OMB No. 0910-0025; Exp. May 31, 2010

Section: eRadHealth Menu

Role

What is your role?	[L]
Note:	*If you are acting as an agent of the actual manufacturer, please select your role, for example, Importer or Consultant. Later in the report, under Manufacturer Data, you will be prompted to enter both manufacturer and submitter information.*

Submission Information

FDA or State Inspector

Abbreviated Report Applicability

OEM Laser Applicability

Section: Manufacturer Data

Introduction

Electronic Product Radiation Safety Reporting Form

This software application is intended to automate the hard copy product reporting forms in the effort of the Center for Devices and Radiological Health (CDRH) to become capable of accepting electronic submissions from industry and to improve our review process. This FDA Electronic Submission (eSub) software is the next version of the application developed to allow us to accept all Radiological Health reports and other submissions electronically and improve the ability of CDRH to accomplish its mandated product and industry evaluations in a timely and efficient manner.

All electronic reports and correspondence can either be transferred to CD and mailed to the address below, or can be sent via the FDA Electronic Submissions Gateway to CDRH. If you follow instructions to set up an account with the FDA Gateway, when you submit through it you will receive your acknowledgement email message with Accession Number within minutes!

Information about the FDA Electronic Submissions Gateway can be found at **www.fda.gov/esg**. Please contact the Gateway Helpdesk with your questions about that system.

Electronic submissions on CD should be mailed directly to the Document Control Center at:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Attn: eSubmitter Team
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submissions received in the mail on CD will be processed within a few days of receipt.

You should be familiar with the regulatory requirements for radiological products at **www.fda.gov/cdrh/radhealth/** and medical devices available at **www.fda.gov/cdrh/devadvice/**. If you have specific questions about the regulations, please contact us at: **DSMICA@fda.hhs.gov**.

If you have specific questions regarding this software, please contact the eSub team by email at: **eSubmitter@fda.hhs.gov**.

Thank you for using our electronic product reporting software. Please communicate your comments and suggestions to the eSub team as often as you like.

Thank you for your continued support of the FDA Electronic Submission Program (eSub).

General Information

General Information for Radiological Health Products

Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product Radiation Control are required to furnish various reports to the Center for Devices and Radiological Health (CDRH).

The Radiological Health staff, CDRH developed this software application for the Product and Annual reports. This application will assist manufacturers of electronic products that 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 1,2,3.

Reports submitted on radiation safety of electronic products must follow the appropriate form (21 CFR 1002.7). This software application serves the same report responsibility, so long as the submitter or manufacturer prints out the cover letter and sends it in along with the CD containing the report files. The submitter of the report will receive an acknowledgment letter (or email message) with the

accession number that CDRH assigns 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.

CDRH DOES 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 product and Annual Reports and to comply with all applicable importation requirements (21CFR 1005). If there are deficiencies, CDRH 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. CDRH 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 (21CFR 1003 - 1004) for products already introduced into commerce.

CDRH can now accept and process 'CeSub' electronic submissions at this time, if all attachments are PDF files only, and the cover letter is printed out and included with a real signature. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy (save a copy to your hard drive) of the completed report in your records.

We are providing our new software applications for the old reporting forms upon request during this beta testing period of development in Spring, 2005. Other regulatory information is still available on the Internet under **www.fda.gov/cdrh/radhealth/**. No copyright exists for these forms.

Reproduce these forms as needed. If you would like to comment on the reporting forms, website, or future electronic submissions, you may direct the comments to **cdrhesub@cdrh.fda.gov**.

A complete Product Report is required for each product model or model family. Product Reports are now more generally referred to as Radiation Safety Reports to distinguish the Radiological Health submissions from medical device submissions. CDRH suggests that a complete report on one model of a family be submitted, with a separate Supplemental Report for each of the other models in the family. The Supplemental Report should respond in detail to the parts of the form where there are differences to report, referencing the number of the affected item. Items that are unchanged will still appear in the supplement from the original report.

When new models of a 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 may be submitted using the Annual Report software included in this application. [See 21 CFR 1002.13(c).]

