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Laser Products – Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56)

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on January 19, 2018.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the Division of Radiological Health at 301-796-2121 or Patrick Hintz at 301-796-6927 or via email at Patrick.Hintz@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

Preface

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Laser Products – Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56)

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance describes the Food and Drug Administration's (FDA) proposed approach regarding compliance with FDA's performance standards for laser products. Because conformance to certain comparable portions of IEC standards identified in this draft guidance adequately address those concerns intended to be addressed by the performance standards of 21 CFR 1040.10 and 1040.11. FDA does not intend to consider whether firms that comply with the comparable IEC standards discussed in this guidance document also comply with 21 CFR 1040.10 and 1040.11.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

FDA regulates radiation-emitting electronic products, including all types of lasers products. *Laser product* means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system that is intended for use as a component of an

electronic product shall itself be considered a laser product (see 21 CFR 1040.10(b)(21)). The Agency sets radiation safety product performance standards that must be met by manufacturers in order for laser products to be legally sold in the U.S. market. Laser products may fall under both the definition of a medical device and that of an electronic product, under sections 201(h) and 531(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), respectively. Such products are subject to the provisions of the FD&C Act and its implementing regulations that apply to medical devices (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm) and electronic products (http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/LawsandRegulations/default.htm).[1]

Among other requirements, laser products for introduction into United States commerce, including imports, must:

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

Manufacturers should be aware that CDRH previously issued notices to laser product manufacturers and importers and those are available on FDA's website at https://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/IndustryGuidance/ucm2007156.htm.

FDA recognizes that the International Electrotechnical Commission ("IEC") is a global organization that prepares and publishes international standards for electrical, electronic, and related technologies, including laser products. This means that manufacturers distributing products in the U.S. and other countries might have to ensure conformance of their products with IEC standards, as well as comply with FDA regulatory requirements. Complying with FDA regulations and conforming to the identified IEC standards may cause manufacturers to duplicate their efforts.

FDA acknowledges the advantages of a universal set of device-specific criteria and requirements. Moreover, FDA believes that under the circumstances described in this guidance, conformance with certain IEC standards would provide adequate protection of the public health and safety for laser products similar to FDA's performance standards in 21 CFR 1040.10 and 1040.11.

FDA eventually intends to amend its standards for laser products at 21 CFR 1040.10 and 1040.11 to harmonize many of its requirements with those of the IEC because FDA acknowledges the advantages of one set of criteria and requirements worldwide.

[1] The regulations specific to medical devices and electronic products are found in 21 CFR Chapter I Subchapter H on Medical Devices and Subchapter J on Radiological Health, respectively.

In June 2007 FDA issued a guidance entitled "Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22 (Laser Notice No. 50); Guidance for Industry and FDA Staff" (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094366.pdf). This guidance recommends that FDA does not intend to consider whether a manufacturer is in compliance with the performance standard requirements in 21 CFR 1040.10 and 1040.11 if the manufacturer is in conformance with the comparable sections of IEC standards 60825-1 (Editions 1.2 and 2.0) and 60601-2-22 (Edition 3) as set forth in the guidance document. This draft guidance, when finalized, will not replace the recommendations in Laser Notice No. 50.

This draft guidance announces that FDA does not intend to consider whether laser products are in compliance with certain sections of 21 CFR 1040.10 and 21 CFR 1040.11 if the manufacturer conforms to the comparable sections of the IEC Standards: IEC 60825-1 Ed. 3.0 and IEC 60601-2-22 Ed. 3.1, as described in Section III.

III. Policy

Because there are some differences between the IEC standards (IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1) and FDA's performance standards regulations for laser products, FDA does not intend to consider whether products or devices comply with 21 CFR Parts 1040.10 and 1040.11 if manufacturers conform to the comparable sections of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1.

Table 1 below clarifies which IEC sections are comparable for the purposes of this guidance to FDA's regulations in 21 CFR Part 1040. FDA eventually intends to harmonize the requirements of 21 CFR Part 1040 through rulemaking with those of the IEC standards.

