Section: eRadHealth Menu

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, it currently may take several weeks,, but when you submit through it you will receive your acknowledgement email message with Accession Number within minutes! Or, in the interest of faster turn-around for a one-time urgent report of if you submit few reports, you may simply fill out this template creating the submission and then at 'Packaging' follow the instructions to transfer the files to a CD to mail in. This method of submitting your report will be acknowledged by an email with the Accession Number within several days.

Information about the FDA Electronic Submissions Gateway can be found at **www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm**. 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.

Note about eSubmitter software:

Instructions provided in this software briefly summarize the requirements of the regulations under the Federal Food, Drug and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product Radiation Control, that applies to manufacturers of electronic products that emit radiation. The software provides questions relevant to requirements in the performance standards and may include explanations or clarification about the performance, labeling, and informational requirements of the standard. It does not replace the regulations, however, and if there is any conflict between the software and the regulations, the regulations must prevail. Throughout this application, pertinent sections of Title 21, Code of Federal Regulations, Chapter I, Subchapter J, are cited in parentheses. Please consult them before making design or procedural decisions.

Regulatory requirements for radiological products can be found at **http://www.fda.gov/Radiation-EmittingProducts/default.htm** and for medical devices are located at **www.fda.gov/M/devaDvices/default.htm**. 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).

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.

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

3640 Laser Light Show rpt (OMB 0910-0025)

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 effect

Role

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

Information:	The following screen provides several options for you to accurately define what type of eSubmission you intend to create for FDA. Below are explanations of your options. Please feel free to review this screen, advance to the next screen and view the picklists, but if you're confused, come back to read this screen again to be certain you are selecting the correct report or correspondence type you want to create.

Submission Information

Use the radio buttons to identify the type of submission you are preparing. (Supplements should be prepared using the same document type as the original submission.) [QUESTION TYPE NOT YET IMPLEMENTED: HEADER STEP]	
What Type of Submission is this? (Supplements should be submitted selecting the same document type as the original report.)	( ) Radiation Safety Report (Product) Report (21 CFR 1002.10) ( ) Annual Report (21 CFR 1002.13) ( ) Laser Light Show Documents (all relevant documents) (21 CFR 1040.11(c)) ( ) Correspondence ( ) Variance Request (General, not Laser Light Show) (21 CFR 1010.4)

	( ) Laser Original Equipment/Component Manufacturer Registration (21 CFR 1040.10(a)(3)(ii)) ( ) Abbreviated Report (21 CFR 1002.12)

After answering the Submission Type question above, one of the questions below may become active and required (see the blue dot to the right of the question). If there is an active question, select the appropriate product area or document type from the question's pick list. [QUESTION TYPE NOT YET IMPLEMENTED: HEADER STEP]
What Type of Product is this Radiation Safety Report about?
[L]
What Type of Product is this Annual Report about?
[L]
What Laser Light Show Document are you filing?
[L]
What Type of Correspondence is this?
[L]
What Type of Product is this Variance Request about?
[L]

FDA or State Inspector

Abbreviated Report Applicability

OEM Laser Applicability

Section: Manufacturer Data

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.

Regulatory information is available on the Internet under **www.fda.gov/Radiation-EmittingProducts/default.htm**. 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).

Burden to Industry

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 24 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

3640 Laser Light Show rpt (OMB 0910-0025)

"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

Confirmation:	This Manufacturer section of this 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. Because some of these entries may be redundant, utilize the 'Contact Address Book' feature so you can save your data and reselect the entries later and in the future. (See the upload/download buttons in upper right corner of the screens). You can check for missing data at any time using the "Missing Data Report" from the "Output" menu across the top of this application. The Missing Data Report lists all missing responses that are required (that have the blue dot).

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. Be sure to enter address information for each tab below:

Select the Manufacturer's address from the Establishment Address book: [QUESTION TYPE NOT YET IMPLEMENTED: ESTABLISHMENT COMPLEX]

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: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

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: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]	

Report Submitter

Note:	The submitter may be a consulting individual or firm providing assistance in report preparation and maintenance. Documents or submissions such as this one that are prepared by the submitter must have an accompanying authorization letter from the manufacturer's reporting official for authenticity.
Select the Submitter from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]	
Internal Reference Number:	

Parent Establishment

Is there a parent establishment?	[L]

Select the Parent Establishment and Contact from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

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:	The manufacturer who is certifying the product being reported is the manufacturer of record. If this firm is not in the United States, please identify your current Importer(s).

