Form Approved: OMB No. 0910-0025
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FORM FDA 3636 (3/14)

Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

More industry guidance and assistance can be found at the FDA homepage, see: http://www.fda.gov/Radiation-EmittingProducts/.

Send your completed report to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

Questions about reporting and suggestions for changes to this guide may be sent to the above address or may be discussed by calling 1-800-638-2041.

Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products

June 1983
(Revised September 1995)

For laser product manufacturers, this guide replaces FDA 82-8127

The reporting and recordkeeping requirements contained herein have been approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1980 (OMB Approval No. 0910-0025).

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Silver Spring, MD 20993

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Foreword

The Office of Compliance, Center for Devices and Radiological Health (CDRH) developed this guide. This guide will assist manufacturers[1] of electronic products which emit radiation in providing adequate reporting of radiation safety testing and compliance with federal performance standards. Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 specify Reporting and Notification requirements[2,3].

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7). If the report does not follow an applicable guide it must contain a sufficient justification for any deviations. The submitter of the report will receive an acknowledgment letter with the accession number we assign to the report. Please reference this accession number in the future when providing additional information about this model family in either a supplement or the annual report. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database. Also, a rejected report will not receive an accession number.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with all applicable standards (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. Prior to the shipment of products in interstate commerce 21 CFR 1002 requires the manufacturer to submit the report and to comply with all applicable importation requirements (21 CFR 1005). If there are deficiencies, we may disapprove the firm's quality control and testing program, determine that the product contains a radiation defect, or determine that the product fails to comply with a standard. We will notify the manufacturer if we make such a determination. CDRH may require the manufacturer to cease introduction into U.S. commerce until deficiencies are corrected, and to initiate a corrective action program (21 CFR 1003 - 1004) for products already introduced into commerce.

Please mail your reports to the address below (FDA can not process electronic submissions at this time). Provide the original report with appropriate signature(s) (no facsimiles, please). Provide extra copies only if this guide specifically requires them. Submit the report written in the English language. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy of the completed reports in your records.

We are making our reporting guides and other regulatory information available on the Internet under http://www.fda.gov/Radiation-EmittingProducts/. No copyright exists for these guides. Reproduce these guides as needed. If you would like to comment on the reporting guides, web site, or future electronic submissions, you may direct the comments to the address below. If you need additional regulations for electronic products or medical devices, you should contact the Division of Small Manufacturers, International and Consumer Assistance by telephone at 1-800-638-2041 or by facsimile at 301-847-8149.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance

E-MAIL ADDRESS: dsmica@fda.hhs.gov

MAILING ADDRESS (see 21 CFR 1002.7 for further information):

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

[1] **Manufacturer** (see 21) CFR § 1000.3(n)) means any person engaged in the business of manufacturing, assembling, or importing electronic products.

[2] **Accidental Radiation Occurrences:** 21 CFR 1002.20 requires manufacturers to immediately report accidental radiation occurrences (see 21 CFR 1000.3(a) for the definition).

[3] **Notification:** Title 21 CFR Part 1003 requires manufacturers to provide Notification of Defects or Failure to Comply. Send these notifications to the above address.

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NOTE

For laser and laser light show product manufacturers, this guide replaces the "Guide for the Filing of Annual Reports (21 CFR Subchapter J, Section 1002.11)," HHS Publication FDA 82-8127. Guides for preparing Annual Reports on other electronic products are available on request, as listed below. Call 1-800-638-2041, or write to:

Center for Devices and Radiological Health
Document Mail Center - WO66-G609
Attn: Electronic Product Reports
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Guides for Preparing Annual Reports on Radiation Safety Testing of:

1. Television Receivers
2. Cathode Ray Tubes
3. Microwave Ovens
4. Laser and Laser Light Show Products
5. Mercury Vapor Lamps
6. Sunlamps and Sunlamp Products
7. Ultrasonic Therapy Products
8. Dielectric and Induction Heaters
9. Diagnostic X-Ray Systems and Major Components
10. Cabinet X-Ray Systems
11. Electronic Products (General)
    - products intended to produce x radiation (accelerators, analytical devices, therapy x-ray machines)
    - microwave diathermy machines
    - cold-cathode discharge tubes
    - vacuum switches and tubes operating at or above 15,000 volts

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REMINDER: ACCIDENTAL RADIATION OCCURRENCES

You are required by 21 CFR Subchapter J, Section 1002.20, to immediately report accidental radiation occurrences. Report to the Director, Center for Devices and Radiological Health, all accidental radiation occurrences reported or otherwise known to you and arising from the manufacture, testing, or use of any product you have introduced, or intend to introduce, into commerce.

TO: All Electronic Product Manufacturers Subject to Annual Reporting Requirements of 21 CFR 1002.11, Pursuant to the "Federal Food, Drug and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product Radiation Control."