Table 1 - Comparable Sections of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1

CDRH 21 CFR requirements	Comparable IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 Section(s) unless noted otherwise	Not Comparable Sections of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1
1040.10(a) Applicability	No comparable clauses	
1040.10(b) Definitions	3	IEC 60825-1 Ed. 3 clauses 3.4, 3.15, 3.16, 3.25, 3.30, 3.37, 3.45, 3.47, 3.48, 3.49, 3.50, 3.52, 3.59, 3.64 & 3.65
1040.10(c)(1) Classification	4.1, 4.2, 4.3, and 5.3	IEC 60825-1 Ed. 3 clause 4.4 †
1040.10(c)(2) Removable laser systems	No comparable clauses	
1040.10(d) Accessible emission limits	5.3 Tables 3, 4, 5, 6, 7 and 8	IEC 60825-1 Ed. 3 clause 6.15.2

CDRH 21 CFR requirements	Comparable IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 Section(s) unless noted otherwise	Not Comparable Sections of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1
1040.10(d) Table VI Accessible Emission Limits for Collateral Radiation From Laser Products	No comparable clauses	
1040.10(e) Tests for determination of compliance	5.1, 5.2, 5.4, 6.12, 6.14	IEC 60825-1 Ed. 3 clause 5.2(f)
1040.10(f)(1) Protective housing	6.2	IEC 60825-1 Ed. 3 clauses 6.2.3, 6.13 †, 6.15.1, 6.16
1040.10(f)(2) Safety interlocks	6.3	
1040.10(f)(3) Remote interlock connector	6.4	
1040.10(f)(4) Key control	6.6	
1040.10(f)(5) Laser radiation emission indicator	6.7	
1040.10(f)(6) Beam attenuator	6.8	
1040.10(f)(7) Location of controls	6.9	
1040.10(f)(8) Viewing optics	6.10	
1040.10(f)(9) Scanning safeguard	6.11	
1040.10(f)(10) Manual reset mechanism	6.5	
1040.10(g) Labeling requirements	7 [Comparable labels found in IEC 60825-1 Ed. 3 clause 7 may be used in lieu of those found in 21 CFR 1040.10(g)]	
1040.10(h)(1) Informational requirements	8.1	
1040.10(h)(2) Purchasing and servicing information	No comparable clauses	
1040.10(i) Modification of a certified laser product	No comparable clauses	
1040.11 Specific purpose laser products	9.2	IEC 60825-1 Ed. 3 clauses 9.1, 9.3, 9.4 †, 9.5
1040.11(a) Medical laser products	60601-2-22 Ed. 3.1, Clauses 201.12.1.101, 201.7.9.2.101 fourth dash, 201.12.4.2 201.7.2.101	

CDRH 21 CFR requirements	Comparable IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 Section(s) unless noted otherwise	Not Comparable Sections of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1
1040.11(b) Surveying, leveling and alignment laser products	No comparable clauses	
1040.11(c) Demonstration laser products	No comparable clauses	

Certain sections of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 are considered not comparable to FDA's performance standards under 21 CFR 1040.10 and 1040.11 for the reasons discussed below.

