increment measured between the half-peak-power points at the leading and trailing edges of a pulse.</p> <p>(36) Radiant energy means energy emitted, transferred or received in the form of radiation, expressed in joules (J).</p> <p>(37) 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 ($J \cdot cm^{-2}$).</p> <p>(38) Radiant power means time-averaged power emitted, transferred or received in the form of radiation, expressed in watts (W).</p> <p>(39) Remote interlock connector means an electrical connector which permits the connection of external remote interlocks.</p> <p>(40) 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.</p> <p>(41) 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).</p> <p>(42) Scanned laser radiation means laser</p> |
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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 described 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

radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference.

(37) Service means the performance of those procedures or adjustments described in the manufacturer's service instructions which may affect any aspect of the product's performance for which this section and Sec. 1040.11 have applicable requirements. It does not include maintenance or operation as defined in paragraphs (b)(22) and (b)(27) of this section.

(38) 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; and

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

(39) Visible radiation means laser or collateral radiation having wavelengths of greater than 400 nm but less than or equal to 700 nm.

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

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

(c) Classification of laser products

All laser products.

Each laser shall be classified in Class 1, 2, 3A, 3B, or 4 in accordance with definitions set forth in paragraphs (b)(5) through (b)(10) of this section. The product classification shall be based on the

radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference.

(43) Service means the performance of those procedures or adjustments described in the manufacturer's service instructions which may affect any aspect of the product's performance for which this section and Sec. 1040.11 have applicable requirements. It does not include maintenance or operation as defined in paragraphs (b)(22) and (b)(27) of this section.

(44) 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; and

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

(45) Visible radiation, as used in this standard, means laser or collateral radiation having wavelengths of greater than 400 nm but less than or equal to 700 nm.

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

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

(c) Classification of laser products

All laser products.

Each laser shall be classified in Class 1, 1M, 2, 2M, 3R, 3B, or 4 in accordance with definitions set forth in paragraphs (b)(5) through (b)(10) of this section. The product classification shall be based

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| <p>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.</p> | <p>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.</p> | <p>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.</p> <p>(i) A laser shall be classified in Class 1 if its level does not exceed the accessible emission limits of Class 1 specified in Table ___ for the required time base when determined in accordance with conditions 1 and 2 for radiant energy or power of Table ___</p> <p>(ii) A laser shall be classified in Class 1M if its level does not exceed the accessible emission limits of Class 1 specified in Table ___ for the required time base when determined in accordance with condition 3 and either condition 1 or 2 for radiant energy or power of Table ___ .</p> <p>(iii) A laser shall be classified in Class 2 if its level exceeds the accessible emission limits of Class 1 or 1M and does not exceed the accessible emission limits of Class 2 specified in Table ___ for the required time base when determined in accordance with conditions 1 and 2 for radiant energy or power of Table ___</p> <p>(iv) A laser shall be classified in Class 2M if its level exceeds the accessible emission limits of Class 1 or 1M and does not exceed the accessible emission limits of Class 2 specified in Table ___ for the required time base when determined in accordance with condition 3 and either condition 1 or 2 for radiant energy or power of Table ___ .</p> <p>(v) A laser shall be classified in Class 3R if its level exceeds the accessible emission limits of Class 2 and does not exceed the accessible emission limits of Class 3R specified in Table ___ for the required time base.</p> <p>(vi) A laser shall be classified in Class 3B if its level exceeds the accessible emission limit of Class 3R and does not exceed the accessible emission limits of Class 3B specified in Table ___ for the</p> |
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| <p>(2) Removable laser systems.</p> <p>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 laser radiation when so removed.</p> <p>(d) Accessible emission limits.</p> <p>Accessible emission limits for laser radiation 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.</p> <p>SEE TABLES IN CFR</p> <p>Notes applicable to Tables I, II A, II, III A and III B:</p> <p>(1) The factors k_1 and k_2 are wavelength-dependent correction factors determined from Table IV.</p> <p>(2) The variable t in the expressions of emission limits is the magnitude of the sampling interval in</p> | <p>(2) Removable laser systems.</p> <p>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 the accessible emission level of laser radiation the system is capable of producing when so removed.</p> <p>(d) Accessible emission limits.</p> <p>Accessible emission limits for laser radiation in each class are specified in Tables 1, 2, 3, and 4 of this paragraph. Accessible emission limits for collateral radiation are specified in Table 7 of this paragraph.</p> <p>NOTE APPLICABLE TO TABLES 1, 2, 3, 4, AND 6 The variable t in the expressions of emission limits is the magnitude of the sampling interval in units of seconds.</p> <p>SEE AEL TABLES IN PRINTED DOCUMENT</p> | <p>required time base when determined in accordance with conditions 1 and 2 for radiant energy or power of Table __</p> <p>(vii) A laser shall be classified in Class 4 if its level exceeds the accessible emission limits of Class 3B as specified in Table __.</p> <p>(2) Removable laser systems.</p> <p>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 the accessible emission level of laser radiation the system is capable of producing when so removed.</p> <p>(d) Accessible emission limits.</p> <p>SEE AEL TABLES IN PRINTED DOCUMENT</p> |
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| <p>units of seconds.</p> <p>-----</p> <p>(1) Beam of a single wavelength.</p> <p>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.</p> <p>(2) Beam of multiple wavelengths in same range.</p> <p>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 corresponding 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.</p> <p>(3) Beam with multiple wavelengths in different ranges.</p> <p>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.</p> <p>(4) Class I dual limits.</p> <p>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:</p> | <p>Beam of a single wavelength.</p> <p>Laser or collateral radiation 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 1, 2, 3, and 4 of this paragraph.</p> <p>(2) Beam of multiple wavelengths in same range.</p> <p>Laser or collateral radiation having two or more wavelengths within any one of the wavelength ranges specified in Tables 1, 2, 3, and 4 of this paragraph exceeds the accessible emission limits of a class if the sum of the ratios of the accessible emission level to the corresponding 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.</p> <p>(3) Beam with multiple wavelengths in different ranges.</p> <p>Laser or collateral radiation having wavelengths within two or more of the wavelength ranges specified in Tables 1, 2, 3, and 4 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 (d)(2) of this section.</p> <p>(4) Maximum sampling interval.</p> <p>Three maximum sampling intervals are used for the classification of laser. Which interval applies depends upon the accessible emission level of the product and whether viewing the radiation is an inherent feature of the product. The accessible</p> | <p>(1) Beam of a single wavelength.</p> <p>Laser or collateral radiation 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 __, __, __, and __ of this paragraph.</p> <p>(2) Beam of multiple wavelengths in same range.</p> <p>Laser or collateral radiation having two or more wavelengths within any one of the wavelength ranges specified as additive in Table __ of this paragraph exceeds the accessible emission limits of a class if the sum of the ratios of the accessible emission level to the corresponding 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.</p> <p>(3) Beam with multiple wavelengths in different ranges.</p> <p>Laser or collateral radiation having wavelengths within two or more of the wavelength ranges not specified as additive in Table __ 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 (d)(2) of this section.</p> <p>(4) Maximum sampling interval.</p> <p>Three maximum sampling intervals are used for the classification of laser. Which interval applies depends upon the accessible emission level of the product and whether viewing the radiation is an inherent feature of the product. The accessible</p> |
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(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.

emission limits of a class are exceeded, if exceeded within any emission duration less than or equal to the following maximum sampling intervals:

- (i) 30,000 seconds for wavelengths less than or equal to 400 nm and for wavelengths greater than 400 nm if intentional viewing of the radiation is inherent in the design or function of the product, or
- (ii) 100 seconds for wavelengths greater than 400 nm unless intentional viewing of the radiation is inherent in the design or function of the product.
- (iii) 0.25 seconds for Class 2 and for Class 3A laser radiation within the wavelength range from 400 to 700 nm.

