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

3639 Cabinet X-Ray Product 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

3639 Cabinet X-Ray Product 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 X-Ray Products

Product Type:	Product Examples:
Cabinet X-Ray Systems, Medical:	Counter Top Medical X-Ray Systems, In-Vitro X-Ray Systems
Cabinet X-Ray Systems, Non-Medical:	Industrial X-ray Systems, Explosive Detection Systems, Security X-Ray (includes Baggage X-Ray), Cargo X-Ray Systems
Personnel Security Systems:	Backscatter X-Ray System, Transmission X-Ray Security Systems
Cargo Non-Intrusive Security Systems:	Mobile Cargo Non-Intrusive Security Systems, Stationary Cargo Non-Intrusive Security Systems
Industrial X-Ray Systems (Excluding Cabinet):	Industrial X-Ray Bottle Fill Checker, Industrial X-Ray Thickness Gauge, Security X-Ray Systems
Analytical X-Ray Systems, Non-Medical:	Diffraction, Spectroscopy, Fluorescence Systems

Medical Diagnostic X-Ray Equipment:	Collimator, Radiographic System, Computed Tomography System, Tomographic System, Cradle, Film Changer, Image Intensified Fluoroscopic System, Radiographic Mobile/Portable System, Mammographic System, X-Ray Camera, Spot Film Device, X-Ray Beam Limiting Device, X-Ray Controls - Fluoroscopic, Radiographic, and Combination, High-Voltage Generator, Radiographic Screen, X-Ray Table, C-Arm Fluoroscopic X-Ray System, X-Ray Image Receptor
Dental Diagnostic X-Ray Equipment:	Radiographic Cone, Extraoral X-Ray Unit, Panoramic Intraoral Dental System, Intraoral X-Ray Source, Dental X-Ray Film Holder, Dental X-Ray Beam Aligner, Cephalometric Devices
Therapeutic X-Ray Systems:	Therapeutic X-Ray Generator, Collimator, Tube Housing Assembly
Veterinary X-Ray Systems:	Veterinary X-Ray Imaging Systems, Veterinary Diagnostic X-Ray Therapy
X-Ray Bone Densitometers:	X-Ray Bone Densitometers
X-Ray Film and Film Processing Materials:	Radiographic Film, Digital Image Storage Device, Radiographic Film/Cassette Programmer, Radiographic-Film Automatic Processor, Radiographic Film Dryer, Radiographic X-Ray Film Marking System

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]
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]

3639 Cabinet X-Ray Product Rpt (OMB 0910-0025)

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	
Item 2	
Item 3	
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	

3639 Cabinet X-Ray Product Rpt (OMB 0910-0025)

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

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

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: Part II: Product Description

Definitions

As used in this guide and 21 CFR 1020.40, the following definitions apply:

(1) Access panel means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open. and permits access to the interior of the cabinet.

(2) Aperture means any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x radiation.

(3) Cabinet x-ray system means an xray system with the x-ray tube installed in an enclosure (hereinafter termed cabinet) which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad. and bus terminals, and in similarfacilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

(4) Door means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet. For the purposes of paragraph (c)(4)(i) of this section, inflexible hardware rigidly affixed to the door shall be considered part of the door.

(5) Exposure means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.

(6) External surface of the cabinet x-ray system, including the high-voltage generator. doors, access panels, latches, control knobs, and other permanently mounted hardware and including the Plane across any aperture or port.

(7) Floor means the underside external surface of the cabinet.

(8) Ground fault means an accidental electrical grounding of an electrical conductor.

(9) Port means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.

(10) Primary beam means the x radiation emitted directly from the from the target and passing through the window of the x-ray tube.

(11) Safety interlock means a device which is intended to prevent the generation of x radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.

(12) X-ray system means an assemblage of components for the controlled generation of x-rays.

(13) X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

A. Model Identification

Note:	Sections A and B are to be completed for each new cabinet x-ray system being reported. Only Section A needs to be modified to report additional brand and/or selling model numbers of a system when all other manufacturing and testing information is the same as previously submitted.	
1.0	Product Type:	[L]
	If other, please provide a description of other product types:	
	[Multi-Line Plain Text]	

	Radiation Source:			[L]
	If other, please provide a description of other radiation source:			
	[Multi-Line Plain Text]			
2.0	Provide the name(s) and model number(s) of the product(s) manufactured or imported to which the cabinet x-ray standard is applicable. Do not report if the item is intended solely for export to countries whose applicable requirements are met.			
	Item			
	Item 1		Item 2	
3.0	If the reported model is sold under brand names, other than those of the manufacturer, please provide the brand name, model number, and name and address of each company under whose name the model is sold.			
	[Multi-Line Plain Text]			
4.0	For each model, list all uses or applications for which the model is intended or attach a file.			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
	Details	[HTML Text]		

B. Technical Information

Section B is to be completed for each new cabinet x-ray system being reported.

1.0 X-Ray Emission

1.0	X-Ray Emission:	
	Is the system designed to limit x-ray emission from the cabinet x-ray system to an exposure of 0.5 milliroentgen in any one hour or less at a point five centimeters outside the external surface?	[L]
	If no, what is the designed limit for x-ray emission and why?	
	[HTML Text]	

1.2 Characteristics

Item: 1 (could contain up to 20 items with 1 required)

Peak Tube Potential Adjustment (minimum):	
Peak Tube Potential Adjustment (maximum):	
Range of Tube Current Adjustment (minimum):	
Range of Tube Current Adjustment (maximum):	
Duty Cycle: (the amount of time x-rays can be generated or the number of x-ray pulses that can be generated in any hour, the limit of which is determined by the design of the x-ray system.)	
Range of Timer Adjustment (minimum):	

Range of Timer Adjustment (maximum):	
Total Filtration:	
If other, please identify the material:	
Beam Divergence:	
Beam Orientation:	[L]
If other, please describe:	
Beam Geometry:	[L]
If other, please describe:	
Provide any supporting details and attach file, if needed.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

1.3 Shielding

Describe the type, thickness, and location of shielding incorporated into the product to limit x-ray emission at the external surface. Provide illustrative drawings.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

1.4 Service Adjustments

1.4	Describe all service adjustments and procedures that affect radiation leakage.
	[HTML Text]

1.5 Doors

1.5	Are any doors included as part of the cabinet x-ray system?	[L]
1.5.1	Describe the intended purpose of each door.	
	[HTML Text]	

1.6 Access Panels

1.6	Are any access panels included as part of the cabinet x-ray system?	[L]
1.6.1	Describe the intended purpose of each access panel.	
	[HTML Text]	

2.0 X-Ray Controls and Indicators

2.0	X-Ray Controls and Indicators:

Provide a circuit diagram as an attachment.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

2.1 Control Device(s)

Describe the control device(s) for initiating and terminating x-ray generation and the physical locations(s). Include the method by which x-ray exposure interruption is accomplished (e.g., release of exposure switch, termination of preset time, etc.) and the method of resuming operation following x-ray generation interruption by the control device(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

2.2 Main Power Control

Describe the characteristics, operation, and location of the main power control.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

2.3 Key Activated Control

Describe the characteristics, operation, and location of the key activated control. Include a statement of the keycapture condition.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

2.4 X-Ray Exposure

2.4	Can an x-ray exposure greater than a period of one-half second be made with this cabinet x-ray system?	[L]
2.4.1	Are means provided to enable the operator to terminate the exposure prior to completion of the preset exposure period?	[L]
If there are no means provided to enable the operator to terminate the exposure prior to completion of the preset exposure period, please explain:		
[HTML Text]		
2.4.2	Are means provided to prevent an additional x-ray exposure from being made?	[L]
If there are no means provided to prevent an additional x-ray exposure from being made, please explain:		
[HTML Text]		

2.5 Devices Indicating X-Rays

Item: 1 (could contain up to 20 items with 1 required)

	Device:
	[HTML Text]
	Dimensions:
	[HTML Text]
	Location:
	[HTML Text]
	Labeling:
	[HTML Text]

2.6 Indicators

How long are indicators actuated when the x-ray generation period is less than one-half second?	

2.7 Component Failure

2.7	Does failure of any single component of the cabinet x-ray system cause failure of more than one x-ray production indicator?	[L]
If the failure of any single component of the cabinet x-ray system cause failure of more than one x-ray production indicators, please explain:		
[HTML Text]		

2.8 Other Means Indicating X-Rays

Item: 1 (could contain up to 20 items with 1 required)

	Device:
	[HTML Text]
	Dimensions:
	[HTML Text]
	Location:
	[HTML Text]
	Labeling:
	[HTML Text]

2.9 Cabinet X-Ray System Designed to Admit Humans

2.9	Is this cabinet x-ray system designed to admit humans?	[L]
Describe all exposure controls within the cabinet and include them in the diagram provided as the attachment in question 2.0.		

