Submission Report

Section: Main Menu

Welcome

Welcome to the CDRH Electronic Submissions Software (CeSub)

This software application is intended to automate the current paper submission process. This software contains a number of data capturing tools and helpful dialog boxes to reduce redundant responses for you, and to allow us to capture data in a more useful, structured format. These benefits will enable CDRH to improve our review process and reduce lengthy review times.

For your convenience, an email account has been established to support any questions that you may have regarding the use of this software. Please email any questions or comments to the CeSub team at: **cdrhesub@cdrh.fda.gov.** Please be sure to include your name, company name and contact information in the email.

Thank you again for using our electronic product reporting software. We look forward to hearing from you soon.

What type of product is this submission referring to? *
Radiation Emitting Product (OMB No. 0910-0025; Expiration Date: December 31, 2006)

Welcome (Cont.)

Department of Health and Human Services
Food and Drug Administration

Form Approved:
OMB Number 0910-0025
Expiration Date: December 31, 2006

Section: eRadHealth Menu

Role

What is your role? *	Manufacturer

Submission Information

What Type of Submission is this? (Supplements should be submitted selecting the same document type as the original report.) *
Radiation Safety Report (Product Report)
What Type of Product is this Annual Report about?
What Type of Correspondence is this?
What Type of Product is this Radiation Safety Report about? *
Cabinet X-Ray Products
What Type of Product is this Variance Request about?
What Laser Light Show Documents are you filing?

Section: Manufacturer Data

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 CDRH Electronic Submission (CeSub) software is the next version of the application the CDRH is developing 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.

We have already received many electronic submissions and are looking forward to receiving more in the future. With this new release of the software we have updated our procedures for packaging a submission to make this a smoother process for all. All electronic reports (your new CD-ROMs) and any other documents you are submitting in hard copy because they cannot be provided in an acceptable electronic format must be mailed to CDRH. A signed hard copy of the submittal letter generated by the submission software, should be printed out and included with your electronic submission. This printed documentation will provide the Document Control Room with enough information to log the submission. The electronic submissions should be sent directly to the Document Control room, which is the same process for the standard paper

submission.

The submission must be addressed to:

Electronic Product Document Control (HFZ-309), Attn: CeSub Team, Center for Devices and Radiological Health, 2094 Gaither Road, Rockville, MD 20850

After sending your submission to the Document Control Room, please send an email to the cdrhesub@cdrh.fda.gov email account so we will know that your submission is forthcoming. Please remember that all correspondence concerning your submission MUST be sent to the Electronic Product Document Control (HFZ-309), at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official notification submission. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. You should also be familiar with the regulatory requirements for radiological products at www.fda.gov/cdrh/comp/eprc.html and medical devices available at Device Advice www.fda.gov/cdrh/devadvice/.

If you have specific questions regarding the software, please contact the CeSub team by email at: **cdrhesub@cdrh.fda.gov**.

Thank you for using our electronic product reporting software. Please communicate your comments and criticisms to the CeSub team as often as you like.

Thank you for your continued support of the CDRH eSubmission Pilot Program.

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.

We are providing our new software applications for the old reporting forms upon request during this beta testing period of development in Spring, 2005. Other regulatory information is still available on the Internet under http://www.fda.gov/cdrh/comp/eprc.html. 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 the address below.

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).

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.

Accidental Radiation Occurrences

An accidental radiation occurrence means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product

radiation as a result of the manufacturing, testing, or use of an electronic product.

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 Act

Sec 536 [21 U.S.C. 360mm](d) Designation of agent for purposes of service

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 effective shielding or other controls would emit) such radiation.

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:

Food and Drug Administration CDRH (HFZ-240)
1350 Piccard Drive Rockville, MD 20850

Please DO NOT RETURN this application to this address.

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

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.*

Copy from the establishment address book *	
Establishment Information:	
Establishment Name	
Division Name	
Home Page	
Physical Location:	
Address	
Telephone Number	

Fax Number	
Mailing Location:	
Address	

Responsible Individual

Note:	*The responsible individual is the highest level and most responsible individual affiliated with this establishment.*

Copy 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	

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.*

Copy 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	

Electronic Signature

Electronic signature (not available in this release of the software)	
File Attachment	

Report Submitter

Note:	*The submittermaybe a consulting individual or firm providing assistance in report preparation and maintenance. All documents prepared by the submitter must have the manufacturer's reporting official signature for authenticity of submitted documentation.*
Copy from contact address list *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Parent Establishment

Is there a parent establishment? *	
Copy 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	

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? *	

Section: Product Data

Product Type Reported

What product type is being reported? *Please note that this list of 66 product types are grouped according to their radiation type and applicable regulations (e.g., laser products, microwave products, ionizing products, etc.) *
What is the product code? * If you know the three letter code, enter it in the space provided. If you do not, - Click the filter search icon (next to the trash can). You will see a product code filter dialog box. -Enter a keyword to search the database. You will be provided a list of product codes from which to choose. (If you are not finding the correct product, try other words and/or variations of the keywords.) - Select the best match to your product. - The remaining fields will be filled in for you when you select your product code. - If you do not find the code that you are looking for, use RZZ (Other)

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

If Other, please identify the specific product type.