SUBJECT: Filing of Annual Reports on Radiation Safety Testing

The Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control directs the Department of Health and Human Services to evaluate testing programs carried out by industry to assure the adequacy of safeguards against hazardous electronic product radiation and to assure that products comply with performance standards. This Act also requires that manufacturers of electronic products establish and maintain records and provide performance data on radiation safety and information on their testing programs.

In order to carry out its responsibilities under the FFDCA, the Food and Drug Administration's Center for Devices and Radiological Health (CDRH) has issued a series of regulations contained in Title 21 of the Code of Federal Regulations (CFR). Part 1002 of 21 CFR deals with records and reports. Section 1002.61 categorizes electronic products into Groups A through C. Section 1002.30 requires manufacturers of products in Groups B and C to establish and maintain certain records, while Section 1002.13 requires such manufacturers to submit an Annual Report summarizing the contents of the required records. Section 1002.7 requires that reports conform to reporting guides issued by CDRH unless an acceptable justification for an alternate format is provided.

SAVE THIS REPORTING GUIDE AND USE IT EACH YEAR. When a revision is issued, you will be sent a copy. You must submit your Annual Report by September 1 of each year unless you have received a letter of exemption from CDRH under 21 CFR 1002.50. You should duplicate the forms in this guide for inclusion in your report and retain a copy for your records. Proprietary information should be specifically and clearly marked. Information submitted in your report will be used to evaluate your testing program, identify safety problems, and make decisions on the level and type of monitoring programs to be conducted by FDA, such as product testing and factory inspections.

Upon receipt of your Annual Report, CDRH will send you an acknowledgment letter with an accession number you should reference whenever you submit additional information. You will receive further notification only if additional information or clarification is needed.

In addition, the Annual Report is the appropriate vehicle for identifying new models for which Supplemental Reports are not required. When new models of a laser product are introduced, if the models satisfy the criteria for an established reporting exemption or if the new models do not involve changes in radiation emission or performance requirements, then the manufacturer need not report the models prior to introduction into commerce. Rather, the manufacturer is only required to identify them in the Annual Report, or in quarterly updates to the Annual Report. Quarterly updates to Annual Reports should be clearly marked as such and be submitted prior to December 1, March 1, and/or June 1 when required, referencing the previous Annual Report. [See 21 CFR 1002.13(c).]

Send your completed report to:

Center for Devices and Radiological Health
Document Mail Center - W066-G609
Attn: Electronic Product Reports
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Questions about reporting and suggestions for changes to this guide may be sent to the above address or may be discussed by calling the Light Products Branch at 1-800-638-2041.

Ronald M. Johnson, Director
Office of Compliance and Surveillance
Center for Devices and Radiological Health

General

For ease in photocopying, all instructions are on the left-hand pages, while the corresponding forms are on the right-hand pages. You need only submit the completed forms and any additional information you have provided on separate sheets. On all separate sheets or attachments be sure to label each page with sequential lettering. Example: Page 3a, Page 3b, Page 3c.

The forms provide blanks to be filled in, boxes ( ) to be checked, and tables or graphs to be completed. They may be prepared with a computer, typewriter, or hand-printed in black ink.

Part 1. Identification of Manufacturer

Fill in the requested information and sign where indicated. Fill in the years in the reporting period. Example: The report due on September 1, 2011, should cover the reporting year July 1, 2010, through June 30, 2011.

Part 2.Product Status

Check the statement that applies to your firm and take that indicated action.

LASER PRODUCT/LASER LIGHT SHOW ANNUAL REPORT: Page 1

Part 1. Identification of Manufacturer Report Date: _____

Company Name: _____

Address: _____

_____

_____

Corresponding Official signature: _____

Name & title: _____

_____

Telephone: ( ) _____ Email address: _____

Firm name & address, if different from above: _____

_____

_____

_____

_____

This Annual Report is submitted in accordance with 21 CFR 1002.13 for the period July 1, 20____ through June 30, 20 ____ .

Part 2. Production Status

(☐) Products were manufactured during this period and the firm is still in business. If you check this, complete and mail this entire report.

(☐) No products were manufactured during this period but the firm is still in business and expects to manufacture in the future. If you check this, complete Part 6 and mail pages 1 and 4.

(☐) No products were manufactured during this period and the firm is now out of business. If you check this, complete Part 6 and mail pages 1 and 4.

(☐) Products were manufactured during this period but the firm is now out of business. If you check this, complete and mail this entire report.

Part 3. Current Production Tabulation

Provide production data, using the forms or comparable tabulations. Complete Part 3.1 for all laser products. For laser light shows, also complete Part 3.2. If additional space is needed, use another copy of the form(s) or attach separate sheet(s) labeled Part 3.