All symbols, units, and unusual terms in the report must be adequately defined and consistently used. Please use the terms as defined in Section 1040.10(b) and in the IEEE Standard Dictionary of Electrical and Electronic Terms (IEEE Std. 1001972 and ANSI C42.1001972).

Definitions

Definitions for Rad Health Products

Manufacturers

Manufacturer is any person or organization engaged in the business of manufacturing, assembling, or importing of electronic products (21 CFR1000.3(n)). Manufacturers of electronic products subject to 21CFR1000-1050 must:

- Design and manufacture their products to be in compliance with applicable performance standards;
- Test their products to assure compliance;
- Certify compliance of their products;
- Maintain test and distribution records and a file of correspondence concerning radiation safety, safety complaints, and inquiries;
- Use the published reporting forms or electronic software application to submit reports to CDRH, including Product reports describing the manner of compliance of the product design and testing program and Annual Reports summarizing their compliance testing;
- Report accidental radiation occurrences (i.e., possible, suspected,or known exposures);
- Report any radiation defects or noncompliances; and
- Recall (i.e., repair, replace, or refund the purchase price of) defective or noncompliant products.

Accidental Radiation Occurrences

An accidental radiation occurrence means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product.

Importers

Importer is any person of organization engaged in the business of importing electronic products. An importer is considered to be a manufacturer. The requirements for Manufacturers given above also apply to importers if the requirements have not been done by the foreign manufacturer.

United States Agent for Foreign Manufacturers

Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer`s agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 536(d) of the Radiation Control for Health and Safety Act of 1968 (21U.S.C. 360mm(d)) and this section. The agent maybe an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

From The Federal Food, Drug, and Cosmetic ActSec 536 [21 U.S.C. 360mm](d) Designation of agent for purposes of service

It shall be the duty of every manufacturer offering an electronic product for importation into the United

States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this part or any standards prescribed pursuant to this part may be made by posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

Sec. 531 [21 U.S.C. 360hh] (1) the term **"electronic product radiation"**means:

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

Sec. 531 [21 U.S.C. 360hh](2) the term **"electronic product"**means:

(A) any manufactured or assembled product which, when in operation,(i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or

(B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation.

Burden to Industry

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 26 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing, and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Manufacturer and Report Information

Information:	*This general report requests names, addresses, phone numbers, etc. for your firm, various officials of your firm, consultants who may assist in preparing the report, parent firm (if any), importer and designated agent (for foreign firms). Some of this information is mandatory and its absence will prevent you from completing the report submission. You can check for missing data using the "Missing Data" report from the "Output" menu.* *If you are acting as an agent or consultant for another firm who is certifying the product (or laser light show), please enter the certifying manufacturer and list yourself as the report submitter, below.*

Information:	*Attention: Variance Applicants* *If you are acting as an agent or consultant for, or on behalf of, or filing for, a company that will be manufacturing or producing a Class IIIb or IV projector or laser light show or both which require an approved variance, the following explanations may provide further clarification.* *Manufacturer: This is the firm or company who is requesting the variance, will certify the product or show, and will be the holder and owner of the variance. This is not the agent or consultant who may be filing this report or Variance request for the manufacturer; that agent may be the submitter, identified in a later screen.* *Responsible Individual: This person works for the Manufacturer and is responsible for compliance of the projector and/or show. In the case of laser light shows, he or she may be the company president, CEO, or the laser light show head operator or a manager who oversees the shows.* *Reporting Official: This person works for the Manufacturer and is responsible for reports, recordkeeping, and submitting FDA required documents and correspondence.*

Manufacturer Responsible for Product Compliance

Note:	*This is the firm that takes responsibility for certification that the product meets the performance standard. This firm develops and maintains the quality control and testing program that is the basis for the certification of this product. Additionally, this firm usually is the owner of the product design and manufacturing process design.*

Select the Manufacturer's address from the Establishment Address book:	
Establishment Information:	
Establishment Name	
Division Name	
Home Page	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Responsible Individual

Note:	*The responsible individual is the highest level and most responsible individual affiliated with this establishment.*

Select the Responsible Individual from the Contact Address book:

Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Manufacturer's Reporting Official

Note:	*This is the person at the manufacturing facility that is knowledgeable and responsible for addressing all aspects of the testing and quality control procedures for certification as reported to FDA in the product report. Documentation of changes intesting and quality control procedures submitted to FDA must be signed by this individual.*

Select the Reporting Official from Contact Address book:	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Report Submitter

Note:	*The submitter maybe a consulting individual or firm providing assistance in report preparation and maintenance. All documents prepared by the submitter must have the manufacturer's reporting official signature for authenticity of submitted*

	documentation.