(5) Repetitively pulsed or scanned laser radiation.

For repetitively pulsed or scanned laser radiation in the wavelength range from 400 nm to 1,000,000 nm (1 millimeter) the AEL is determined by using the most restrictive of requirements in paragraphs (d)(4)(i), (d)(4)(ii), and (d)(4)(iii) of this section as appropriate. For wavelengths less than 400 nm, the AEL is determined by using the most restrictive of requirements in paragraphs (d)(4)(i) and (d)(4)(ii) of this section.

(i) The emission level of any single pulse within a pulse train shall not exceed the AEL for a single pulse.

(ii) The average power of a pulse train of duration t shall not exceed the power corresponding to the AEL given in Tables 1, 2, 3, and 4 of this paragraph, respectively, for a single pulse of duration t .

(iii) The emission level of any single pulse within a pulse train shall not exceed the AEL for a single pulse multiplied by the correction factor C_5 :

$$AEL_{train} = AEL_{single} \times C_5.$$

Note: C_5 is only applicable to pulse durations shorter than 0.25 sec. where:

$AEL_{train} = AEL$ for any single pulse in the pulse train

$AEL_{single} = AEL$ for a single pulse

$$C_5 = N^{1/4}$$

N = number of pulses in the pulse train during the

emission limits of a class are exceeded, if exceeded within any emission duration less than or equal to the following maximum sampling intervals:

- (i) 30,000 seconds for wavelengths less than or equal to 400 nm and for wavelengths greater than 400 nm if intentional viewing of the radiation is inherent in the design or function of the product, or
- (ii) 100 seconds for wavelengths greater than 400 nm unless intentional viewing of the radiation is inherent in the design or function of the product.

(5) Repetitively pulsed or scanned laser radiation.

The AEL for wavelengths from 400 nm to 10^6 nm is the lowest value of (i), (ii) and (iii). For other wavelengths, the AEL is the lowest value of (i) and (ii).

(i) The AEL for the emission duration of a single pulse.

(ii) The AEL for the duration of a pulse train.

(iii) The AEL for a single pulse multiplied by the correction factor C_5 . (Note. If pulses are of variable amplitude, pulses of each amplitude and the entire train of pulses are to be considered.)

$$AEL_{train} = AEL_{single} \times C_5 \text{ where:}$$

$AEL_{train} = AEL$ for any single pulse in the pulse train
 $AEL_{single} = AEL$ for a single pulse

$$C_5 = N^{-0.25} \text{ for pulses shorter than 0.25 s, where}$$

N = the number of pulses in the pulse train during the following durations:

| Wavelength | Duration to determine N |
|------------------|--------------------------------|
| 400 nm – 1400 nm | T_2 (see note 2 of the notes |

| <p>(e) Tests for determination of compliance</p> <p>(1) Tests for certification.</p> <p>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.</p> | <p>sampling interval.</p> <p>NOTE: In some cases, AEL_{train} this value may fall below the AEL that would apply for continuous operation at the same peak power using the same time base. Under these circumstances, the AEL for continuous operation may be used.</p> <p>(e) Tests for determination of compliance—</p> <p>Tests for certification.</p> <p>Tests on which certification under Sec. 1010.2 of this chapter 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</p> | <p>to Tables _ and _) or the Applicable time base, Whichever is shorter.</p> <p>$> 1400 \text{ nm}$ 10 s.</p> <p>If multiple pulses appear within the period of T_i (see table X), they shall be considered to be a single pulse to determine N. The energies of the individual pulses shall be summed and compared to the AEL of T_i, provided that all pulse durations are greater than 10^{-9} s.</p> <p>Times T_i below which pulse groups shall be summed:</p> <table border="1" data-bbox="1339 493 1774 737"> <thead> <tr> <th>Wavelength</th> <th>T_i</th> </tr> </thead> <tbody> <tr> <td>$400 \text{ nm} \leq \lambda < 1050 \text{ nm}$</td> <td>$18 \times 10^{-6} \text{ s}$</td> </tr> <tr> <td>$1050 \text{ nm} \leq \lambda < 1400 \text{ nm}$</td> <td>$50 \times 10^{-6} \text{ s}$</td> </tr> <tr> <td>$1400 \text{ nm} \leq \lambda < 1500 \text{ nm}$</td> <td>$10^{-3} \text{ s}$</td> </tr> <tr> <td>$1500 \text{ nm} \leq \lambda < 1800 \text{ nm}$</td> <td>10 s</td> </tr> <tr> <td>$1800 \text{ nm} \leq \lambda < 2600 \text{ nm}$</td> <td>$10^{-3} \text{ s}$</td> </tr> <tr> <td>$2600 \text{ nm} \leq \lambda \leq 10^6 \text{ nm}$</td> <td>$10^{-7} \text{ s}$</td> </tr> </tbody> </table> <p>For varying pulse widths, pulse intervals, or peak power, in (iii) the AEL may be determined for the duration of the sum of all pulse durations within the emission duration or T_2, whichever is smaller. Pulses with durations less than T_i, shall be considered as pulse durations of T_i. If two or more pulses occur within a duration of T_i, these pulse groups shall be considered to have pulse durations of T_i. For comparison with the AEL for the corresponding duration, all individual pulse energies shall be added.</p> <p>(e) Tests for determination of compliance—</p> <p>(1) Tests for certification.</p> <p>Tests on which certification under Sec. 1010.2 of this chapter 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</p> | Wavelength | T_i | $400 \text{ nm} \leq \lambda < 1050 \text{ nm}$ | $18 \times 10^{-6} \text{ s}$ | $1050 \text{ nm} \leq \lambda < 1400 \text{ nm}$ | $50 \times 10^{-6} \text{ s}$ | $1400 \text{ nm} \leq \lambda < 1500 \text{ nm}$ | 10^{-3} s | $1500 \text{ nm} \leq \lambda < 1800 \text{ nm}$ | 10 s | $1800 \text{ nm} \leq \lambda < 2600 \text{ nm}$ | 10^{-3} s | $2600 \text{ nm} \leq \lambda \leq 10^6 \text{ nm}$ | 10^{-7} s |
|---|--|--|------------|-------|---|-------------------------------|--|-------------------------------|--|---------------------|--|------|--|---------------------|---|---------------------|
| Wavelength | T_i | | | | | | | | | | | | | | | |
| $400 \text{ nm} \leq \lambda < 1050 \text{ nm}$ | $18 \times 10^{-6} \text{ s}$ | | | | | | | | | | | | | | | |
| $1050 \text{ nm} \leq \lambda < 1400 \text{ nm}$ | $50 \times 10^{-6} \text{ s}$ | | | | | | | | | | | | | | | |
| $1400 \text{ nm} \leq \lambda < 1500 \text{ nm}$ | 10^{-3} s | | | | | | | | | | | | | | | |
| $1500 \text{ nm} \leq \lambda < 1800 \text{ nm}$ | 10 s | | | | | | | | | | | | | | | |
| $1800 \text{ nm} \leq \lambda < 2600 \text{ nm}$ | 10^{-3} s | | | | | | | | | | | | | | | |
| $2600 \text{ nm} \leq \lambda \leq 10^6 \text{ nm}$ | 10^{-7} s | | | | | | | | | | | | | | | |

