Section:	eRadHealth Menu
Role	
What is your r	role?
Note:	If you are acting as an agent of the actual manufacturer, please select your role, for example, Importer or Consultant. Later in the report, under Manufacturer Data, you will be prompted to enter both manufacturer and submitter information.
Submissio	n Information
FDA or Sta	ate Inspector
Abbreviate	ed Report Applicability
OEM Lase	er Applicability
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 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, when you submit through it you will receive your acknowledgement email message with Accession Number within minutes!

Information about the FDA Electronic Submissions Gateway can be found at <a href="www.fda.gov/esg">www.fda.gov/esg</a>. 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.

You should be familiar with the regulatory requirements for radiological products at <a href="www.fda.gov/cdrh/radhealth/">www.fda.gov/cdrh/radhealth/</a> and medical devices available at <a href="www.fda.gov/cdrh/devadvice/">www.fda.gov/cdrh/devadvice/</a>. If you have specific questions about the regulations, please contact us at: <a href="DSMICA@fda.hhs.gov">DSMICA@fda.hhs.gov</a>.

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).

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 <a href="https://www.fda.gov/cdrh/radhealth/">www.fda.gov/cdrh/radhealth/</a>. 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).

**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 21 CFR1000-1050 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 ActSec 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 26 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

"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

#### Information:

This general 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. You can check for missing data using the "Missing Data" report from the "Output" menu.

If you are acting as an agent or consultant for another firm who is certifying the product (or laser light show), please enter the certifying manufacturer and list yourself as the report submitter, below.

#### 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

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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.

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		

# 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	Occupation Title	
Email Address	Email Address	
Establishment Inform	ation:	
Establishment Name		
Division Name		
Physical Location:		
Address		
Telephone Number		
Fax Number		
Mailing Location:		
Address		
Manufacturer's F	Report	ting Official
Note:	and qu	s the person at the manufacturing facility that is knowledgeable and responsible for addressing all aspects of the testing uality control procedures for certification as reported to FDA in the product report. Documentation of changes intesting uality control procedures submitted to FDA must be signed by this individual.
Select the Reporting	Official f	from Contact Address book:
Contact Information:		
Contact Name		
Occupation Title		
Email Address		
Establishment Inform	ation:	
Establishment Name		
Division Name		
Physical Location:		
Address		
Telephone Number		
Fax Number		
Mailing Location:		
Address		
Report Submitte	r	
	T'	
Note:	docum	ubmitter maybe a consulting individual or firm providing assistance in report preparation and maintenance. All nents prepared by the submitter must have the manufacturer's reporting official signature for authenticity of submitted

doc	rumentation.				
Select the Submitter from	the Contact Address book:				
Contact Information:	Contact Information:				
Contact Name					
Occupation Title					
Email Address					
Establishment Information					
Establishment Name					
Division Name					
Physical Location:					
Address					
Telephone Number					
Fax Number					
Mailing Location:					
Address					
Comments:					
Internal Reference Number	or:				
Parent Establishme	nt				
Is there a parent establish	ment?				
	•				
Select the Parent Establish	hment 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				
Manufacturer Designated United States Agent				
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 State	es agen	t that has been designated by the manufacturer?	[L]	
Written Agreeme	ent			
Item: 1 (could conta	in up to	10 items with none required)		
Note:	If any	of the required responses below do not apply to your designated agent, enter 'NOT APF	PLICABLE' or 'NA.'	
Select the Designated	d Agent	from the Contact Address book:		
Contact Information:				
Contact Name				
Occupation Title				
Email Address	Email Address			
Address				
Establishment Name				
Division Name				
Address				
Telephone Number	Telephone Number			
Fax Number				
Attach a copy of writte	Attach a copy of written agreement with the designated U.S. agent:			
[Multi-Line Plain Text]				
File Attachment				
Importer				
Item: 1 (could contain up to 10 items with none required)				
Select the Importer from the Contact Address book:				
Contact Information:				
Contact Name				
Occupation Title				
Email Address				
1			l l	