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 Name	
Occupation Title	

Email 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: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

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: [QUESTION TYPE NOT YET IMPLEMENTED: ESTABLISHMENT COMPLEX]	
Code used on identification labels:	

Section: Product Data

Product and Model Identification

Attention - Information about this section

In this section you'll be asked to identify several required or optional things which will help FDA/CDRH staff to prioritize their reviews. You'll be asked to consider the following aspects:

(1) Identify your product's radiation type and the CDRH Product Code.

(2) Enter an Accession number if this will be a report supplment. If you are preparing a supplement, you'll see that after entering a valid 7-digit Accession number many questions will no longer be required (they will either be disabled or will be optional, meaning they will no longer have the blue dot).

(3) You will also have several questions that are of high significance for FDA/CDRH - why you might be submitting this report or

correspondence. Please read these questions carefully, referring to the 21 CFR regulations on the website www.FDA.gov if you are unsure if the question is relevant to your firm's situation.
(4) If you find that you have more information that you want the FDA/CDRH to read but it doesn't seem to fit under other questions, we have a final "***Additional Information***" question in this section which invites you to add comments and/or attach a file that provides further information from your firm about this submission. This is the place to add that extra information.

Product Type Reported

Note:	Each product that CDRH regulates is assigned a product code by CDRH.

What is the product code?

To select the three letter product code,

- Click the plus sign. You will see a product code filter dialog box.
- Select the appropriate category name from the pick list. You will be provided a list of product codes from which to choose.
- Select the best match to your product.
- The remaining fields will be filled in for you when you select your product code. [QUESTION TYPE NOT YET IMPLEMENTED: RH SINGLE PRODUCT CODE]

If Other, provide a category name for this specific product.

Examples of Laser Products

Product Type:	Product Examples:
Medical Laser Products:	Ophthalmic, Dermatological, Laser Hair Removal, Cardiovascular, Angioplasty, Photodynamic Therapy Laser with fiber Optics, ENT, Ob/Gyn, Urology, Laser for Pain Therapy, Laser for Wound Healing, Dental Lasers
In Vitro and Other Medical Laser Products:	Veterinary Laser, Automated Blood Cell Separator, Automated Differential Cell Counter, Cell Sorters
Positioning Medical Laser Products:	X-Ray Field Indicator Laser Light, Patient Positioning Monitor
Laser Light Show/Display Products:	Low and High-Power Laser Light Show Projectors, Laser Light Shows,Laser Video Projectors
Other Demonstration Laser Products	Laser Science Education Products

Surveying, Leveling, Alignment Laser Products:	Ranging (Geodimeter) Laser Products, Alignment Laser Product, Laser Pointers, Laser Target Designator, Laser Aiming Products
Safety, Security, Surveillance Laser Products:	IR Laser Night Vision Illuminator System, Collision-Avoidance Laser System, Laser Automotive Lighting & Signals, IR Laser Intrusion Detection/Security System, Laser Radar (Lidar) or Speed Measurement, Laser Weapon (Military or Police)
Toy, Novelty, Play Laser Products:	Laser Toys, Pet Laser Toys, Laser Tag, Laser Play Guns
Research, Scientific, Laboratory Laser Products:	Laser Spectroscopy Instrument, Particle-Size Measuring Instrument, Analytical Measuring and Detection Laser Product
Material Processing Laser Products:	Laser Cutters, Laser Welders, Microelectronic Mask or Chip Checking/Repair, UV Curing, Laser Print Industry Plate Maker, Laser Process Control, Laser Vision System
Data Measurement, Transmit, Control Laser Products:	Fiber Optic Communication and Data Transfer Laser System, IR Free-Space Data Transmit/Control Laser, Laser Remote Controller
Utility/Peripheral Laser Products:	Laser Reprographics, Laser Printer, FAX Machine, CD, CD-ROM, DVD, DVD-ROM Players, CD-R, CD-RW, DVD-R, DVD+R, DVD-RAM, DVD+RW, DVD-RW Recorder, UPC Reader (Bar Code Reader)
Other Laser Products:	Laser Automotive or Transport Vehicle Accessory, General Purpose Laser Products

Report Information

Is this the first time you've submitted a report on the particular type of product selected in the Product Type Reported section?	[L]
Since this is not the first time you've reported on this type of product, then is this a report supplement to a previously reported model family?	[L]

3640 Laser Light Show rpt (OMB 0910-0025)

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. See Accession number description below.)	

