**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 1002, 1010, and 1040**

**[Docket No. FDA–2011–N–0070]**

**RIN 0910–AF87**

## Laser Products; Proposed Amendment to Performance Standard

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is proposing to amend the performance standard for laser products to achieve closer harmonization between the current standard and the International Electrotechnical Commission (IEC) standards for laser products and medical laser products, to reduce the economic burden on affected manufacturers, to improve the effectiveness of FDA's regulation of laser products, and to better protect and promote the public health.

**DATES:** Submit either electronic or written comments on the proposed rule by September 23, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by July 24, 2013 (see section VIII, the ''Paperwork Reduction Act of 1995'' section of this document). See section IV of this document for the proposed effective date of a final rule based on this proposed rule.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA–2011–N–0070 and/or Regulatory Information Number (RIN) 0910–AF87, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB) (see section VIII ''Paperwork Reduction Act of 1995'' of this document):

### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

### Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name, Docket No. FDA–2011–N–0070, and RIN 0910–AF87 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

### Information Collection Provisions

The information collection provisions of this proposed rule have been submitted to OMB for review. Interested persons are requested to fax or email comments regarding the information collection provisions to the Office of Information and Regulatory Affairs, OMB (see DATES). To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–5806, or emailed to *oira-submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0025. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Robert J. Doyle, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4672, Silver Spring, MD 20993, 301–796–5863.

**SUPPLEMENTARY INFORMATION:**

### Table of Contents



## I. Background

### *A. Laser Standards and the Laser Industry*

The Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629) transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) from title III of the Public Health Service Act (42 U.S.C. 201 *et seq.*) to Chapter V of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351 *et seq.*). Under the FD&C Act, FDA administers an electronic product radiation control program to protect the public health and safety. FDA also develops and administers radiation safety performance standards for electronic products, including lasers.

The Agency is proposing to amend its regulations applicable to laser products under Chapter 1, Subchapter J of Title 21 of the Code of Federal Regulations (21 CFR) because the current performance standard for laser products, last updated in 1985, is based on an outdated understanding of photobiological science and no longer reflects the current state of a technologically-evolving industry. Lasers now commonly used in the semiconductor and communications industries, for example, had not yet been invented at the time of the last update. FDA is proposing this amendment in order to make its standard consistent with current science and achieve closer harmonization with international standards already in use by the global laser industry. Moreover, this amendment to the performance standard addresses laser technology advancements and concomitant risks and benefits in order to more effectively protect and promote the public health.

The term ''laser industry'' covers manufacturers in numerous industries. Examples of products that incorporate lasers are compact disc and DVD players, fax machines, fiber optic and free-air communication peripherals, bar code scanners, cutting and welding tools, and laser speed detectors.

Through this action, the Agency intends to better harmonize its standard applicable to the laser industry with the current IEC standards (IEC 60825–1, Safety of laser products—Part 1: Equipment classification and requirements, 2d edition, 2007–03 as corrected by IEC 60825–1 (2d edition—2007), Corrigendum 1:2008–08

(identified as ''IEC 60825–1:2007'') and (IEC 60601–2–22, Medical electrical equipment—Part 2–22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment, Edition 3.0, 2007–05 (identified as ''IEC 60601–2–22:2007'')) by adopting various aspects of the IEC standards. By doing so, we would bring FDA's standard up to date with current science and better align FDA's standard for emission limits and hazard classes with those in international use. Currently, firms producing laser products for sale within the United States and abroad have to follow both IEC and FDA standards. Aligning such standards would mean that firms currently complying with two different sets of standards would generally need to comply with only one, except where the standards differ (e.g., collateral radiation limit). In addition, this rule results in better protection of public health because adherence to the rule will mitigate identified risks associated with laser technology.

*B. Harmonization Efforts*

In the Federal Register of March 24, 1999 (64 FR 14180), FDA published a proposed rule to amend the performance standard for laser products to achieve harmonization between the current standard and the IEC standards in place at that time for laser products and medical laser products (the March 1999 proposal). Since the time of that proposal, the IEC has amended its standards, and continued work on the March 1999 proposal would no longer have achieved FDA's goal of increased harmonization of requirements. In the **Federal Register** of November 26, 2004 (69 FR 68831), the Agency withdrew its March 1999 proposal.

In September 1999, FDA consulted with its advisory committee, the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), and discussed the options for responding to the developing changes in the IEC standards. At that time, amendments to the 1993 version of IEC 60825–1 had been distributed as a Committee Draft for Vote (CDV) by the members of IEC Technical Committee 76 (TC76). The advice from TEPRSSC was for FDA to wait upon the results of that voting. The TEPRSSC recommended that if the CDV was approved by the IEC and it appeared that the amendments to the 1993 version of IEC 60825–1 would continue to progress toward adoption, FDA should modify its March 1999 proposal accordingly. The CDV was approved in October 1999. At its plenary meeting in November 1999, TC76 approved circulation for vote of the amendments as a Final Draft International Standard (FDIS). FDA then began drafting this reproposal of its amendments based on the FDIS.

In June 2000, FDA presented a status report to TEPRSSC. TEPRSSC recommended that FDA continue on this course towards increased harmonization with IEC standards regardless of the outcome of the vote on the IEC FDIS. The IEC approved the FDIS in October 2000, resulting in an amended version of the standard which, at that time, was IEC 60825–1, Ed. 1.2: 2001–08. IEC subsequently made additional amendments to IEC 60825–1, resulting in the current version, IEC 60825–1, Ed. 2:2007–03 (as corrected by Corrigendum 1: 2008–08), major portions of which are incorporated by reference in these proposed amendments. FDA kept TEPRSSC apprised of its efforts to amend the Agency's performance standard for laser products through the presentation of status reports in May 2001, May 2002, and October 2003.

In response to concerns some manufacturers expressed about having to comply with two different standards (i.e., the IEC and FDA standards), in the Federal Register of July 26, 2001 (66 FR 39049), FDA published a notice of availability of a guidance entitled, ''Laser Products—Conformance with IEC 60825–1, Am. 2 and IEC 60601–2–22; Final Guidance for Industry and FDA (Laser Notice 50) (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094361.htm*).'' This notice announced the Agency's intent to amend its standard for laser products and stated that, while that process is underway, FDA would not object to industry's compliance with certain aspects of the IEC standards instead of meeting the corresponding FDA requirements. These corresponding requirements include hazard classification, measurements, performance requirements, and labeling. Laser Notice 50 was revised on June 24, 2007, to reference the revised IEC standards, IEC 60825–1, Ed. 2:2007–03 and IEC 60601–2–22, Ed. 3: 2007–05.

At this time, we are proposing specific amendments aimed at achieving closer alignment with the amended IEC standards, IEC 60825–1:2007 and IEC 60601–2–22:2007, by incorporating by reference many of the provisions found in these standards. However, FDA believes that some differences remain appropriate where FDA's standard is more precise than the IEC's. For example, FDA's current standard with respect to collateral radiation, human access, modification of laser products, and key control capability protect against other hazards not reflected in the IEC standards. These differences relate specifically to the criteria in the IEC standards for determining human access to low levels of laser radiation that are recognized to be ocular hazards only, and concern the emission limits for surveying and visual display laser products.

Because the organization and structure of the IEC standards have been considerably different from the FDA standard for the past quarter century, the proposed amendments have adopted the concepts of the IEC standards while retaining the traditional organizational structure of the FDA standard. We believe this approach is appropriate because the manufacturers who have been producing laser products for the U.S. market are accustomed to the organization and structure of the FDA standard. We seek comments on this approach, specifically whether manufacturers would prefer that the Agency organize and structure its rules to match the IEC standards.

## II. Contents of the Proposed Regulation

Proposed § 1002.1 (21 CFR 1002.1) revises the entries in table 1, for laser products, to reflect the hazard classification designations used in the IEC standards.

Proposed § 1010.1 (21 CFR 1010.1), Scope, is amended to update the reference to the legal authority for these regulations and amendments.

Proposed §§ 1010.2(d) and 1010.3(b) (21 CFR 1010.2(d) and 1010.3(b)) would authorize the Director, Center for Devices and Radiological Health (CDRH), or as delegated, on the Director's own initiative or upon written application by the manufacturer, to approve alternate means of providing certification and identification information.

Proposed § 1040.5 (21 CFR 1040.5) incorporates by reference into §§ 1040.10 and 1040.11 (21 CFR 1040.10 and 1040.11) many of the provisions found in two amended IEC standards relating to laser products (i.e., IEC 60825–1:2007 and IEC 60601–2–22:2007) in order to bring the FDA standard up to date and achieve closer alignment with the IEC standards.

Proposed § 1040.10(a) retains the existing applicability stipulations and contains a note emphasizing that the standard is not being expanded to apply to light emitting diodes (LEDs) unless such products are also laser products as defined in § 1040.10(b)(4). LEDs do not typically meet the definition of laser

product because they do not exhibit light amplification by controlled stimulated emission (capable of producing a high-intensity, long-distance hazard) and FDA does not want to apply unnecessarily-stringent requirements to LED manufacturers.

FDA is proposing to amend § 1040.10(a)(3) by adding a new paragraph (iii) as a means of addressing uncertified, unreported complete laser systems that are sold as components. FDA has observed that some manufacturers and distributors are marketing what are actually complete laser systems as components or original equipment manufacturer (OEM) parts. New § 1040.10(a)(3)(iii) would require that the seller document that the purchaser meets the definition of manufacturer in § 1000.3(n) (21 CFR 1000.3(n)) or that the purchaser is excluded from applicability of the standard in accordance with § 1040.10(a)(1) or § 1040.10(a)(2). The provision also would require the seller to maintain such documentation as specified in § 1002.31 (21 CFR 1002.31). FDA is seeking comments on our proposed approach to addressing this issue.

