Laser Products – Conformance with IEC 60825-1, Am. 2 and IEC 60601-2-22; Final Guidance for Industry and FDA

(Laser Notice No. 50)

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

Electronic Product Devices Branch
Division of Enforcement III
Office of Compliance

Preface

Public Comment

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Such comments will be considered when determining whether to amend the current guidance.

After 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Jerome E. Dennis at (301) 594-4654, ext. 135, or by electronic mail at jxd@cdrh.fda.gov.

Additional Copies

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Guidance on Laser Products – Conformance with IEC 60825-1, Am. 2 and IEC 60601-2-22 (Laser Notice No. 50)

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Purpose

This guidance describes the conditions under which laser product manufacturers may introduce into United States commerce laser products that comply with the IEC standards 60825-1, as amended, and 60601-2-22. This guidance also describes additional requirements of the CDRH standard and alternate certification statements to be used with such products.

Issue

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) 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 60825-1 and 60601-2-22 standards. Although CDRH began its amendment process in anticipation of the amendment of IEC 60825-1, it is not yet ready to publish an amendment. CDRH has acknowledged the advantages of one set of criteria and requirements worldwide. Amendment 2 to IEC 60825-1 was published in January 2001. As a result, manufacturers distributing products in both the U.S. and countries that require conformance with, or that recognize IEC 60825-1, will have to evaluate the conformance of their products with this standard. This requires them to often change the hazard classification of their products. These manufacturers are requesting relief from CDRH so that they will have to comply with only one laser product radiation safety standard.

Background

Laser products for introduction into commerce in or imported into the United States 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.

CDRH has issued notices to laser product manufacturers and importers stating non-objection to:

- Lack of emission indicators or beam attenuators on Class II and Class IIIa systems, and
- Hazard warning labels as specified in IEC 60825-1.

These notices reduced the regulatory burden on both the industry and the agency.

CDRH will not object to conformance with many sections of IEC 60825-1, as amended, and IEC 60601-2-22 as alternatives to comparable sections of 21 CFR §1040.10 and §1040.11. CDRH plans to amend federal regulations for laser products to reflect those sections of the IEC standards. CDRH is also listing sections of its standard that contain requirements to which manufacturers must conform. This action is appropriate because of the numerous requests for relief, the amendment of IEC 60825-1, and the Center's intent to harmonize its requirements with many of those of the IEC standards.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of regulated products. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html.

Guidance

Effective immediately, and until the effective date(s) of any amendments of the Federal regulations affecting laser products, CDRH will not object to conformance with the comparable sections of IEC 60825-1, as amended by Amendment 2 of January 2001 in lieu of conformance with the following sections of 21 CFR §1040:

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

CDRH intends to harmonize the requirements of these sections with those of the IEC standards.

However, laser products must conform to the following sections of the CDRH standards:

1010.2	Certification
1010.3	Identification
1010.4	Variances
1040.10(a)	Applicability
1040.10(c)(2)	Removable laser systems
1040.10(f)(10)	Manual reset mechanism
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

CDRH intends to retain these requirements even if they differ from the IEC. They are either beyond the scope of the IEC standard, are sufficiently different, or are not normative and included as recommendations in the User's Guide section of the IEC standard.

In using this guidance, manufacturers should:

1. Use the following modified statement of compliance on the certification label: "Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated (Insert date of this guidance.)" or "Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated (Insert date of this guidance.);" and
2. Submit product reports or supplemental reports to describe changes to products in accordance with this guidance.

The effectiveness of this guidance will end on the effective date(s) of any amendments to the Federal regulations applicable to laser products under Chapter 1, Subchapter J of Title 21 of the Code of Federal Regulations.

Getting More Information

You can get more information about our requirements for lasers from our electronic product radiation control web page at http://www.fda.gov/cdrh/radhlth/.

If you have questions about this guidance, contact Jerome Dennis, CDRH, Office of Compliance (HFZ-342), 2094 Gaither Rd., Rockville, MD 20850, FAX 301-594-4672, or e-mail jxd@cdrh.fda.gov.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health