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| <p>(2) Test conditions.</p> <p>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:</p> <p>(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</p> <p>(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</p> <p>(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</p> <p>(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</p> <p>(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.</p> <p>(3) Measurement parameters.</p> <p>Accessible emission levels of laser and collateral radiation shall be based upon the following measurements as appropriate, or their equivalent:</p> <p>(i) For laser products intended to be used in a</p> | <p>radiation safety with age.</p> <p>Test conditions.</p> <p>Except as provided in Sec. 1010.13 of this chapter, tests for compliance with each of the applicable requirements of this section and Sec. 1040.11 shall be made as appropriate during operation, maintenance, service, or single failure as follows:</p> <p>(i) Under those conditions and procedures that maximize the accessible emission levels, including start-up, stabilized emission, and shut-down of the laser product; and</p> <p>(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</p> <p>(iii) At locations where human access to laser radiation is possible, 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</p> <p>(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</p> <p>(v) For a laser product other than a laser system, with the laser connected to that type of laser energy source that is specified as compatible by the laser product manufacturer and that produces the maximum emission level of accessible radiation from that product.</p> <p>(3) Measurement parameters.</p> <p>Accessible emission levels of laser and collateral radiation shall be based upon the measurements in paragraph (e)(3)(i) of this section as appropriate, or their equivalent. For the purposes of the</p> | <p>in radiation safety with age.</p> <p>(2) Test conditions</p> <p>Except as provided in Sec. 1010.13 of this chapter, tests for compliance with each of the applicable requirements of this section and Sec. 1040.11 shall be made as appropriate during operation, maintenance, service, or single failure as follows:</p> <p>(i) Under those conditions and procedures that maximize the accessible emission levels, including start-up, stabilized emission, and shut-down of the laser product; and</p> <p>(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</p> <p>(iii) With the use of any accessories supplied or offered by the manufacturer that may increase the level of radiation as determined in accordance with paragraph (e)(3) of this section; and</p> <p>(iv) At locations where human access to laser radiation is possible, 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</p> <p>(v) 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</p> <p>(vi) For a laser product other than a laser system, with the laser connected to that type of laser energy source that is specified as compatible by the laser product manufacturer and that produces the maximum emission level of accessible radiation from that product.</p> <p>(3) Measurement parameters</p> <p>Accessible emission levels of laser and collateral radiation shall be based upon the measurements in paragraph (e)(3) of this section as appropriate, or their equivalent analyses.</p> |
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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 0.001 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 / sq. cm.) or radiant exposure (J / sq. cm.) 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 0.001 steradian with collimating optics of 5 diopters or less, divided by the area of the aperture stop.

(iii) The radiance (W / sq. cm. / sr.) or integrated radiance (J / sq. cm. / sr.) 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 0.00001 steradian with collimating optics of 5 diopters or less, divided by that solid angle (sr) and by the area of the aperture stop.

measurements in paragraphs (e)(3)(i)(A) through (e)(3)(i)(D), and paragraph (e)(3)(ii) of this section, the 50-millimeter aperture will be the limiting case with collimated beams, and the measurement distances referring to the apparent source are measured from the apparent source irrespective of any optical element placed between the source and the measurement aperture.

(i) Radiant power (W) or radiant energy (J) measurable under the following conditions:

(a) Within a circular aperture stop of 50-millimeter diameter placed at a distance of 2 meters from the closest point of human access. In general, the 50-millimeter aperture will be the limiting case with collimated beams, or

(b) In the wavelength range from 400 nm to 1,400 nm within a circular aperture stop of 7-millimeter diameter placed at a distance of 100 millimeters from the apparent source.

(c) For apparent sources subtending an angle (α) (measured at a minimum distance of 100 millimeters) less than α_{max} and within the wavelength range from 400 nm to 1,400 nm, within a circular aperture stop of 7 millimeter diameter positioned at a distance (r) from the source depending upon the angular subtense α (between a minimum of 1.5 mrad and a maximum of α_{max}) of the source. The distance (r) of the 7 millimeter measurement aperture from the source is determined by:

$$r = (100 \text{ mm}) \sqrt{\frac{\alpha + 0.46 \text{ mrad}}{\alpha_{max}}}$$

NOTE: In cases where the apparent source is recessed within the product at a distance greater than that specified in paragraph (e)(3)(i)(B) or (e)(3)(i)(C) of this section, the minimum measurement distance should be at the closest point of human access, such as the exit window or lens. This measurement is needed to determine the user information required for Class 1 laser products (see paragraph (h)(1)(vi) of this section).

(d) For wavelengths less than 400 nm and greater than 1,400 nm, within a circular aperture stop of 7 millimeter diameter (or as otherwise specified)