Proposed § 1040.10(b) incorporates by reference many of the numbered definitions in clause 3 of IEC 60825–1:2007 that apply to laser products, but excludes those aspects of the definition in clause 3 that are not applicable in the context of FDA's regulation because they pertain to the purchaser's use of the laser product, an aspect generally not regulated by FDA.

Proposed § 1040.10(b)(2) provides a definition for children's toy laser products to distinguish between laser products provided for use as tools in professional or academic settings and those promoted for novelty use by children (Refs. 1, 2, and 3). In general, FDA's criterion for a children's toy laser product is a laser product when the expected use is by children under 14 years of age and the laser emission has a novelty or visual entertainment purpose. FDA's proposed standard focuses on radiation safety while the corresponding IEC standards are much broader in terms of product safety.

Proposed § 1040.10(b)(8) seeks to avoid confusion and clarifies that the terms must as used in §§ 1040.10 and 1040.11 and shall as used in §§ 1040.10 and 1040.11 and the IEC standards are equivalent in meaning and signify a requirement.

Proposed § 1040.10(b)(9) would add two sentences to the definition at subclause 3.24 of IEC 60825–1:2007, which would be incorporated by reference by proposed § 1040.10(b)(1). This language would clarify the definition of the term ''collateral radiation'' consistent with current and proposed requirements as well as longstanding FDA policy. The proposal specifies that x-radiation would also be included in the definition of ''collateral radiation,'' which is consistent with the current definition at § 1040.10(b)(12) and the requirements of both current and proposed § 1040.10(d), but is not included in subclause 3.24 of IEC 60825–1:2007. FDA remains concerned about the potential for unintentional exposure to x-radiation from laser products and this potential hazard is not addressed in the IEC subclause. For this reason, FDA wants to retain its x-ray collateral radiation accessible emission limit in 1040.10(d). In the 1992 HHS Publication FDA 86–8260—Compliance Guide for Laser Products (*http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm095304.pdf*), FDA specified that collateral radiation includes ''x-radiation produced by a high voltage power supply, plasma glow in a discharge tube, excitation lamp light, or reradiation from a workpiece.'' Proposed § 1040.10(b)(9) includes similar language to make clear that the definition of ''collateral radiation'' includes, but is not limited to, these types of radiation. FDA believes this will inform the public and clarify the breadth of objects that can, unbeknownst to the user, absorb and then re-emit radiation.

Proposed § 1040.10(c) incorporates by reference the hazard classifications of the IEC standard IEC 60825–1:2007.

Proposed § 1040.10(d) incorporates by reference tables of accessible emission limits (AELs) for the classes of laser products identified in IEC 60825–1:2007. FDA acknowledges that the AELs of the IEC are more up to date and better represent current understanding of the biological hazards of laser radiation. However, FDA is not proposing to eliminate its more-precise emission limits for collateral radiation. FDA believes that its experience demonstrates that the collateral radiation limits provide objective criteria for safety. Proposed § 1040.10(d) retains the AELs for collateral radiation but reduces the time base for which collateral radiation is to be evaluated. FDA is adopting the IEC collateral radiation standard in whole but retaining its own additional, more precise limits for collateral x-ray radiation because this aspect is not addressed in the IEC collateral radiation standard.

Proposed § 1040.10(e) incorporates by reference the measurement conditions set forth in IEC 60825–1:2007 for use in determining the hazard classification of the laser product. However, FDA retains its requirement that tests under this section be part of the basis of the required certification of the product. FDA considers the IEC stipulation that conformance be evaluated under each and every reasonably foreseeable single failure condition to be impractical and is not proposing to adopt this stipulation. The stipulation is also unnecessary because FDA's notification and correction requirements in parts 1003 and 1004 (21 CFR parts 1003 and 1004) already provide an effective procedure for dealing with failures to comply or product radiation safety defects.

Proposed § 1040.10(f) incorporates by reference the engineering specifications provisions of clause 4 of IEC 60825–1:2007 with certain exceptions. The exceptions include retention of the existing authority in current § 1040.10(f)(6) for CDRH to approve alternate means of safety in lieu of a beam attenuator. Proposed § 1040.10(f)(4) is intended to allow more flexibility to manufacturers in providing means to preclude unintended or unauthorized use of Class 3B or 4 laser systems. The existing FDA requirement in current § 1040.10(f)(4) is for a ''key control'' that prevents ''operation of the laser'' when the key is removed. The wording of the existing FDA requirement precludes the use of momentary key switches to start the laser or, if taken very literally, the use of computer passwords. FDA believes that the critical aspects of access control are the necessity for the use of the key to permit activation of the laser and the ability to turn off the laser without a key. Because FDA had concerns that the flexibility to use a key that is not captured by the key switch mechanism or to use a computer password only addressed the starting of the laser, the proposed change also includes a requirement that there be a means for terminating operation of the laser. The title of this section has also been changed to ''security master control'' to reflect the broadening of the section.

Proposed § 1040.10(f)(12) relating to collateral radiation would not incorporate subclause 4.14.2 of IEC 60825–1:2007, but instead require that the protective housing of laser products must prevent human access to collateral radiation that exceeds the limits for collateral radiation as specified in proposed § 1040.10(d)(2). This requirement is necessary to assure the safety of laser product users because the

IEC standard allows the use of protective housing to be at the discretion of the manufacturer, rather than a safety requirement.

Proposed § 1040.10(g) incorporates by reference the labeling provisions of IEC 60825–1:2007 but allows labeling in the format specified in the American National Standards Institute (ANSI) 535 series for labels. Under this provision, either type of labeling could comply with the regulations.

Proposed § 1040.10(h)(1) includes minor conforming changes. Proposed § 1040.10(h)(2)(ii) reorganizes and clarifies what service information must be made available by manufacturers. In particular, the service information addresses procedures or adjustments which may affect any aspect of the products performance. The preambles of the proposed FDA standard published in 1974 (39 FR 32097) and the final rule published in 1975 (40 FR 32256) indicate that the Agency's main intent in issuing the service information requirement was to safeguard the persons performing service on the laser equipment from possible exposure to unsafe levels of radiation. Subsequent to the standard's issuance, some stakeholders have interpreted this provision to apply to all service instructions, often leading to inappropriate access to non-safety related service information by dealers, distributors, and other unqualified personnel. Proposed § 1040.10(h)(2)(ii) clarifies that this part of the standard is intended to address laser radiation safety during service procedures and that the decision to provide additional information is at the discretion of the manufacturer.

Proposed § 1040.11(a), which applies to medical laser products, would incorporate by reference certain pertinent clauses and subclauses from the IEC standard IEC 60601–2–22:2007 including instructions for use (subclause 201.7.9.2) and laser radiation (clause 201.10). These clauses and subclauses are more current than the existing FDA standard in addressing current technology and use conditions. FDA is not proposing to adopt other clauses and subclauses of the IEC standards with respect to medical laser products because they do not pertain to radiation safety, but rather relate to other product safety concerns.

FDA is proposing to amend § 1040.11(b) and (c) to change the highest allowed class designation from Class IIIa to Class 3R. This change is necessitated by the incorporation of the IEC classifications and measurements for classification by reference into § 1040.10(d) and (e).

FDA is also proposing to amend § 1040.11 by adding a new paragraph (d). Proposed § 1040.11(d) would restrict to Class 1 under any conditions of operation, maintenance, service, or failure, any laser products that are made or promoted as children's toys. We are proposing this amendment to ensure children will not be harmed by laser radiation under any conditions including disassembly or breakage. Because the class of the laser within the toy could be higher than the class of the toy product itself, the amendment protects children from unanticipated harmful exposure. The Consumer Product Safety Commission has requirements that address other safety concerns pertaining to children's toys (see 16 CFR part 1500).

FDA, in response to a specific request from the U.S. Department of Defense (DOD), is proposing a new § 1040.11(e) that codifies an exemption from the standard granted for the DOD in 1976 for laser products that are intended for use in combat, combat training, or that are classified in the interest of national security. This proposed amendment states that these laser products must have specific authorization from the procuring DOD authority in order for the exemption to apply. Detailed information about the implementation of this exemption is contained in the CDRH guidance document, which is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094416.htm*.

## III. Legal Authority

FDA is taking this action under the FD&C Act, as amended by the SMDA. Section 532 of the FD&C Act (21 U.S.C. 360ii) authorizes FDA to establish and administer an electronic product radiation control program to protect the public health and safety. Section 534 of the FD&C Act (21 U.S.C. 360kk) authorizes FDA by regulation to prescribe, amend, and revoke performance standards for electronic products. Section 1003(b)(2)(E) of the FD&C Act (21 U.S.C. 393(b)(2)(E)) requires FDA to ensure that public health and safety are protected from electronic product radiation. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act.

## IV. Proposed Effective Date

FDA proposes that any final rule that issues based on this proposed rule become effective 2 years after the date of publication of the final rule in the **Federal Register**. A product is certified compliant with a particular standard as that standard exists on the Date of Manufacture, that is, the date it passed final testing including the compliance tests. Therefore, products which were completed and dated before the effective date of the amendments would not have to be recertified even if they are sold after that effective date.

## V. Environmental Impact

The Agency has determined under 21 CFR 25.34(c) that this proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environment impact statement is required.

## VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This proposed rule is a significant regulatory action as defined by Executive Order 12866, and as such, it has been reviewed by OMB.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Agency prepared an initial regulatory flexibility analysis (see section VI.G ''Impact on Small Entities'' of this document).

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

*A. Need for Regulation*

As discussed previously in this document, the Agency is proposing to amend its regulations relating to laser products. The current FDA standard for laser products is based on an outdated understanding of photobiological science and no longer reflects the current state of a technologically evolving industry. For example, lasers now commonly used in the semiconductor and communications industries had not yet been invented at the time the standard was last updated by FDA.

