**----- PROPOSED DRAFT June 18, 2013 -----**

**Sec. 1040. 10 Laser Products.**

**(a) Applicability.** The provisions of this section and Sec. 1040.11, as amended, are applicable as specified to all laser products manufactured or assembled after [A DATE WILL BE ADDED 2 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], except when:

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

(2) Such a laser product is sold by or for a manufacturer of an electronic product for use as a component (or replacement for such component) in an electronic product subject to this standard, provided that the component (or replacement for such component) laser product:

(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,

(ii) Is labeled with a statement that it is designated for use solely as a component or replacement for such component in an electronic product subject to this standard and therefore is not required to comply with the appropriate requirements of this section and Sec. 1040.11 for complete laser products, and

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

(3) The manufacturer of the component (or replacement) laser product, if manufactured after August 20, 1986,

(i) Registers and provides a listing by type of component (or replacement) laser products manufactured that includes the product name, model number, and laser medium or emitted wavelength(s). The registration and listing must include the name and address of the manufacturer and must be submitted to the Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993-0002;

(ii) Maintains and allows access to any sales, shipping, or distribution records that identify the purchaser of the component (or replacement) laser product by name and address, the product type, the number of units sold, and the date of sale (shipment) . These records must be maintained and made available as specified in Sec. 1002.31 of this subchapter; and

(iii) Documents that the purchaser of such laser product is a manufacturer as defined in Sec. 1000.3(n) of this subchapter who will incorporate the component (or replacement for such component) into a certified laser product, or that the purchaser is another component (or replacement) supplier excluded from applicability of the standard as described in paragraphs (a)(1) or (a)(2) of this section. These records must be maintained and made available as specified in Sec. 1002.31 of this subchapter. Note to paragraph (a) : Sections 1040.10 and 1040.11 are not applicable to light emitting diodes (LEDs) or products containing LEDs unless such products are also laser products as defined in Sec. 1040.10( b)(4).

**(b) Definitions.**

(1) The numbered definitions in clause 3 of IEC 60825-1:2007 that apply to laser products are incorporated by reference (see Sec. 1040.5), except as otherwise noted in this section.

(2) “Children's toy laser product” means a product that is manufactured, designed, intended or promoted for use by children under 14 years of age.

(3) “Invisible radiation” means laser or collateral radiation having wavelengths equal to or greater than 180 nanometers (nm) but less than or equal to 400nm or greater than 700nm but less than or equal to 1,000,000 nm (1 millimeter). Note to paragraph(b)(3): Although vision scientists consider the wavelength ranges from about 380 to 400 nm and from 700 to about 780 nm to be visible, these ranges are treated as invisible in this standard because of the reduced visual sensation.

(4) “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 is also a laser product.

(5) “Protective housing” means those portions of a laser product that prevent human access to laser radiation as required by subclause 4.2.1 of IEC 60825-1:2007 (incorporated by reference, see Sec. 1040.5).

(6) The definitions from the following subclauses of IEC 60825-1:2007 are not applicable under this section:

(i) 3.4 administrative control;

(ii) 3.15 beam expander;

(iii) 3.42 laser controlled area;

(iv) 3.44 laser hazard area;

(v) 3.47 laser safety officer;

(vi) 3.61 nominal ocular hazard area;

(vii) 3.62 nominal ocular hazard distance.

(7) The reference to IEC 60050-845 in the first paragraph of Clause 3 of IEC 60825-1:2007 does not apply.

(8) “Must” as used in Sec. Sec. 1040.10 and 1040.11 and “shall” as used in Sec. Sec. 1040.10, 1040.11, IEC 60825-1:2007, and IEC 60601-2-22:2007 (incorporated by reference, see Sec. 1040.5) are equivalent in meaning and signify a requirement.

(9) In addition to the wavelengths specified in the definition at subclause 3.24 of IEC 60825-1:2007 (incorporated by reference, see Sec. 1040.5), collateral radiation includes x-radiation. Collateral radiation includes but is not limited to electronic product radiation that may arise from a high voltage laser power supply, laser medium flashlamp excitation, laser tube plasma glow, or secondary radiation from a work piece.

