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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)

Guidance for Industry and Food and Drug Administration Staff

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

Preface

Public Comment

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 guidance describes the Food and Drug Administration's (FDA) approach regarding manufacturers' compliance with FDA's performance standards for laser products. FDA recognizes that while there are many similarities between International Electrotechnical Commission (IEC) standards 60825-1: Safety of laser products - Part 1: Equipment *classification, and requirements*, Edition 3.0 and 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. 3.1 and FDA's laser performance standards, there are clauses of these IEC standards that differ significantly from FDA's performance standards for laser products. For the manufacturers that conform to the clauses of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 that FDA identifies as comparable with 21 CFR 1040.10 and 1040.11, FDA does not intend to enforce the applicable requirements in 21 CFR 1040.10 and 1040.11.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes 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[1] and electronic products.[2,3]

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 1002.1.

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-emitting-products/electronic-product-radiation-control- program/electronic-product-radiation-control-program-industry-guidance.

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 21CFR 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. Until these requirements are harmonized, for laser product manufacturers that conform with the comparable clauses in IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, as described in this document, FDA does not intend to

[1] https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation
[2] https://www.fda.gov/radiation-emitting-products/electronic-product-radiation-control-program
[3] 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.

enforce the comparable requirements in 21 CFR 1040.10 and 21 CFR 1040.11.

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."[4] Laser Notice No. 50 states that FDA does not intend to enforce applicable requirements of 21 CFR 1040.10 if the manufacturers comply with comparable clauses of IEC 60825-1 Ed. 1.2 or 2 and IEC 60601-2-22 Ed. 3, as set forth in Laser Notice No. 50. This guidance (Laser Notice No. 56) does not replace the recommendations in Laser Notice No. 50.

This guidance announces that if the laser product conforms to the clauses of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 identified in Section III as comparable with 21 CFR 1040.10 and 1040.11, FDA does not intend to enforce applicable FDA requirements. For example, FDA does not intend to enforce requirements relating to obtaining variances for laser products that conform to the relevant portions of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 identified as comparable with 21 CFR 1040.10 and 1040.11, as described in Section III below.

III. Policy

FDA recognizes that there are many similarities between FDA's performance standards for laser products (21 CFR 1040.10 and 1040.11) and comparable clauses of IEC standards (IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1).

In particular, FDA does not intend to enforce the requirements in the following sections of 21 CFR part 1040, if the laser products are in conformance with the comparable clauses of IEC 60825-1 Ed. 3, and when applicable, 60601-2-22 Ed. 3.1 (for medical devices). Unless identified as a not comparable IEC clause in subsection A below, FDA considers all other clauses of IEC 60825-1, Ed. 3 and IEC 60601-2-22 Ed. 3.1 as comparable to the following FDA performance standards:

1040.10(b) Definitions
1040.10(c)(1) Classification*
1040.10(d) Accessible emission limits
1040.10(e) Tests for determination ofcompliance
1040.10(f)(1) Protective housing

[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-and-iec-60601-2-22-laser-notice-no-50

1040.10(f)(2) Safety interlocks**
1040.10(f)(3) Remote Interlock connector
1040.10(f)(4) Key control
1040.10(f)(5) Laser radiation emission indicator
1040.10(f)(6) Beam attenuator
1040.10(f)(7) Location of controls
1040.10(f)(8) Viewing optics
1040.10(f)(9) Scanning safeguard
1040.10(g) Labeling requirements
1040.10(h)(1) User information
1040.11(a) Medical laser products

* Manufacturers should apply the interpretation sheets IEC 60825-1/ISH1:Interpration sheet 1 – Safety of laser products – Part 1: Equipment classification and requirements and IEC 60825-1/ISH2: Interpretation sheet 2 – Safety of laser products – Part 2: Safety of optical fibre communication systems (OFCS). FDA may request additional information from your product Classification Testing to confirm that the laser product is properly classified.

** IEC 60825-1 Ed. 3 (6.3) indirectly requires redundancy or safe-failure for safety interlocks designed to protect against human access from Class IIIb or IV laser radiation. This indirect requirement is through the Classification Rules (4.3), reasonably foreseeable single-fault condition sub-clause. Accordingly, laser products conforming to the identified clauses of the IEC standards must have a redundancy or safe-failure in order to be considered comparable to 21 CFR 1040.10.

FDA eventually intends to harmonize, through rulemaking, the requirements of 21 CFR Part 1040 with those of the IEC standards.