Through this rulemaking, the Agency intends to better harmonize its standard with the current IEC standards (IEC 60825–1:2007 and IEC 60601–2–22:2007). By doing so, we would bring the FDA's standard up to date with current science and better align the FDA's standard for emission limits and hazard classes with those used by most countries of the world. Currently, firms producing laser products for sale within the United States and abroad have had to follow both IEC and FDA standards. Aligning such standards would mean that firms currently complying with two different sets of standards would generally need to comply with only one, except where the standards differ.

Despite the advantages of using an updated internationally-recognized safety standard, private incentives alone would be inadequate to move the laser industry to this new standard. Current regulations, based on a different standard, would prevent such a move. Some entities might choose not to adopt the new standard. Under section 534(a)(4) of the FD&C Act, a new regulation is necessary to amend FDA's existing standard. For these reasons, FDA concludes this rule is necessary.

*B. Background*

Lasers are given hazard classifications according to the radiation hazard they present. Class I lasers, such as DVD players, are considered to be safe under intended conditions of operation. Under the harmonized standard, these lasers would be in Class 1 (not known to be hazardous) and Class 1M (not known to be hazardous to the unaided eye).[1] Class II lasers are more hazardous, but should be safe as long as humans blink and aversion responses operate. These lasers would be either Class 2 or Class 2M (safe as long as one did not use optical instruments for viewing and one's blink and aversion responses did operate). Class IIIa lasers are more powerful, but are still considered as low risk. These lasers would be classified in class 3R under the harmonized standard. Class IIIb lasers are potentially dangerous and most would be classified as Class 3B under the harmonized standard. Some lower power lasers that are currently in Class IIIb may be able to move to lower classes under the harmonized standard. Class IV lasers, such as those used for cutting, are particularly dangerous. These would be in Class 4 under the harmonized standard.

While some firms in the laser industry would incur a burden associated with adopting a new standard, our impression from discussion with industry experts is that greater harmonization should lower the overall economic burden on the U.S. laser industry. The Agency believes increased harmonization to be consistent with the goal of adopting voluntary consensus standards, as has been articulated in OMB Circular A–119 (Ref. 4). Moreover, to the extent that the current FDA standard differs from those used by other trading partners, harmonization would reduce costs associated with trade and would indirectly benefit U.S. consumers of laser products.

In addition to bringing FDA's laser standard in line with current science and partially harmonizing with the rest of the laser industry, this action would also clarify the scope of existing laser regulations. Children's toy laser products, not currently included among ''specific purpose laser products,'' would now be covered. These could include, for example, lasers mounted on toy guns for ''aiming,'' spinning tops which project laser beams while they spin, dancing laser beams projected from a stationary column, or lasers intended for creating entertaining optical effects. We do not know the number of firms manufacturing these products but believe nearly all are located outside the United States. Laser products claiming exemption as a product intended for use in combat, combat training, or classified in the interest of national security would continue to be required to have specific authorization from the DOD. This proposed rule clarifies when the exemption applies.

The Agency believes rulemaking to be the preferred approach to moving this large, heterogeneous industry to a partially harmonized standard. As previously mentioned in this document, some laser manufacturers would incur one-time additional costs from increased harmonization, approximately $6.7 million at 7 percent and $5.9 million at 3 percent, but expected recurring benefits to laser manufacturers of $13.4 million would exceed these costs. In 2001, the Agency addressed the need for an updated standard by issuing Laser Notice 50 (Ref. 5). Laser Notice 50 declared that FDA would not object to compliance with IEC standards to satisfy certain FDA requirements while the Agency was in the process of amending its own standard. Firms following the approach described in Laser Notice 50 have been allowed to benefit from harmonization during this period of transition to a new harmonized standard. We seek comments from firms using the Laser Notice 50 approach to help us examine the costs and benefits of this regulatory action. Laser Notice 50, however, was intended only as a stopgap measure. Through this action, laser product manufacturers will benefit from increased regulatory certainty. Also, safety inspectors examining these products will be able to work from far more similar standards.

By moving to a safety standard more attuned to current science, the Agency expects this action to benefit public health. There is a risk of serious injury associated with the use of lasers. High-powered lasers have the potential to burn human tissue, but nearly all of the reported injuries from the use of lasers have been retinal (Ref. 6, p. 466). A study published in 2000 found over 100 reports of laser eye injuries over the course of 35 years (1965–2000) in the medical literature, but noted many more injuries went unreported because of confidentiality requirements associated with the legal proceedings and the sensitivity of military operations (Ref. 6, p. 465). Another study estimated that there are fewer than 15 retinal injuries each year worldwide from industrial and military lasers (Ref. 7, p. 1211). Accidents involving higher-powered lasers have resulted in permanent loss of visual acuity and even blindness. Injuries from lower powered lasers have been associated with temporary disturbances in vision. While these eye injuries are not permanent, the temporary loss of vision can result in serious accidents (Refs. 14, 15). Our understanding of potential sources of laser injuries has evolved significantly over time because of developments in the science. FDA believes its standard should be aligned with the most recent valid science in order to minimize risk of injury. Scientific studies have identified radiation safety issues associated with lasers that were previously unknown such as repetitive pulse output and additional spectral regions where photochemical hazards must be considered. This regulation

[1] A laser could be in Class I(1) because it emits very little radiation or because the radiation is fully contained, as in a laser printer.

accounts for variables that were not addressed by the previous regulation.

*C. Affected Entities*

The proposed rule would directly affect establishments that manufacture laser products. In general, all products incorporating a laser or laser system are subject to the current performance standard. Laser products that are also medical devices are also subject to the Agency's regulations pertaining to medical devices. Manufacturers that market products internationally must also comply with internationally-recognized standards, such as IEC 60825–1:2007 and 60601–2–22:2007.

Because a wide variety of products contain lasers, the term ''laser industry'' actually refers to manufacturers in numerous industries. Examples of products that incorporate lasers are compact disc and DVD players, fax machines, fiber optic and free-air communication peripherals, bar code scanners, cutting and welding tools, and laser speed detectors. For the year 2006, worldwide revenues for the laser industry were approximately $5.6 billion (Ref. 8). In 1997, U.S. sales accounted for approximately 60 percent of industry revenues according to the January 1998 edition of the trade publication Laser Focus World, the last edition to report that statistic. Assuming that share still holds, the domestic laser industry has annual sales of approximately $3.4 billion. Global revenues increased slightly between 2005 and 2006.

The Agency contracted with the Eastern Research Group (ERG), Inc. to estimate the economic impact of partial FDA harmonization with these two IEC standards. ERG's report, ''Technical Quality and Economic Implications of International Harmonization of Laser Performance Standards—An Update'' (ERG Report) (Ref. 9) is summarized here and on file with the Division of Dockets Management as well as *http://www.regulations.gov* (see **ADDRESSES**).

ERG estimates that there are 1,283 U.S. manufacturers of laser products spanning 18 North American Industrial Classification System (NAICS) classifications. All of these firms would be affected by this proposed rule because all are assumed to produce for U.S. consumers and, therefore, required to meet the FDA standard. Those firms producing only for U.S. consumers (875 of the 1,283 firms according to ERG) would bear costs because they would need to adopt a new set of standards. Firms producing for both U.S. consumers and for export (408 of the 1,283 firms) would benefit from this proposed rule because they would generally need to comply with only one standard instead of two sets, except where the standards differ. Based on our experience regulating and inspecting these exporting firms and our understanding that the current IEC standards and this proposal that would incorporate the IEC standards by reference are similar, we assume for this analysis that exporting firms are already in compliance with the IEC standards. We recognize, however, that this is a critical assumption and welcome comments from the public. The Agency does not know of any U.S. firms producing solely for export.

*D. Costs of the Proposed Regulation*

The costs of complying with this proposed rule would be the costs associated with elements of the harmonized standard that are not in the existing standard. Because exporting firms are presumed to already be in compliance with the IEC standards, only firms not currently producing for export would be expected to incur these costs. The ERG Report identifies four cost-generating elements: Protective housing labeling, repetitive pulse correction factor, testing with 50 millimeters (mm) aperture, and compliance testing for de minimis changes. We also recognize that there may be some costs associated with IEC standards documentation, documentation requirements for manufacturers of some laser products that are intended as components, and DOD exemption documentation. We do not rule out potential additional training costs associated with learning the new standard, but believe estimated costs would be so minor that they would be difficult to reliably quantify.

1. Protective Housing Labeling

Section 1040.10(d)(2) of the proposed rule changes the wording on the label that must appear on all housings that prevent access to laser light. The cost of making this change would depend on the labor associated with the change, any IT system changes required, and on the cost of creating and printing new labels. The ERG Report noted that manufacturers of consumer products have shorter product cycles than manufacturers of industrial products and that many consumer product manufacturers would be able to make the label change in the ordinary cycle of production. This analysis assumes similarity between the manufacturers of consumer products and manufacturers of laser products. Nevertheless, because of the difficulty in identifying consumer products among the various NAICS classifications, ERG applied the protective housing label costs to all NAICS industries affected (Ref. 9, p. 42). Because firms in classification 334119 (other computer peripheral equipment manufacturing) are believed to export, they are assumed to be unaffected. According to the ERG Report, a label change would cost an estimated $4,966, or approximately $5,000, per product. The costs roughly break down as approximately $4,300 for an engineering change order, including $400 in label design and tooling expenses, plus $600 in label inventory losses.

The total cost of this provision would be a function of the number of affected products. Firms with a single product would face a cost of about $5,000. ERG estimates that the 875 non-exporting firms affected by this provision of the proposed rule produce approximately 3,100 products, resulting in a cost of $15.4 million. Because the ERG analysis was completed in 2005, we adjust for inflation using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. Adjusting for inflation of 9.77 percent, the estimated cost is $16.9 million. The annualized cost of this provision, at a 7 percent discount rate over a 10-year horizon is $2.2 million. At 3 percent, the annualized cost is $1.8 million (Ref. 9, Table 3–5, p. 53). Adjusting for inflation, these amounts are $2.4 million and $2.0 million.

This estimate may substantially overstate the cost of compliance because it does not consider product labeling that could be updated during the 2-year implementation period. If the labeling for some products would normally be updated every 6 years, a sizable fraction of these products would be able to revise the labeling as part of the normal product cycle during the 2-year implementation period. Because the Agency does not know the lifespan of these labels and the ERG Report does not cover this issue, we have not attempted to calculate the fraction that would be updated in a 2-year period.

2. Repetitive Pulse Correction Factor

The harmonized standard for laser products includes a new technical specification for calculating the power of scanning or repetitively pulsed laser products. Pulse repetition potentially increases the risk of injury and was not a standard feature of laser products when the current standard was issued (Ref. 16). Because of this new technical specification, certain products might be reclassified as presenting a greater threat to safety and may require more safety-related features. Due to the increased granularity of the classifications in the IEC standards as compared to FDA's existing standard, some Class I

products, such as certain laser range finders or laser pointers, might be reclassified as Class 1M or 3R. Some Class II or IIIa products might be reclassified as Class 3B. The impact of this provision would be felt among firms in NAICS classification 334519 (other measuring and controlling device manufacturing), where, according to Table 2–5 of the ERG Report, there are 71 affected firms.

Under this proposal, Class 3B laser products require more safety-related features than products in Class I, II, or IIIa. Such safety features would include an indicator light at each aperture to show when the laser is operating, a key or password lock, a connector to facilitate remote interlocking, and a beam attenuator. The increase in safety requirements may also lead to other changes, such as the revision of safety manuals or the use of more elaborate installation procedures. Manufacturer costs associated with this provision would include both one-time engineering costs relating to changes to design and documentation, plus recurring production costs for the inclusion of these safety-related features in the manufacture of each unit.

To comply with this provision, manufacturers faced with reclassification to a more stringent class would face the costs of redesigning the product. In some cases, however, a manufacturer might be able to make adjustments to the product, itself, to stay in a lower class. For example, if power output is a factor in moving a product to a more stringent class, the manufacturer might avoid the move if it can lower the power of the unit without harming the functionality of the product.

The one-time cost for product design to incorporate the additional safety features would be between $25,000 and $100,000 per product (Ref. 9, p. 43). These costs would include labor and materials for redesign, purchasing, establishing manufacturing and quality control procedures, and product documentation changes. The range for these costs reflects that the required safety changes can vary from being fairly straightforward to being substantially more complex. The average expected one-time cost of compliance is $55,400 per affected product, as derived in Table 3–1 of the ERG report.[2] Over all affected products in NAICS classification 334519, the estimated one-time cost of this provision is $6.3 million. Adjusting for inflation of 9.77 percent, the estimated cost is $6.9 million. The 10-year annualized cost at a 7 percent discount rate is $892,000. At 3 percent, the annualized cost is $734,000 (Ref. 9, Table 3–5, p. 54). Adjusting for inflation, these amounts are $979,000 and $806,000.

In addition to the one-time costs associated with making these changes, there would also be recurring costs for the increased material and labor used in manufacturing. Based on information in the ERG Report from discussions with industry experts, the Agency estimates that these additional components would cost approximately $5 per unit and would require an additional 0.1 hours to install for each unit. Assuming a 1,000 unit production run for a typical product affected by this rule, ERG has estimated that the total recurring costs per product for this aspect of the proposed rule to be $7,004 per product (Ref. 9, p. 43). Many laser product manufacturers have significantly higher production volumes, but an ERG analysis of U.S. International Trade Commission export statistics for the affected NAICS codes supports this lower estimate. Moreover, companies with higher production volumes are likely to be exporters already familiar with IEC standards and manufacturers of Class I devices which would not be affected by this proposal. Nevertheless, estimated recurring costs for a hypothetical affected company with a production volume of 100,000 units would be 100 times as great, or $700,000 per product. We therefore request comment on this assumption.

Over the estimated 113 affected products in NAICS classification 334519, the cost would be $792,000. Adjusting for 9.77 percent inflation, the cost is $870,000. Adding this to the annualized one-time cost, the annualized total cost of this provision at a 7 percent discount rate over 10 years is $1.7 million. At a 3 percent discount rate, the annualized cost is $1.5 million. Adjusting for inflation, these amounts are $1.8 million and $1.7 million.

3. Testing With 50 mm Aperture

Under the proposed rule, the power of many visible and near infrared lasers would be tested using an aperture of 50 mm. Previous test methods used a smaller aperture and did not capture some power from lasers with a wide beam width. According to the ERG Report, most laser products have a beam width smaller than 50 mm and would not be affected by this provision. But a few products with diverging or expanded beam diameters may be affected. Examples of potentially affected products with wide beam widths are laser speed guns and distance-measuring products used in construction.

With the larger test aperture leading to more measured power, some products may move into more stringent class designations. As with the previously discussed repetitive pulse correction factor, a manufacturer with a product that has moved to a more stringent class could either redesign the product to meet the stricter requirements or lower the product's power. For the purposes of this analysis, we assume the manufacturer redesigns the product. The Agency assumes the cost of the provision to be the same as that in the repetitive pulse correction factor: $55,400 for one-time product design and a little over $7,000 for increases in the cost of production.

In its report, ERG assumed this provision would affect products manufactured by firms in NAICS classifications 334511 (search, detection, navigation, guidance, aeronautical, and nautical system and instrument manufacturing) and 334519 (other measuring and controlling device manufacturing). ERG estimated there to be 11 affected firms with 33 affected products in classification 334511 and 71 affected firms with 113 affected products in classification 3345193.[3]

The estimated one-time cost for classification 334511 for this provision is approximately $1.8 million ($55,400 per product × 33 affected products). The estimated recurring costs are approximately $229,000 ($7,000 per product × 33 products). The estimated one-time cost for classification 334519 is $6.3 million ($55,400 per product × 113 products) and the recurring costs are $792,000 ($7,000 per product × 113 products).

For both classifications combined, the one-time cost for this provision is approximately $8.1 million ($1.8 million + $6.3 million), which is $1.1 million when annualized at 7 percent and $946,000 when annualized at 3 percent. The recurring cost is approximately $1.0 million ($229,000 + $792,000). The estimated total cost of this provision, annualized over 10 years at 7 percent is $2.2 million, and at 3 percent, the cost is $2.0 million. Adjusting for inflation of 9.77 percent, the one-time cost is $8.9 million, and the recurring cost is $1.1 million. Annualized over 10 years at 7 percent,

[2] The estimate assumes 160 hours of managerial time at a rate of $53.28 per hour, 1,200 hours of professional staff time at $38.47 per hour, and 40 hours of clerical time at $18.08 per hour.

[3] See ERG report, Tables 3–3 and 3–5. Table 3–5 does not explicitly list the number of affected products, but this can be deducted from the total costs in the table on p. 55 and the per-device cost as calculated in table 3–1.

the inflation-adjusted cost is $2.4 million, and at 3 percent the cost is $2.2 million.

4. Compliance Reporting for de Minimis Changes

Changes in laser products must be reported to FDA under both the current regulation and the proposed regulation. As noted earlier, some firms would be required to change their protective housing labeling. When a firm changes the labeling of a product, it must submit to FDA a report of the change and a copy of the new label.

In addition to the costs associated with the actual label change, a firm would also incur the costs to compile and submit the information for the change notice to FDA. ERG estimates this cost to be about $100 per product (Ref. 9, p. 45). This estimate potentially overstates the impact, as many firms would be able to notify FDA of product changes through the annual report process and would not need to submit an additional notice.

As noted previously in this document, the 875 non-exporting firms affected by the label change provision (and, therefore, this provision) are responsible for approximately 3,100 laser products. ERG estimates the one-time cost of these notifications to be $334,000, which is $47,000 when annualized at 7 percent and $39,000 when annualized at 3 percent (Ref. 9, Table 3–5, p. 56). Adjusted for inflation, the one-time cost is $366,000, which is $52,000 annualized at 7 percent and $43,000 annualized at 3 percent.

5. IEC Standards Documentation

In addition to the issues addressed in the ERG Report, the Agency recognizes that some laser manufacturers may need to purchase an official set of IEC Standards.[4] Document IEC 60825–1, Edition 2, March 2007, costs CHF 255 (Ref. 10).[5] Document IEC 60601–2–22, Edition 3.0, May 2007, costs CHF 135. Thus, these IEC standards can be purchased for CHF 390, which is about $350. Assuming all 875 laser manufacturing firms not currently producing for export would purchase these documents, the total one-time cost would be $289,500. When annualized at 7 percent over 10 years this cost is $41,200, and when annualized at 3 percent, it is $33,900.

[4] The standards are sold through the IEC Web site (*http://www.iec.ch*).

[5] Swiss Francs are represented by the symbol CHF. 1 Swiss Franc = 0.9342 U.S. Dollars. Per midrates 21:20 UTC, April 21, 2010.

6. Manufacturer Status Documentation

Regulatory requirements for those selling components or OEM parts to manufacturers are less burdensome than are the requirements for those selling complete laser systems to consumers. Under current regulations, components and OEM parts may only be sold to manufacturers. New § 1040.10(a)(3)(iii) would reinforce these provisions by requiring those selling components or OEM parts to document that the purchaser meets the definition of manufacturer in § 1000.3(n) or that the purchaser is excluded from the standard in accordance with § 1040.10(a)(1) or § 1040.10(a)(2). The provision would also require the seller to maintain documentation as specified in § 1002.31.