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 (General, not Laser Light Show)" as your Type of Submission in the Submission Information Screen. If you select "Variance Request (General, not Laser Light Show)r" you must select the product for which you are requesting a variance with the pick list in the bottom section of the screen.

Special Considerations

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

Information:	If this product will require a formally approved Variance from a certain performance requirement, you will need to complete two Reports for FDA, both (1) this Radiation Safety Report (RSR) on this product, and (2) a Variance Request report. This eSubmitter software application package includes a general Variance Request form as well as the specific Laser Light Show Variance Request form. Both the Product RSR file and the appropriate Variance Request Correspondence file must be submitted to CDRH following the regular files packaging procedures in this application. Both may be transferred to the same CD or submitted via the FDA ESG to submit to the FDA/CDRH. In addition, any Variance Request form must be printed out and the signed hard-copy sent to FDA's Division of Dockets Management at: Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane Rockville, MD 20852 NOTE: There is no need to send a copy of the CD to Division of Dockets Management.

Noncompliances or Defects

Does this document or any of its attachments contain:	
A notification of noncompliance or defect?	[L]
You may provide an explanation and/or attach a document here:	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Responses to Noncompliances or Defects

Does this document or any of its attachments contain any of these responses concerning noncompliances or defects?

A refutation of noncompliances or defects identified to your firm?	[L]
A request for an exemption from notification to purchasers (see 21 CFR 1003.21 and 1003.30)?	[L]
Corrective action plans you intend to implement to correct noncompliances or defects discovered in past or current production?	[L]
Note:	If you are submitting a Corrective Action Plan (CAP) following 21 CFR 1004 and information on design changes for future production, the design change information must be submitted in a Radiation Safety (Product) Report or supplemental report. Both the proposed CAP and the design changes may be submitted in one document if you prepare a product report and choose to include the CAP in it as a file attachment. Alternatively, you may create a separate eSubmission for the CAP using the "Correspondence" type template and selecting "Follow-up correspondence to FDA."
A description of any design changes that correct noncompliances for future production?	[L]
Note:	If you are submitting information on product design changes for future production due to a discovery of noncompliances or defects in current production, you must use the Radiation Safety (Product) Report template to create the report . Correspondence templates may be used to submit other information such as a proposed corrective action plan pertaining to a noncompliance or defect.
You may add an explanation and/or attach a document here:	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Exemption Requests

Does this document or any of its attachments contain:	
Exemption of a product for government use from a standard (21 CFR 1010.5)?	[L]
Exemption for products for government use from reporting and recordkeeping (21 CFR 1002.51)?	[L]
Special exemption of products from reporting and/or recordkeeping (21 CFR 1002.50)?	[L]
Request for approval of alternate labeling?	[L]
Application for alternate test procedures (21 CFR 1010.13)?	[L]
You may provide an explanation and/or attach any relevant documents here:	
[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

Information:	Please note: in addition to responding to these questions below, a separate General Variance Request or Laser Light Show Variance Request form must be completed and submitted to CDRH, with a hard copy sent to FDA's Division of Dockets Management as instructed below for any variance request. The information requested on this screen does not constitute the full structured content of the variance request. The 2 types of Variance forms can be created in eSubmitter by selecting the appropriate Variance submission type under the eRad Health Menu section of this application.
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	

3640 Laser Light Show rpt (OMB 0910-0025)

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 FDA inspection?	[L]
What was the date of the inspection?	[Date]
A response to a Warning letter or a Notification of Noncompliance or Defect from the FDA?	[L]
What was the date of the Warning Letter or other notification letter?	[Date]
A response to a report review inquiry from the 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

3640 Laser Light Show rpt (OMB 0910-0025)

Here's your opportunity to add anything else to this submission that you want to tell the FDA! 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 Name	
Division Name	
Email 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

3640 Laser Light Show rpt (OMB 0910-0025)

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 submitted yet, or if your device is exempt from premarket clearance or approval, please provide an explanation. The device regulations can be found in 21 CFR 807 - device manufacturer registration and device listing.
[Multi-Line Plain Text]

Note:	See also http://www.fda.gov/MedicalDevices/default.htm for more information on medical device premarket clearance procedures.

