

Guidance for Industry and FDA Staff

Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22; Guidance for Industry and FDA Staff (Laser Notice No. 50)

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This document supersedes Laser Products – Conformance with IEC 60825-1, Am. 2 and IEC 60601-2-22; Final Guidance for Industry and FDA (Laser Notice No. 50), July 26, 2001.

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Electronic Products Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs**

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at:
<http://www.fda.gov/cdrh/ocer/guidance/1346.html>. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (**1346**) to identify the guidance you are requesting.

Guidance for Industry and FDA Staff

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

This guidance represents the Food and Drug Administration's (FDA'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 FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

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.

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.

CDRH will not object to conformance with many sections of IEC 60825-1, as amended, and

Contains Nonbinding Recommendations

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 Center's intent to harmonize its requirements with many of those of the IEC standards.

FDA's guidance documents, including this 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.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device and electronic product regulation. 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/ombudsman/>.

1. 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. Edition 1.2 of IEC 60825-1 was published in August, 2001. Edition 2 was published in March, 2007. Edition 2 of IEC 60601-2-22 was published in November, 1995. Edition 3 was published in May, 2007. 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.

2. Guidance

For what sections of 21 CFR can conformance with sections of IEC 60825-1 and 60601-2-22 be substituted?

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, Editions 1.2 or 2 or 60601-2-22 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.

Which applicable sections of 21 CFR are unaffected by this guidance?

The following sections are unaffected. 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.

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What should manufacturers do in using this guidance?

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 June 24, 2007”; 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.

3. 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/radhealth/>.

If you have questions about this guidance, contact F cp"J gy gw, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health, 32; 25'P gy 'J co r uj ltg'Cxgpwg.'Ukxgt'Ur tlpj . 'O F '42; ; 5, Fax: (523) : 69-: 724, or e-mail daniel.hewett@fda.hhs.gov.