ERG did not analyze this provision in their report. The regulation would require those selling components to maintain records showing that their customers are manufacturers. The Agency believes sellers could generally comply with this provision by accumulating information gathered in the course of doing business. Additional information required to verify that a particular purchaser was a manufacturer could be obtained through email or fax. The Agency assumes that it would take, on average, approximately 10 minutes, or 0.17 hours for a component seller to obtain and file information on each customer. The ERG Report assumes an average wage rate for clerical and administrative staff of $18.08 per hour, so the cost per record would be $3 (Ref. 9, p. 13).

FDA does not know how many manufacturers or suppliers are purchasers from each manufacturer with a registered component product. According to the FDA product registration database, there were 574 component product registrations from 155 component manufacturers filed during the 11-year period from 1997 to 2007, an annual average of 52 product registrations (574 ÷ 11) from 14 manufacturers (155 ÷ 11). Assuming each accession number in the registration database represents a unique purchaser who is a manufacturer or supplier, there would be 52 new records each year. At $3 per record and adjusting for 9.77 percent inflation, the annual cost of this provision would be $172. We invite comment on these estimates and the extent to which this provision would prevent manufacturers from improperly shifting the responsibility for certifying, reporting, or registering products to end users.

7. Department of Defense Exemption

The FDA laser safety standard may not be appropriate for laser products used in combat, combat training, or other national security situations. Visible or audible emission indicators and highly visible warning labels, for example, may be inappropriate when concealment is vital. For this reason, laser products procured for combat, combat training, or classified for reasons of national security are exempted by FDA from the laser safety standard (Ref. 11).

Nevertheless, FDA is concerned that the lack of clear regulatory language hampers the effectiveness of this exemption. FDA has become aware of manufacturers claiming to possess a DOD exemption when they have not followed the proper procedures and obtained the required exemption letter. FDA is also concerned that the manufacturer may attempt to import laser products without an exemption letter, resulting in the products being detained because there is no proof that the products have been exempted by the laser performance standard. FDA believes incorporating this exemption into this Agency's regulations would make it more effective.

FDA estimates 25 manufacturers per year would obtain exemption letters from the DOD. An unknown number of manufacturers are currently obtaining exemption letters from the DOD, as required in current guidance. Assuming it takes 5 minutes to request the exemption letter and then 10 minutes to file it, each exemption letter would require 15 minutes of time from a clerical worker. The ERG Report uses an average wage rate for clerical and administrative staff of $18.08 per hour, so the cost per exemption letter would be $4.50. With an upper bound of 25 letters each year and adjusting for 9.77 percent inflation, the annual cost of this provision would be $123. If each of these manufacturers are already obtaining exemption letters as required in current guidance, there would be no additional cost incurred by these manufacturers.

8. Total Costs of the Regulation

Table 1 of this document summarizes and totals the costs of the regulation. The total one-time costs of this proposed regulation are estimated to be $33.4 million. Annualized over 10 years at 7 percent, this cost is $4.7 million; at 3 percent the annualized cost is $3.9 million (Ref. 9, Table 3–5, p. 57).[6] The

[6] These figures differ slightly from those in the ERG Report (Ref. 6) because of the inclusion of the cost of purchasing copies of the IEC standards.

estimated total recurring costs of the regulation are $2.0 million. The estimated total cost of this regulation annualized over 10 years at 7 percent is $6.7 million. When annualized at 3 percent, the cost is $5.9 million.

TABLE 1—TOTAL COST OF THE REGULATION

| Issue | One-time (millions) | Recurring (millions) |
|---|---|---|
| Protective Housing Labeling | $16.9 | ..... |
| Repetitive Pulse Correction Factor | 6.9 | $0.9 |
| Testing with 50 mm Aperture | 8.9 | 1.1 |
| Reporting for de Minimis Changes | 0.4 | ..... |
| IEC Standards Documentation | 0.3 | ..... |
| Validation of Manufacturer Status | ..... | 0.0 |
| Department of Defense Exemption | ..... | 0.0 |
| Sum All Provisions | 33.4 | 2.0 |
| Annualized Costs at 7 percent | 4.7 | 2.0 |
| Annualized Costs at 3 percent | 3.9 | 2.0 |
| Total Annualized Costs at 7 percent | ..... | 6.7 |
| Total Annualized Costs at 3 percent | ..... | 5.9 |

This cost estimate is based on available data, but may overstate certain items, especially those associated with changing the wording of the label appearing on protective housings. This is estimated to be the most expensive provision, but, as previously stated, some firms would already be revising their labels during the 2-year compliance period and would bear a lesser burden. We seek comments on our estimates, including whether this proposed rule triggers costs for the 408 firms which produce for both U.S. consumers and for export.

*E. Benefits of the Proposed Regulation*

This proposed rule would be beneficial in a number of ways. The proposed rule would align safety standards to the current scientific knowledge and thinking on laser safety and update rules that were established before many current laser products existed. In doing so, we expect there to be benefits to public health. The benefits associated with improved laser safety, such as the reduced risk of retinal injury, have been described qualitatively earlier in this document. Such benefits, however, are difficult to quantify and, therefore, are not included here.

Taking steps towards the harmonization of laser safety standards potentially benefits consumers through lower prices. Requiring foreign laser manufacturers to maintain completely separate safety standards for the U.S. market increases the cost of doing business. Reducing such divergences encourages trade, increases social welfare, and benefits U.S. consumers. These benefits are difficult to quantify and are not included in this analysis. Nevertheless, we have estimated the U.S. market for laser products to be $3.4 billion. As summarized above, the estimated total annualized costs of this proposed rule are $6.7 million. Gains to consumers of at least 0.2 percent of sales would be enough to outweigh the estimated costs of the proposed rule.

In this analysis, we limit the quantified benefits to the savings that would be expected to be realized by laser manufacturers currently exporting and in compliance with IEC standards. Under this proposed rule, manufacturers currently complying with two standards would generally only need to comply with a single harmonized standard, except where the standards differ. Under harmonization, these firms would be partially relieved of a burden. The Agency believes these benefits could be substantial.

In its report, ERG noted that most industry representatives believed harmonization would be beneficial to the U.S. laser product industry (Ref. 9, p. 12). Yet, ERG found it difficult to accurately quantify the expected savings from this proposed rule and did not do so in their report. In response to a prior proposed rulemaking, the Agency received several comments from industry encouraging harmonization of laser safety requirements, citing potential administrative savings from the elimination of multiple regulatory requirements (Ref. 12). We attempt to quantify these administrative benefits from harmonization of laser safety standards, but due to the uncertainty in our methodology, we request comment on our approach.

This proposed rule would reduce the expenditures needed to comply with two sets of safety standards. This burden would include costs associated with physically testing products to satisfy existing FDA and IEC standards. Firms currently producing multiple variations of products to comply with both sets of standards would save on manufacturing costs. In addition, under the proposed rule, if finalized, all class IIa products and certain class II products will move to less stringent class 1 or class 1M laser classifications, thereby reducing the costs of meeting safety requirements. There also would be cost savings associated with the reduction of administrative elements of compliance, such as the creation of duplicate labeling and documentation.

According to the ERG report, 408 of the 1,283 U.S. firms manufacturing laser products are exporters that currently comply with multiple standards. The 875 non-exporters manufacture 3,100 products, or about 3.5 products per firm. We do not have information on the numbers of products for exporting firms, but we assume that firms serving a larger customer base would in general have larger product assortments. ERG assumed that small firms have, on average, a single product, but larger firms have potentially dozens (Ref. 9, Table 2–6).[7] As exporters serve a larger potential market, we assume they are more likely to be larger, and, for the purposes of this analysis, to have an average of 5 products. As we lack hard data to support this assumption, we request comment on this estimate. Assuming that the 408 exporting manufacturers have on average 5 products each results in an estimated 2,000 affected products.

As we previously stated in this document, a manufacturer producing for both U.S. and foreign consumers currently must comply with dual standards. Compliance with multiple standards might involve the production

[7] Includes estimates for the average number of products per firm for each affected NAICS.

of multiple versions of the same product. Such costs would be incurred on an annual basis.

According to ERG's work on compliance costs, the burden of modifying a product to comply with safety regulations is estimated to be approximately $7,000 (Ref. 9, Table 3–1 and p. 43). This estimate assumes small production runs typically faced by non-exporting manufacturers. Exporting manufacturers, according to the ERG report, would generally have larger production runs and the estimate would be higher (Ref. 9, p. 43). So while we use a recurring $7,000 per product as an acceptable proxy for the additional cost of production to comply with multiple standards, we believe this may be an underestimate.

Because of uncertainty, we also consider a scenario in which we assume the administrative burden of complying with an extra set of standards to be equivalent to designing a new label each year. As discussed previously in this analysis (see section VI.D.1 of this document), ERG has estimated that a labeling change would cost the manufacturer approximately $5,000. Thus, reducing the expenditures needed to comply with two sets of safety standards would save manufacturers $5,000 per product per year. Of course, we realize some firms may be producing drastically different product versions to comply with both IEC and current FDA standards. In those instances, firms would see substantially higher benefits from harmonization.

Assuming 2,000 products are manufactured by exporters, the estimated annual benefit would be $14.3 million ($7,004 per product × 2,040 products). These are annual benefits with no one-time impacts. Using our lower estimate of $5,000 per product per year, our annual benefits would be $10.1 million ($4,966 × 2,040). The total quantified annual benefits of this proposed rule fall within a range from $10.1 million to $14.3 million. For the purposes of our analysis, we use the midpoint of this range, which is $12.2 million. Adjusting for 9.77 percent inflation, the annual benefits would be $13.4 million.

As previously noted in this document, we do not attempt to quantify the public health benefits of this proposed rule. Harmonization would also be expected to benefit consumers by reducing the cost of products sold domestically, thus facilitating trade.

