

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 or 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/medicalDevices/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

| | |
|--|--|
| | <input type="checkbox"/> Variance Request (General, not Laser Light Show) (21 CFR 1010.4) <input type="checkbox"/> Laser Original Equipment/Component Manufacturer Registration (21 CFR 1040.10(a)(3)(ii)) <input type="checkbox"/> Abbreviated Report (21 CFR 1002.12) |
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| 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. |
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| | |
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| What Type of Product is this Radiation Safety Report about? | |
| | |
| What Type of Product is this Annual Report about? | !* |
| Laser Products (Includes Projection Systems) | |
| What Laser Light Show Document are you filing? | |
| | |
| What Type of Correspondence is this? | |
| | |
| What Type of Product is this Variance Request about? | |
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| Manufacturer Data |
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| Manufacturer Responsible for Product Compliance |
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| Note: | <p><i>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.</i></p> <p><i>Be sure to enter address information for each tab below:</i></p> |
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| Select the Manufacturer's address from the Establishment Address book: | * |
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| <i>Establishment Information:</i> |
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|--------------------|--|
| Establishment Name | |
|--------------------|--|

| | |
|---------------|--|
| Division Name | |
|---------------|--|

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|-----------|--|
| Home Page | |
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|---------------------------|
| <i>Physical Location:</i> |
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| | |
|---------|--|
| Address | |
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| | |
|------------------|--|
| Telephone Number | |
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| Fax Number | |
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|--------------------------|
| <i>Mailing Location:</i> |
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|---------|--|
| Address | |
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|------------------|--|
| Telephone Number | |
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| Fax Number | |
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| Responsible Individual |
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| Note: | <p><i>The responsible individual is the highest level and most responsible individual affiliated with this establishment.</i></p> |
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| Select the Responsible Individual from the Contact Address book: | * |
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| <i>Contact Information:</i> |
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| | |
|--------------|--|
| Contact Name | |
|--------------|--|

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|------------------|--|
| Occupation Title | |
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|---------------|--|
| Email Address | |
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| <i>Establishment Information:</i> |
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| Establishment Name | |
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|---------------|--|
| Division Name | |
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|---------------------------|
| <i>Physical Location:</i> |
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| | |
|---------|--|
| Address | |
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| Telephone Number | |
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| Fax Number | |
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Mailing Location:

| | |
|------------------|--|
| Address | |
| Telephone Number | |
| Fax Number | |

Manufacturer's Reporting Official

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| Note: | <i>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 in testing and quality control procedures submitted to FDA must be signed by this individual.</i> |
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Select the Reporting Official from Contact Address book: *

Contact Information:

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| Contact Name | |
| Occupation Title | |
| Email Address | |

Establishment Information:

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|--------------------|--|
| Establishment Name | |
| Division Name | |

Physical Location:

| | |
|------------------|--|
| Address | |
| Telephone Number | |
| Fax Number | |

Mailing Location:

| | |
|------------------|--|
| Address | |
| Telephone Number | |
| Fax Number | |

Report Submitter

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| Note: | <i>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.</i> |
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Select the Submitter from the Contact Address book: *

Contact Information:

| | |
|------------------|--|
| Contact Name | |
| Occupation Title | |
| Email Address | |

Establishment Information:

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|--------------------|--|
| Establishment Name | |
| Division Name | |

| | |
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| <i>Physical Location:</i> | |
| Address | |
| Telephone Number | |
| Fax Number | |
| <i>Mailing Location:</i> | |
| Address | |
| Telephone Number | |
| Fax Number | |
| <i>Comments:</i> | |
| | |
| Internal Reference Number: | |
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| Parent Establishment |
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| Is there a parent establishment? | * |
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| Select the Parent Establishment and Contact from the Contact Address book: | |
| <i>Contact Information:</i> | |
| Contact Name | |
| Occupation Title | |
| Email Address | |
| <i>Establishment Information:</i> | |
| Establishment Name | |
| Division Name | |
| <i>Physical Location:</i> | |
| Address | |
| Telephone Number | |
| Fax Number | |
| <i>Mailing Location:</i> | |
| Address | |
| Telephone Number | |
| Fax Number | |

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| Manufacturer Designated United States Agent |
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| <i>Note:</i> | <i>Manufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.</i> |
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| Is there a United States agent that has been designated by the manufacturer? | * |
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| Importer |
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Additional Manufacturing Locations

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| Product Data |
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| Product and Model Identification |
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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 supplement. 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.

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| Report Information |
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| Is this submission a supplement to an Annual Report submitted previously for the same reporting year? | * | |
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| 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.) | |
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| Are you requesting a new variance, a renewal, extension or amendment to a previous variance? | * | |
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| Stop: | <i>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.</i> |
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| Special Considerations |
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| Noncompliances or Defects |
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| Does this document or any of its attachments contain: | |
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| A notification of noncompliance or defect? | * |
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| You may provide an explanation and/or attach a document here: | |
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| Details | |
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| Responses to Noncompliances or Defects |
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| Does this document or any of its attachments contain any of these responses concerning noncompliances or defects? | |
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| A refutation of noncompliances or defects identified to your firm? | * |
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| A request for an exemption from notification to purchasers (see 21 CFR 1003.21 and 1003.30)? | * |
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| Corrective action plans you intend to implement to correct noncompliances or defects discovered in past or current production? | * |
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| <i>Note:</i> | <i>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."</i> |
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| A description of any design changes that correct noncompliances for future production? | * |
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| <i>Note:</i> | <i>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.</i> |
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| You may add an explanation and/or attach a document here: | |
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| Details | |
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| Exemption Requests |
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| Does this document or any of its attachments contain: | |
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| Exemption of a product for government use from a standard (21 CFR 1010.5)? | * |
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| Exemption for products for government use from reporting and recordkeeping (21 CFR 1002.51)? | * |
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| Special exemption of products from reporting and/or recordkeeping (21 CFR 1002.50)? | * |
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| Request for approval of alternate labeling? | * |
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Application for alternate test procedures (21 CFR 1010.13)? *