Establishment Information:				
Establishment Name				
Division Name				
Physical Location:				
Address				
Telephone Number				
Fax Number				
Mailing Location:				
Address				
Additional Manufactu	ring Locations			
Item: 1 (could contain up t	o 100 items with none required)			
•				
Producodes proces	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 Add	lress from the Establishment Address book:			
Establishment Information:				
Establishment Name	stablishment Name			
Division Name				
Home Page				
Physical Location:				
Address				
Telephone Number				
Fax Number				
Mailing Location:				
Address	Address			
Comments:	Comments:			
Code used on identification	abels:			
	<b>'</b>			
Section: Product	Section: Product Data			
Product and Model Id	antification			

At this time we are only accepting electronic versions of reporting guides contained within this software. Other reporting Note: guides that are not yet electronic are available for downloading from http://www.fda.gov/cdrh/comp/eprc.html. Product Type Reported Report Information Is this submission a supplement to an Annual Report submitted previously for the same reporting year? [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, Please verify that your accession number matches the report type that is being filed. The third character of your accession number must correspond with its associated report type as shown in the table below: Third Character: **Report Type Description: Initial Product Report** Model Change Product Report 3 Annual Report 8 Abbreviated Report Variance Request Α R Laser OEM Registration and Listing Report [L] 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. If you are requesting a new variance, renewal, extension, or amendment, you must file a Variance Request separate from this Stop: 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. Special Considerations Note: Check all items in this section that may apply to this submission. Noncompliances or Defects Does this document or any of its attachments contain: [L] A self-declaration or notification of noncompliance or defect? Provide an explanation:

[Multi-Line Plain Text]

# Responses to Noncompliances or Defects

Does this document or any of its attachments contain and of these responses concerning noncompliances?			
A refutation of noncompliances?			
A request for an exemption from notification?			
Corrective action plans you may be conducting?			
A description of any design changes that correct noncompliances for future production?			
Provide an explanation:			
[Multi-Line Plain Text]			

# **Exemption Requests**

Does this document or any of its attachments contain:			
Exemption of a product for Q	exemption of a product for government use from a standard (1010.5)?		
Exemption for products for Q	Exemption for products for government use from reporting and recordkeeping (1002.51)?		
Special exemption of produc	Special exemption of products from reporting and/or recordkeeping (1002.50)?		
Request for approval of alte	Request for approval of alternate labeling?		
Application for alternate test procedures (1010.13)? [L]			
Provide an explanation:			
[Multi-Line Plain Text]			
Attach any necessary files.	Attach any necessary files.		
[Multi-Line Plain Text]	[Multi-Line Plain Text]		
[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			

# Variance Requests

Message:	Click the plus sign to list the requirements from which you are requesting a variance.				
This submission inc	This submission includes an application for a variance from certain requirements.				
Item 1					
Item 2					
Item 3	tem 3				
Provide an explana	Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.				
Details [HTML Text]		HTML Text]			

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
The el the Me  U.S. F Cente. Attn: e Docum 10903 Silver Additio Food a Divisio 5630 I	I Variance requests, two submissions must be made to the FDA.  Idectronic version should be submitted following the Packaging Files for Submission instructions located under Output in enu bar, and explained in subsection 4.3 of the User Manual. If sending a CD & submittal letter, please mail to:  Food and Drug Administration refor Devices and Radiological Health essubmitter Team ment Mail Center - WO66-0609  8 New Hampshire Avenue Spring, MD 20993-0002  Fonally, a paper version (hard-copy) of the signed Variance request document should be submitted to:  and Drug Administration on of Dockets Management (HFA-305)  Fishers Lane, Room 1061  ville, MD 20857

