Form Approved: OMB No. 0910-0025
Expiration Date: January 31, 2017

FORM FDA 3631 (2/14)

Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamp 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 SUNLAMP PRODUCTS

SEPTEMBER 1995

For sunlamp product manufacturers, this guide replaces FDA 82-8127.

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

This page is deliberately blank.

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.

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.

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.

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 forms, 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 blank 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, 1991, should cover the reporting year July 1, 2010, through June 30, 2011.

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 unique reference 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.

“Type”: Indicate whether the model is Lamp Only UVA (LA), Lamp Only UVB (LB), Home Portable UVA (PA). Home Portable UVB (PB), Booth UVA (BA), Booth UVB (BB), Booth UVA and UVB (BC), Couch Bed UVA (CA), Couch and Top UVA (CTA), or Other (0). If (0) is indicated, provide a description on a separate sheet labeled Part 3.

“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.

“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.

SUNLAMP PRODUCT ANNUAL REPORT: Page 1

Part 1. Identification of Manufacturer Report Date: _____

Corporate Name: _____

Address: _____

_____

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

Corresponding Official (signature): _____

Name & title: _____

Telephone number: _____ Email address: _____

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 3.

(☐) 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 3.

(☐) 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	Model	Brand	Type	Plant Location	No. Units Produced	Discon-tinued (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 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) 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 1040.20).

5.1 Results of Final Product Tests

Complete the table or provide comparable data on a separate sheet and label it Part 5.1.

“Irradiance Ratio Maximum”: Indicate the maximum irradiance ratio UVC/UVB for the sunlamps or sunlamp products, where 180 nm < UVC ≤ 260 nm and 260 nm < UVB ≤ 320 nm.

“Max. Time Error”: Indicate the maximum error (in percent) of all times measured at the maximum timer setting.

“Protective Eyewear Transmittance”: Provide transmittance data for three wavelength ranges.

T1 (180 nm < wavelength ≤ 320 nm): Indicate maximum measured value.

T2 (320 nm < wavelength ≤ 360 nm): Indicate maximum measured value.

T3 (wavelength > 360 nm): Is the transmittance sufficient to allow the user to read the labels and reset the timer? Indicate (Y) yes or (N) no.

If transmittance measurements are not conducted, provide (on a separate sheet labeled 5.1) an explanation of why they are not needed and the model number and manufacturer’s name for the protective eyewear.

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

5.1. Results of Final Product Tests

Model	Number of Units Tested			Irrad. Ratio (Max.)	Max. Timer Error (%)	Protective Eyewear Transmittance			
	Irradiance	Timer	Eyewear			T1 (%)	T2 (%)	T3 (%)	Adeq. Vis. (Y/N)

If necessary, use an additional sheet of paper to display other models and their final test results.

5.2 Results of Life Tests

You are required by 21 CFR 1002.30(a)(3) to maintain results of life tests. Summarize tests on prototypes and on final products to show how extended use can affect radiation safety, or provide comparable data on a separate sheet and label it Part 5.2.

“Number Tested”: Indicate how many units were tested.

“Max. Irrad. Ratio”: Indicate the results of irradiance ratio tests. Use column (W) for results of tests performed with UV filter/absorbers used in the product (if any) and/or use column (W/O) for test results with no filters. Products that use filter/absorbers should be tested both with and without them. For each model, indicate the maximum irradiance ratio for all units at the beginning (Beg) of the test and also at the end. In order to fit data in the column width provided, you may want to use scientific notation and place the power of 10 on the second line.

“Timer”: Indicate the number of cycles, number of failures, and the maximum timer errors (Max. Er (%)) measured at the maximum timer setting at the beginning (Beg) and the end of the test. On a separate sheet, describe the types of timer failure, e.g., failure to turn on, failure to turn off, or intermittent on and off problem. Label the sheet Part 5.2.

“Eyewear Transmit”: Indicate the maximum transmittance values for the three wavelength ranges at the beginning of the test and also at the end. In the “Code” column, indicate (B) for beginning and (E) for end. (See Part 5.1, “Protective Eyewear Transmittance,” for definitions of ranges.)

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.

5.2 Results of Life Tests

Model No.	Test Length (hr)	Number Tested	Max. Irrad. Ratio				Timer				Eyewear Transmitance				
			W		W/O				Max. Er. (%)			Max. Value (%)			Adeq. Vis. (Y/N)
			B	E	B	E	No. Cycle	No. Fail	B	E	Code (B/E)	T1	T2	T3	

If necessary, use an additional sheet of paper to display other models and their final test results.

Part 6. Correspondence Concerning Radiation Safety

The number of letters received from users, dealers, or others about possible radiation exposure or timer 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: _____ .