

GUIDE FOR PREPARING
ANNUAL REPORTS ON
RADIATION SAFETY TESTING OF
MERCURY VAPOR LAMPS

September 1995

(Address corrections Aug. 2008)

For mercury vapor lamp 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 mercury vapor lamp 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.

TO: All Electronic Product Manufacturers Subject to Annual Reporting Requirements Pursuant to the "Federal Food, Drug and Cosmetic Act, 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 Act, 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 1002.13 requires manufacturers to submit an Annual Report summarizing the contents of the required reports.

SAVE THIS REPORTING GUIDE AND USE IT EACH YEAR. When a revision is issued, you will be sent a notice. 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. Send your completed report to:

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

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.

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

GENERAL

For ease of photocopying, all instructions are on the left-hand pages with the corresponding forms are on the right-hand pages. 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 typewriter or hand-printed in black ink. Submit only the completed forms and any information you have provided on separate sheets. Label each separate sheet with the Part number.

PART 1. IDENTIFICATION OF MANUFACTURER

Fill in the information and sign as indicated. Specify the reporting period. Example: The report due September 1, 1993, should cover 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 3. CURRENT PRODUCTION TABULATION

Provide production data, using the form or a comparable tabulation. If additional space is needed, use another copy of the form or attach a separate sheet and label it Part 3.

"Accession No.": For previously reported models, CDRH will have assigned this number and reported it to you.

"Lamp Family Designation": Indicate the lamp family designation. A lamp family is a group of one or more mercury vapor lamp models that have basically similar parameters regarding the performance requirements in the standard and that are manufactured using the same or very similar quality control and testing procedures. Mercury vapor lamp models within the same family may have different wattage values, different shapes, and different bases.

"Brand": You may use a code for each brand listed. On a separate sheet labeled Part 3, identify the code and provide the complete address of each importer or distributor of each brand.

"Lamp Type": Indicate if the model is Metal Halide Self-Extinguishing (MHT), Metal Halide Non-Self-Extinguishing (MHR), Mercury Vapor Self-Extinguishing (HT), or Mercury Vapor Non-Self-Extinguishing (HR).

"Plant Location": Codes may be used if each is identified on a sheet labeled Part 3 with the complete address for each manufacturing plant.

"Discontinued (mo/yr)": Provide discontinuation date for any model that is no longer in production but was produced at some time during the reporting period.

PART 1. IDENTIFICATION OF MANUFACTURER Report Date:

Company Name:

Address:

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

Corresponding Official (signature):

Name & title:

Telephone:

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 2.
- () 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 2.
- () 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

Accession Number	Lamp Family Designation	Brand	Selling Model	Lamp Type	No. of units produced	Plant Location	Discontinued (mo/yr)

INSTRUCTIONS: Page 2

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 Product Reports should be reviewed and updated.

Compare your current procedures with those submitted in your 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) and (3) to maintain results of quality control tests and life 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 1040.30). Summarize the results of these tests by completing the table, or provide comparable data on a separate sheet and label it Part 5.

"Type of Test": On each line of the table indicate which type of test was conducted, using these codes:

- (Q) = quality control test
- (L) = life test

"Labeling Check": Complete this column only for quality control tests.

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 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 No.	Type of Test	No. of Units Tested		Extinguishing Time			Labeling Check (No. of Lots)	
		"T"	"R"	Mean	Std. Dev.	No. of Lots Failed	Pass	Fail

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 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 () A SAMPLE OF CORRESPONDENCE IS ATTACHED.