We also believe there would be difficult-to-quantify benefits to having a globally recognized scientific standard and to ensuring that manufacturers selling finished laser products to end users were properly certifying and/or registering their products.

*F. Summary of Costs and Benefits*

The total costs and benefits are summarized in Table 2 of this document. The estimated total cost of this proposed rule, annualized at 7 percent, is approximately $6.7 million. The annualized cost at 3 percent is $5.9 million. The estimated total annualized benefit of this proposed rule is approximately $13.4 million.

The annualized benefits exceed the annualized costs by approximately $6.7 million at a 7 percent discount rate and $7.5 million at a 3 percent discount rate. Moreover, as stated earlier in the report, we may have overestimated costs and underestimated benefits. Thus, net benefits, annualized at 7 percent, may be larger than $5.9 million (and larger than $6.7 million annualized at 3 percent).

TABLE 2—SUMMARY OF COSTS AND BENEFITS

| Impact | Total (millions) |
|---|---|
| Total Annualized Costs at 7 percent | $6.7 |
| Total Annualized Costs at 3 percent | 5.9 |
| Total Annualized Benefits | 13.4 |
| Net Benefits (Costs) at 7 percent | 6.7 |
| Net Benefits (Costs) at 3 percent | 7.5 |

*G. Impact on Small Entities*

FDA recognizes that many of the manufacturers that would be required to modify their products to comply with the harmonized standard may be small entities with limited resources. As a result, the Agency has prepared this initial Regulatory Flexibility Analysis and requests public comment regarding the economic impact of the proposed rule on small entities.

ERG estimates 875 firms may incur increased costs as a result of one or more of the provisions in this proposed rule. Of these affected firms, 811, or 93 percent are small entities as defined by the criteria established by the Small Business Administration (SBA) and listed in Table 4–1 of the ERG Report (Ref. 9, p. 57). Under these criteria, firms are small entities if they have fewer than a certain critical number of employees. Depending on the relevant NAICS classification, this critical number of employees could be 500, 750, or 1,000 employees. ERG has extended this to estimate impacts on very small firms with fewer than 20 employees.

Table 4–2 of the ERG Report provides a breakdown of the estimated compliance costs as a percentage of firm revenues for each of the affected NAICS classes, by firm size.[8] ERG finds no NAICS category for which this percentage exceeds the threshold of three to five percent typically used for unequivocally establishing the existence of a significant impact (Ref. 13). ERG does identify two NAICS classifications with subclasses of small firms facing burdens of greater than 1 percent of sales. ERG small firms (defined by ERG as having fewer than 20 employees) in NAICS classification 334511 (Search, Detection, Navigation, Guidance, and Nautical System & Instrument Manufacturing) face an estimated burden of 1.7 percent of sales (annualizing at a 7 percent discount rate). ERG small firms (fewer than 20 employees) in classification 334519 (Other Measuring and Controlling Device Manufacturing) face an estimated burden of 1.4 percent of sales. The burden on firms in that class with fewer than 500 employees (SBA small) is 1 percent. No other NAICS class has a subclass of firms facing a burden greater than 0.15 percent of sales. Thus, no small entities face significant impacts in any of the other NAICS classifications.

The two classifications mentioned previously in this document, 334511 and 334519, are affected by the provisions associated with the repetitive pulse correction factor and testing with the 50 mm aperture. ERG estimates there to be 6 affected firms with fewer than 20 employees in NAICS 334511 and 44 affected firms with fewer than 20 employees in class 334519 (Ref. 9, Table 4–2). Firms in classification 334511 with fewer than 750 employees and firms in classification 334519 with fewer than 500 employees are defined by the SBA to be small. Thus, all 50 firms would meet the SBA criteria for small.

The Agency finds it highly unlikely that all 50 firms necessarily face a significant burden from this proposed rule, but we cannot rule out the possibility that some small subset of the 50 might face a significant impact. The Agency expects the impact among these firms to be uneven and that the harmonized standard may have a significant impact on a few of them.

Some of these affected firms, for example, may need to make engineering changes to comply with the harmonized

[8] The ERG analysis does not include the cost of obtaining a copy of the IEC standards. As the estimated $350 cost would be a fraction of a percent of revenues, the impact would be negligible.

standard. These changes may be minor or, as stated in the cost section of this document, may be more substantial and cost up to $100,000 if the difference between the standards is large. Based on our understanding of the requirements imposed by this proposed rule and the state of the industry in the relevant NAICS classes, we conclude that few, if any, firms would be faced with such a burden. The Agency does not believe a substantial number of firms would be faced with a significant impact.

We identified and assessed regulatory options to mitigate impacts on small entities. We considered allowing manufacturers to continue to comply with the current FDA standard indefinitely, thus avoiding burdens altogether. We also considered leaving the harmonized standard as optional, essentially extending the provisions of Laser Notice 50 indefinitely. These alternatives would both be inconsistent with the goal of establishing a more uniform recognized safety standard for laser products. Multiple existing standards or indefinite compliance periods could increase confusion as to proper safety standards. Indefinite compliance periods with multiple standards may dissuade risk-averse firms from abandoning the current FDA standard. In an attempt to strike a balance between the need for a recognized safety standard while minimizing the burdens on affected entities, the Agency would allow for a 2-year effective date to minimize the burden on affected entities.

The Agency also analyzed modifying the harmonized standard for certain laser classes to bring such firms into compliance. That is, the Agency considered adopting certain modifications to the IEC standards so as not to move firms out of compliance due to the repetitive pulse correction factor or the 50 mm testing aperture. Such a move would have eliminated the costs associated with these specific provisions. This alternative would have been inconsistent with the objective of establishing a safety standard that is harmonized with current science and internationally-recognized standards. Moreover, the benefits associated with this alternative would have likely been minimal, because few, if any, firms would face large costs in the shift to a harmonized standard.

The Agency believes that the provisions of the proposed rule, combined with a 2 year effective date that will give industry ample time to make any necessary changes without undue burden, are the best approach to establishing a harmonized standard.

## VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision at section 542 of the FD&C Act (21 U.S.C. 360ss) that preempts the States from establishing, or continuing in effect, any standard with respect to an electronic product which is applicable to the same aspect of product performance as a Federal standard prescribed pursuant to section 534 of the FD&C Act (21 U.S.C. 360kk) and which is not identical to the Federal standard. See *Medtronic* v. *Lohr,* 518 U.S. 470 (1996); *Riegel* v. *Medtronic,* Inc., 128 S. Ct. 999 (2008). If this proposed rule is made final, the final rule would prescribe a Federal standard pursuant to section 534 of the FD&C Act. However, section 542 of the FD&C Act does not ''prevent the Federal Government or the government of any State or political subdivision thereof from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if such requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard.'' 21 U.S.C. 360ss.

## VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Proposed Amendment to Laser Product Performance Standard.

*Description:* Sections 532 through 542 of the FD&C Act (21 U.S.C. 360ii through 360ss) direct the Secretary of the Department of Health and Human Services (the Secretary) to establish and carry out an electronic product radiation control program to protect the public from unnecessary radiation from electronic products.

The Agency is proposing to amend its regulation of laser products in § 1040.11 by adding a new paragraph (e) which requires that manufacturers of laser products intended for DOD use who wish to have the exemption from the performance standard that was granted to DOD apply to their specific products must obtain a letter from the 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 to any DOD Agency.

The Agency is proposing to amend its regulation of laser products in § 1040.10 by adding new paragraph (a)(3)(iii) that requires manufacturers of laser product components or replacement parts to maintain a record that identifies the purchaser as the party that will certify or register a host product that contains the manufacturer's component or replacement part, or identifies the purchaser as a supplier who sells the manufacturer's registered laser component or replacement part. Records do not need to identify purchasers who acquire the product as a replacement part for a certified product for purposes other than resale.

*Description of Respondents:* Manufacturers and importers of laser products.

FDA estimates the burden of this information collection as follows:

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours | Total operating and maintenance costs |
|---|---|---|---|---|---|---|
| 1040.11(e) ..... | 25 | 1 | 25 | 0.08 (5 minutes) ..... | 2 | $2.00 |

[1] There are no capital costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR Section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours | Total operating and maintenance costs |
|---|---|---|---|---|---|---|
| 1040.10(a)(3)(iii) ..... | 14 | 4 | 56 | 0.17 (10 minutes) ..... | 10 | $2.00 |
| 1040.11(e) ..... | 25 | 1 | 25 | 0.17 (10 minutes) ..... | 4 | $2.00 |
| Total Hours ..... | ..... | ..... | ..... | ..... | ..... | 14 |

[1] There are no capital costs associated with this collection of information.

*Reporting Burden:* For § 1040.11(e) we estimate 25 respondents would need to collect information once per year for a total of 25 correspondences. Manufacturers would request information from DOD and this process is estimated to take 5 minutes (.08 hours) per letter, for a total of 2 hours.

*Recordkeeping Burden:* For § 1040.10(a)(3)(iii) we estimate 14 respondents would generate 4 records per year for a total of 56 records. Under the existing regulation at § 1002.31, we require records to be kept for 5 years. Since many companies correspond regularly with customers as a matter of business practice, the recordkeeping burden for maintaining a file of documentation obtained from customers (correspondence, cancelled check, purchase agreement) over the course of 5 years are considered usual and customary, although FDA requests comment on whether this recordkeeping requirement, including its duration, continues to be appropriate. Documentation obtained actively (electronic copy of company Web site or brochure, proof of business license, signed agreement, etc.) could be obtained via fax or email attachment. This task is expected to be performed by clerical staff, who prepare a letter, email or fax requesting the information from the manufacturer or supplier, and respondent manufacturer or supplier clerical staff, who prepare a response that verifies the purchaser is a bona fide business that will certify or register the component or replacement part as a manufacturer or sell the part as a supplier. This process is estimated to take 10 minutes (0.17 hours) per record to scan and email or photocopy and mail documentation, for a total of 10 hours annually.