**(c) Classification of laser products.**

(1) All laser products. Laser products shall be classified in accordance with subclauses 8.1, 8.2, and 8.3 of IEC 60825-1:2007 (incorporated by reference, see Sec. 1040.5).

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

**(d) Accessible emission limits.**

(1) Accessible emission limits for laser radiation. The requirements of the accessible emission limits in Tables 4, 5, 6, 7, 8, 9, and 10 of IEC 60825-1:2007 (incorporated by reference, see Sec. 1040.5).

(2) Accessible emission limits for collateral radiation from laser products.

(i) Accessible emission limits for collateral radiation having wavelengths greater than 180 nm but less than or equal to 1.0x106 nm are identical to the accessible emission limits for Class 1 laser radiation for emission durations less than or equal to 100 seconds.

(ii) Accessible emission limits for collateral radiation within the x-ray range of wavelengths is 0.5 milliroentgen in an hour, averaged over a cross-section parallel to the external surface of the product, having an area of 10 square centimeters with no dimension greater than 5 centimeters (cm).

**(e) Tests for determination of compliance.**

(1) Tests for certification. Tests on which certification under Sec. 1010.2 of this subchapter is based must account for all errors and statistical uncertainties in the measurement process.

(2) Rules and tests for classification. Clause 9 of IEC 60825-1:2007 (incorporated by reference, see Sec. 1040.5) applies, except that the portion of subclause 9.1 which prescribes that tests must be made under each and every reasonably foreseeable single fault condition is not applicable.

**(f) Performance requirements.** Each laser product must comply with the applicable performance requirements as specified in the subclauses cited in paragraphs (f)(1) through (f)(5) and (f)(7) through (f)(11) of this section from IEC 60825-1:2007, Clause 4 (incorporated by reference, see Sec. 1040.5) except as otherwise noted.

(1) Protective housing. The requirements for protective housings are found in subclauses 4.2.1, 4.2.2, and 4.12 of IEC 60825-1:2007.

(2) Safety interlocks. The requirements for safety interlocks are found in subclause 4.3 of IEC 60825-1:2007.

(3) Remote interlock connector. Follow the requirements of subclause 4.4 of IEC 60825-1:2007. The following requirement is added to the requirements of subclause 4.4: The electrical potential difference between the terminals must not be greater than 130 root-mean-square volts.

(4) Security master control. Follow the requirements of subclause 4.6 of IEC 60825-1:2007, except for the second sentence. The following requirement is added to the requirements of subclause 4.6: The key may be removable and in the absence of the key, there shall be a means to terminate production of laser radiation.

(5) Laser radiation emission indicator. Follow the requirements found in subclause 4.7 of IEC 60825-1:2007. The following requirement is added to those in subclause 4.7: The warning shall occur sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to the laser radiation.

(6) Beam stop or attenuator. Subclause 4.8 of IEC 60825-1:2007 is not applicable. The following is instead applicable:

(i) Each laser system classified as a Class 3B or 4 laser product, must be provided with one or more permanently attached means, other than laser energy source switch(es), electrical supply main connectors, or the security 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, 1M, 2, or 2M as applicable.

(ii) Upon written application by the manufacturer or on the initiative of the Director, Center for Devices and Radiological Health, the Director may, upon determination that the configuration, design, or function of the laser product would make compliance with this requirement unnecessary, approve alternate means to accomplish the radiation protection provided by the beam stop or attenuator.

(7) Location of controls. Follow the requirements of subclause 4.9 of IEC 60825-1:2007.

(8) Viewing optics. Follow the requirements of subclause 4.10 of IEC 60825-1:2007.

(9) Scanning safeguard. Follow the requirements of subclause 4.11 of IEC 60825-1:2007.

(10) Manual reset mechanism. Follow the requirements of subclause 4.5 of IEC 60825-1:2007.

(11) Environmental conditions. Subclause 4.13 of IEC 60825-1:2007 applies except the references to IEC 61010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use-- Part 1-- General requirements, 2d edition, 2001-02, in subclause 4.13 are not applicable.

(12) Collateral radiation. The protective housing of laser products must prevent human access to collateral radiation that exceeds the limits for collateral radiation as specified in Sec. 1040.10(d)(2). Subclause 4.14.2 of IEC 60825-1:2007, Collateral radiation, is not applicable.

