## **Submission Report**

Section: Main Menu

Welcome

# Welcome to the CDRH Electronic Submissions Software (CeSub)

This software application is intended to automate the current paper submission process. This software contains a number of data capturing tools and helpful dialog boxes to reduce redundant responses for you, and to allow us to capture data in a more useful, structured format. These benefits will enable CDRH to improve our review process and reduce lengthy review times.

For your convenience, an email account has been established to support any questions that you may have regarding the use of this software. Please email any questions or comments to the CeSub team at: **cdrhesub@cdrh.fda.gov.** Please be sure to include your name, company name and contact information in the email.

Thank you again for using our electronic product reporting software. We look forward to hearing from you soon.

What type of product is this submission referring to?

Radiation Emitting Product (OMB No. 0910-0025; Expiration Date: December 31, 2006)

#### Welcome (Cont.)

Department of Health and Human Services Food and Drug Administration

Form Approved:
OMB Number 0910-0025
Expiration Date: December 31, 2006

Section: eRadHealth Menu

Role

What is your role?

\* Manufacturer

#### Submission Information

What Type of Submission is this? (Supplements should be submitted selecting the same document type as the original report.)

Annual Report

What Type of Product is this Annual Report about?

Laser Light Shows

What Type of Correspondence is this?

What Type of Product is this Radiation Safety Report about?

What Type of Product is this Variance Request about?

What Laser Light Show Documents are you filing?

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 CDRH Electronic Submission (CeSub) software is the next version of the application the CDRH is developing 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.

We have already received many electronic submissions and are looking forward to receiving more in the future. With this new release of the software we have updated our procedures for packaging a submission to make this a smoother process for all. All electronic reports (your new CD-ROMs) and any other documents you are submitting in hard copy because they cannot be provided in an acceptable electronic format must be mailed to CDRH. A signed hard copy of the submittal letter generated by the submission software, should be printed out and included with your electronic submission. This printed documentation will provide the Document Control Room with enough information to log the submission. The electronic submissions should be sent directly to the Document Control room, which is the same process for the standard paper

submission.

The submission must be addressed to:

Electronic Product Document Control (HFZ-309), Attn: CeSub Team, Center for Devices and Radiological Health, 2094 Gaither Road, Rockville, MD 20850

After sending your submission to the Document Control Room, please send an email to the cdrhesub@cdrh.fda.gov email account so we will know that your submission is forthcoming. Please remember that all correspondence concerning your submission MUST be sent to the Electronic Product Document Control (HFZ-309), at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official notification submission. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. You should also be familiar with the regulatory requirements for radiological products at www.fda.gov/cdrh/comp/eprc.html and medical devices available at Device Advice www.fda.gov/cdrh/devadvice/.

If you have specific questions regarding the software, please contact the CeSub team by email at: **cdrhesub@cdrh.fda.gov**.

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

Thank you for your continued support of the CDRH eSubmission Pilot Program.

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 <a href="http://www.fda.gov/cdrh/comp/eprc.html">http://www.fda.gov/cdrh/comp/eprc.html</a>. 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 the address below.

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 21 CFR1000-1050 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 Act

### Sec 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:

Food and Drug Administration CDRH (HFZ-240) 1350 Piccard Drive Rockville, MD 20850

## Please DO NOT RETURN this application to this address.

"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 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.

Copy from the establishm	opy from the establishment address book *				
Establishment Information	1:				
Establishment Name					
Division Name					
Home Page					
Physical Location:					
Address					
Telephone Number					

Fax Number		
Mailing Location:		
Address		
Responsible I	ndivic	lual
Note:		esponsible individual is the highest level and most responsible individual affiliated with this lishment.
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Occupation Title		
Email Address		
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Establishment Nar	ne	
Division Name		
Physical Location:		
Address		
Telephone Numbe	r	
Fax Number		
Mailing Location:		
Address		
Manufacturer'	s Rep	porting Official
Note:	aspec	is the person at the manufacturing facility that is knowledgeable and responsible for addressing all cts of the testing and quality control procedures for certification as reported to FDA in the product report. mentation of changes intesting and quality control procedures submitted to FDA must be signed by this dual.
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Telephone Numbe	r	

Fax Number

Mailing Location:

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Electronic Signat	ure
Electronic signature (ne	ot available in this release of the software)
File Attachment	
Report Submitter	
ma	e submittermaybe a consulting individual or firm providing assistance in report preparation and intenance. All documents prepared by the submitter must have the manufacturer's reporting official nature for authenticity of submitted documentation.
Copy from contact add	ress list
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
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Establishment Name	
Division Name	
Physical Location:	
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Fax Number	
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Is there a parent estab	ishment? *
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Telephone Number	
Fax Number	

Mailing Location:

Address							
Manufacturer Designation	gnated United States Agent						
Note: Manu	afacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005	5.25.					
Is there a United States a	gent that has been designated by the manufacturer? *						
Section: Produ	ict Data						
Product Type Repo	orted						
	ng reported? *Please note that this list of 66 product types are grouped according ations (e.g., laser products, microwave products, ionizing products, etc.)	ng to their radiation *					
Report Information							
Is this submission a supp year?	lement to an Annual Report submitted previously for the same reporting *	i					
	umber of the report for which this is a supplement (Do not enter any Device Notification document number here, such as PMAs, 510(k)s, IDEs, etc.):						
Are you requesting a new	variance, a renewal, extension or amendment to a previous variance?	*					
If you are requesting a re was issued by CDRH.	newal, extension, or amendment, please provide the variance number that						
sepa. Varia Scree	Error:  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.						
Noncompliances o	r Defects						
Does this document or	any of its attachments contain:						
A self-declaration or notif	ication of noncompliance or defect?	*					
Provide an explanation:							
Responses to Non-	compliances or Defects						
Does this documentor a	any of its attachments contain:						
A refutation of noncompli	ances?	*					
A request for an exemption	on from notification and corrective action?	*					
Information on corrective	actions you may be conducting?	*					
A description of any design	A description of any design changes for future production? *						

Provide a	n explana	tion:			
Exemp	tion Re	quests			
Does this	s docume	ent or any o	f its attachments contain:		
Exemptio	n of a pro	duct for gove	ernment use from a standard (1010.5)?	*	
Exemptio	n for prod	ucts for gove	ernment use from reporting and recordkeeping (1002.51)?	*	
Special e	xemption	of products t	from reporting and/or recordkeeping (1002.50)?	*	
Request f	or approv	al of alterna	te labeling?	*	
Application	n for alte	nate test pro	ocedures (1010.13)?	*	
Provide a	n explana	tion:			
Attach an	y necess	ary files.			
File Attac	hment				
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Item					
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Respor	nses to	Commun	ications from FDA		
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			rom the Food and Drug Administration (FDA)? *		
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			nquiry from the Center for Devices and Radiological Health (CDRH) (the * rm of a letter, email, or phone call)?		
What was	the date	of the inquir	ν?		

A response to any other communication from FDA? *							
What was the date of the	What was the date of the communication?						
Provide an explanation:							
Use Environment							
Who are the intended use	ers?						
[ ] Children and/or Youth [ ] Consumers [ ] Elderly [ ] Employees/Workers [ ] Engineers or Scientist: [ ] General Public [ ] Medical Staff [ ] Patients [ ] Other							
What is the use environm	ent?						
[ ] Consumer Home [ ] Hospital or Clinic [ ] Industrial Facility or Fa [ ] Office/Warehouse/Sto [ ] Outdoors [ ] Public Arena [ ] Schools, Gymnasium/, [ ] Lab or Research Facil [ ] Transportation Facility [ ] Other	re Auditorium ity						
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[ ] Children and/or Youth [ ] Consumers [ ] Elderly [ ] Employees/Workers [ ] Engineers or Scientist [ ] General Public [ ] Medical Staff [ ] Patients [ ] Other							
Additional Informati	ion						
Is there any other relevan Add button below to atta	it information or additional comments that would help expedite the review of this submach any supporting files.	ission? Click	the				
File Attachment							
Details							
Private Labeling							
Is the product sold by other	er companies under different brand names?	*					
Medical Devices							

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 Pa	rt 2	Produc	tion Status					
Pro	ductio	on Status	(Click on the right butto	n and select the sta	atement that applies	to your firm an	d take the indicate	d action) *
Pa	rt 3	Curren	t Production Tabu	lation				
lten	n: 1							