Section: Report Identification

1.0 General Definitions

General Definitions

This software application should be followed for all lasers and products containing, incorporating, or intended to incorporate, a laser or laser system [see the definition of "laser product" in section 21 CFR1040.10(b)(21)].

Laser Reporting and Recordkeeping (21 CFR 1002)

Applicability of reporting and recordkeeping requirements for laser products:
Class I, IIa, II, and IIIa laser products and laser products containing such lasers will require: Product Report, Annual Report, test records, manufacturer's distribution records, and dealer/distributor distribution records.
Note that for Class I laser products containing lasers of Class I, IIa, II, or IIIa no Supplemental Reports are required.Furthermore, some Class I laser products have already been exempted from the requirement for distribution records (see Notice to Industry dated August 9, 1988, Laser Notice # 41).
Class IIIb and IV laser products require all of the above plus Supplemental Reports when the criteria requiring submission of Supplemental Reports are met.
The laser standard applies to all laser products manufactured after August 1, 1976 (1040.10(a)), unless the products are either: sold to a manufacturer for use as components (or replacements) in products that will be certified (1040.10(a)(l)); sold by or for a manufacturer as repair or replacement components if they are properly labeled as such and have installation instructions (1040.10)(a)(2)); or intended for export only, are labeled as such, and comply with the requirements of the importing country (1010.20). Manufacturers of laser products that are sold to other manufacturers for use as components in their products are required to register and list such products.

Laser Definitions from 21 CFR 1040.10(b)

Laser means any product that can be made to produce or amplify electromagnetic radiation at wavelengths greater than 250 nm but less than or equal to 13,000 nm or, after August 20, 1986, at wavelengths equal to or greater than 180 nm but less than or equal to 1.0X106 nmprimarily by the process of controlled stimulated emission.
Laser energy source means any product intended for use inconjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries shall not be considered to constitute laser energy sources.
Laser product means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser product is any device that constitutes, incorporates, or is intended to incorporate a laser or laser system (1040.10(b)(21)). A laser or laser system that is intended for use as a component of an electronic product shall itself be considered a laser product.
Laser radiation means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph1040.10(b)(19) that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop and within the appropriate solid angle of acceptance, as specified in 1040.10(e).
Laser system means a laser in combination with an appropriate laser energy source with or without additional incorporated components. See paragraph 1040.10(c)(2) of the laser product performance standard for an explanation of the term "removable laser system."

2.0 Specific-Purpose Product Definitions

Specific-Purpose Product Definitions

Demonstration laser product means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition. The term "demonstration laser product" does not apply to laser products which are not manufactured, designed, intended, or promoted for such purposes, even though they may be used for those purposes or are intended to demonstrate other applications. Demonstration laser products(1040.10(b)(13)) include:
laser products promoted for classroom demonstration of optical phenomena;
artistic displays and their associated apparatus;
laser light show projectors; and
laser light shows and displays themselves.
A general-purpose, scientific, medical or industrial laser product is not considered to be a demonstration laser product when it is demonstrated to a prospective purchaser. Demonstration laser products are restricted in their outputs to Class IIIa with its accompanying restrictions to Class I for short pulses and invisiblewavelengths(1040.11(c)). Because these levels are too low for effective use incommercial theatrical lighting effects, CDRH may grant variances (1010.4) to manufacturers of laser light shows and display devices. As a condition of the variance, the manufacturer must agree to adhere to several safety conditions to provide a level of safety to the publice quivalent to a fully compliant product. Consult the Compliance Guide for Laser Products, September 1985, Appendix B, Clarification of Certain Laser Light Show Requirements, for more information.