Select the Submitter from the Contact Address book:	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Comments:	

Internal Reference Number:	

Parent Establishment

Is there a parent establishment?	[L]

Select the Parent Establishment and Contact from the Contact Address book:	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	

Address	

Manufacturer Designated United States Agent

Note:	*Manufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.*

Is there a United States agent that has been designated by the manufacturer?	[L]

Written Agreement

Item: 1 (could contain up to 10 items with none required)

Note:	*If any of the required responses below do not apply to your designated agent, enter 'NOT APPLICABLE' or 'NA.'*
Select the Designated Agent from the Contact Address book:	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Address	
Establishment Name	
Division Name	
Address	
Telephone Number	
Fax Number	
Attach a copy of written agreement with the designated U.S. agent:	
[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Importer

Item: 1 (could contain up to 10 items with none required)

Select the Importer from the Contact Address book:	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	

Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Additional Manufacturing Locations

Item: 1 (could contain up to 100 items with none required)

Note:	*If any of the products certified in this report are manufactured at locations other than listed in the Manufacturer Responsiblefor Product Compliance section, then the names, addresses, and FDA registration numbers should be provided. In addition any codes used on labels to identify a manufacturing location must be provided. Each factory location must assure all production procedures are followed identically step by step as provided in this report.If the procedures are not the same then separate reports should be filed.*

Select the Manufacturer Address from the Establishment Address book:	
Establishment Information:	
Establishment Name	
Division Name	
Home Page	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Comments:	
Code used on identification labels:	

Section: Product Data

Product and Model Identification

Note:	*At this time we are only accepting electronic versions of reporting guides contained within this software. Other reporting guides that are not yet electronic are available for downloading from http://www.fda.gov/cdrh/comp/eprc.html.*

Product Type Reported

Report Information

Is this submission a supplement to an Annual Report submitted previously for the same reporting year?	[L]
Provide the Accession Number of the original report for which this is a supplement: (Note: Do not enter any Device Premarket Application or Notification document number here, such as PMAs, 510(k)s, IDEs, etc.)	

Please verify that your accession number matches the report type that is being filed. The third character of your accession number must correspond with its associated report type as shown in the table below:

Report Type Description:	Third Character:
Initial Product Report	1
Model Change Product Report	2
Annual Report	3
Abbreviated Report	8
Variance Request	A
Laser OEM Registration and Listing Report	R

Are you requesting a new variance, a renewal, extension or amendment to a previous variance?	[L]
If you are requesting a renewal, extension, or amendment, please provide the variance number that was issued by CDRH.	
Stop:	*If you are requesting a new variance, renewal, extension, or amendment, you must file a Variance Request separate from this report. To do this, open a new report (File > New) and select either "Laser Light Show Variance Request" or "Variance Request, Other" as your Type of Submission in the Submission Information Screen. If you select "Variance Request, Other" you must select the product for which you are requesting a variance at the end of the screen.*

Special Considerations

Note:	*Check all items in this section that may apply to this submission.*

Noncompliances or Defects

Does this document or any of its attachments contain:	
A self-declaration or notification of noncompliance or defect?	[L]
Provide an explanation:	

[Multi-Line Plain Text]

Responses to Noncompliances or Defects

Does this document or any of its attachments contain and of these responses concerning noncompliances?	
A refutation of noncompliances?	[L]
A request for an exemption from notification?	[L]
Corrective action plans you may be conducting?	[L]
A description of any design changes that correct noncompliances for future production?	[L]
Provide an explanation:	
[Multi-Line Plain Text]	