# Responses to Communications from FDA

Does this document or any of its attachments contain:			
A response to an inspection?	[L]		
What was the date of the inspection?	[Date]		
A response to a warning letter from the Food and Drug Administration (FDA)?	[L]		
What was the date of the Warning Letter?	[Date]		
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)?	[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

Is there any other relevant in attach any supporting files.	formation or additional comments that would help expedite the review of this submission? Click the plus sign below to
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	o 20 items with 1 required)		
a			
Give the name and address	of the manufacturer:		
Establishment Information:			
Establishment Name			
Division Name			
Email Address			
Address			
Address			
Telephone Number			
Fax Number			
Give the firm establishment r	egistration number of the manufacturer listed above (if known):		
	odel designations in the following table by clicking on the Add button. If	you prefer to attach a file, please click on the	
Item 1			
Item 2			
Item 3			
List of Brand Names and/or I	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 Man	ufacturer (OEM) accession number (if known):		
Explain how the brand name	s and model designations correspond with your own brand names and	model designations:	
[Multi-Line Plain Text]			
Medical Devices			
Provide the premarket 510(k FDA yet.	), IDE, HDE, PDP, or PMA filing numbers related to this medical produc	t, if one of these numbers has been assigned by	
[Multi-Line Plain Text]			
If it has not been assigned ye	et, provide an explanation and submit it as soon as you receive such a f	iling number.	
[Multi-Line Plain Text]			

Note: See www.fda.gov/cdrh for more information onmedical device premarket clearance procedures.

Document Key: Specialized Response content is defined within straight brackets []; Special code: [L] List of Values.

OMB No. 0910-0025; Exp. May 31, 2010

Section: Product & Model ID

1.0 X-RAY REPORTING

# INTRODUCTION TO DIAGNOSTIC X-RAY REPORTING

This guide outlines for a manufacturer, a format for the presentation of product and supplemental reports on diagnostic x-ray systems and their major components which are subject to the Performance Standard 21 CFR 1020.30, 1020.31, and 1020.32. The types of components covered by the diagnostic x-ray equipment standard includes: tube housing assemblies, x-ray controls, x-ray high voltage generators, tables, cradles, film changers, cassette holders, beam-limiting devices, spot film devices, image intensifiers, fluoroscopic imaging systems, cephalometric devices, image receptor support devices for mammographic x-ray systems, and diagnostic x-ray systems incorporating one or more previously listed components. Each type of component is a finished device and must be certified by the component manufacturer prior to introduction into US commerce. Each certifiable component must have a product report which identifies all applicable testing and quality control procedures used to establish certification. Compatibility of the components in a subassembly or system, must be established by the component or system manufacturer prior to installation and turn over for use on human patients.

#### 2.1 REPORTING GUIDE

#### INTRODUCTION TO THE DIAGNOSTIC X-RAY REPORTING GUIDE

All material shall be submitted in the English language or with an accurate attached English translation. Definitions for technical terms used in this guide may be found in the Definitions section of this template.

The subject reporting guide is an attempt to identify the pertinent information needed by the Center for Devices and Radiological Health (CDRH) to fulfill its delegated responsibilities under Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) of Chapter V of the Federal Food, Drug and Cosmetic Act (Act). It is also believed that identification of this information will make the manufacturer's reporting task somewhat easier since, after the initial organization of the material, the manufacturer will not be obligated to prepare and submit such voluminous reports as in the past. Manufacturers may elect to continue using a previous version of the Reporting Guide when supplementing old reports. It is required that all new product reports follow this revision of the Reporting Guide consistent with 21 CFR 1002.7(b).

The guide asks for information with regard to the product manufacturer, and product model identification. The manufacturer must answer all applicable questions in sections 1.0 and 2.0 of this part both as a product report or supplemental report. Section 2 should list all models for which the present report is used as the basis for certification of the component. Each time the report is supplemented it should contain the updatedlist of all models. A list of compatible components combined in the system or subsystem should also be provided when marketed together. If the

accession number of the product report for other certified components mentioned in this report is known, it should be provided. There should be only one product report for each certified component produced and that report should contain all the test and quality control information upon which certification is based. However, one report may address several components and models that have similar characteristics and/or uses.