3.0 Show Name

What is (are) the name(s) of the light show or display?			
Item	Projector Model	Show Name	Brand or Trade Name
Item 1		Item 2	

4.0 Variance

Attach a copy of your variance application (FDA Form 3147) and/or, if approved, attach your variance approval letter (or variance number). Click on 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)]	
>	Is variance application attached?	[L]
>	Is a copy of your variance approval letter attached?	[L]
>	Or provide current variance number:	

Section: Equipment Information

5.0 Projection Equipment

Item: 1 (could contain up to 5 items with 1 required)

5.1	Manufacturer:	
>	Model number or other designation:	

>	CDRH accession number:	

6.0 Show Venue

The laser light show or display takes place in:		
Item 1		
Item 2		
Item 3		
>	If "other" has been selected, please specify:	
Note:	Be sure to provide beam path diagrams/floor plans for each of the types of venues listed above, unless certain drawings are general enough to cover more than one type. Drawings shall be attached following Part 9.0 Diagrams and Drawings of Show Venue.	

The laser light show or display takes place:		
Item 1		
Item 2		
Item 3		
>	If "other" has been selected, please specify:	

7.0 Show Locations, Dates, and Times

Note:	Give specific location(s), date(s), and time(s) for the show if this information is known at the time this report is submitted. If not, advanced written notification must be made as early as possible to appropriate Federal, State, and local authorities. To be considered timely, this written notice must be submitted 30 days prior to the opening of the show. When the show dates become known to the manufacturer less than 30 days prior to the show date, the required information must be provided verbally by phone or by FAX to CDRH. A confirming formal written notice, including the date of the phone notification and the name of the CDRH individual to whom the information was given must be submitted within 14 days. Written confirmation would not be needed following a FAXed notification. CDRH must be notified of every show that your firm intends to produce. If notifications are not routinely received in a timely manner your variance may be revoked.
Click on the Add... button 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]

8.0 Light Show Effects Produced

The laser light show uses the following laser effects:	
Item 1	
Item 2	
Item 3	

If "other" has been selected, please specify:	
[Multi-Line Plain Text]	
Note:	Be sure that the beam path diagrams included in your response to Part 9.0 are sufficient to illustrate all of the effects indicated above. Several effects may be included in a single diagram.

9.0 Diagrams and Drawings of Show Venue

9.1	Provide both plan and elevation drawings with dimensions of the show or display. If the setup varies from show to show, then provide this information for a typical show. * If no drawings are attached, please add an explanation in the text box. Click on the Add... button 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)]
	[Multi-Line Plain Text]	

*Be sure to include in the drawings:

(1) the location of the projector(s) and control panel(s), audience, performer(s), operator(s), mirrors, mirror balls, display screens (or other targets), and beam termination points;

(2) the direct and reflected laser radiation beam path;

(3) the laser radiation levels in each beam including the wavelength, maximum power, and scan parameters (if scanned) for the worst case from a human access point of view;

(4) the minimum separations of the laser radiation fields (or beams) from reference locations in audience and performer areas in both vertical and horizontal directions; and

(5) any direct or reflected beams into audience or performer locations.

Are drawings attached?	[L]

10.0 Laser Radiation Levels

10.1	Describe how each of the laser radiation levels, indicated on the drawings attached in 9.0, were determined. If any levels were derived from calculations rather than directly measured, provide the actual calculations that were made. Click on the Add... button 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)]
	[Multi-Line Plain Text]	

11.0 Scanning Safeguards

11.1	Will there be audience scanning* from any of the planned effects?	[L]
Note:	* Audience scanning is considered to be any scanning, projection, or reflection of laser or collateral radiation into audience or other accessible, uncontrolled area. Scattered radiation coming from diffuse reflectors such as fog, smoke, mist or similar diffusing media is not considered audience scanning. However, all radiation must be below Class I levels if it reaches into audience or other uncontrolled areas. A scanning safeguard is required whenever a laser light show includes audience	

	scanning to assure that the laser radiation levels in audience areas will not exceed Class I limits if there is a scan failure. See the companion publication, "Compliance Guide for Laser Products," for further discussion.	
11.2	Do any of the planned effects require laser radiation (direct or scanned beams) to be viewed by operators, performers, or employees?	[L]
>	If the answer to 11.1 or 11.2 is yes, describe how the radiation levels that reach into audience areas are maintained at Class I levels by scanning. Your attached description must include details of the required scan failure safeguard, including a discussion of the means of detection of the scanning, the theory of the operation of the scanning safeguard, and its speed of response in order to show that it will prevent the scanned radiation from exceeding the Class I limits.	
	File Attachment: [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	[Multi-Line Plain Text]	