Exemption Requests

Does this document or any of its attachments contain:	
Exemption of a product for government use from a standard (1010.5)?	[L]
Exemption for products for government use from reporting and recordkeeping (1002.51)?	[L]
Special exemption of products from reporting and/or recordkeeping (1002.50)?	[L]
Request for approval of alternate labeling?	[L]
Application for alternate test procedures (1010.13)?	[L]
Provide an explanation:	
[Multi-Line Plain Text]	
Attach any necessary files.	
[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Variance Requests

Message:	*Click the plus sign to list the requirements from which you are requesting a variance.*
This submission includes an application for a variance from certain requirements.	
Item 1	
Item 2	
Item 3	
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	
Details	[HTML Text]

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Stop:	*For all Variance requests, two submissions must be made to the FDA.* *The electronic version should be submitted following the Packaging Files for Submission instructions located under Output in the Menu bar, and explained in subsection 4.3 of the User Manual. If sending a CD & submittal letter, please mail to:* *U.S. Food and Drug Administration* *Center for Devices and Radiological Health* *Attn: eSubmitter Team* *Document Mail Center - WO66-0609* *10903 New Hampshire Avenue* *Silver Spring, MD 20993-0002* *Additionally, a paper version (hard-copy) of the signed Variance request document should be submitted to:* *Food and Drug Administration* *Division of Dockets Management (HFA-305)* *5630 Fishers Lane, Room 1061* *Rockville, MD 20857*

Responses to Communications from FDA

Does this document or any of its attachments contain:	
A response to an inspection?	[L]
What was the date of the inspection?	[Date]
A response to a warning letter from the Food and Drug Administration (FDA)?	[L]
What was the date of the Warning Letter?	[Date]
A response to a report review inquiry from the Center for Devices and Radiological Health (CDRH) (the inquiry may have been in the form of a letter, email, or phone call)?	[L]
What was the date of the inquiry?	[Date]
A response to any other communication from FDA?	[L]
What was the date of the communication?	[Date]
Provide an explanation:	
[Multi-Line Plain Text]	

Additional Information

Is there any other relevant information or additional comments that would help expedite the review of this submission? Click the plus sign below to attach any supporting files.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Private Labeling

Is the product sold by other companies under different brand names?	[L]

Private Labeling-Table

Item: 1 (could contain up to 20 items with 1 required)

Give the name and address of the manufacturer:	
Establishment Information:	
Establishment Name	
Division Name	
Email Address	
Address	
Address	
Telephone Number	
Fax Number	

Give the firm establishment registration number of the manufacturer listed above (if known):	

Enter brand names and/or model designations in the following table by clicking on the Add button. If you prefer to attach a file, please click on the Add button and enter the text "See File Attachment" as the first table entry.

Item 1	
Item 2	
Item 3	

List of Brand Names and/or Model Designations	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

The Original Equipment Manufacturer (OEM) accession number (if known):	

Explain how the brand names and model designations correspond with your own brand names and model designations:

[Multi-Line Plain Text]

Medical Devices

Provide the premarket 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one of these numbers has been assigned by FDA yet.

[Multi-Line Plain Text]

If it has not been assigned yet, provide an explanation and submit it as soon as you receive such a filing number.

[Multi-Line Plain Text]

Note:	*See www.fda.gov/cdrh for more information onmedical device premarket clearance procedures.*

Document Key: Specialized Response content is defined within straight brackets [ ]; Special code: [L] List of Values.

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Section: General Annual Report

Part 1 Report Identification

Note:	*This document will serve as a guide for all x-ray component manufacturers in complying with 21 CFR Subchapter J regarding Annual Reports.*
Message:	*This Annual Report is submitted in accordance with 21 CFR 1002.13 for the period:*

-	From July 1, 20 _ _(Provide the last two digits of the year)	
-	Through June 30, 20 _ _(Provide the last two digits of the year)	

What voluntary standards related to radiation safety are your products designed to meet?	
Item 1	
Item 2	
Item 3	

Part 2 Production Status

Production Status:	( ) Products were manufactured during this period and the firm is still in business. ( ) No products were manufactured during this period but the firm is still in business. ( ) No products were manufactured during this period and the firm is now out of business. ( ) Products were manufactured during this period but the firm is now out of business.