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
2.9.2	Is a method provided to reset, override, or bypass the controls described in 2.9.1 from outside the cabinet?	[L]
If there Is a method provided to reset, override, or bypass the controls described in 2.9.1 from outside the cabinet, please explain:		
[HTML Text]		
2.9.3	Describe the audible and visible warning signals provided in the cabinet.	
	[HTML Text]	
2.9.4	How long are the warning signals activated prior to the first initiation of x-ray generation after closing any door or access panel designed to admit humans?	
2.9.5	If any single component of the cabinet x-ray system fails, can x-rays be produced without either the audible or visible warning systems indicating x-ray production?	[L]
	Please explain:	
	[HTML Text]	
2.9.6	Does a visible signal within the cabinet remain activated for the entire period of x-ray generation?	[L]
	Please explain:	
	[HTML Text]	
Provide copies (or replicas) of all signs that are illuminated within the cabinet which explain the meanings of the warning devices. Indicate the sign location with pictures and/or drawings.		
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	

3.0 Safety Interlocks

3.0	Safety Interlocks:
Describe the interlock system and provide circuit diagrams showing interlocks and safety systems for each door and each access panel. Include the electrical and mechanical characteristics of each interlock device in the description.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

3.2 Provisions for Interlock Adjustment

3.2	Describe any provisions for adjustment of the interlocks.
	[HTML Text]

3.3 Door or Access Panel Movement

3.3	Indicate the amount of door or access panel movement in millimeters that is possible prior to actuation of the interlock.	

3.4 High Voltage Generator

3.4	Is any part of the circuit physically removed from the energy supply circuit to the high voltage generator when a door is opened?	[L]
	If no, explain further:	
	[HTML Text]	

3.5 Disconnect

3.5	Is such disconnect dependent upon any moving part other than the door?	[L]
	Please explain:	
	[HTML Text]	
Provide drawings, sketches or engineering drawings to clearly illustrate operation of the door's interlock.		
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	

3.6 Resuming X-Ray Production

3.6	Describe how x-ray production can be resumed after any safety interlock has been activated.
	[HTML Text]

3.7 Component Failure

3.7	Are the required interlock circuits designed to insure that the failure of one component does not result in the failure of more than one required safety interlock?	[L]
	If no, explain further:	
	[HTML Text]	

3.8 Circuit Analysis

Provide a circuit analysis describing the effects of critical component failure on the interlock system.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

4.0 Warning, Certification, and Identification Labels

4.0	Warning, Certification, and Identification Labels:		
4.1	Provide an exact replica of all labels which show any of the following: (a) The certification statement (b) The name and address of the manufacturer (or individual or company under whose name it is sold) (c) The date and place of manufacturer (these should be spelled out in full) (d) The model number and serial number		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
4.1.2	Is this labeling permanently affixed to or inscribed on the system and legible and accessible to view when the system is fully assembled for use?		[L]
	Please explain:		
	[HTML Text]		

4.2 Warning Label

4.2	Is a warning label affixed at the location of any control which can be used to indicate x-ray generation?	[L]
	Please explain:	
	[HTML Text]	
4.2.1	Is this warning label permanently affixed to or inscribed at the location of the control, legible and accessible to view?	[L]
	Please explain:	
	[HTML Text]	

Provide a copy of the warning label affixed at the control(s) as an attachment.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

4.3 Other Warning Labels

Describe all other warning labels and their locations and include copies of the labels as attachments.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

5.0 Ports and Apertures

5.0	Ports and Apertures: Complete this section to describe the ports and apertures of the Cabinet X-Ray System.	
–	Are there any ports?	[L]

–	Are there any apertures?	[L]

5.1/2 Port Dimensions, Shape & Primary Beam Distance

Item: 1 (could contain up to 20 items with 1 required)

5.1	Port Number:	[L]
	Port Shape:	[L]
	Dimensions (Length/Width):	
	[HTML Text]	
	Dimensions-Other:	
	[HTML Text]	
5.2	Shortest Distance from the Primary Beam to Port Location:	
	[Multi-Line Plain Text]	

5.3 Means for Preventing Insertion

Describe all means specifically provided as part of the cabinet x-ray system to prevent insertion of any part of the body through a port into primary beam.
[HTML Text]

5.4/5/6 Apertures

Item: 1 (could contain up to 20 items with 1 required)

5.4	Aperture Number:	[L]
	Aperture Shape:	[L]
	Dimensions (Length/Width):	
	[HTML Text]	
	Dimensions - Other:	
	[HTML Text]	
5.5	Purpose:	
	[HTML Text]	
5.6	Means for Preventing Insertion:	
	[HTML Text]	

6.0 Floors of the Cabinet X-Ray System

6.0	Floors of the Cabinet X-Ray Systems:	
6.1	Does the design of the cabinet x-ray system depend upon the purchaser providing a support surface that becomes the floor of the system when installed?	[L]

6.2	Describe these installation requirements.	
	[HTML Text]	
6.3	Does the installation described in 6.2 constitute a permanent installation?	[L]

7.0 Ground Fault

7.0	Ground Fault:	
7.1	Can a ground fault result in generation of x-rays?	[L]
	Please explain:	
	[HTML Text]	
Provide a ground fault analysis.		
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	

8.0/9.0 User Information

Attach a copy of the information packet on safety, installation, and maintenance procedures, that is supplied to users as required by 1020.40 (c) (9) of the Standard for each model.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Provide copies of any additional operating instructions, published product technical data sheets, specifications sheets, applications notes, or other published material relating to product specifications, applications, radiation emission or radiation safety as an attachment. Also include a picture or drawing of each product. Promotional sales literature may be included if appropriate.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

10.0 Systems for Screening Hand Carried Items

10.	Systems designed primarily for screening of hand carried items in public facilities:	
Is this product intended for security screening hand carried items in a public area?		[L]
10.1	Describe the means provided to require operator presence at the control area during generation of x radiation.	
	[HTML Text]	
10.2	Do the means described in 10.1 permit surveillance of all ports and doors?	[L]
10.2.1	If no, explain:	
	[Multi-Line Plain Text]	

10.3	Do the means described in 10.1 permit the operator to terminate x-ray generation at any time?	[L]
10.3.1	If no, explain:	
	[Multi-Line Plain Text]	

Section: Part III: Product Testing

A. Direct Testing

1.0	Message:	Briefly explain the concept of each direct x-ray measurement test that is done to verify compliance with the emission limit of the standard. Include in this explanation a copy of the test method(s).
The test described shall include, but not be limited to: (a) Testing to evaluate effects of scattering object and placement, (b) Testing to evaluate x-ray emission prior to interruption of x-ray generation through operation of any required safety interlock, (c) Testing to evaluate the effects on shielding from shipping, transporting or moving the cabinet system, (d) Testing to evaluate line voltage fluctuations and critical component deterioration, (e) Testing to evaluate effects ofservice adjustments and procedures, (f) Final acceptance testing.		
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	

2.0/3.0 Stage for Compliance Testing

Item: 1 (could contain up to 20 items with 1 required)

2.0	Test:
	[HTML Text]
	Stage:
	[HTML Text]
2.1	Percentage or Number:
	[HTML Text]
3.0	Limit(s):
	[HTML Text]

4.0 Procedure for Maximum Radiation Intensity

4.0	Provide the procedure used to determine the location(s) of maximum radiation intensity.
	[Multi-Line Plain Text]

5.0 Rate of Scan

If the direct test utilizes a radiation measurement instrument that scans the cabinet x-ray system, what is the rate of

scan (in cm/sec)?
[Multi-Line Plain Text]

6.0 Maximum External Surface X-Ray Exposure

Item: 1 (could contain up to 10 items with 1 required)

Tube Potential:	
Current:	
Beam Orientation:	
[HTML Text]	
Scatter Object:	
Scatter Object Position:	
[HTML Text]	

7.0 Distance

7.0	State the distance (in cm) between the external surface and the radiation measurement instrument.	

B. Radiation Instrumentation Used for Testing

Item: 1 (could contain up to 20 items with 1 required)

Note:	Complete the following for each instrument used for radiation measurement.	
Manufacturer:		
Model Number:		
Instrument Type:		
Precision of the Instrument:		
Accuracy of the Instrument:		
Response Time:		
Identify the energy dependence:		
Identify the angular response:		
Identify the exposure rate dependence:		
Identify the range:		
Identify the effective measurement area:		
Interval of time between calibration:		
Method of calibration, including accuracy and source of calibration:		
[HTML Text]		

Verification procedure used to assure proper day to day operation of instrumentation:
[HTML Text]

C. Indirect Testing

If the test method used to monitor compliance with the emission limit performance requirement is other than the direct measurement described in 2.0, describe the method and attach a copy of the test procedure. In addition, provide the basis for the indirect method (any method other than a radiation exposure measurement); explain why it is an accurate indication of compliance with the emission requirements, and submit the technical data which supports this conclusion.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

2.0 Indirect Test Information

Item: 1 (could contain up to 20 items with 1 required)

Note:	For each indirect test attachment provided in 1.0, answer the following questions.
Identify the test:	
Identify the purpose of the test:	
[HTML Text]	
Specify the system stage (the design, production or installation) that the test is made:	
[HTML Text]	
Identify the rejection limit of the product (for acceptance test):	
Specify who conducts test:	
Identify the number of units tested (for acceptance test):	
Identify the proportion of productionoutput (for acceptance test):	

D. Sampling

Item: 1 (could contain up to 20 items with 1 required)

Note:	For each production line test performed for the purpose of determining product acceptability on less than 100 percent of the output, answer the following questions:
Specify the sampling plan used and provide the parameters of the plan: (ie., lot size, sample size, acceptance criteria, etc.). If the sampling plan is obtained from a set of standard sampling tables, indicate the source and type of plan. If the sampling plan was designed specifically for this application, indicate the requirements which were established for the plan and the assumptions used, and whether acceptance criteria is based upon attributes or variables.	
[Multi-Line Plain Text]	
Describe the procedure used for selecting the sample and indicate how randomness is assured.	
[Multi-Line Plain Text]	

For each test or inspection specify the quality characteristics and the specification limit(s) by which acceptable quality is distinguished from unacceptable.
[Multi-Line Plain Text]
Provide the operating characteristic (O.C.) curve of the sampling plan.
[Multi-Line Plain Text]
Specify the distribution assumed and the procedures used for computing acceptance probabilities for the O.C. curve of the sampling plan.
[Multi-Line Plain Text]
Specify the producer's and consumer's risk of the sampling plan and indicate at what quality level each applies.
[HTML Text]
Describe the action taken if the sampling plan leads to a rejection decision.
[HTML Text]

E. Critical Component Testing

1.	Message:	Describe all applicable quality control and testing procedures for critical components conducted prior to installation of the components into your product which you consider a necessary and vital part of your testing program to assure compliance with the Federal Performance Standard. This shall include, but not be limited to, incoming inspection and/or sub-assembly testing of such items as x-ray sources, pressure pads, interlock switches, relays and shielding components.
Where applicable, the description should include: (a) Vendor qualification requirements. (b) Incoming inspection procedures, accept/reject criteria, and lot and sample size if not 100 percent tested. If 100 percent tested, so state. (c) Corrective action following unit or lot rejection.		
File Attachment		[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details		[HTML Text]

2.	Message:	Describe all applicable life testing procedures on the x-ray system or on those critical components incorporated into the x-ray system which you consider a necessary and vital part of your testing program to assure compliance with the Federal Performance Standard for the life of the product.
This description shall include, but not be limited to the following information: (a) The State(s) in the development or production of a specific model or design when life testing is conducted on the system or critical component. (b) A copy of the life testing protocol, including the test method used. If previously addressed, reference may be made to your response to other appropriate sections of your report. (c) A copy of the life testing protocol, including the test method used. If previously addressed, reference may be made to your response to other appropriate sections of your report.		
File Attachment		[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Details	[HTML Text]

F. Test Results

1.0	Note:	Attach the results of Quality Control testing to date as follows:	
1.1	Attach the numerical results of the direct radiation tests upon which you base your certification, including: a) date of the test, b) state of development, production or installation at which the test was made.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
1.2	Attach a summary of the numerical results of direct and/or indirect quality control tests of production line units.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
1.3	Where sufficient data are available, attach the mean, range, and standard deviation of each type of measurement. If these values are unavailable, other representative statistics or expressions or results may be reported.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
2.0	Attach a summary of results of tests performed to determine "worst case" conditions for x-ray emission at the external surface of the cabinet x-ray system.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
3.0	Attach a summary of the results of critical component testing.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
4.0	Attach a summary of the results of critical component or system life testing.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
5.0	Describe changes in critical components occuring with time that affect the performance of the unit with respect to applicable performance requirements.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	

3639 Cabinet X-Ray Product Rpt (OMB 0910-0025)

Note:	FDA Form 3639 Cabinet X-Ray Products Product Report (10/31/2013)