

Guidance for Industry and FDA Staff

Exemption from Reporting and Recordkeeping Requirements for Low Power Laser Products

(Laser Notice 54)

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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 Mammography Quality
Assurance 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/radhlth>, you may also send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use document number (1592) to identify the guidance you are requesting.

Contains Nonbinding Recommendations

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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

Under 21 CFR 1002.50, FDA may exempt manufacturers of electronic products from reporting and record requirements subject to any conditions necessary to protect the public health and safety. This guidance provides notification of FDA's exemption of specified low power laser products from certain reporting requirements because of the low risk of exposure to laser radiation and minimal risk to health posed by the products identified in this guidance.

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.

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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/>.

Issue

All manufacturers of electronic products, which includes all laser products, must submit product and supplemental reports according to Title 21 of the Code of Federal Regulations (21 CFR) Parts 1002.10 and 1002.11. In 1988, FDA exempted manufacturers of certain low power laser products from some reporting and recordkeeping requirements if the exempted models met specified criteria (<http://www.fda.gov/cdrh/radhlt/pdf/laser-notice-41.pdf>). FDA is now superseding that guidance and expanding that exemption to additional laser products that do not pose a risk to the public based on their design or use.

Guidance

What products does the exemption include?

- Class I optical disc products, such as CD or DVD players, readers, or recorders, whether the products are stand-alone units, installed into other systems (such as computers or automobiles), or intended to be installed into other systems, and
- Class I laser products intended for home or office use, such as laser printers, that totally enclose any laser radiation that they generate, and in addition
- Any laser products that do not by virtue of their design allow human access to laser radiation in excess of the accessible emission limits of Class I specified in 21 CFR 1040.10(d), as determined in accordance with 21 CFR 1040.10(e), under any condition of operation, maintenance, service, or failure.

What are the conditions for use of the exemption?

- The manufacturer must test and certify that the exempted class I laser products comply with the Federal performance standard contained in 21 CFR 1040.10 and 1040.11.
- The manufacturer must have submitted at least one product report on any similar or different type of laser product.

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What requirements are reduced by this exemption?

Manufacturers of the class I laser products described above are exempted from:

- Certain product reports required by 21 CFR 1002.10
- All supplemental reports required by 21 CFR 1002.11
- Certain recordkeeping requirements described in 21 CFR 1002.30(b), 1002.40 and 1002.41

provided the conditions for use described above are met.

What requirements are not included in this exemption?

1. Annual reports:

The manufacturer must continue to submit annual reports required by 21 CFR 1002.13, which contain listings of all products tested and certified during the reporting year. The listing must include all laser products that were distributed into U.S. commerce during the reporting period, both those that are and those that are not exempt from submission of product reports and supplements.

2. Manufacturers must continue to meet all other applicable requirements, including:

- 21 CFR 1002.20 (Reporting of Accidental Radiation Occurrences)
- 21 CFR 1002.30(a) and 1002.31 (Manufacturer's Records)
- 21 CFR 1003 (Notification of Defects or Failure to Comply)
- 21 CFR 1004 (Repurchase, Repairs, or Replacement of Electronic Products).

Can the Center revoke this exemption?

Yes. FDA reserves the right to request information concerning these products or full reports and recordkeeping if it determines this to be necessary in keeping with the intent of the Radiation Control for Health and Safety Act of 1968 (Public Law 90-602). This would be the case if FDA has reason to believe that a manufacturer is not abiding by the conditions of the exemption.

Why is FDA granting this exemption?

This exemption reduces the regulatory burden on manufacturers of laser products meeting these criteria.

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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 Communication, Education, and Radiation Programs, 9200 Corporate Boulevard, Rockville, MD 20850 or jerome.dennis@fda.hhs.gov.