Part 3 Current Production Tabulation

Item: 1 (could contain up to 1000 items with 1 required)

Model Family Designation:	
Model Designation (Name and/or Number):	

Accession Number (For previously reported models, CDRH will have assigned this number and reported it to you)	
What is the oven type?	[L]
What is the lamp type?	[L]

Note:	*Each product that CDRH regulates is assigned a product code by CDRH. Click the hint button (e.g., Light Bulb) below if you needed additional instructions.*

Identify the product code.	
Category	

Product Code	
Performance Standard	

Number of units produced:	
Number of ovens audited:	

Is this model now discontinued but was produced during this reporting period?	[L]
If so, provide the date of discontinuation (MM/DD/YYYY)	[Date]

Plant Location:	
Establishment Information:	
Establishment Name	
Address	
Address	
Telephone Number	
Fax Number	

Part 4 Procedures for Quality Control and Testing

Note:	*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 or Abbreviated Reports should be reviewed and updated.* *Compare your current procedures with those submitted in your Product Reports or Abbreviated Reports.*

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.	[L]
The initial report(s) provided to CDRH for each model family currently in production have been reviewed and the procedures contained within are up-to-date, complete, and accurate.	[L]
Do your products undergo 100% Quality Assurance testing?	[L]
What test sampling program do you follow?	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Part 5 Changes to Product Specifications

Have any product specifications that affect radiation safety changed ?	[L]
Identify models and their corresponding Accession Numbers where these have been reported. If you haven't reported them yet indicate when the reports will be submitted.	
Item 1	
Item 2	
Item 3	

Part 6 Correspondence Concerning Radiation Safety

Note:	*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.*

Did your firm receive or send any correspondence regarding radiation safety of your products this year?	[L]
Attach a copy of each correspondence.	
[HTML Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Were reports of death/injury/malfunction reports investigated, root cause determined, trend analysis conducted?	[L]
Attach a copy of your firm's investigation(s).	
[HTML Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Indicate the number of letters from dealers.	
Attach a summary of correspondence or a sample.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Part 7 Distribution Records

Provide address of the Production facility that maintains shipping records	
Establishment Information:	
Establishment Name	
Division Name	
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Home Page	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	

Address	
Information:	*Please note: The FDA may request further records and test results in the future pursuant to Sec. 1002.31 Preservation and inspection of records.* *(c) Upon request of the Director, Center for Devices and Radiological Health, a manufacturer of products listed in table 1 of 1002.1 shall submit to the Director, copies of the records required to be maintained by paragraph (b) of 1002.30.* *[38 FR 28625, Oct. 15, 1973, as amended at 53 FR 11254, Apr. 6, 1988; 60 FR 48386, Sept. 19, 1995]*
Stop:	*You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.*
Message:	*FORM FDA 3628 (03/06) Guide for Preparing Annual Reports for Medical, Analytical, and Industrial X-Ray Products*
Message:	*FORM FDA 3645 (03/06) Guide for Preparing Annual Reports for Ultrasonic Therapy Products*
Message:	*FORM FDA 3634 (03/06) Guide for Preparing Annual Reports for Television Products*
Message:	*FORM FDA 3643 (03/06) Guide for Preparing Annual Reports for Microwave Oven Products*
Message:	*FORM FDA 3638 (03/06) Guide for Preparing Annual Reports for X-Ray Components and Systems*
Message:	*FORM FDA 3636 (03/06) Guide for Preparing Annual Reports for Radiation Safety Testing of Laser and Laser Light Show Products*
Message:	*FORM FDA 3631 (03/06) Guide for Preparing Annual Reports for Radiation Safety Testing of Sunlamps and Sunlamp Products*
Message:	*FORM FDA 3647 (03/06) Guide for Preparing Annual Reports for Radiation Safety Testing of Mercury Vapor Lamps*

Document Key: Specialized Response content is defined within straight brackets [ ]; Special code: [L] List of Values.

OMB No. 0910-0025; Exp. May 31, 2010

Section: Mercury Vapor Lamp Annual Report

Definitions

Definitions for Mercury Vapor Lamp Products

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 with regard to 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.

Lamp Type:

Indicate whether 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).