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| <p>(f) Performance requirements</p> <p>(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.</p> | <p>placed at a distance of 14 millimeters from the closest point of human access.</p> <p>(e) For the calculation of the AEL expressed in terms of radiant power, radiant energy, irradiance, or radiant exposure, the value of the angular subtense of a rectangular or linear source is determined by the arithmetic mean of the two angular dimensions of the source. Any angular dimension that is greater than α_{max} or less than α_{min} shall be limited to α_{max} or α_{min} respectively, prior to calculating the mean.</p> <p>(f) 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.</p> <p>(ii) The irradiance (Wcm^{-2}) or radiant exposure (Jcm^{-2}) equivalent to the radiant power (W) or radiant energy (J) measurable through a circular aperture stop having a diameter as specified in Table 6 shall be divided by the area of the aperture stop.</p> <p>(f) Performance requirements</p> <p>--(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 Tables 1 or 7 of paragraph (d) of this section 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 1 is necessary, these levels shall not exceed the limits of the lowest class necessary to perform the intended function(s) of the product.</p> <p>NOTE: If there is an opening or openings, such as for cooling, in a protective housing that encloses Class 3B or 4 levels of laser radiation, the adequacy of the protective housing shall be determined by whether the level of radiation that can be reflected out through the opening(s) by a single flat reflector exceeds the accessible emission limits of Class 1.</p> | <p>(f) Performance requirements</p> <p>(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 Tables 1 or 7 of paragraph (d) of this section 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 1M is necessary, these levels shall not exceed the limits of the lowest class necessary to perform the intended function(s) of the product. NOTE: If there is an opening or openings, such as for cooling, in a protective housing that encloses Class 3B or 4 levels of laser radiation, the adequacy of the protective housing shall be determined by whether the level of radiation that can be reflected out through the opening(s) by a single flat reflector exceeds the accessible emission limits of Class 1M.</p> |
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| <p>(2) Safety interlocks.</p> <p>(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.</p> <p>(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</p> <p>(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;</p> <p>(a) Human access to a level of laser radiation in excess of the accessible emission limits of Class IIIa; or</p> <p>(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.</p> <p>(iv) Laser products that incorporate safety</p> | <p>(2) Safety interlocks</p> <p>--(i) Each laser, 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:</p> <p>(A) Laser radiation in excess of the accessible emission limits of Class 3A; or</p> <p>(B) Laser radiation in excess of the accessible emission limits of Class 2 to be emitted directly through the opening created by removal or displacement of the interlocked portion of the protective housing.</p> <p>(ii) Each required safety interlock, unless defeated, shall prevent human access to laser radiation as described in paragraphs (f)(2)(i)(A) through (f)(2)(i)(B) of this section upon removal or displacement of such portion of the protective housing.</p> <p>(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:</p> <p>(A) Human access to a level of laser radiation in excess of the accessible emission limits of Class 3A; or</p> <p>(B) Laser radiation in excess of the accessible emission limits of Class 2 to be emitted directly through the opening created by removal or displacement of the interlocked portion of the protective housing.</p> <p>(iv) Laser products that incorporate safety</p> | <p>(2) Safety interlocks.</p> <p>(i) Each laser, 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 of maintenance, if removal or displacement of the protective housing could permit, in the absence of such interlock(s):</p> <p>(A) Human access to laser radiation in excess of the accessible emission limits of Class 3R; or</p> <p>(B) Emission of laser radiation in excess of the accessible emission limits of Class 2M directly through the opening created by removal or displacement of the interlocked portion of the protective housing.</p> <p>(ii) Each required safety interlock, unless defeated, shall prevent human access to laser radiation as described in paragraphs (f)(2)(i)(A) through (f)(2)(i)(B) of this section upon removal or displacement of such portion of the protective housing.</p> <p>(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:</p> <p>(A) Human access to laser radiation in excess of the accessible emission limits of Class 3R; or</p> <p>(B) Emission of laser radiation in excess of the accessible emission limits of Class 2M directly through the opening created by removal or displacement of the interlocked portion of the protective housing.</p> <p>(iv) Upon written application by the manufacturer or on the initiative of the Director, Office of Compliance, Center for Devices and Radiological Health, the Director may, upon determination that the configuration, design, or function of the laser product would make unnecessary compliance with the requirement in paragraph (f)(2)(iii) of this section, approve alternate means to accomplish the radiation protection provided by multiple safety interlocks</p> <p>(v) Laser products that incorporate safety</p> |
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| <p>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.</p> <p>(v) Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated.</p> <p>(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.</p> <p>(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.</p> <p>(5) Laser radiation emission indicator.</p> <p>(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.</p> <p>(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</p> | <p>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.</p> <p>(v) Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated.</p> <p>(3) Remote interlock connector. Each laser system classified as a Class 3B or 4 laser product, except for Class 3B with not more than five times the AEL of Class 2 in the wavelength range of 400 to 700 nm, 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 1 and Table 7 of paragraph (d) of this section shall be prevented.</p> <p>(4) Key control. Each laser system classified as a Class 3B or 4 laser product, except for Class 3B with not more than five times the AEL of Class 2 in the wavelength range of 400 to 700 nm, shall incorporate a key-actuated master control. The key shall be removable and the laser shall not be operable when the key is removed.</p> <p>(5) Laser radiation emission indicator--(i) Each laser system classified as a Class 3B or 4 laser product, except for Class 3B with not more than five times the AEL of Class 2 in the wavelength range of 400 to 700 nm, 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 1, and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to the laser radiation.</p> <p>(ii) For laser systems manufactured on or before August 20, 1986, if the laser and laser energy</p> | <p>interlocks designed to allow safety interlock defeat shall incorporate an indicator which provides a visible or audible signal during interlock defeat whenever the laser product is energized, with and without the associated portion of the protective housing removed or displaced.</p> <p>(vi) Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated.</p> <p>(3) Remote interlock connector. Each laser system classified as a Class 3B or 4 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 the 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 1M and Table 7 of paragraph (d) of this section shall be prevented.</p> <p>(4) Key control. Each laser system classified as a Class 3B or 4 laser 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.</p> <p>(5) Laser radiation emission indicator. (i) Each laser system classified as a Class 3B or 4 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 1M, and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to the laser radiation.</p> |
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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

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) of this section.

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

(iv) Emission indicators required by paragraph (f)(5)(i) or (f)(5)(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 1 and Table 7 of paragraph (d) of this section.

(6) Beam attenuator—

(i) Each laser system classified as a Class 3B or 4 laser product, except for Class 3B with not more than five times the AEL of Class 2 in the wavelength range of 400 to 700 nm, 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 1 and Table 7 of paragraph (d) of this section.

(ii) Upon written application by the manufacturer or on the initiative of the Director, Office of Compliance, Center for Devices and Radiological

(iv) Emission indicators required by paragraph (f)(5)(i) or (f)(5)(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 1M and Table 7 of paragraph (d) of this section.

(5) Beam attenuator.

(i) Each laser system classified as a Class 3B or 4 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 1M and Table 7 of paragraph (d) of this section.

(ii) Upon written application by the manufacturer or on the initiative of the Director, Office of Compliance, Center for Devices and Radiological

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

Health, the Director may, upon determination that the configuration, design, or function of the laser product would make unnecessary compliance with the requirement in paragraph (f)(6)(i) of this section, approve alternate means to accomplish the radiation protection provided by the beam attenuator.

(7) Location of controls.

Each Class 2, 3, or 4 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 1 and Table 7 of paragraph (d) of this section 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 1 and Table 7 of paragraph (d) of this section. 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 1 and Table 7 of paragraph (d) of this section 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 1 and Table 7 of paragraph (d) of this section.

(9) Scanning safeguard.

Laser products that emit accessible scanned laser radiation shall not, as a result of any failure causing

Health, the Director may, upon determination that the configuration, design, or function of the laser product would make unnecessary compliance with the requirement in paragraph (f)(6)(i) of this section, approve alternate means to accomplish the radiation protection provided by the beam attenuator.

(7) Location of controls.

Each Class 2, 3, or 4 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 1M and a Table 7 of paragraph (d) of this section is unnecessary for operation or adjustment of such controls.

(8) Viewing optics.

All viewing optics, viewports and display screens incorporated into a laser products, 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 1M and Table 7 of paragraph (d) of this section. 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 1M and Table 7 of paragraph (d) of this section 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 1M and Table 7 of paragraph (d) of this section.