PART 200 - COMPONENT DESCRIPTION, containing eight sections, asks for information pertaining to specific performance characteristics of the component being certified by the report. The manufacturer should answer all questions in the section(s) relative to the component(s) being certified and identified in PART 2. Components certified by other manufacturers and used in the system or subsystem are also identified in Part 2 and would not be covered in part 300 since the certifying manufacturer would address these issues in their product report. However, compatibility of components in the system must be established by the manufacturer.

PART 300 - QUALITY CONTROL TESTING, containing twenty-five sections, asks for presentations of prototype, production and assembler test methods and results. Sections to be answered in this part are identified in sections 201 through 208 of PART 200 and in Table 1. The prototype testing phase may not be the same as production testing and may or may not apply depending on manufacturing phase. If appropriate, the manufacturer should notify FDA when prototype testingwnds and production begins by supplemental submission.

PART 400 - COMMON ASPECTS, containing two sections, asks for test instrument specifications and sampling protocols. This section is used to identify the testing equipment and documentation. The manufacturer must answer all questions in the applicable paragraphs of section 401.0 and, when appropriate, all questions in section 402.0 of this part. The report should be supplemented whenever any testing equipment is changed or modified.

# 2.2 COMMON ASPECTS REPORT

# INTRODUCTION TO THE COMMON ASPECTS REPORT

Manufacturers are encouraged to submit a "Common Aspects Report" in order to simplify their reporting obligations. The Common Aspects Report is a separate product report that incorporates a description of test methods, instrumentation, and sampling plans common to several models. This Common Aspects Report is not intended as a means for certification of any specific model. Currently, separate product reports from the same manufacturer often provide identical descriptions of the quality control program. Such duplication is costly and entails extra effort for both the manufacturer and the Center. By development of a Common Aspects Report, standardized test methods, instrumentation, and sampling plansmay be collected into one report. Product reports for specific models can then reference the applicable section and page number of the Common Aspects Report where the required information can be found. For example, a product report on an x-ray control must include responses to the appropriate sections of PART 1And 2 -MANUFACTURER AND REPORT IDENTIFICATION, PRODUCT AND MODEL IDENTIFICATION and PART 200-COMPONENT DESCRIPTION, however, information with respect to test methods in PART 300-QUALITY CONTROL TESTING and also PART 400 -COMMON ASPECTS may be provided by referencing specific sections and pages to the Common Aspects Report. Sample test data solicited in PART 300 must still be included in the product report.

Manufacturers may simplify reporting of the test data by grouping similar models within one report.

For example, all x-ray tables with the same tabletop material and performance criteria may be reported in the same product report. Whenever several models are related by design and/or performance, presentation of test results in PART 300 QUALITY CONTROL TESTING may apply to all models without reference to each model designation. Future reporting of similar models would not require the submission of sample test results when specifically referenced to results presented in an earlier product report or report supplement. In each case, the manufacturer must clarify his intent to group similar models for a given test in PART 300, provide the technical basis for this grouping, and affirm test results comparability. The manufacturer is also responsible for maintaining records of testing results that are the basis of certification. Such records would be made available when requested by FDA.

Table 1 provides a reference to aid the manufacturer in readily identifying which sections of each part he must complete for the particular component(s) that he is reporting. To use the table, the component is found in the left hand column and the sections within each part to be completed for that component are found in the columns to the right. The electronic reporting version of this report will automatically pull up required sections based on responses to related questions in PARTs 2 and 200.

