Form Approved: OMB No. 0910-0025
Expiration Date: February 28, 2026

FORM FDA 3628 (02/23)

Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General)

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.

HHS Publication FDA 88-8127

Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General)

October 1987
(Supersedes June 1983 version)

For manufacturers of electronic products (general),
this guide replaces FDA 82-8127

The reporting and/or recordkeeping requirements contained herein have been approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1980 (OMB Approved 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857
December 1, 1987

TO: All electronic product manufacturers subject to the annual reporting requirements of 21 CFR 1002.11, pursuant to the "Radiation Control for Health and Safety Act of 1968"

SUBJECT: Filing of Annual Reports on Radiation Safety Testing

Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, 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 Law also requires that manufacturers of electronic products establish and maintain records and provide performance data on radiation safety and information on their testing programs.

To carry out its responsibilities under P.L. 90-602, 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 1002.11 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. Separate guides are available for other types of products as indicated on the facing page. 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 of the completed report 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 which you should reference whenever you submit additional information. You will receive further notification only if additional information or clarification is needed.

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

EMAIL ADDRESS: dice@fda.hhs.gov

Walter E. Gundaker
Director
Office of Compliance

NOTE

For manufacturers of electronic products other than those for which a specific guide has been issued, this guide replaces the "Guide for the Filing of Annual Reports (21 CFR Subchapter J, Section 1002.11)," HHS Publication FDA 82-8127. The electronic product (general) annual reporting guide is applicable to the following products:

- 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.

Guides for preparing Annual Reports on specific products are available on request, as listed below. Contact the Division of Small Manufacturers Assistance by telephone at 1-800-638-2041, or by facsimile at 301-847-8149. They are also available under http://www.fda.gov/cdrh.

Guides for Preparing Annual Reports on Radiation Safety Testing of:

1. Television Receivers
2. Cathode Ray Tubes
3. Laser and Laser Light Show Products
4. Mercury Vapor Lamps
5. Sunlamps and Sunlamp Products
6. Ultrasonic Therapy Products
7. Dielectric and Induction Heaters
8. X-Ray Components and Systems
9. Microwave Ovens (this guide is combined with the "Guide for Preparing Reports on Radiation Safety of Microwave Ovens")

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.

INSTRUCTIONS: Page 1

General

For ease of photocopying, all instructions are on the left-hand pages while the corresponding forms are on the right-hand pages. You need to submit only the completed forms and any information you have provided on separate sheets. If you use separate sheets or additional copies of the form, 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 typewriter or hand-printed in black ink (or filled out electronically in provided PDF file).

Part 1. Manufacturer/Importer Identification

Fill in the requested information and sign where indicated. Fill in the years in the reporting period. Example: The report due on September 1, 1988, should cover the reporting year July 1, 1987, through June 30, 1988.

Check the statement and fill in the report identification if you are submitting a supplement to an Annual Report.

Type of Product: Check the type of product you are reporting.

Product Specifications: List any voluntary industry standards your product is designed to meet.

Part 2. Production Status

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

ELECTRONIC PRODUCTS (GENERAL) ANNUAL REPORT: Page 1

Part 1. Manufacturer/Importer Identification Report Date: _____

Manufacturer:

Company Name: _____

Address: _____

_____

This Annual Report is submitted in accordance with 21 CFR 1002.11 for the period July 1, 20___ through June 30, 20___ .

☐ This is a supplement to Annual Report CDRH Accession No. _____ submitted on _____.
(date)

Corresponding Official: _____
(Signature)

_____ _____ (___) _____
(Name) (Title) (Telephone)

_____
(Email)

Importer: (Complete if applicable)

Company Name: _____

Address: _____

_____

Corresponding Official: _____
(Signature)

_____ _____ (___) _____
(Name) (Title) (Telephone)

_____
(Email)

Type of Product:

☐ Accelerators, analytical devices, or therapy x-ray machines
☐ Microwave diathermy machines
☐ Cold-cathode discharge tubes
☐ Vacuum switches or tubes operating at or above 15,000 volts
☐ Other (Specify): _____

Product Specifications:

The product meets the following voluntary industry standards: _____

_____

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 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.

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

"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.

"Plant Location": Codes may be used. On a separate sheet, provide the complete address for each manufacturing location and identify any codes. Label the sheet "Part 3."

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 Initial, Model Change, or Annual Reports should be reviewed and updated.

Compare your current procedures with those submitted in your Initial, Model Change, or Annual Reports. Check the appropriate answers and take any indicated action.

Part 3. Current Production Tabulation

Accession Number	Model Number	Brand	No. of Units Produced	Intro. Into Commerce (mo/yr)	Discontinued (mo/yr)	Plant Location

Part 4. Procedures for Quality Control and Testing

The written procedures for assessing and maintaining radiation safety have been reviewed. (These may include prototype testing, type testing of accelerators, 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 questions, provide the current procedures in a supplement to the appropriate model family report.

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.

For products displaying aging effects that may increase electronic products radiation emission, you are required by 21 CFR 1002.30(a)(3) to maintain results of life tests. Summarize tests on prototypes (if applicable) and on final products.

Report all test results, using the table provided, or give comparable data on a separate sheet and label it Part 5.

"Type of Test": On each line of the table indicate the type of Test with a letter and a number, using these codes:

C = Component test

P = Prototype test (or type test of accelerators)

Q = Quality control test during or after production

A = Audit test of a sample of completed products

L = Life test

1 = Maximum output of radiation intended to be emitted

2 = Maximum leakage (unintentionally emitted) radiation

3 = Timer (e.g., accuracy, reproducibility)

4 = Calibration of controls for setting radiation output (e.g., kVp, mA)

Examples:
1. For tests during production of microwave diathermy applicators, to determine leakage radiation, indicate "Q-2".
2. For tests on a new accelerator design for proper function of controls, indicate "P-4".

If you use other codes, identify them on the bottom of the table or on a separate sheet labled "Part 5".

"Measurements": Specify the quantity and units.

"Failed Components": If any components failed that could affect the radiation safety of the product, indicate the type of components and number of failures.

Part 5. Summary of Test Results

Model Number	No. Units Tested	Type of Test	Measurements Mean or Range	Measurements Std. Dev.	Failed Components

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

All manufacturers or products subject to this guide, except manufacturers of vacuum switches and tubes operating at or above 15,000 volts or manufacturers who have been granted an exemption, 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. Enter "not applicable" "NA" if you manufacture vacuum switches or tubes operating at or above 15,000 volts.

Part 6. Correspondence Concerning Radiation Safety

The number of letters received from users, dealers, or others about possible radiation exposure 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 are maintained at _____

_____

Products can be traced from these records by:

- ☐ Models
- ☐ Serial number
- ☐ Date of manufacture
- ☐ Other (Specify): _____