(9) Scanning safeguard.

Laser products that emit accessible scanned laser radiation shall incorporate a means to prevent

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| <p>change in either scan velocity or amplitude, permit human access to laser radiation in excess of:</p> <p>(i) The accessible emission limits of the class of the product, or</p> <p>(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.</p> <p>(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.</p> <p>(g) Labeling requirements.</p> <p>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.</p> <p>(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."</p> | <p>a change in either scan velocity or amplitude, permit human access to laser radiation in excess of the accessible emission limits of the class of the product.</p> <p>(10) Manual reset mechanism. Each laser system manufactured after August 20, 1986, classified as a Class 4 laser 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.</p> <p>(g) <i>Labeling requirements.</i></p> <p>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. Labeling in accordance with the International Electrotechnical Commission (IEC) Document 825-1 will satisfy the requirements of (g)(1) through (g)(10) of this section.</p> <p>(1) <i>Class 2 designation and warnings.</i></p> | <p>human access to laser radiation in excess of the accessible emission limits of the class of the product.</p> <p>(10) Manual reset mechanism. Each laser system manufactured after August 20, 1986, classified as a Class 4 laser 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.</p> <p>(g) Labeling requirements.</p> <p>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. Labeling in accordance with the International Electrotechnical Commission (IEC) Document 60825-1 will satisfy the requirements of (g)(1) through (g)(10) of this section.</p> <p>(1) Class 1M designation and warning. Each Class 1M laser product shall have a label bearing the following wording: "LASER RADIATION DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS CLASS 1M LASER PRODUCT" Instead of affixing this label to the Class 1M laser product, the manufacturer may include the specification in the user instructions.</p> <p>(2) Class 2 and 2M designations and warnings.</p> |
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| <p>[Graphic: Figure 1, warning logotype A] [To display graphic, press <Alt> I with cursor on or below this line.]</p> <p>(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:</p> <p>[Position 1 on the logotype]</p> <p>"LASER RADIATION_DO NOT STARE INTO BEAM"; and [Position 3 on the logotype]</p> <p>"CLASS II LASER PRODUCT".</p> <p>(2) Class IIIa and IIIb designations and warnings. (i) Each Class IIIa laser product with an irradiance less than or equal to 0.0025 W / sq. cm. 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:</p> <p>[Position 1 on the logotype]</p> <p>"LASER RADIATION_DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS"; and, [Position 3 on the logotype]</p> | <p>Each Class 2 laser product shall have affixed a label bearing the warning logotype A (Figure 1 in this paragraph) that includes the following wording:</p> <p>[Position 1 on the logotype]</p> <p>"LASER RADIATION_DO NOT STARE INTO BEAM"; and [Position 3 on the logotype]</p> <p>"CLASS 2 LASER PRODUCT".</p> <p>(2) <i>Class 3A and 3B designations and warnings.</i> (i) Each Class 3 laser product that does not exceed the accessible emission limits of Table 3A shall have affixed a label bearing the warning logotype A (Figure 1 of paragraph (g)(1) of this section) that includes the following wording:</p> <p>[Position 1 on the logotype]</p> <p>"LASER RADIATION DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS"; and, [Position 3 on the logotype]</p> | <p>(i) Each Class 2 laser product shall have affixed a label bearing the warning logotype A (Figure 1 in this paragraph) and including the following wording:</p> <p>[Position 1 on the logotype]</p> <p>"LASER RADIATION - DO NOT STARE INTO BEAM"; and [Position 3 on the logotype]</p> <p>"CLASS 2 LASER PRODUCT."</p> <p>(ii) Each Class 2M 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]</p> <p>"LASER RADIATION -DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS"; and [Position 3 on the logotype]</p> <p>"CLASS 2M LASER PRODUCT."</p> <p>(3) Class 3R and 3B designations and warnings. (i) Each Class 3R laser product with accessible radiation in the wavelength range from 400 nm to 1400 nm 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:</p> <p>[Position 1 on the logotype]</p> <p>"LASER RADIATION - AVIOD DIRECT EYE EXPOSURE "; and, [Position 3R on the logotype]</p> <p>"CLASS 3R LASER PRODUCT."</p> |
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| <p>“CLASS IIIa LASER PRODUCT”.</p> <p>(ii) Each Class IIIa laser product with an irradiance greater than 0.0025 W / sq. cm. shall have affixed a label bearing the warning logotype B (Figure 2 in this paragraph) and including the following wording:</p> <p>[Position 1 on the logotype]</p> <p>“LASER RADIATION_AVOID DIRECT EYE EXPOSURE”; and,</p> <p>[Position 3 on the logotype]</p> | <p>"CLASS 3A LASER PRODUCT".</p> <p>(ii) Each Class 3 laser product that exceeds the accessible emission limits of Table 3A in the wavelength range of 400 to 700 nm and less than the AEL of Class 3A at other wavelengths shall have affixed a label bearing the warning logotype B (Figure 2 in this paragraph) and including the following wording:</p> <p>[Position 1 on the logotype]</p> <p>"LASER RADIATION AVOID DIRECT EYE EXPOSURE"; and,</p> <p>[Position 3 on the logotype]</p> | <p>(ii) Each Class 3R laser product with accessible radiation is outside the wavelength range from 400 nm to 1400 nm shall have affixed a label bearing the warning logotype A (Figure 1 in this paragraph) and including the following wording:</p> <p>[Position 1 on the logotype]</p> <p>“LASER RADIATION – AVOID DIRECT EXPOSURE TO BEAM”; and,</p> <p>[Position 3 on the logotype]</p> <p>“CLASS 3R LASER PRODUCT.”</p> |
| <p>“CLASS IIIa LASER PRODUCT”.</p> <p>(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:</p> <p>[Position 1 on the logotype]</p> <p>“LASER RADIATION_AVOID DIRECT EXPOSURE TO BEAM”; and,</p> <p>[Position 3 on the logotype]</p> | <p>"CLASS 3B LASER PRODUCT".</p> <p>(iii) Each Class 3B laser product except as specified in (g)(2)(ii) 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:</p> <p>[Position 1 on the logotype]</p> <p>"LASER RADIATION AVOID DIRECT EXPOSURE TO BEAM"; and,</p> <p>[Position 3 on the logotype]</p> | <p>(iii) Each Class 3B 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:</p> <p>[Position 1 on the logotype]</p> <p>“LASER RADIATION - AVOID EXPOSURE TO BEAM”; and,</p> <p>[Position 3 on the logotype]</p> |
| <p>“CLASS IIIb LASER PRODUCT”.</p> <p>(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:</p> <p>[Position 1 on the logotype]</p> <p>“LASER RADIATION - AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION”; and,</p> | <p>"CLASS 3B LASER PRODUCT".</p> <p>(3) <i>Class 4 designation and warning.</i> Each Class 4 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:</p> <p>[Position 1 on the logotype]</p> <p>"LASER RADIATION - AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION"; and,</p> | <p>“CLASS 3B LASER PRODUCT”.</p> <p>(4) Class 4 designation and warning. Each Class 4 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:</p> <p>[Position 1 on the logotype]</p> <p>“LASER RADIATION - AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION”; and,</p> |