#### 2.3 DEFINITIONS

# As used in this guide and 21 CFR 1020.30, 1020.31 and 1020.32, the following definitions apply:

- (1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
- (2) "accessory component" means
  - a) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this subchapter but which requires an initial determination of compatibility with the system; or
  - b) A component necessary for compliance of the system with applicable provisions of this subchapter but which may be interchanged with similarcompatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or
  - c)A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.
- (3) "Air kerma" means kerma in air (see kerma).
- (4) "Air kerma rate" (AKR) means the air kerma per unit time.
- (5) "Aluminum equivalent" means the thickness of aluminum (type 1100alloy) affording the same attenuation, under specified conditions, as the material in question.
- (6) "Articulated joint" means a joint between two separate sections of a tabletop which joint provides the capacity for one of the sections to pivot on the line segment along which the sections join.
- (7) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray

system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

- (8) "Attenuation block" means a block or stack of type 1100 aluminumalloy or aluminum alloy having equivalent attenuation with dimensions 20 centimeters or larger by 20 centimeters or larger by 3.8 centimeters. When used, the attenuation block shall be large enough to intercept the entire x-ray beam.
- (9) "Automatic exposure control" (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.
- (10) "Automatic exposure rate control" (AERC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation per unit time.
- (11) "Beam axis" means a line from the source through the centers of the x-ray fields.
- (12) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.
- (13) "C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.
- (14) "Cantilevered tabletop" means a tabletop designed such that the unsupported portion can be extended at least 100 centimeters beyond the support.
- (15) "Cassette holder" means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film cassette during an x-ray exposure.
- (16) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
- (17) "Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations.
- (18) "Computed Tomography" (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission -.
- (19) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.
- (20) "Cooling curve" means the graphical relationship between heat units stored and cooling time.
- (21) "Cradle" means:
  - (a) A removable device which supports and may restrain a patient above an x-ray table; or
  - (b) A device; (i) Whose patient support structure is interposed between the patient and the image

receptor during normal use; (ii) Which is equipped with means for patient restraint; and(iii) Which is capable of rotation about its long (longitudinal) axis

- (22) "CT Gantry" means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components.
- (23) "Cumulative air kerma" means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.
- (24) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.
- (25) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.
- (26) "Dose" means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, isthe quotient of de by dm, where de is the mean energy imparted by ionizing radiation to matter of mass dm.
- (27) "Equipment" means x-ray equipment."Exposure" (X) 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 andpositrons) liberated by photons in a volume element of air having mass dm are completely stopped in air. "Exposure" is also used with a second meaning to refer to the process or condition during which the x-ray tube produces x-ray radiation. Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to action of an electric field.
- (28) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.
- (29) "Fluoroscopic radiation-emissions-display device" means a device, subsystem or component that provides the displays of AKR and cumulative air kerma required by 1020.32(k). It includes radiation detectors, if any, electronic and computer components, associated software, and data displays.
- (30) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the imagereceptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.
- (31) "Fluoroscopy" means a technique for generating x-ray images and presenting them continuously as visible images for the purpose of providing the user a visual display of dynamic processes.
- (32) "General purpose radiographic x-ray system" means any radiographicx-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.
- (33) "Half-value layer, (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the air kerma rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

- (34) "Image Intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.
- (35) "Image receptor" means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "imagereceptor" shall mean the preselected portion of thedevice.
- (36) "Image receptor support device" means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.
- (37) "Isocenter" means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about a common center.
- (38) "Kerma" (K) means the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm where dEtr is the sum of the initial kineticenergies of all the charged ionizing particles liberated by uncharged ionizing particles in a material of mass dm. When the material is air, the quantity is "air kerma."
- (39) "Last image hold (LIH) radiograph" means an image obtained either by retaining one or more fluoroscopic images, which may be temporally integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.
- (40) "Lateral fluoroscope" means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.
- (41) "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:
  - (i)The useful beam and
  - (ii) Radiation produced when the exposure switch or timer is not activated.
- (42) "Leakage technique factors" means the technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:
  - (i)For tube housing assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peaktube potential with the quantity of charge per exposure being 10 millicoulombs (or 10 mAs) or the minimum obtainable from the unit, whichever is larger.
  - (ii) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and(iii) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

- (43) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor whose perimeter is the locus of points at which the illumination is one-fourth of the maximum the intersection.
- (44) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is, Percent line-voltage regulation = 100(Vn Vi)/Viwhere: Vn = No-load line potential and Vi = Load line potential.
- (45) "Maximum line current" means the route mean square current in the supply line of an x-ray machine operating at its maximum rating.
- (46) "Mode of operation" means, for fluoroscopic systems, a distinctmethod of fluoroscopy or radiography selected with a set of technique factors or other control settings uniquely associated with the mode. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog), digital cineradiography, digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, air kerma rate, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses per exposure series, SID, or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different than the one that has been selected.
- (47) "Movable tabletop" means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.
- (48) "Nonimage-intensified fluoroscopy" means fluoroscopy using only a fluorescent screen.
- (49) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
- (50) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.
- (51) "Pulsed mode" means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.
- (52) "Quick change x-ray tube" means an x-ray tube designed for use in its associated tube housing such that:
  - (i) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of paragraphs (k) and (m) of section 1020.30;
  - (ii) The focal spot position will not cause noncompliance with the provisions of sections 1020.30 through 1020.33;
  - (iii) The shielding within the tube housing cannot be displaced; and
  - (iv) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube housing will not result in noncompliance of the x-ray system with the applicable field limitation and alignment requirements of 1020.31 through 1020.33.

- (53) "Radiation therapy simulation system" means a radiographic orfluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field
- (54) "Radiography" means a technique for generating and recording anx-ray pattern for the purpose of providing the user withanimage(s) after termination of the exposure.
- (55) "Rated line voltage" means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.
- (56) "Rated output current" means the maximum allowable load current of the x-ray high-voltage generator.
- (57) "Rated output voltage" means the allowable peak potential, involts, at the output terminals of the x-ray high-voltage generator.
- (58) "Rating" means the operating limits specified by the manufacturer.
- (59) "Recording" means producing a permanent form of an image resulting from x-ray photons (e.g., film, videotape).
- (60) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.
- (61) "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data maybe collected simultaneously during a single scan for the production of one or moretomograms.
- (62) "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.
- (63) "Solid state x-ray imaging device" means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.
- (64) "Source" means the focal spot of the x-ray tube.
- (65) "Source-image receptor distance, (SID)" means the distance from the source to the center of the input surface of the image receptor.
- (66) "Source-skin distance (SSD)" means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.
- (67) "Spot-film device" means a device intended to transportand/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

- (68) "Stationary equipment" means equipment which is installed in a fixed location.
- (69) "Stationary tabletop" means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.
- (70) "Technique factors" means the conditions of operation. They are specified as follows:i. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;ii. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses; andiii. For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of the tube current, x-ray pulse width, and the number of x-ray pulses in mAsiv. For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; andv. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.
- (71) "Tomogram" means the depiction of the x-ray attenuation properties of a section through a body.
- (72) "Tube" means an x-ray tube, unless otherwise specified.
- (73) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and otherappropriate elements when they are contained within the tube housing.
- (74) "Tube ratingchart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
- (75) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.
- (76) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray fieldsize at a given SID.
- (77) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.
- (78) "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, photo timers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.
- (79) "X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-raye quipment are as follows:(i) Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;(ii) Portable x-ray equipment means x-ray equipment designed to be hand-carried; and(iii)Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.
- (80) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

- (81) "X-ray high-voltage generator" means a device which transformselectrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filamenttransformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.
- (82) "X-ray system" means an assemblage of components for the controlled production of x rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of thesystem.
- (83) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in 1020.30, 1020.31 and 1020.32.
- (84) "X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel,fluoroscopic image receptor, or spot-film device beneath the tabletop.
- (85) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

# 2.4 MODEL DESIGNATION

Give the model designation for any components (including combination components) that are being certified in this report. Also, provide the model designation for each combination that is being certified in this report. Do not list components which are not being certified by this report. For all components certified by this report and its supplements identify the model exactly as it appears on the identification label. If reporting a model family, provide the model designation of each model. If you do not have a model family or brand name, leave the field blank.

