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.) *
Correspondence
What Type of Product is this Annual Report about?
What Type of Correspondence is this? *
Accidental Radiation Occurrence
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: Correspondence

Introduction

Information:	*This section allows you to submit certain types of information or inquiries that are not part of a manufacturer's Product Report, Annual Report, or other reports as specified under 21 CFR 1002. However, some correspondence types would likely be submitted in conjunction with Product Reports. Examples of these would be Variance requests, Exemption requests, Laser Light Show notifications, follow-ups from FDA communications and audits, corrective actions, and notifications of product issues.* *The following questions may seem a little too vague or not exactly appropriate to your situation but they are designed to be generic questions to suit many situations and issues. Please respond as well as possible and you have the opportunity to attach PDF letters or files if you like.*

Burden to Industry

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 2 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."

Submitter Information

Message:	*Please provide the following information regarding the submitter of this report. If you are not associated with a manufacturing establishment, enter N/A for Establishment Name on the Establishment Identification Tab. If you are associated with a Government Agency, please complete the Establishment Identification information.*
Copy from contact address list *	
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	

Manufacturer Information

Message:	*Please provide any information known regarding the manufacturer of the product being reported.*
Copy from contact address list	
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	

Product Information

Message:	*Please provide the following information regarding the product being reported.*
What product type is being reported? *	
Note:	*Each product that CDRH regulates is assigned a product code by CDRH.*

What is the product code?

If you know the three letter code, enter it in the space provided.

If you do not,

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

Product Code	
Device Class	
Classification Panel	
C.F.R. Section	

Describe the product and its intended use. Attach any supporting documents if necessary.

File Attachment	
Details	

Section: Accidental Radiation Occurrence

Description of the Radiation Occurrence

Is this a new Accidental Radiation Occurrence (ARO) report or a supplement to a previous ARO report?	
What was the date of the previous ARO report? *	

Please describe the circumstances surrounding the accidental radiation occurrence, including affected person(s)' actions when exposed to the radiation, and causes of the occurrence. Please attach any supplemental files or medical reports by clicking on the Add... button below. *

Details	
File Attachment	

Location of Occurrence

Please provide the physical location where the Accidental Radiation Occurrence took place (eg. at a residence, a factory, a *

tanning salon, school, restaurant, airport, etc). If you do not know the exact address, provide responses to the best of your ability, or enter Unknown.	
Establishment Name	
Division Name	
Address	
Telephone Number	
Fax Number	

Persons Involved

Please list the number of people exposed in the Accidental Radiation Occurrence. *	
Please list the number of people adversely affected. *	
Please list the nature and magnitude of exposure and/or injuries. *	
File Attachment	
Details	
Are the affected person(s) employees of the product manufacturer? *	
Did the affected person(s) have any responsibility toward the operation of the equipment? *	
Remarks	

Actions Taken

Actions taken to control, correct, or eliminate the causes and to prevent reoccurrence. If unknown, please indicate as such in your response.	
Please list the actions, to date, taken by the manufacturer in response to the Accidental Radiation Occurrence. *	
File Attachment	
Details	
Please list future actions to be taken by the manufacturer in response to the Accidental Radiation Occurrence. *	
File Attachment	
Details	

Other Important Information

Please list any other pertinent information and/or attach a file.	
File Attachment	
Details	
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 3649 Accidental Radiation Occurrence (03/06)*