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| <p>[Position 3 on the logotype]</p> <p>“CLASS IV LASER PRODUCT”.</p> <p>(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).</p> <p>(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 it 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:</p> <p>(i) “AVOID EXPOSURE - Laser radiation is emitted from this aperture,” if the radiation emitted through such aperture is laser radiation.</p> <p>(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.</p> <p>(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.</p> <p>(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</p> | <p>[Position 3 on the logotype]</p> <p>“CLASS 4 LASER PRODUCT”.</p> <p>(3) <i>Radiation output information on warning logotype.</i> Each Class 2, 3, and 4 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).</p> <p>(5) <i>Aperture label.</i> Each laser, except medical lasers, shall have affixed, in close proximity to each aperture through which it is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class 1 and Table 7 of paragraph (d) of this section, a label or labels bearing the following wording as applicable:</p> <p>(i) “AVOID EXPOSURE - Laser radiation is emitted from this aperture,” if the radiation emitted through such aperture is laser radiation.</p> <p>(ii) “AVOID EXPOSURE - Hazardous electromagnetic radiation is emitted from this aperture,” if the radiation emitted through such aperture is collateral radiation described in Table 7, item 1.</p> <p>(iii) “AVOID EXPOSURE - Hazardous x-rays are emitted from this aperture,” if the radiation emitted through such aperture is collateral radiation described in Table 7, item 2.</p> <p>(6) <i>Labels for noninterlocked protective housings.</i> 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 1 and Table 7. 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</p> | <p>[Position 3 on the logotype]</p> <p>“CLASS 4 LASER PRODUCT.”</p> <p>(5) Radiation output information on warning logotype. Each Class 2, 2M, 3R, 3, and 4 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).</p> <p>(6) Aperture label. Each laser product, except medical laser products shall have affixed, in close proximity to each aperture through which it is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class 1 and 1M and Table VI of paragraph (d) of this section, a label(s) bearing the following wording as applicable:</p> <p>(i) “AVOID EXPOSURE - Laser radiation is emitted from this aperture,” if the radiation emitted through such aperture is laser radiation.</p> <p>(ii) “AVOID EXPOSURE - Hazardous electromagnetic radiation is emitted from this aperture,” if the radiation emitted through such aperture is collateral radiation described in Table 4, item 1.</p> <p>(iii) “AVOID EXPOSURE - Hazardous x-rays are emitted from this aperture,” if the radiation emitted through such aperture is collateral radiation described in Table 4, item 2.</p> <p>(7) 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 1 and Table ?. 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</p> |
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| <p>the wording:</p> <p>(i) "CAUTION - Laser radiation when open. DO NOT STARE INTO BEAM." for Class II accessible laser radiation.</p> <p>(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 0.0025 W / sq. cm.</p> <p>(iii) "DANGER - Laser radiation when open. AVOID DIRECT EYE EXPOSURE." for Class IIIa accessible laser radiation with an irradiance greater than 0.0025 W / sq. cm.</p> <p>(iv) "DANGER Laser radiation when open. AVOID DIRECT EXPOSURE TO BEAM." for Class IIIb accessible laser radiation.</p> <p>(v) "DANGER Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for Class IV accessible laser radiation.</p> <p>(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.</p> <p>(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.</p> | <p>housing, and shall include the wording:</p> <p>(i) "CAUTION - Laser radiation when open. DO NOT STARE INTO BEAM." for Class 2 accessible laser radiation.</p> <p>ii) "CAUTION - Laser radiation when open. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS." for Class 3A accessible laser radiation.</p> <p>(iii) "DANGER - Laser radiation when open. AVOID DIRECT EYE EXPOSURE." for Class 3B accessible laser radiation with an irradiance greater than 0.0025 W/cm² and with not more than 5 times the AEL of Class 2 in the wavelength range of 400 to 700 nm.</p> <p>(iv) "DANGER Laser radiation when open. AVOID DIRECT EXPOSURE TO BEAM." for Class 3B accessible laser radiation other than that described in paragraph (g)(6)(iii) of this section.</p> <p>(v) "DANGER Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for Class 4 accessible laser radiation.</p> <p>(vi) "CAUTION Hazardous electromagnetic radiation when open." for collateral radiation in excess of the accessible emission limits in Table 7, item 1 of paragraph (d) of this section.</p> <p>(vii) "CAUTION Hazardous x-rays when open." for collateral radiation in excess of the accessible emission limits in Table 7, item 2 of paragraph (d) of this section.</p> | <p>the wording:</p> <p>(i) "CAUTION – LASER RADIATION WHEN OPEN. DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS" for Class 1M accessible laser radiation</p> <p>(ii) "CAUTION – LASER RADIATION WHEN OPEN. DO NOT STARE INTO BEAM." for Class 2 accessible laser radiation.</p> <p>(iii) "CAUTION – LASER RADIATION WHEN OPEN. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS" for Class 2M accessible laser radiation.</p> <p>(iv) "CAUTION – LASER RADIATION WHEN OPEN. AVOID DIRECT EYE EXPOSURE." for Class 3R accessible laser radiation in the wavelength range from 400 nm to 1400 nm.</p> <p>(v) "CAUTION – LASER RADIATION WHEN OPEN. AVOID DIRECT EXPOSURE." For Class 3R accessible laser radiation outside the wavelength range from 400 nm to 1400 nm and for Class 3B accessible laser radiation.</p> <p>(vi) "CAUTION – LASER RADIATION WHEN OPEN. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for Class 4 accessible laser radiation.</p> <p>(vii) "CAUTION – HAZARDOUS ELECTROMAGNETIC RADIATION WHEN OPEN." for collateral radiation in excess of the accessible emission limits in Table ?, item 1 of paragraph (d) of this section.</p> <p>(viii) "CAUTION – HAZARDOUS X-RAYS WHEN OPEN." for collateral radiation in excess of the accessible emission limits in Table ?, item 2 of paragraph (d) of this section.</p> |
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(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 0.0025 W / sq. cm.

(iii) "DANGER_Laser radiation when open and interlock defeated. AVOID DIRECT EYE EXPOSURE." for Class IIIa accessible laser radiation when an irradiance greater than 0.0025 W / sq. cm.

(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

(6) *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 7. Such labels shall be visible on the product prior to and during interlock defeat and shall be 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 2 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 3A accessible laser radiation with an irradiance less than or equal to 0.0025 W/cm².

(iii) "DANGER Laser radiation when open and interlock defeated. AVOID DIRECT EYE EXPOSURE." for Class 3B accessible laser radiation with an irradiance greater than 0.0025 W/cm² and with not more than 5 times the AEL of Class 2 in the wavelength range of 400 to 700 nm.

(iv) "DANGER Laser radiation when open and interlock defeated. AVOID DIRECT EXPOSURE TO BEAM." for Class 3B accessible laser radiation other than that described in paragraph (g)(7)(iii) of this section.