For § 1040.11(e) we estimate 25 respondents would need to collect information once per year for a total of 25 records. Manufacturers would file the information received from DOD and this process is estimated to take 10 minutes (0.17 hours) per record, for a total of 4 hours.

The operating and maintenance costs associated with this information collection are based upon correspondence costs (postage) for non-email communications for 20 percent of respondents (8), estimated at $0.50 per correspondence for a total of $4.00.

Time estimates are based on experience performing similar activities in FDA's Division of Mammography Quality and Radiation Programs, CDRH.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Proposed Amendment to Laser Product Performance Standard.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

This proposed rule also refers to currently approved collections of information found in FDA regulations. The collections of information in § 1040.10(a)(3)(i), (h)(1)(i) through (h)(1)(vi), (h)(2)(i) and (h)(2)(ii) have been approved under OMB control number 0910–0025.

The labeling requirements in § 1040.10(g) are not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

## IX. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

## X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites

after this document publishes in the **Federal Register**.)


1. Israeli, D., Y. Hod, and O. Geyer, ''Laser Pointers: Not to be Taken Lightly,'' *British Journal of Ophthalmology,* 84 (5), 554d (2000).
2. Seeley, D., ''Laser Pointer Causes Eye Injuries,'' ILSC Proceedings of the International Laser Conference, pp. 560–563 (1997).
3. Sell, C. H. and J. S. Bryan, ''Maculopathy From Handheld Diode Laser Pointer,'' *Archives of Ophthalmology,* 117: 1557–1558 (1999).
4. ''Circular No. A–119—**Federal Register** (Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities),'' *http://www.whitehouse.gov/omb/circulars/a119/a119.html,* accessed May 2008.
5. ''Laser Products—Conformance with IEC 60825—1, Am. 2 and IEC 60601–2–22 (Laser Notice 50)'' (66 FR 39049, July 26, 2001) (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094361.htm*).
6. Barkana, Yaniv and Michael Belkin, ''Laser Eye Injuries,'' *Survey of Opthalmology,* 44: 459–478, 2000.
7. Mainster, Martin A., Bruce E. Stuck, and Jeremiah Brown, ''Assessment of Alleged Retinal Laser Injuries,'' *Archives of Ophthalmology,''* 122: 1210–1217, 2004.
8. Kincade, Kathy and Stephen G. Anderson, ''Laser Marketplace 2007: Laser Industry Navigates its Way Back to Profitability.'' *LaserFocus World,* January 2007, *http://www.laserfocusworld.com/articles/print/volume-43/issue-1/features/laser-marketplace-2007-laser-industry-navigates-its-way-back-to-profitability.html.*
9. Eastern Research Group ''Technical Quality and Economic Implications of International Harmonization of Laser Performance Standards—An Update,'' Eastern Research Group, September 2005.
10. Universal Currency Converter, *http://www.xe.com/ucc/,* accessed April 21, 2010.
11. ''Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products (Laser Notice No. 52),'' issued July 12, 2002.
12. ''Laser Products; Proposed Amendment to Performance Standard'' (64 FR 14180, March 24, 1999).
13. U.S. Department of Health & Human Services, ''Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services,'' May 2003.
14. Wyrsch, Stefan, M.D., Philipp B. Baenninger, M.D., and Martin K. Schmid, M.D., ''Retinal Injuries from a Handheld Laser Pointer'' *New England Journal of Medicine* 2010; 363:1089–1091 AND.
15. ''Party Laser 'Blinds' Russian Ravers,'' New Scientist, 14 July 2008, *http://www.newscientist.com/article/dn14310?DCMP=ILC-tabView&nsref=dn14310.*
16. Sliney, David H., John Mellerio, Veit-Peter Gabel, and Karl Shulmeister, ''What is the Meaning of Threshold in Laser Injury Experiments? Implications for Human Exposure Limits.'' *Health Physics,* 82(3):335–347; 2002.


**List of Subjects**

*21 CFR Part 1002*

Electronic products, Radiation protection, Reporting and recordkeeping requirements.

*21 CFR Part 1010*

Administrative practice and procedure, Electronic products, Exports, Radiation protection.

*21 CFR Part 1040*

Electronic products, Incorporation by reference, Labeling, Lasers, Medical devices, Radiation protection, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1002, 1010, and 1040 be amended as follows:

## PART 1002—RECORDS AND REPORTS

■ 1. The authority citation for 21 CFR part 1002 is revised to read as follows:

**Authority:** 21 U.S.C. 352, 360, 360i, 360j, 360hh–360ss, 371, 374, 393.

■ 2. Section 1002.1 is amended by revising Table 1 to read as follows:

**§ 1002.1 Applicability.**

* * * * *

TABLE 1—RECORD AND REPORTING REQUIREMENTS BY PRODUCT

| Products | Manufacturer | | | | | | Dealer & Distributor |
|---|---|---|---|---|---|---|---|
| | Product reports § 1002.10 | Supplemental reports § 1002.11 | Abbreviated reports § 1002.12 | Annual reports § 1002.13 | Test records § 1002.30(a) [1] | Distribution records § 1002.30(b) [2] | Distribution records §§ 1002.40 and 1002.41 |
| DIAGNOSTIC X–RAY [3] (1020.30, 1020.31, 1020.32, 1020.33): | | | | | | | |
| Computed tomography | X | X | | X | X | X | X |
| X-ray system [4] | X | X | | X | X | X | X |
| Tube housing assembly | X | X | | X | X | X | |
| X-ray control | X | X | | X | X | X | X |
| X-ray high voltage generator | X | X | | X | X | X | X |
| X-ray table or cradle | | | X | | X | X | X |
| X-ray film changer | | | X | | X | X | |
| Vertical cassette holders mounted in a fixed location and cassette holders with front panels | | | X | | X | X | X |
| Beam-limiting devices | X | X | | X | X | X | X |
| Spot-film devices and image intensifiers manufactured after April 26, 1977 | X | X | | X | X | X | X |
| Cephalometric devices manufactured after February 25, 1978 | | | X | | X | X | |
| Image receptor support devices for mammographic X-ray systems manufactured after September 5, 1978 | | | X | | X | X | X |
| CABINET X RAY (1020.40): | | | | | | | |
| Baggage inspection | X | X | | X | X | X | X |
| Other | X | X | | X | X | X | |
| PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X–RAYS OTHER THAN DIAGNOSTIC OR CABINET DIAGNOSTIC X-RAY: | | | | | | | |
| Medical | | | X | X | X | X | |
| Analytical | | | X | X | X | X | |
| Industrial | | | X | X | X | X | |
| TELEVISION PRODUCTS (1020.10): | | | | | | | |

TABLE 1—RECORD AND REPORTING REQUIREMENTS BY PRODUCT—Continued

| Products | Manufacturer | | | | | | Dealer & Distributor |
|---|---|---|---|---|---|---|---|
| | Product reports § 1002.10 | Supplemental reports § 1002.11 | Abbreviated reports § 1002.12 | Annual reports § 1002.13 | Test records § 1002.30(a) [1] | Distribution records § 1002.30(b) [2] | Distribution records §§ 1002.40 and 1002.41 |
| <25 kilovolt (kV) and <0.1 milliroentgen per hour (mR/hr IRLC [5] [6] | | | X | X [6] | | | |
| ≥25kV and <0.1mR/hr IRLC [5] | X | X | | X | | | |
| ≥0.1mR/hr IRLC [5] | X | X | | X | X | X | |
| MICROWAVE/RF: | | | | | | | |
| MW ovens (1030.10) | X | X | | X | X | X | |
| MW diathermy | | | X | | | | |
| MW heating, drying, security systems | | | X | | | | |
| RF sealers, electromagnetic induction and heating equipment, dielectric heaters (2–500 megahertz) | | | X | | | | |
| OPTICAL: | | | | | | | |
| Phototherapy products | X | X | | | | | |
| Laser products (1040.10, 1040.11) | | | | | | | |
| Class 1 lasers and products containing such lasers [7] | X | | | X | X | | |
| Class 1 laser products containing class 1M, 2, 2M, 3R lasers [7] | X | | | X | X | X | |
| Class 1M, 2, 2M, 3R lasers and products other than class 1 products containing such lasers [7] | X | X | | X | X | X | X |
| Class 3B and 4 lasers and products containing such lasers [7] | X | X | | X | X | X | X |
| Sunlamp products (1040.20) | | | | | | | |
| Lamps only | X | | | | | | |
| Sunlamp products | X | X | | X | X | X | X |
| Mercury vapor lamps (1040.30) | | | | | | | |
| T lamps | X | X | | X | | | |
| R lamps | | | X | | | | |
| ACOUSTIC: | | | | | | | |
| Ultrasonic therapy (1050.10) | X | X | | X | X | X | X |
| Diagnostic ultrasound | | | X | | | | |
| Medical ultrasound other than therapy or diagnostic | X | X | | | | | |
| Nonmedical ultrasound | | | X | | | | |

[1] However, authority to inspect all appropriate documents supporting the adequacy of a manufacturer's compliance testing program is retained.
[2] The requirement includes §§ 1002.31 and 1002.42, if applicable.
[3] Report of Assembly (Form FDA 2579) is required for diagnostic x-ray components; see 21 CFR 1020.30(d)(1) through (d)(3).
[4] Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in 21 CFR 1020.30(c).
[5] Determined using the isoexposure rate limit curve (IRLC) under phase III test conditions (§ 1020.10(c)(3)(iii)).
[6] Annual report is for production status information only.
[7] Determination of the applicable reporting category for a laser product shall be based on the worst-case hazard present within the laser product.

## PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

■ 3. The authority citation for 21 CFR part 1010 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381, 393.