11.3	Will any laser radiation greater than Class I STRIKE BUT NOT BE VIEWED by operators, performers or other employees?	[L]
>	Describe, in detail, the operation of the scan failure safeguard or other means which will prevent exposure to beams exceeding Class II. If a scan safeguard is used, include a discussion of the detection of scanning, the operation, and the speed of response of the safeguard to show that it will prevent the scanned radiation from exceeding the limits of Class II. If other means are used, such as pressure pads or infared beams, describe in detail as well.	
	File Attachment: [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details: [Multi-Line Plain Text]	

12.0 Operator Controls

12.1	Is the show under the continuous control of an operator?	[L]

12.2	Does the laser operator perform tasks in addition to operation of the laser projector?	[L]
>	Describe those tasks:	
	[Multi-Line Plain Text]	

12.3	Can the operator see all of the propagating beam paths, their terminations and the audience at all times during the performance?	[L]
>	Explain how adequate surveillance is provided:	
	[Multi-Line Plain Text]	

12.4	Do any other personnel assist in providing surveillance of the laser display?	[L]
>	State the number of persons, their identification (job titles), their duties, and how they assist in providing surveillance. Describe how they are in constant communication with the operator.	
	File Attachment: [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	[Multi-Line Plain Text]	

What qualifications* are required of laser operators for your show?	
[HTML Text]	
Note:	* Holders of variances are required by the variance to employ trained operators or to assure that the operators receive adequate training to qualify them for the safe use of the laser projection system and presentation of the light show effects. Useful information including training films, reference books, and programs on the safe use of lasers may be obtained from the Laser Institute of America (LIA) and from the American National Standards Institute (request ANSI standard Z136.1).

12.6	If your show is not under the continuous control of an operator, is a person designated to be responsible for the immediate termination of the laser radiation in the event of equipment malfunction, audience unruliness, or other unsafe conditions?	[L]
>	Explain alternate control:	
	[Multi-Line Plain Text]	

12.7	How is this person designated? What are his or her duties?
	[Multi-Line Plain Text]
12.8	What qualifications are required for this person?
	[Multi-Line Plain Text]

13.0 Projection Equipment Controls

13.1	Are one or more readily accessible controls provided to immediately terminate laser radiation?	[L]
>	Number of controls:	

13.2	Describe the location of these controls and their operation relative to your show.
	[Multi-Line Plain Text]

Section: Test and Notification Procedures

14.0 Test Procedures

14.1	Attach a copy of the written setup, alignment, and test procedures to be followed prior to the operation of the laser light show at each location. If setup procedures are not a seperate form, provide a detailed description below of procedures that are followed. Click on the Add... button 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)]
	[Multi-Line Plain Text]	

14.2	When are these setup, alignment, and test procedures performed?
	[Multi-Line Plain Text]

14.3	What laser radiation levels are used during setup, alignment, and checkout? (in milliwatts)

14.4	Is a written record of the results of the setup, alignment, and test procedures maintained?		[L]
>	Explain how adequate quality assurance is maintained:		
	[Multi-Line Plain Text]		
>	You may attach records such as Standard Operating Procedures (SOPs), Quality Safety Checklists, and Daily Logs.		
	File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Note:	Adequate recordkeeping would include, but not limited to: (1) sketches showing the location of the laser projector(s), operator(s), performer(s), audience, beam paths, viewing screens, wall mirrors, mirror balls, and other surfaces that may be struck by the laser beams; (2) information on scanning patterns, velocity, and frequency; and/or (3) laser radiation levels used in each effect.		

15.0 Notification Procedures

15.1	What procedures are followed for notification of appropriate Federal (CDRH, FAA), State and local agencies? Either attach a file, form letters, or describe procedures in the text box below. Click on the Add... button to attach any supporting files.	
	File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	[Multi-Line Plain Text]	

What Federal, State and local agencies are notified or would be notified?	
Item 1	
Item 2	
Item 3	
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 3640 Reporting Guide for Laser Light Shows and Displays (10/31/2013)