Submission Report

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).

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. The OMB control number for this information collection is 0910-0025 (expires January 31, 2017).

Role

What is your role?	!*	Manufacturer

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

Step 1	**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.)**

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)

Step 2	**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.**
What Type of Product is this Radiation Safety Report about?	
What Type of Product is this Annual Report about?	
What Laser Light Show Document are you filing?	
What Type of Correspondence is this?	**!***
Inquiry	
What Type of Product is this Variance Request about?	

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 1 hour 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
Attn: eSubmitter Team
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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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	
D&B D-U-N-S Number	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

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	
D&B D-U-N-S Number	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Telephone Number	
Fax Number	

Product Information

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

What is the product code? *

- 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)

Item	Category	Product Code	Performance Standard
Details			

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

Accidental Radiation Occurrence

ARO Introduction

Note:	*Accidental radiation occurrences (AROs) must be reported to CDRH by manufacturers (pursuant to 21 CFR 1002.20), regardless of whether injury occurred, or it was a situation presenting the potential for injury, or involving a product malfunction. The report must include identification of the product involved, the circumstances and details of the incident, and actions taken to prevent recurrence.* *If your product is a medical device, an adverse event must be reported using the MedWatch form and following the Medical Device Reporting regulations explained on the following website: http://www.fda.gov/cdrh/mdr/.*

Model Designation

Note:	*Report the model name and/or number, model family, brand name, or other designation of the product. If reporting a model family, provide the model designation of each model. If you do not have a model family or brand name, leave the field blank.*

Model Designation (Names and/or Numbers): *			
Item	Model Name	Family Name	Brand Name

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	
If this involves a medical device, has a Medical Device Report (MDR) been submitted to FDA?	

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. For numerical fields, enter zeroes if unknown. *	
Establishment Name	
Address	

Telephone Number	
Please give start and end dates of event. (They may be the same.) *	

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 number of potentially exposed people who have not exhibited any adverse reactions. *	
Please list the number of unexposed people who were involved. *	
Type of reportable event *	[ ] Death [ ] Serious Injury [ ] Malfunction [ ] Other ...
If Other..., specify the the type of event.	
Please list the nature and magnitude of exposure and/or injuries. *	
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. *	
Details	
Please list future actions to be taken by the manufacturer in response to the Accidental Radiation Occurrence. *	
Details	

Other Important Information

Please list any other pertinent information and/or attach a file.	
Details	
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.

Correspondence Details

Model Designation

Note:	*If known, report the model name and/or number, model family, brand name, or other designation of the product. If reporting a model family, provide the model designation of each model. If you do not have a model family or brand name, leave the field blank.*

Model Designation (Names and/or Numbers):			
Item	Model Name	Family Name	Brand Name

Additional Information

Please provide an explanation of your actions, concerns, questions, notifications, and/or your requests below.	
Details	
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 3642 General Correspondence (10/31/2013)*