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 report for which this is a supplement (Do not enter any Device Premarket Application or Notification document number here, such as PMAs, 510(k)s, IDEs, etc.):	
Are you requesting a new variance, a renewal, extension or amendment to a previous variance? *	
If you are requesting a renewal, extension, or amendment, please provide the variance number that was issued by CDRH.	

Error:	*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, Other" as your Type of Submission in the Submission Information Screen. If you select "Variance Request, Other" you must select the product for which you are requesting a variance at the end of the screen.*

Noncompliances or Defects

Does this document or any of its attachments contain:	
A self-declaration or notification of noncompliance or defect? *	
Provide an explanation:	

Responses to Noncompliances or Defects

Does this documentor any of its attachments contain:	
A refutation of noncompliances? *	
A request for an exemption from notification and corrective action? *	
Information on corrective actions you may be conducting? *	
A description of any design changes for future production? *	
Provide an explanation:	

Exemption Requests

Does this document or any of its attachments contain:	
Exemption of a product for government use from a standard (1010.5)? *	
Exemption for products for government use from reporting and recordkeeping (1002.51)? *	
Special exemption of products from reporting and/or recordkeeping (1002.50)? *	
Request for approval of alternate labeling? *	
Application for alternate test procedures (1010.13)? *	
Provide an explanation:	
Attach any necessary files.	
File Attachment	

Variance Requests

Message:	*Click the "Add" button to select the desired requirement from which you are seeking a variance.*
This submission includes an application for a variance from certain requirements. *	
Item	
Provide an explanation and attach supporting files, if necessary. Click on the Add... button below to attach files.	
Details	

File Attachment	
Error:	*In addition to the electronic copy of this submission, please be sure to submit one hard-copy of the signed variance request document to the following address:* *Division of Dockets Management (HFA-305)* *Food and Drug Administration* *Rm 1061, 5630 Fishers Lane* *Rockville, MD 20852*

Responses to Communications from FDA

Does this document or any of its attachments contain:		
A response to an inspection?	*	
What was the date of the inspection?		
A response to a warning letter from the Food and Drug Administration (FDA)?	*	
What was the date of the Warning Letter?		
A response to a report review inquiry from the Center for Devices and Radiological Health (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:		

Use Environment

Who are the intended users?
[ ] Children and/or Youth [ ] Consumers [ ] Elderly [ ] Employees/Workers [ ] Engineers or Scientists [ ] General Public [ ] Medical Staff [ ] Patients [ ] Other
What is the use environment?
[ ] Consumer Home [ ] Hospital or Clinic [ ] Industrial Facility or Factory [ ] Office/Warehouse/Store [ ] Outdoors [ ] Public Arena [ ] Schools, Gymnasium/Auditorium [ ] Lab or Research Facility [ ] Transportation Facility [ ] Other
Please select the best match for the affected population:
[ ] Children and/or Youth [ ] Consumers [ ] Elderly [ ] Employees/Workers [ ] Engineers or Scientists

[ ] General Public
[ ] Medical Staff
[ ] Patients
[ ] Other

Additional Information

Is there any other relevant information or additional comments that would help expedite the review of this submission? Click the Add... button below to attach any supporting files.	
File Attachment	
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 assigned yet, provide an explanation and submit it as soon as you receive such a filing number.

Electromagnetic Compatibility and Interference

Electromagnetic Compatibility with other Products
Provide description of analysis and indicate any shielding you have for your product to protect other products from EMI:

Susceptibility to EMI from other Products
Provide description of analysis and indicate any protective shielding your product has to protect it from EMI:

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.

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:**	
1.1	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?	

1.3 Shielding

1.3	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	

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.	
	File Attachment	

2.1 Control Device(s)

2.1	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	

2.2 Main Power Control

2.2	Describe the characteristics, operation, and location of the main power control.	
	File Attachment	

2.3 Key Activated Control

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

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:		

2.6 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:		

2.9 Cabinet X-Ray System Designed to Admit Humans

2.9	Is this cabinet x-ray system designed to admit humans? *	
2.9.1	Describe all exposure controls within the cabinet and include them in the diagram provided as the attachment in question 2.0.	
	File Attachment	
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:	
2.9.7	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	

3.0 Safety Interlocks

3.0	**Safety Interlocks:**
3.1	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

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. *	
	File Attachment	

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

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

	File Attachment	

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	
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 initiate 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:	
4.2.2	Provide a copy of the warning label affixed at the control(s) as an attachment.	
	File Attachment	

4.3 Other Warning Labels

4.3	Describe all other warning labels and their locations and include copies of the labels as attachments.	
	File Attachment	

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.**

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.

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:	
7.2	Provide a ground fault analysis as an attachment.	
	File Attachment	

8.0/9.0 User Information

8.0	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	
9.0	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	

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:	

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	

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)?

7.0 Distance

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

C. Indirect Testing

1.0	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	

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	
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	

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	
1.2	Attach a summary of the numerical results of direct and/or indirect quality control tests of production line units.	
	File Attachment	
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	
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	
3.0	Attach a summary of the results of critical component testing.	
	File Attachment	
4.0	Attach a summary of the results of critical component or system life testing.	
	File Attachment	
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	

Error:	*You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.*
Message:	*Form FDA 3639 Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21-CFR 1020.40 (03/06)*