3.1. All Laser Products

"Accession Number": For previously reported models, CDRH will have assigned this reference number and reported it to you. New Class I models that satisfy the exemption criteria given in the Laser Notices to Industry dated August 23, 1985, and August 9, 1988, should be listed under the initial product report for that family of products. Other models that satisfy the post-market reporting criteria in section 1002.13(c) should be listed under the model family report as well.

"Family Designation": A model family consists of more than one model essentially identical in application, design, and performance.

"Product Function": Indicate the primary application of each model, e.g.,cutting; trimming; welding; surgery; alignment; surveying.

"Class": Give the laser product class of each model listed.

"Production Status (Active)": If the model is currently being manufactured, place an "X" in this column.

"Production Status (Discontinued)": Provide discontinuation date (month and year) for any model that is no longer in production but was produced at some time during the reporting period.

"Production Status (Plant)": Codes may be used for each plant location if you provide the codes and complete address for each manufacturing location on a separate sheet, labeled Part 3.

3.2. Laser Light Shows

"Permanent or touring": Indicate type of use environment. For multiple performances at a fixed location, such as at a planetarium, indicate (permanent). For one or more performances at multiple locations, indicate (touring).

"Production Status (Number of Shows Performed)": Give separate figures for touring and permanent performances.

Part 3. Current Production Tabulation

3.1. All Laser Products

Accession Number	Family Designation	Selling Model Numbers	Product Function	Class	Production Status		
					Active	Discont. (mo/yr)	Plant

3.2. Laser Light Shows

Accession Number	Projector or Show Family Designation	Permanent or Touring	Class	Lasing Media	Production Status	
					No. Shows Performed	Discont. (mo/yr)

Part 4. Procedures for Quality Control and Testing

You are required by 21 CFR 1002.30(a)(1) and (2) to maintain written procedures for quality control and testing. The procedures in use and those submitted in the Laser Product Reports should be reviewed and updated.

Compare your current procedures with those submitted in your Laser Product Reports. Check the appropriate answers and take any indicated action.

Part 5. Summary of Test Results

You are required by 21 CFR 1002.30(a)(2) to maintain results of quality control tests. For each product introduced into commerce, you should evaluate test results to be certain that the total program is adequate to assure radiation safety and compliance with the standard (21 CFR 1040.10 and 1040.11).

Complete Part 5 for all laser products and/or laser light shows. For each model or show produced, review your quality control records and indicate the number of units or shows that were tested for performance requirements, labels, and light show variance conditions, if applicable.

Part 4. Procedures for Quality Control and Testing

The written procedures for assessing and controlling radiation safety have been reviewed. (These include prototype testing, incoming materials testing, assembly testing, retesting after repair, and service testing.) The procedures for maintaining quality control testing equipment have also been reviewed. All procedures are up-to-date, complete, and accurate.

(☐) YES (☐) NO

The reports provided to CDRH for each model family currently in production have been reviewed and the procedures contained in them are up-to-date, complete, and accurate.

(☐) YES (☐) NO

If you answered "no" to either question, provide the current procedures in a supplement to the appropriate model family report.

Part 5. Summary of Test Results

Model Number or Name of Show	Number Produced	Number Tested		
		Performance Requirements	Labels	Light Show Variance Conditions

Part 6. Correspondence Concerning Radiation Safety

You are required by 21 CFR 1002.30(a)(4) to maintain copies of communications to orfrom dealers, distributors, and purchasers concerning radiation safety. Correspondence should be reviewed if it involves any of the following: complaints or concerns about radiation exposure; difficulties with safety components in use or servicing of the product; investigations made or instructions issued concerning use, adjustment, and repair.

Fill in the number of documents sent or received and attach the copies, summaries, or samples as indicated.

NOTE: This summary does not replace the notification requirements for potential defects or noncompliances under 21 CFR 1003.10 or for suspected accidental radiation occurrences under 21 CFR 1002.20.

Part 7. Distribution Records

You are required by 21 CFR 1002.30(b)(1) and (2) to maintain distribution records. Such records must allow tracing of products to the dealer and, if possible, to the user.

Fill in the information on the location of records storage and check the means of tracing products.

Part 6. Correspondence Concerning Radiation Safety

The number of letters received from users, dealers, or others about possible radiation exposure or safety-related failures during use of the product was _____ .

Attach a copy of each letter.

The number of letters received from dealers, distributors, or others concerning the need for repair, adjustment, or replacement of a part to maintain radiation safety of the product was _____ .

Attach a summary of correspondence or a sample. Identify any trends in failed components or adjustments needed during servicing.

The number of notices or brochures sent to users, dealers, or service personnel on precautions or actions to be taken to maintain radiation safety of the product was _____ .

Attach a summary of correspondence or a sample.

Part 7. Distribution Records

Production facility shipping records and dealer records (when returned) are maintained at _____

_____ .

Products can be traced from these records by:

(☐) Model
(☐) Serial number
(☐) Date of Manufacture
(☐) Other, specify: _____