(13) Non-optical hazards. Subclause 4.14.1 of IEC 60825-1:2007, Non-optical hazards, is not applicable.

**(g) Labeling requirements.** In addition to the requirements of Sec. Sec. 1010.2 and 1010.3 of this subchapter, each laser product must comply with the applicable labeling requirements of this paragraph. Clause 5 of IEC 60825-1:2007 (incorporated by reference, see Sec. 1040.5) applies, except as otherwise noted in this paragraph.

(1) Applicability. The second and third paragraphs of subclause 5.1 are not applicable.

(2) Alternate labeling. If the labeling prescribed in subclauses 5.1 through 5.8 of IEC 60825-1:2007 are not used, the following alternative labeling shall be used:

(i) Class 1M designation and warning. Each Class 1M laser product must 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 specified warning in the user instructions.

(ii) Class 2 and 2M designations and warnings.

(A) Each Class 2 laser product must have affixed a label bearing the warning logotype A (Figure 1 in this paragraph) and include the following wording:

*[Position 1 on the logotype]*

**“LASER RADIATION-- DO NOT STARE INTO BEAM”** and,

*[Position 3 on the logotype]*

**“CLASS 2 LASER PRODUCT”**

(B) Each Class 2M laser product must have affixed a label bearing the warning logotype A (Figure 1 of this paragraph) and include the following wording:

*[Position 1 on the logotype]*

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

*[Position 3 on the logotype]*

**“CLASS 2M LASER PRODUCT”**

(iii) Class 3R and 3B designations and warnings.

(A) Each Class 3R laser product with accessible radiation in the wavelength range from 400 nm to 1400 nm must have affixed a label bearing the warning logotype A (Figure 1 of this paragraph) and include the following wording:

*[Position 1 on the logotype]*

**“LASER RADIATION-- AVOID DIRECT EYE EXPOSURE”** and,

*[Position 3 on the logotype]*

**“CLASS 3R LASER PRODUCT”**

(B) Each Class 3R laser product with accessible radiation outside the wavelength range from 400 nm to 1400 nm must have affixed a label bearing the warning logotype A (Figure 1 of this paragraph) and include the following wording:

*[Position 1 on the logotype]*

**“LASER RADIATION-- AVOID DIRECT EXPOSURE TO BEAM”** and,

*[Position 3 on the logotype]*

**“CLASS 3R LASER PRODUCT”**

(C) Each Class 3B laser product must have affixed a label bearing the warning logotype B (Figure 2 of this paragraph) and include the following wording:

*[Position 1 on the logotype]*

**“LASER RADIATION-- AVOID EXPOSURE TO BEAM”** and,

*[Position 3 on the logotype]*

**“CLASS 3B LASER PRODUCT”**

(iv) Class 4 designation and warning. Each Class 4 laser product must have affixed a label bearing the warning logotype B (Figure 2 of this paragraph) and include the following wording:

*[Position 1 on the logotype]*

**“LASER RADIATION-- AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION”** and,

*[Position 3 on the logotype]*

**“CLASS 4 LASER PRODUCT”**

(v) Radiation output information on warning logotype. Each Class 1M, 2, 2M, 3R, 3B, and 4 laser product must 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 emitted wavelength(s).

(3) Additional wording. In addition to the wording for labels for access panels as specified in subclause 5.9 of IEC 60825-1:2007 (incorporated by reference, see Sec. 1040.5), the following wording is required.

(i) “CAUTION-- Hazardous electromagnetic radiation when open” for collateral radiation in excess of the accessible emission limit in paragraph (d)(2)(i) of this section.

(ii) “CAUTION—Hazardous x-rays when open” for collateral radiation in excess of the accessible emission limit in paragraph (d)(2)(ii) of this section.

(4) 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 1 radiation or the limits of collateral radiation specified in paragraph (d)(2) of this section.

(5) Visible and/or invisible laser radiation. Subclauses 5.10 and 5.11 of IEC 60825-1:2007 (incorporated by reference, see Sec. 1040.5) are applicable.

