

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

September 1995

(Address corrections Aug. 2008)

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

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

Foreword

This guide was developed by the Office of Compliance, Center for Devices and Radiological Health (CDRH), to assist electronic product manufacturers in providing adequate reporting of radiation safety testing and compliance with performance standards. Reporting requirements are specified in Title 21 of the Code of Federal Regulations (CFR), Part 1002.

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7), or contain a justification why it was not followed. CDRH may reject an incomplete report and return it for completion. When the report is adequate for filing, it will be logged into the CDRH computer system and assigned an accession number. 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.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with the applicable standard (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. The manufacturer is required to submit the report (21 CFR 1002) and to comply with all applicable importation requirements (21 CFR 1005) prior to the shipment of products in interstate commerce. If there are deficiencies, we may disapprove the firm's quality control and testing program or determine that the product contains a radiation defect or fails to comply with a standard. We will notify the manufacturer if we make such a determination. Then the manufacturer may be required 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.

We are making our reporting guides available on the CDRH web site at <http://www.fda.gov/cdrh/comp/eprc.html>, for downloading and reproduction. They are not copyrighted and may be reproduced as needed.

Please mail your reports to the address below (electronic submissions cannot be processed yet). Provide one original IN ENGLISH (no facsimile, please) unless specified otherwise in the guide. Make a copy of the completed report for your records. If you would like to comment on the reporting guides or the electronic docket or future electronic submissions, you may direct the comments to the same address. If you need additional regulations for electronic products or medical devices, contact the Division of Small Manufacturers, International, and Consumer Assistance by telephone at 1-800-638-2041 or 301-443-6597, or by facsimile at 301-443-8818.

Lillian J. Gill



Director
Office of Compliance

MAILING ADDRESS:

Center for Devices and Radiological Health
ATTN: Electronic Product Reports
Electronic Product Document Control (HFZ-309)
Office of Communication, Education, and Radiation Programs
9200 Corporate Blvd.
Rockville, MD 20850

NOTE

For laser and laser light show product manufacturers, this guide replaces the "Guide for the Filing of Annual Reports," HHS Publication FDA 82-8127. Guides for preparing Annual Reports on other electronic products are available on request, as listed below. Call (301) 443-6597 or 1-800-638-2041, or write to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Rockville, MD 20850.

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.

PREFACE

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.

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 submitted prior to October 1, December 1, March 1, and/or June 1 when required, referencing the previous Annual Report. [See 21 CFR 1002.13(c).]

Questions about reporting and suggestions for changes to this guide may be sent to the above address or may be discussed by calling the Electronic Products Branch at 240-276-3332.

INSTRUCTIONS: Page 1

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, 1993, should cover the reporting year July 1, 1992, through June 30, 1993.

Part 2. Production Status

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

Part 1. Identification of Manufacturer Report Date:

Company Name:

Address:

Corresponding Official signature:

Name & title:

Telephone:

Firm name & address, if different from above:

This Annual Report is submitted in accordance with 21 CFR 1002 for the period July 1, 19 through June 30, 19 .

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 or from 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:

() A COPY OF EACH LETTER IS ATTACHED.

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:

() A SUMMARY OR () A SAMPLE OF CORRESPONDENCE IS ATTACHED.
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:

() A SUMMARY OR () A SAMPLE OF CORRESPONDENCE IS ATTACHED.

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: