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.

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

Section: Laser Show Notification

Contact Information

FDA Docket Number:	
Accession Number:	
Date of Issue:	[Date]
Date of Expiration:	[Date]

Identify the name of the event(s):

Item	Show Name	Projector	Brand Name
Item 1			
Item 2			
Item 3			

Please provide the contact information for the venue:

Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Venue Contact Information

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

Contact information for the venue:	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Is this a permanent installation?	[L]
Enter the first date for the show at this location:	[Date]
How many days will the show be at this location?	

Enter the time(s) of the show for this location (HH:MM AM/PM):	
Item 1	
Item 2	
Item 3	

Laser Safety Officer

Item: 1 (could contain up to 10 items with 1 required)

Laser Safety Officer(s) in charge of the show:	
Contact Name	

Occupation Title	
Email Address	

Projector and Show Information

Please provide the following product information:	
Projector manufacturer:	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Comments:	
Projector model:	
Product accession number:	
Maximum anticipated output:	
Select the Agencies notified:	
Item 1	
Item 2	
Item 3	
If "Other" has been selected, please explain further:	
[HTML Text]	

Description of Effects Utilized:	
Item 1	
Item 2	
Item 3	
If "Other" has been selected, please explain further:	
[HTML Text]	
Please provide a description of safety factors and attach show diagrams. Click the Add... button below to attach any supporting files.	
Details	[HTML Text]
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Provide any necessary comments below:	
[HTML Text]	
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 3635 Laser Light Show Notification (03/06)*

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