You may provide an explanation and/or attach any relevant documents here:

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 No Information Provided.

Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.

Details

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? *

What was the date of the inspection?

A response to a Warning letter or a Notification of Noncompliance or Defect from the FDA? *

What was the date of the Warning Letter or other notification letter?

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| 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)? | * | |
| What was the date of the inquiry? | | |
| A response to any other communication from FDA? | * | |
| What was the date of the communication? | | |
| Provide an explanation: | | |
| | | |

Additional Information

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.

Details

Private Labeling

Is the product sold by other companies under different brand names?

*

Medical Devices

Provide the premarket 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one of these numbers has been assigned by FDA yet.

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.

General Annual Report

Part 1 Report Identification

| | | |
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| Note: | <i>This document will serve as a guide for all x-ray component manufacturers in complying with 21 CFR Subchapter J regarding Annual Reports.</i> | |
| Message: | <i>This Annual Report is submitted in accordance with 21 CFR 1002.13 for the period:</i> | |
| - | From July 1, 20 __ __ (Provide the last two digits of the year) | * |
| - | Through June 30, 20 __ __ (Provide the last two digits of the year) | * |

What voluntary standards related to radiation safety are your products designed to meet?

Item No Information Provided.

Part 2 Production Status

| | |
|--------------------|--|
| Production Status: | * <input type="checkbox"/> Products were manufactured during this period and the firm is still in business. |
| | <input type="checkbox"/> No products were manufactured during this period but the firm is still in business. |
| | <input type="checkbox"/> No products were manufactured during this period and the firm is now out of business. |
| | <input type="checkbox"/> Products were manufactured during this period but the firm is now out of business. |

Part 3 Current Production Tabulation

Part 4 Procedures for Quality Control and Testing

| | | |
|---------|--|---|
| Note: | <i>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 or Abbreviated Reports should be reviewed and updated. Compare your current procedures with those submitted in your Product Reports or Abbreviated Reports.</i> | |
| | The written procedures for assessing and controlling radiation safety have been reviewed. (These include prototype testing, incoming materials testing, assembly testing, retesting after repair, and service testing.) The procedures for maintaining quality control testing equipment have also been reviewed. All procedures are up-to-date, complete, and accurate. | * |
| | The initial report(s) provided to CDRH for each model family currently in production have been reviewed and the procedures contained within are up-to-date, complete, and accurate. | * |
| | Do your products undergo 100% Quality Assurance testing? | * |
| | What test sampling program do you follow? | |
| Details | | |

Part 5 Changes to Product Specifications

Have any product specifications that affect radiation safety changed ?

Identify models and their corresponding Accession Numbers where these have been reported. If you haven't reported them yet indicate when the reports will be submitted.

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| Item | No Information Provided. |
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Part 6 Correspondence Concerning Radiation Safety

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| Note: | <i>You are required by 21 CFR 1002.30 (a) (4) to maintain copies of all written 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.</i> |
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| Did your firm receive or send any communications regarding radiation safety of your products this year? | * |
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| Attach a copy of each written communication. |
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| Were reports of death/injury/malfunction reports investigated, root cause determined, trend analysis conducted? | |
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| Attach a copy of your firm's investigation(s). |
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| Indicate the number of written communications from dealers. | |
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| Attach a summary of communication(s) or a sample. |
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Part 7 Distribution Records

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| Provide address of the Production facility that maintains shipping records | * |
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| <i>Establishment Information:</i> | |
| Establishment Name | |
| Division Name | |
| FDA Establishment Identifier (FEI) | |
| Central File Number (CFN) | |
| Registration Number | |
| Owner/Operator Number | |
| D&B D-U-N-S Number | |
| Home Page | |
| <i>Physical Location:</i> | |
| Address | |
| Telephone Number | |
| Fax Number | |
| <i>Mailing Location:</i> | |
| Address | |
| Telephone Number | |

| | |
|---------------------|---|
| Fax Number | |
| <i>Information:</i> | <p><i>Please note: The FDA may request further records and test results in the future pursuant to Sec. 1002.31 Preservation and inspection of records.</i></p> <p><i>(c) Upon request of the Director, Center for Devices and Radiological Health, a manufacturer of products listed in table 1 of 1002.1 shall submit to the Director, copies of the records required to be maintained by paragraph (b) of 1002.30.</i></p> <p><i>[38 FR 28625, Oct. 15, 1973, as amended at 53 FR 11254, Apr. 6, 1988; 60 FR 48386, Sept. 19, 1995]</i></p> |
| <i>Stop:</i> | <p><i>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.</i></p> |