(v) "DANGER Laser radiation when open and interlock defeated. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for Class 4 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 7 item 1 of paragraph (d)

(8) 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 ?. 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 VIEW DIRECTLY WITH OPTICAL INSTRUMENTS" for Class 1M accessible laser radiation

(ii) "CAUTION - LASER RADIATION WHEN OPEN AND INTERLOCK DEFEATED. DO NOT STARE INTO BEAM." for Class 2 accessible laser radiation.

(iii) "CAUTION - LASER RADIATION WHEN OPEN AND INTERLOCK DEFEATED. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS" for Class 2M accessible laser radiation.

(iv) "CAUTION - LASER RADIATION WHEN OPEN AND INTERLOCK DEFEATED. AVOID DIRECT EYE EXPOSURE." for Class 3R accessible laser radiation in the wavelength range from 400 nm to 1400 nm.

(v) "CAUTION - LASER RADIATION WHEN OPEN AND INTERLOCK DEFEATED. AVOID DIRECT EXPOSURE." For Class 3R accessible laser radiation outside the wavelength range from 400 nm to 1400 nm and for Class 3B accessible laser radiation.

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| <p>emission limits in Table VI. item 1 of paragraph (d) of this section.</p> <p>(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.</p> <p>(8) Warning for visible and/or invisible radiation. On the labels specified in this paragraph, if the laser or collateral radiation referred to is:</p> <p>(i) Invisible radiation, the word "invisible" shall appropriately precede the word "radiation"; or</p> <p>(ii) Visible and invisible radiation, the words "visible and invisible" or "visible and/or invisible" shall appropriately precede the word "radiation."</p> <p>(iii) Visible laser radiation only, the phrase "laser light" may replace the phrase "laser radiation."</p> <p>(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.</p> <p>(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,</p> | <p>of this section.</p> <p>(vii) "CAUTION Hazardous x-rays when open and interlock defeated." for collateral radiation in excess of the accessible emission limits in Table 7, item 2 of paragraph (d) of this section.</p> <p>(8) <i>Warning for visible and/or invisible radiation.</i> On the labels specified in this paragraph, if the laser or collateral radiation referred to is:</p> <p>(i) Invisible radiation, the word "invisible" shall appropriately precede the word "radiation"; or</p> <p>(ii) Visible and invisible radiation, the words "visible and invisible" or "visible and/or invisible" shall appropriately precede the word "radiation."</p> <p>(iii) Visible laser radiation only, the phrase "laser light" may replace the phrase "laser radiation."</p> <p>(9) <i>Positioning of labels.</i> 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 7 of paragraph (d) of this section.</p> <p>(10) <i>Label specifications.</i> Labels required by this section and § 1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during</p> | <p>(vi) "CAUTION – LASER RADIATION WHEN OPEN AND INTERLOCK DEFEATED. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for Class 4 accessible laser radiation.</p> <p>(vii) "CAUTION – HAZARDOUS ELECTROMAGNETIC RADIATION WHEN OPEN AND INTERLOCK DEFEATED." for collateral radiation in excess of the accessible emission limits in Table ?, item 1 of paragraph (d) of this section.</p> <p>(viii) "CAUTION – HAZARDOUS X-RAYS WHEN OPEN AND INTERLOCK DEFEATED." for collateral radiation in excess of the accessible emission limits in Table ?, item 2 of paragraph (d) of this section.</p> <p>(9) Warning for visible and/or invisible radiation. On the labels specified in this paragraph, if the laser or collateral radiation referred to is:</p> <p>(i) Invisible radiation, the word "invisible" shall appropriately precede the word "radiation"; or</p> <p>(ii) Visible and invisible radiation, the words "visible and invisible" or "visible and/or invisible" shall appropriately precede the word "radiation."</p> <p>(iii) Visible laser radiation only, the phrase "laser light" may replace the phrase "laser radiation."</p> <p>(10) 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 ? of paragraph (d) of this section.</p> <p>(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,</p> |
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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 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)(i) or Figure 2 or paragraph (g)(2)(ii) of this

operation, maintenance, and service, as appropriate. Upon written application by the manufacturer, or on the initiative of the Director, Office of Compliance, Center for Devices and Radiological Health, the Director may, upon determination that 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, 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 :

(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 1, 2, 3, 4 and 7 of paragraph (d) of this section determined under paragraph (e) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and, if applicable, § 1040.11.

(ii) A statement of the magnitude, in appropriate units, of the pulse duration(s), maximum radiant power and, where applicable, the maximum radiant energy per pulse of the accessible laser detectable in each direction in excess of the accessible emission limits in Table 1 of paragraph (d) of this section.

(iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and, if applicable, §1040.11, to be affixed to the laser product or provided with the laser product, including the information and warnings required for positions 1, 2, and 3 of the applicable logotype (Figure 1 of paragraph (g)(1) or

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 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 :

(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 _____ of paragraph (d) of this section determined under paragraph (e) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and, if applicable, § 1040.11.

(ii) A statement of the magnitude, in appropriate units, of the pulse duration(s), maximum radiant power and, where applicable, the maximum radiant energy per pulse of the accessible laser detectable in each direction in excess of the accessible emission limits in Table 1 of paragraph (d) of this section.

(iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and, if applicable, §1040.11, to be affixed to the laser product or provided with the laser product, including the information and warnings required for positions 1, 2, and 3 of the applicable logotype (Figure 1 of paragraph (g)(1) or

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

Figure 2 of 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 a cautionary warning that the use of controls or adjustments or performance of procedures other than specified 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, if applicable, § 1040.11.

(vi) For Class 1 laser products, if the output power (or energy) measured according to (e)(3)(i)(d) is greater than that measured in accordance with (e)(3)(i)(a) or (b) and that level exceeds the Class 1 limit, an additional warning is required. This warning shall state that viewing the laser output with optical instruments having a magnifying power greater than 2.5 (e.g., eye loupes) may pose an 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) 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

or Figure 2 of 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 a cautionary warning that the use of controls or adjustments or performance of procedures other than specified 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, if applicable, § 1040.11.

(vi) For Class 1M and 2M laser products, an additional warning is required. This warning shall state that viewing the laser output with optical instruments may result in an eye hazard for Class 1M or an increased eye hazard for Class 2M.