- The following IEC clauses and annexes of IEC 60825-1 Ed. 3 are not comparable to FDA's performance standards under 21 CFR 1040.10 and 1040.11 because they are either not applicable or inconsistent with FDA's performance standards: 1, 2, 3.4., 3.15, 3.16, 3.37, 3.45, 3.47, 3.50, 3.52, 3.59, 3.64, 3.65, 4.4†, 6.13†, 6.15.1, 6.16, 8.2, 9.1, 9.3, 9.4†, 9.5 and Annexes A through G.
- Clause 3.25 (definition of collateral radiation) of IEC 60825-1 Ed. 3 is considered not comparable to FDA's performance standards under 21 CFR 1040.10 because it does not include all electromagnetic radiation (e.g., X-ray emissions) found in the FDA definition at 21 CFR 1040.10(b)(12).
- Clause 3.30 (definition of demonstration laser product) of IEC 60825-1 Ed. 3 is considered not comparable to FDA's performance standards under 21 CFR 1040.10 because its statement of non-applicability is inconsistent with the FDA definition at 21 CFR 1040.10(b)(13).
- Clause 3.48 (definition of laser product) of IEC 60825-1 Ed. 3 is considered not comparable to FDA's performance standards under 21 CFR 1040.10 because the IEC's definition does not include laser products intended for use as components, which are defined as laser products in the FDA definition at 21 CFR 1040.10(b)(21).
- Clause 3.49 (definition of laser radiation) of IEC 60825-1 Ed. 3 is considered not comparable to FDA's performance standards under 21 CFR 1040.10 because it does not include all radiation emitted by the laser product as found in the FDA definition at 21 CFR 1040.10(b)(22).
- Clause 5.2(f) of IEC 60825-1 Ed. 3 is considered not comparable to FDA's performance standards under 21 CFR 1040.10 because it instructs to avoid or eliminate the contribution of collateral radiation to the measurement of laser radiation and because it contradicts clause 4.3(b)(1).
- Clause 6.1 (general remarks and modifications) of IEC 60825-1 Ed. 3 is considered not comparable to FDA's performance standards under 21 CFR 1040.10 because it does not require recertification and re-identification as required by 21 CFR 1040.10(i).

- Clause 6.2.3 (removable laser system) of IEC 60825-1 Ed. 3 is considered not comparable to FDA's performance standards under 21 CFR 1040.10 because it requires a plug-in for fitting to electrical mains or a battery.
- Clause 6.15.2 (collateral radiation) of IEC 60825-1 Ed. 3 is considered not comparable to FDA's performance standards under 21 CFR 1040.10 because it limits collateral radiation by laser MPE values instead of a laser class accessible emission limit as in 21 CFR 1040.10(d).
- Clause 8.2 (purchasing and servicing information) of IEC 60825-1 Ed. 3 is considered not comparable to FDA's performance standards under 21 CFR 1040.10 because it does not include collateral radiation as in 21 CFR 1040.10(h)(2).

[†]For the IEC sections listed below, FDA recommends you follow other FDA issued guidance documents , as appropriate:

- Clause 4.4 (Laser products designed to function as conventional lamps) of IEC 60825-1 Ed. 3: For guidance on the application of international consensus standards to laser illuminated projectors, please see FDA's guidance entitled "Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors (LIPs); Guidance for Industry and Food and Drug Administration Staff," dated February 18, 2015 (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm434502.pdf).
- Clause 6.13 "Walk-in" access of IEC 60825-1 Ed. 3: For guidance on "walk-in access," please see FDA's guidance entitled "Walk-In Workstations," dated October 21, 1985 (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095331.pdf).
- Clause 9.4 Electric toys of IEC 60825-1 Ed. 3: For guidance on "electric toys," please see FDA's guidance entitled "Minimizing Risk for Children's Toy Laser Products," dated December 19, 2014 (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM363731.pdf).

Manufacturers of laser products must certify that their products comply with FDA's performance standards (see 21 CFR 1010.2). The certification must be provided on a label or tag permanently affixed to or inscribed on the product so as to be legible, readily accessible to view when the product is fully assembled for use, and the label or tag must be in the English language (see 21 CFR 1010.2(b)). FDA does not intend to confirm compliance with 21 CFR 1010.2 for manufacturers that conform to comparable sections of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, and who use the following statement on the certification label or tag:

1. "Complies with FDA performance standards for laser products except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1. For more information see Laser Notice No. 56, dated [Date of Issuance of Final Guidance]." or

2. "Complies with 21 CFR 1040.10 and 1040.11 except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1. For more information see Laser Notice No. 56, dated [Date of Issuance of Final Guidance]."

Under 21 CFR 1010.2(c), this certification must be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program that is in accordance with good manufacturing practice. The manufacturer's quality system should address various aspects of radiation safety and conformity to standards through design controls. Testing results should be documented and placed in the firm's records.

Under 21 CFR part 1002, manufacturers of laser products must submit product reports or supplemental reports that describe changes to products made in accordance with this guidance. Manufacturers may use Form FDA 3632 "Guide for Preparing Product Reports for Lasers and Products Containing Lasers" (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081592.pdf) to submit these reports.