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? **!***	
Cabinet X-Ray Products	
What Type of Product is this Annual Report about?	
What Laser Light Show Document are you filing?	
What Type of Correspondence is this?	
What Type of Product is this Variance Request about?	

Manufacturer Data

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: *	
Establishment Information:	
Establishment Name	
Division Name	
Home Page	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

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: *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	

Mailing Location:	
Address	
Telephone Number	
Fax Number	

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: *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

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: *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	

Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	
Comments:	

Internal Reference Number:	

Parent Establishment

Is there a parent establishment? *	

Select the Parent Establishment and Contact from the Contact Address book:	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

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? *	

Importer

Additional Manufacturing Locations

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

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.

Category	
Product Code	
Performance Standard	

If Other, provide a category name for this specific product.

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? *	
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?	
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? *	
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

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? *	
You may provide an explanation and/or attach a document here:	
Details	

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? *	
A request for an exemption from notification to purchasers (see 21 CFR 1003.21 and 1003.30)? *	
Corrective action plans you intend to implement to correct noncompliances or defects discovered in past or current production? *	
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? *	
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:	
Details	

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)? *	
Exemption for products for government use from reporting and recordkeeping (21 CFR 1002.51)? *	
Special exemption of products from reporting and/or recordkeeping (21 CFR 1002.50)? *	
Request for approval of alternate labeling? *	
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?		
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.

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: *	
	If other, please provide a description of other product types:	
	Radiation Source: *	
	If other, please provide a description of other radiation source:	
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	Model Name	Family Name	Brand Name

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.
4.0	For each model, list all uses or applications for which the model is intended or attach a file.
	Details

B. Technical Information

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? *
	If no, what is the designed limit for x-ray emission and why?

1.2 Characteristics

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. *	
Details	

1.4 Service Adjustments

1.4	Describe all service adjustments and procedures that affect radiation leakage. *

1.5 Doors

1.5	Are any doors included as part of the cabinet x-ray system? *	
1.5.1	Describe the intended purpose of each door.	

1.6 Access Panels

1.6	Are any access panels included as part of the cabinet x-ray system? *	
1.6.1	Describe the intended purpose of each access panel.	

2.0 X-Ray Controls and Indicators

2.0	**X-Ray Controls and Indicators:**
Provide a circuit diagram as an attachment.	
Details	

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).	
Details	

2.2 Main Power Control

Describe the characteristics, operation, and location of the main power control.	
Details	

2.3 Key Activated Control

Describe the characteristics, operation, and location of the key activated control. Include a statement of the keycapture condition.	
Details	

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? *	
2.4.1	Are means provided to enable the operator to terminate the exposure prior to completion of the preset exposure period?	
If there are no means provided to enable the operator to terminate the exposure prior to completion of the preset exposure period, please explain:		
2.4.2	Are means provided to prevent an additional x-ray exposure from being made?	
If there are no means provided to prevent an additional x-ray exposure from being made, please explain:		

2.5 Devices Indicating X-Rays

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? *	
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:		

2.8 Other Means Indicating X-Rays

2.9 Cabinet X-Ray System Designed to Admit Humans

2.9	Is this cabinet x-ray system designed to admit humans? *	

Describe all exposure controls within the cabinet and include them in the diagram provided as the attachment in question 2.0.		
Details		
2.9.2	Is a method provided to reset, override, or bypass the controls described in 2.9.1 from outside the cabinet?	
If there Is a method provided to reset, override, or bypass the controls described in 2.9.1 from outside the cabinet, please explain:		
2.9.3	Describe the audible and visible warning signals provided in the cabinet.	
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?	
	Please explain:	
2.9.6	Does a visible signal within the cabinet remain activated for the entire period of x-ray generation?	
	Please explain:	
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.		
Details		

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.	
Details	

3.2 Provisions for Interlock Adjustment

3.2	Describe any provisions for adjustment of the interlocks.

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?	
	If no, explain further:	

3.5 Disconnect

3.5	Is such disconnect dependent upon any moving part other than the door? *	
	Please explain:	

Provide drawings, sketches or engineering drawings to clearly illustrate operation of the door's interlock.	
Details	

3.6 Resuming X-Ray Production

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

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?	
	If no, explain further:	

3.8 Circuit Analysis

Provide a circuit analysis describing the effects of critical component failure on the interlock system.	
Details	

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	
	Details	
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?	
	Please explain:	

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?	
	Please explain:	
4.2.1	Is this warning label permanently affixed to or inscribed at the location of the control, legible and accessible to view?	
	Please explain:	
Provide a copy of the warning label affixed at the control(s) as an attachment.		
Details		

4.3 Other Warning Labels

Describe all other warning labels and their locations and include copies of the labels as attachments.	
Details	

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?	
-	Are there any apertures?	

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? *	
6.2	Describe these installation requirements.	
6.3	Does the installation described in 6.2 constitute a permanent installation?	

7.0 Ground Fault

7.0	**Ground Fault:**

7.1	Can a ground fault result in generation of x-rays? *	
	Please explain:	
Provide a ground fault analysis.		
Details		

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.	
Details	
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.	
Details	

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? *		
10.1	Describe the means provided to require operator presence at the control area during generation of x radiation.	
10.2	Do the means described in 10.1 permit surveillance of all ports and doors?	
10.2.1	If no, explain:	
10.3	Do the means described in 10.1 permit the operator to terminate x-ray generation at any time?	
10.3.1	If no, explain:	

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.

Details	

2.0/3.0 Stage for Compliance Testing

4.0 Procedure for Maximum Radiation Intensity

4.0	Provide the procedure used to determine the location(s) of maximum radiation intensity.

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)?

6.0 Maximum External Surface X-Ray Exposure

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

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.

Details	

2.0 Indirect Test Information

D. Sampling

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.

Details	

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.

Details	

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.	
	Details	
1.2	Attach a summary of the numerical results of direct and/or indirect quality control tests of production line units.	
	Details	

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.	
	Details	
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.	
	Details	
3.0	Attach a summary of the results of critical component testing.	
	Details	
4.0	Attach a summary of the results of critical component or system life testing.	
	Details	
5.0	Describe changes in critical components occuring with time that affect the performance of the unit with respect to applicable performance requirements.	
	Details	