Model Family Design	gnatior	า:						
Model Designation	Model Designation (Name and/or Number):							
Accession Number number and reporte	Accession Number (For previously reported models, CDRH will have assigned this * number and reported it to you)							
Note:	Each	product that CDRH	regulates is assigned a product code by CD	RH	1.			
	If you	know the three lette	er code, enter it in the space provided.					
	If you	ı do not,						
	- Ente (If you - Sele - The	- 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	t code.							
Product Code								
Device Class								
Classification Pane	el							
C.F.R. Section								
Number of Units Pr	roduce	d		*				
Introduction Into Co	ommei	rce (MM/DD/YYYY)		*				
Is this model now o	discont	inued but was produ	ced during this reporting period?	*				
If so, provide the da	ate of	discontinuation:						
Plant Location					*			
Establishment Info	rmatio	n:						
Establishment Nan	ne							
Division Name								
FDA Establishmen	t Ident	ifier (FEI)						
Central File Number	er (CFI	N)						
Registration Numb	er							
Owner/Operator No	umber							
Home Page								
Physical Location:								
Address								
Telephone Number	Telephone Number							
Fax Number								
Mailing Location:								
Address								
Provide any inform	ation t	hat is needed for any	y of the items as an attachment.					
File Attachment								

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.						
testing, incoming m	ures for assessing and controlling radiation safety have been review naterials testing, assembly testing, retesting after repair, and service control testing equipment have also been reviewed. All procedures a	testing.) The procedures for				
	provided to CDRH for each model family currently in production have	e been reviewed and the *				
1'						
4.1 Current Pr	ocedures					
Item: 1						
	t procedures as a PDF file attachment here, identifying the model acc	cession number or provide an explanation.				
File Attachment						
Details						
Model Accession N	lumber:					
Part 5 Summa	ary of Test Results					
Item: 1						
	[v	W				
Note:	You are required by 21 CFR 1002.30 (a) (2) to maintain results of q introduced into commerce, you should evaluate test results to be causasure radiation safety and compliance with the standard (21 CFR)	ertain that the total program is adequate to				
Model or Show De	signation: *					
Number of units tes	sted for compliance with performance requirements: *					
Number of units te	sted for compliance labels:					
·						
Select additional te	ests performed on this model:					
If you selected "Otl	her," provide an explanation:					
Select the Type of	Measure for the test:	*				
If you selected "Otl	her," provide an explanation:					
Specify the Measu	rement Mean or Range:					
Specify the Standa	ard Deviation Measurement:					
Indicate the type of	f components that could affect radiation safety of the product if they f	ail:				
Specify the numbe	r of component failures:					

# 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.						
		ters received from users,dealers, or others about possible radiation * e product, defects or noncompliances.					
Attach a copy of ea	ach lett	er. Click the Add button below to attach any supporting files.					
File Attachment							
		ters received from dealers, distributors, or others concerning the need for * lacement of a part to maintain radiation safety of the product.					
		espondence or a sample. Identify any trends in failed components or adjustmen button below to attach any supporting files.	ts needed during				
File Attachment							
		tices or brochures sent to users, dealers, or service personnel regarding or precautions and actions to be taken to maintain radiation safety of the					
Attach a summary	of corr	espondence or a sample. Click the Add button below to attach the files.					
File Attachment							

# Part 7 Distribution Records

Provide address of the Production facility that maintains shipping records *					
Establishment Info	Establishment Information:				
Establishment Nan	ne				
Division Name					
FDA Establishmen	t Identifier (FEI)				
Central File Number	er (CFN)				
Registration Numb	er				
Owner/Operator Number					
Home Page					
Physical Location:					
Address					
Telephone Numbe	r				
Fax Number					
Mailing Location:					
Address					
Note:	Note: Indicate how the products can be traced from the records. Check all that apply.				
By Model	By Model [ ]				

By Serial Number					
By Date of Manufacture					
Other					
If you selected the checkbox for Other, please specify					
Section: Laser Light Show Report					

# Laser Light Show Production Tabulation

# Item: 1

Accession Number: *		
Family Designation of Show: *		
Is the laser light show:		
Class: *		
Lasing Media: *		
Production Status:		
Number of shows performed: *		
Active: *		
Product discontinued date:		
Number of shows tested for compliance with variance conditions: *		
Error:	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 3636 Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (03/06)	