Part 1 Report Identification

Message:	*This Annual Report is submitted in accordance with 21 CFR 1002.13 for the period:*	
-	From July 1, 20 _ _(Provide the last two digits of the year)	
-	Through June 30, 20 _ _(Provide the last two digits of the year)	

If your products meet other voluntary industry standards, provide below:

Item	Standard Title and Reference Number	Category	Organization

If your product is designed to meet additional voluntary industry standards, list them in the table below.

Item 1	
Item 2	
Item 3	

Part 2 Production Status

Production Status (Click on the right button and select the statement that applies to your firm and take the indicated action)

Part 3 Current Production Tabulation

Item: 1 (could contain up to 500 items with 1 required)

Model Designation (Name and/or Number of the Selling Model):	
Accession Number (For previously reported models, CDRH will have assigned this number and reported it to you)	
What is the lamp type?	[L]

Note:	*Each product that CDRH regulates is assigned a product code by CDRH.* *If you know the three letter code, enter it in the space provided.* *If you do not,* *- Click the filter search icon (next to the trash can). You will see a product code filter dialog box.* *- Enter a keyword to search the database. You will be provided a list of product codes from which to choose.* *(If you are not finding the correct product, try other words and/or variations of the keywords.)* *- Select the best match to your product.* *- The remaining fields will be filled in for you when you select your product code.* *- If you do not find the code that you are looking for, use RZZ (Other)*

Identify the product code.	
Category	
Product Code	
Performance Standard	

Number of Units Produced	
Introduction Into Commerce (MM/DD/YYYY)	[Date]
Is this model now discontinued but was produced during this reporting period?	[L]
If so, provide the date of discontinuation:	[Date]

Plant Location	
Establishment Information:	
Establishment Name	
Division Name	
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Home Page	
Physical Location:	
Address	
Telephone Number	

Fax Number	
Mailing Location:	
Address	
Provide any information that is needed for any of the items as an attachment.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[Multi-Line Plain Text]	

Part 4 Procedures for Quality Control and Testing

Note:	*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.*

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.	[L]
The initial report(s) provided to CDRH for each model family currently in production have been reviewed and the procedures contained within are up-to-date, complete, and accurate.	[L]

4.1 Current Procedures

Item: 1 (could contain up to 500 items with none required)

Provide the current procedures as a PDF file attachment here, identifying the model accession number or provide an explanation.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Model Accession Number:	

Part 5 Summary of Test Results

Item: 1 (could contain up to 10 items with none required)

Note:	*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).*

Model Designation:	
Select the tests performed on this model:	[L]
Number of Units Tested:	
Number of units tested for compliance with performance requirements:	
Number of units tested for compliance labels:	
Extinguishing Time:	

Specify the Measurement Mean or Range:	
Specify the Standard Deviation Measurement:	
Specify the number of lots that failed:	
Indicate the type of components that could affect radiation safety of the product if they fail:	
[HTML Text]	
Labeling Check: Complete this column only for quality control tests.	
Specify the number of lots that passed:	
Specify the number of lots that failed:	

Part 6 Correspondence Concerning Radiation Safety

Note:	*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.*

Specifiy the number of letters received from users, dealers, or others about possible radiation exposure during use of the product, defects or noncompliances.	
Attach a copy of each letter. Click the Add... button below to attach any supporting files.	
[HTML Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Indicate 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.	
Attach a summary of correspondence or a sample. Identify any trends in failed components or adjustments needed during servicing. Click the Add... button below to attach any supporting files.	
[HTML Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Indicate the number of notices or brochures sent to users, dealers, or service personnel regarding defects, noncompliances, or precautions and actions to be taken to maintain radiation safety of the product.	
Attach a summary of correspondence or a sample. Click the Add... button below to attach the files.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Part 7 Distribution Records

Provide address of the Production facility that maintains shipping records	
Establishment Information:	
Establishment Name	
Division Name	

FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Home Page	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Note:	*Indicate how the products can be traced from the records. Check all that apply.*

By Model	[ ]
By Serial Number	[ ]
By Date of Manufacture	[ ]
Other	[ ]

If you selected the checkbox for Other, please specify	

Stop:	*You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.*
Message:	*FDA 3647 (03/06) Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps*

Document Key: Specialized Response content is defined within straight brackets [ ]; Special code: [L] List of Values.