(6) Label specifications. Labels required by this section and Sec. 1040. 11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, or service, as appropriate. If the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, 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 must provide or cause to be provided with any user instruction or operation manual that is regularly supplied with the product or, if a manual is not so supplied, must provide 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 of paragraph (d) of this section determined using the tests prescribed under paragraph (e) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and, if applicable, with Sec. 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 radiation detectable in each direction in excess of the accessible emission limits of Class 1.

(iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and, if applicable, by Sec. 1040.11, are to be affixed to the laser product or provided with the laser product , including all required information and warnings. The corresponding position of each label affixed to the product must 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 must 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 as 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, with Sec. 1040.11.

(vi) For Class 1M and 2M laser products, an additional warning is required. This warning must 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 must provide or cause to be provided:

(i) In all catalogs, specification sheets, and descriptive brochures pertaining to each laser product, a statement of the class designation of the laser product.

(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 must include:

(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 utilized by persons other than the manufacturer or the manufacturer's agents to increase the hazard by increasing 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 required by paragraph (g) of this section and, if applicable, by Sec. 1040.11, to be affixed to the laser product or provided with the laser product.

**(i) Modification of certified laser products.** The modification of a laser product previously certified under Sec. 1010.2 of this subchapter 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 Sec. 1040.11 have an applicable requirement. The person who performs such modification must recertify and re-identify the product in accordance with the provisions of Sec. Sec. 1010.2 and 1010.3 of this subchapter.

**Sec. 1040.11 Specific purpose laser products.**

**(a) Medical laser products.** Each medical laser product must comply with all of the applicable requirements of Sec. 1040.10 for laser products of its class. In addition, such products must comply with the following specified clauses and subclauses of IEC 60601-2-22:2007 and IEC 60825-1:2007 (incorporated by reference; see Sec. 1040.5).

(1) Instructions for use, subclause 201.7.9.2 of IEC 60601-2-22:2007;

(2) Protection against unwanted and excessive radiation hazards, clause 201.10 of IEC 60601-2-22:2007, except for:

(i) Applicability to medical LED products, and

(ii) Emission indicator, subclause 201.10.4(e) of IEC 60601-2-22:2007, for which subclause 4.7 of IEC 60825-1:2007 is applicable;

(3) Indication of laser output, subclause 201.12.1.101 of IEC 60601-2-22:2007;

(4) Indication of parameters relevant to safety, subclause 201.12.4.2 of IEC 60601-2-22:2007;

(5) Calibration procedures, subclause 201.7.9.2.101, 4th dash of IEC 60601-2-22:2007;

(6) Incorrect output, subclause 201.12.4.4 of IEC 60601-2-22:2007; and

(7) Emergency laser stop, subclause 201.12.4.4.101 of IEC 60601-2-22:2007.

**(b) Surveying, leveling, and alignment laser products.** Each surveying, leveling, or alignment laser product must comply with all of the applicable requirements of Sec. 1040.10 for a Class 1, 2, or 3R laser product and must not permit human access to laser radiation in excess of the accessible emission limits of Class 3R.

**(c) Demonstration laser products.** Each demonstration laser product must comply with all of the applicable requirements of Sec. 1040.10 for a Class 1, 2, or 3R laser product and must not permit human access to laser radiation in excess of the accessible emission limits of Class 3R.

**(d) Children's toy laser products.** Each children's toy laser product must comply with all of the applicable requirements of Sec. 1040.10 for a Class 1 laser product and must not permit human access to laser radiation in excess of the accessible emission limits of Class 1 under any conditions of operation, maintenance, service, or failure. If a children's toy laser product also meets the definition of a demonstration laser product or surveying, leveling, and alignment laser product, then the classification limit for children's toy laser product applies.

**(e) Laser products procured by the U. S. Department of Defense (DOD).** Laser products procured by the DOD for use in combat, combat training, or that are classified in the interest of national security are exempt from the other provisions of this section, and from Sec. Sec. 1002.10, 1002.11, 1002.13 of this subchapter, and those provisions of Sec. 1040.10 that are determined not to be appropriate for the intended military application. In order for this exemption to apply to a specific laser product, the manufacturer of such product shall obtain a letter from an authorized DOD procuring Agency that applies the exemption to the products. The exemption letter must be obtained prior to sale and must be retained for subsequent sales of the exempted products under the specific contract to any DOD Agency.