A. Not Comparable IEC Clauses

Certain clauses 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. While some information in these clauses of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 are not comparable with, or there may not be a comparable section in 21 CFR 1040.10 and 1040.11, laser product manufacturers may find this information useful for inclusion in correspondence and applications for variance or exemption submitted to FDA under 21 CFR 1010.4 or 1010.5, respectively. These clauses of IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 may also be useful in preparation of required reports in 21 CFR 1002 or in inclusion in the informational requirements in 21 CFR 1040.10(h), provided the information does not conflict with FDA's performance standards.

- 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.
- Sub-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). However, it is not likely that laser products with electrical potentials of less than 20 kV will emit X-rays.

- Sub-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). However, IEC 608-25-1 Ed.3 acknowledges in Clause 1 – Scope and Object that certain components or repair parts are laser products. FDA requires that component and repair (or replacement) laser products comply with FDA's performance standards for laser products (see 21 CFR 1040.10(a)).
- Sub-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 electromagnetic radiation emitted by the laser product that is detectable with such controlled, stimulated radiation emitted through the aperture stop (except collateral radiation) as found in the FDA definition at 21 CFR 1040.10(b)(22).
- Sub-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). While it would not be appropriate to include collateral radiation in measurements of laser radiation in Clause 5.2 Measurement of laser radiation, manufacturers are instructed by clause 4.3(b)(1) to include collateral radiation in measurements when classifying laser products. FDA also requires that collateral radiation be measured separately when making classification measurements under 21 CFR 1040.10(c).
- Sub-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). Otherwise, Clause 6.1 contains information that manufacturers may find helpful, such as ensuring that personnel responsible for classification receive training. You may wish to include such information in reports/submissions to FDA.
- Sub-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(c)(2) because the FDA definition is not limited to plug-in connections to electrical mains or a battery.
- Sub-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 maximum permissible exposure values instead of a laser class accessible emission limit as in 21 CFR 1040.10(d).
  The FDA performance standards for laser products requires the use of admissible emissions limits values, including those for x-rays. Specifically, the performance standard does not make assessments of collateral radiation dependent upon levels of concern, rather such assessments are mandatory in 21 CFR 1040.10(d).
- Clause 8 (Other informational requirements) 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). Otherwise, Clause 8 contains information that manufacturers may find helpful, such as the applicable MPE and NOHD for Class 3B and Class 4 laser products. You may wish to include such information in reports/submissions to FDA.

–For the IEC clauses listed below, FDA recommends you follow other FDA issued guidance documents, as appropriate:

- Sub-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 "Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57); Guidance for Industry and Food and Drug Administration Staff."[5]
- Sub-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; Guidance for Industry and Food and Drug Administration Staff."[6]

B. Performance Standards Not Subject to this Guidance

This guidance does not affect the following sections of FDA's performance standards for laser products. These FDA performance standards are beyond the scope of the IEC standards, are sufficiently different from the IEC standards, or are not normative and included as recommendations in the User's Guide clause of the IEC standards. Specifically:

1010.2 Certification
1010.3 Identification
1010.4 Variances
1010.5 Exemptions for products intended for United States Government use
1040.10(a) Applicability
1040.10(c)(2) Removable laser systems
1040.10(h)(2) Purchasing and servicing information
1040.10(i) Modification of a certified product
1040.11(b) Surveying, leveling and alignment laser products
1040.11(c) Demonstration laser products

[5] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-and-requirements-laser-illuminated-projectors-lips-laser-notice-no-57
[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/minimizing-risk-childrens-toy-laser-products

C. Certification Requirements

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 enforce the requirements in 21 CFR 1010.2 for manufacturers that conform to comparable clauses 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:

For laser products that are also considered a medical device:

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, as described in Laser Notice No. 56, dated May 8, 2019." 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, as described in Laser Notice No. 56, dated May 8, 2019."

For laser products that are not considered a medical device:

1. "Complies with FDA performance standards for laser products except for conformance with IEC 60825-1 Ed. 3., as described in Laser Notice No. 56, dated May 8, 2019." or

2. "Complies with 21 CFR 1040.10 and 1040.11 except for conformance with IEC 60825-1 Ed. 3., as described in Laser Notice No. 56, dated May 8, 2019."

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.

As identified in Table 1 of 21 CFR 1002.1, manufacturers of certain 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"[7] to submit these reports.

[7] https://www.fda.gov/media/72593/download