■ 4. Section 1010.1 is revised to read as follows:

### § 1010.1 Scope.

The standards listed in this subchapter are prescribed pursuant to section 534 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360kk) and are applicable to electronic products as specified herein to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined necessary for the protection of the public health and safety.

■ 5. Section 1010.2 is amended by revising paragraph (d) to read as follows:

### § 1010.2 Certification.

* * * * *

(d) In the case of products for which it is not feasible to certify in accordance with paragraph (b) of this section, the Director, Center for Devices and Radiological Health (or delegate) may approve an alternate means by which such certification may be provided. Approval may be granted either upon written application by the manufacturer or on the Director's own initiative.

■ 6. Section 1010.3 is amended by revising paragraph (b) as follows:

### § 1010.3 Identification.

* * * * *

(b) In the case of products for which it is not feasible to affix identification labeling in accordance with paragraph (a) of this section, the Director, Center for Devices and Radiological Health (or delegate) may approve an alternate means by which such identification may be provided. Approval may be granted either upon written application by the manufacturer or on the Director's own initiative.

* * * * *

## PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

■ 7. The authority citation for 21 CFR part 1040 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381, 393.

■ 8. Section 1040.5 is added to read as follows:

### § 1040.5 Standards incorporated by reference.

(a) Certain material from the standards identified in paragraph (b) of this section relating to lasers is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect copies of the standards identified in this section at FDA's Electronic Products Branch, Office of Communication, Education, and Radiation Programs,

Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4621, Silver Spring, MD 20993, 301–796–5710; or FDA's Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; or the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* In addition, you may obtain copies of these standards from the sources listed in paragraph (b) of this section.

(b) International Electrotechnical Commission (IEC), 3, rue de Varembé, P.O. Box 131, CH–1211 GENEVA 20, Switzerland (Phone: +41 22 919 02 11, Fax: +41 22 919 03 00, email: *inmail@iec.ch*), or the American National Standards Institute, Attn: Customer Service Department, 25 West 43d St., 4th Floor, New York, NY 10036, USA (Phone: +1 212 642 4980, Fax: +1 212 302 1286, email: *info@ansi.org*).

(1) IEC 60601–2–22 (IEC 60601–2–22:2007), Medical electrical equipment—Part 2–22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment, Edition 3.0, May 2007, incorporated by reference in §§ 1040.10 and 1040.11 except as otherwise noted in those sections.

(2) IEC 60825–1 (IEC 60825–1:2007), Safety of laser products—Part 1: Equipment classification and requirements, Edition 2.0, March 2007, including Corrigendum 1, dated August 2008, incorporated by reference in §§ 1040.10 and 1040.11 except as otherwise noted in those sections.

■ 9. Section 1040.10 is revised to read as follows:

**§ 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 [*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 § 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 § 1002.31 of this subchapter; and

(iii) Documents that the purchaser of such laser product is a manufacturer as defined in § 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 § 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 § 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 § 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 400 nm or greater than 700 nm 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 § 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 §§ 1040.10 and 1040.11 and ''shall'' as used in §§ 1040.10, 1040.11, IEC 60825–1:2007, and IEC 60601–2–22:2007 (incorporated by reference, see § 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 § 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 § 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 § 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 $1.0 \times 10^6$ 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 § 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 § 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 § 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 § 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 §§ 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 § 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.''

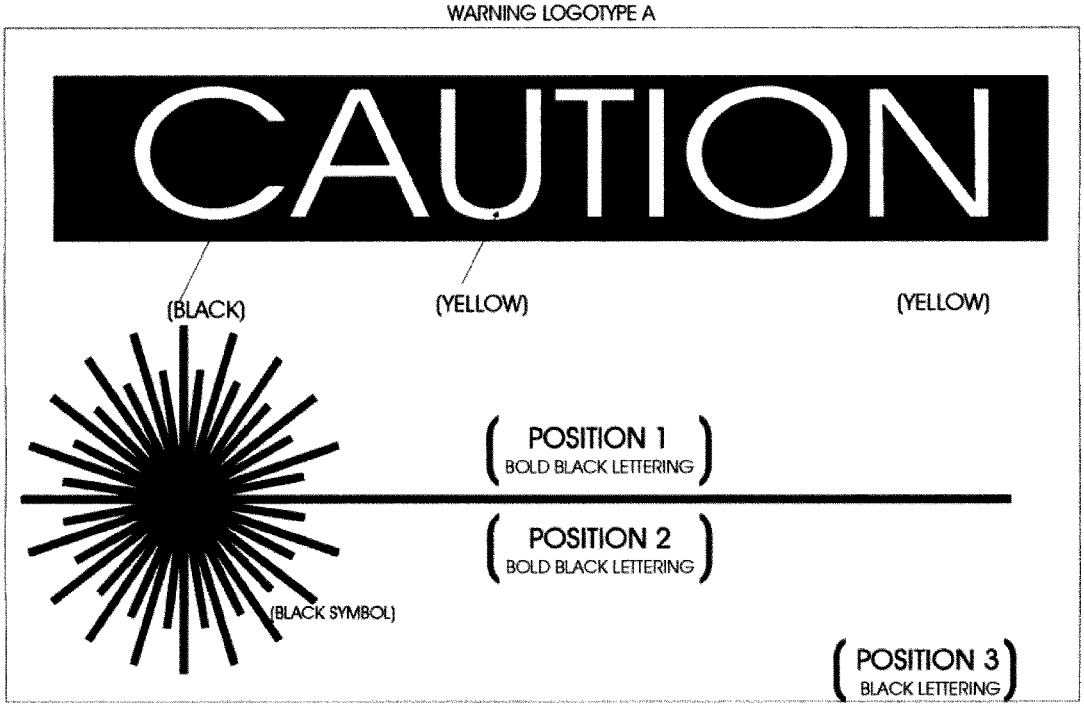


FIGURE 1

(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''.

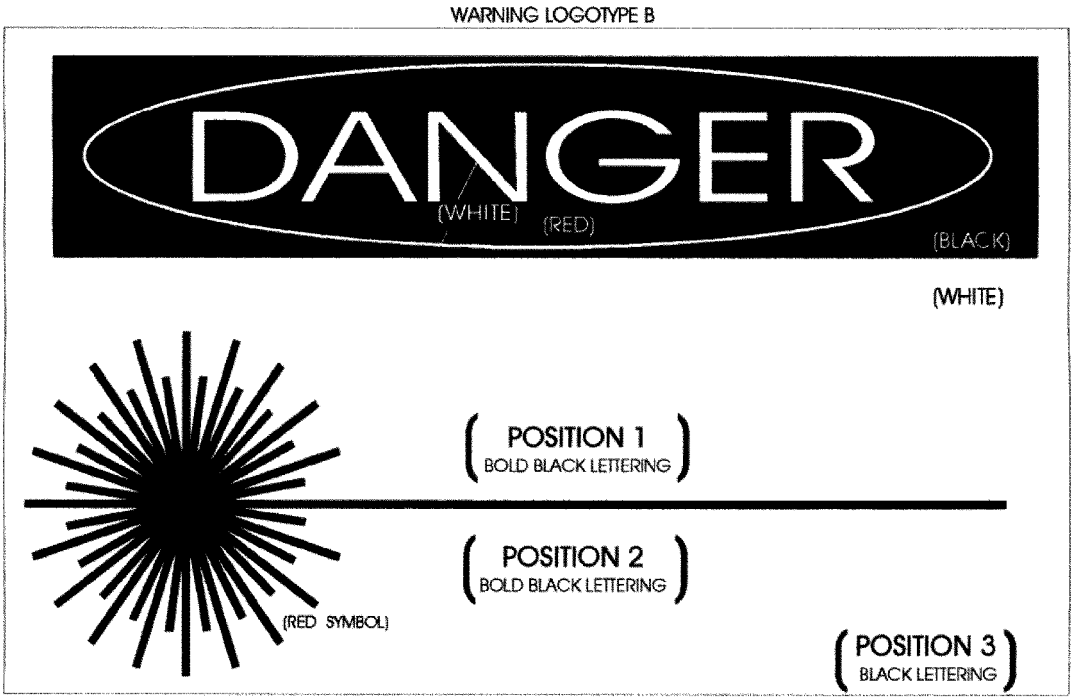


FIGURE 2

(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 § 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 § 1040.5) are applicable.

(6) *Label specifications.* Labels required by this section and § 1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, or service, as appropriate. If the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, 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 § 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 § 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 § 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 § 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 § 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 § 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 §§ 1010.2 and 1010.3 of this subchapter.

■ 10. Section 1040.11 is revised to read as follows:

**§ 1040.11 Specific purpose laser products.**

(a) *Medical laser products.* Each medical laser product must comply with all of the applicable requirements of § 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 § 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 § 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 § 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 § 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 §§ 1002.10, 1002.11, 1002.13 of this subchapter, and those provisions of § 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.

Dated: June 18, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–14846 Filed 6–21–13; 8:45 am]

**BILLING CODE 4160–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R09–OAR–2013–0384; FRL–9826–2]**

## Approval and Promulgation of Implementation Plans; California; South Coast; Contingency Measures for 1997 $PM_{2.5}$ Standards

**AGENCY:** U.S. Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve a state implementation plan (SIP) revision submitted by California to address Clean Air Act (CAA) contingency measure requirements for the 1997 annual and 24-hour national ambient air quality standards (NAAQS) for fine particulate matter ($PM_{2.5}$) in the Los Angeles-South Coast Air Basin (South Coast). Final approval of this SIP revision would terminate the sanctions clocks and a federal implementation plan (FIP) clock that were triggered by EPA's partial disapproval of a related SIP submission on November 9, 2011 (76 FR 69928).

**DATES:** Any comments must arrive by July 24, 2013.

**ADDRESSES:** Submit comments, identified by docket number EPA–R09–