(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) 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 radiation safety procedures during service. The radiation safety procedures shall include:

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| <p>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.</p> <p>(i) <u>Modification of a certified product.</u> 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.</p> <p>(The information collection requirements contained in paragraph (a)(3)(ii) were approved by the Office of Management and Budget under control number 0910 0176)</p> <p>50 FR 33688, Aug. 20, 1985; 50 FR 42156, Oct. 18, 1985 .21 CFR Part 1040.11 Specific purpose laser products.</p> | <p>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 1, 2, 3, 4 and 7 of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and, if applicable, § 1040.11. All such service instructions shall include a listing of those controls and procedures that could be used by persons other than the manufacturers or their 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 1, 2, 3, 4 and 7 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.</p> <p>(i) <u>Modification of a certified product.</u> 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 constitutes manufacturing under the Federal Food, Drug, and Cosmetic Act if the modification affects any aspect of the product's performance or intended function(s) for which this section or § 1040.11 have an applicable requirement. The person who performs such modification shall recertify and reidentify the product in accordance with the provisions of §§ 1010.2 and 1010.3.</p> <p>1040.11 Specific purpose laser products.</p> | <p>(A) precautions to be taken to avoid possible exposure of service and other personnel to hazardous levels of laser and collateral radiation, (B) a listing of controls and procedures that could be used to increase accessible levels of radiation, (C) a description of the displaceable portions of protective housings that could allow human access to hazardous levels of laser or collateral radiation, and (D) legible reproductions (color optional) of required labels and hazard warnings.</p> <p>(i) <u>Modification of a certified product.</u> 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 constitutes manufacturing under the Federal Food, Drug, and Cosmetic Act if the modification affects any aspect of the product's performance or intended function(s) for which this section or § 1040.11 have an applicable requirement. The person who performs such modification shall recertify and reidentify the product in accordance with the provisions of §§ 1010.2 and 1010.3.</p> <p>1040.11 Specific purpose laser products.</p> |
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| <p>(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:</p> <p>(1) Incorporate in 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:</p> <p>(i) Of a level less than the accessible limits of Class IIIa; and</p> <p>(ii) Used for relative positioning of the human body; and</p> <p>(iii) Not used for irradiation of the human eye for ophthalmic purposes.</p> <p>(2) Supply with each Class III or IV medical laser product instructions specifying a procedure and schedule for calibration of the measurement system required by paragraph (a)(1) of this section.</p> <p>(3) Affix to each medical laser product, in close proximity to each aperture through which is emitted accessible laser radiation in excess of the accessible emission limits of Class I, a label bearing the wording: "Laser aperture."</p> <p>(b) Surveying, leveling, and alignment laser products. Each surveying, leveling, or alignment laser product shall comply with all of the applicable requirements of 1040.10 for a Class I, IIa, II or IIIa laser product and shall not permit human access to laser radiation</p> | <p>(a) <i>Medical laser products.</i> Each medical laser product shall comply with all of the applicable requirements of § 1040.10 for laser products of its class. In addition:</p> <p>(1) a label bearing the wording: "Laser aperture." shall be affixed in close proximity to each aperture through which is emitted accessible laser radiation in excess of the accessible emission limits of Class I, and</p> <p>(2) for each Class 3B or 4 medical laser system, except those of Class 3B not exceeding 5 mW at visible wavelengths and not intended for ocular exposure:</p> <p>(i) the accessible emission level, shall not deviate from the preset or selected level by more than $\pm 20\%$,</p> <p>(ii) an electrical or optical quantity that is directly related to the laser level generated shall be continually monitored during operation,</p> <p>(iii) a visible or audible indication shall be given whenever the monitored quantity denotes deviation from the preset or selected level by more than $\pm 20\%$,</p> <p>(iv) the user instructions shall specify an instrument, procedure and schedule for calibration of the accessible emission level,</p> <p>(v) if the system emits either continuously or a series of pulses for longer than 0.25 seconds, the system shall incorporate a visual or audible indication of actual emission in addition to the emission indicator required by § 1040.10(f)(5),</p> <p>(vi) the system shall include a hand or foot operated control to stop the emission of laser radiation. The switch shall be colored red and be located so that it is clearly visible and quickly accessible to the operator from the operating position. If it is a push-button type, it shall be of the "mushroom-head" type.</p> <p>(b) <i>Surveying, leveling and alignment laser products.</i> Each surveying, leveling, or alignment laser product shall comply with all of the applicable requirements of § 1040.10 for a Class 1, 2 or 3A laser product and shall not permit human access to</p> | <p>(b) <i>Medical laser products.</i> Each medical laser product shall comply with all of the applicable requirements of § 1040.10 for laser products of its class. In addition:</p> <p>(1) a label bearing the wording: "Laser aperture." shall be affixed in close proximity to each aperture through which is emitted accessible laser radiation in excess of the accessible emission limits of Class I, and</p> <p>(2) for each Class 3B or 4 medical laser system, except those of Class 3B not exceeding 5 mW at visible wavelengths and not intended for ocular exposure:</p> <p>(i) the accessible emission level, shall not deviate from the preset or selected level by more than $\pm 20\%$,</p> <p>(ii) an electrical or optical quantity that is directly related to the laser level generated shall be continually monitored during operation,</p> <p>(iii) a visible or audible indication shall be given whenever the monitored quantity denotes deviation from the preset or selected level by more than $\pm 20\%$,</p> <p>(iv) the user instructions shall specify an instrument, procedure and schedule for calibration of the accessible emission level,</p> <p>(v) if the system emits either continuously or a series of pulses for longer than 0.25 seconds, the system shall incorporate a visual or audible indication of actual emission in addition to the emission indicator required by § 1040.10(f)(5),</p> <p>(vi) the system shall include a hand or foot operated control to stop the emission of laser radiation. The switch shall be colored red and be located so that it is clearly visible and quickly accessible to the operator from the operating position. If it is a push-button type, it shall be of the "mushroom-head" type.</p> <p>(b) <i>Surveying, leveling and alignment laser products.</i> Each surveying, leveling, or alignment laser product shall comply with all of the applicable requirements of § 1040.10 for a Class 1, 2 or 3R laser product and shall not permit human access to</p> |
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| <p>in excess of the accessible emission limits of Class IIIa.</p> <p>(c) <i>Demonstration laser products.</i> Each demonstration laser product shall comply with all of the applicable requirements of 1040.10 for a Class I, IIa, II, or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.</p> <p>50 FR 33702, Aug. 20, 1985</p> | <p>laser radiation in excess of the accessible emission limits of Class 3A.</p> <p>(c) <i>Demonstration laser products.</i> Each demonstration laser product shall comply with all of the applicable requirements of § 1040.10 for a Class 1, 2, 3A or Class 3B laser, except for Class 3B with not more than 5 times the AEL of Class 2 in the wavelength range of 400 to 700 nm, and shall not permit human access to laser radiation in excess of the accessible emission limits of such classes.</p> | <p>laser radiation in excess of the accessible emission limits of Class 3R.</p> <p>(c) <i>Demonstration laser products.</i> Each demonstration laser product shall comply with all of the applicable requirements of § 1040.10 for a Class 1, 2, or 3R and shall not permit human access to laser radiation in excess of the accessible emission limits of such classes.</p> <p>... (d). Novelty or toy laser products. Each novelty or toy laser product shall comply with all of the applicable requirements of § 1040.10 for a Class 1 laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class 1.</p> <p>(f) Laser products procured by the U.S. Department of Defense for combat, combat training or that are classified in national defense interests.. Each laser product that does not fully comply with all applicable requirements of § 1040.10 and of this section and that is intended solely for purchase by the U.S. Department of Defense (DoD) for use in combat, combat training or that is classified for reasons of national security shall have specific authorization by the cognizant DoD purchasing authority for any deviation from the requirements of . § 1040.10 or 1040.11</p> |
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