Item	Model Name	Family Name	Brand Name
Item 1			
Item 2			
Item 3			

Note:	Please note that if any of these components are sold separately, they cannot be listed as single labeled. Examples of single labeled components are high voltage generators contained within tube housing assemblies, beam-limiting devices contained within tube housing assemblies, beam-limiting devices which are integral parts of tube housings, and high voltage generators and x-ray controls which are inseparable and housed jointly. These are the combinations that may be combined under a single certification label. Other combinations may be authorized by the Center for Devices and Radiological Health upon application by their manufacturer. Authorization for single labeling may be granted only for inseparable combinations of
	components that are contained within a single housing.

2.4.1 MODEL TYPE DESIGNATIO	N
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Item: 1 (could contain up to 500 items with 1 required)			
Component Type:	ц		
Model Designation:			

# 2.5 INDIVISIBLE COMBINATION OF COMPONENTS Please note that if any of these components are sold separately, they cannot be listed as single labeled. Examples of single Note: labeled components are high voltage generators contained within tube housing assemblies, beam-limiting devices contained within tube housing assemblies, beam-limiting devices which are integral parts of tube housings, and high voltage generators and x-ray controls which are inseparable and housed jointly. These are the combinations that may be combined under a single certification label. Other combinations may be authorized by the Center for Devices and Radiological Health upon application by their manufacturer. Authorization for single labeling may be granted only for inseparable combinations of components that are contained within a single housing. [L] Do you combine components under a single certification label pursuant to 21 CFR 1020.30(c)? 2.5.1 COMBINATION OF COMPONENTS Item: 1 (could contain up to 10 items with none required) Please note that if any of these components are sold separately, they cannot be listed as single labeled. Examples of single Note: labeled components are high voltage generators contained within tube housing assemblies, beam-limiting devices contained within tube housing assemblies, beam-limiting devices which are integral parts of tube housings, and high voltage generators and x-ray controls which are inseparable and housed jointly. These are the combinations that may be combined under a single certification label. Other combinations may be authorized by the Center for Devices and Radiological Health upon application by their manufacturer. Authorization for single labeling may be granted only for inseparable combinations of components that are contained within a single housing. Certifiable Combination: [L] Model Designation: 2.6 OTHER NAMES OR LABELS Are any of the models you manufacture reported in 2.4 and/or 2.5 sold under name(s) other than the certifying manufacturer? [L] 2.6.1 Names or Labels Item: 1 (could contain up to 10 items with none required) Component Type? [L] Model Designation: Other Company Under Whose Name The Model Is Sold?

#### 2.7 LABEL DESCRIPTION

Model Name Sold Under Other Company?

Note:		ommerce. Atta	ed under 2.4, 2.5 and 2.6, provide an exact replica of all labels filled out as they would be when in ch copies of the labels and the requested information. The label should include the following as	troduced
2. T so 3. T al 4. T 5. T 6. In to	old) The date and bove, then the model de he manufactor addition, the view when ertifiable con	place of me code us esignation turer, module standard the produmponent a	of the manufacturer (or the individual or company under whose name annufacture. If the place of manufacturer is not the address in item 2 ed on the label to identify the location of manufacture as listed under and sample serial number el designation and sample serial number of the tube insert if applicated requires that the labels be permanently affixed, legible, and access ct is fully assembled for use. Provide a drawing or photograph of eand/or combination showing where the attached label is located.	2 er 1.8 able sible
[HTML Tex		eplica of labels	s for every model listed under 2.4, 2.5 and 2.6. Click on the plus sign below to attach files.	
File Attachi	-	[Multiple File	Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
		•		
2.8 Part	1: COMPLET	TE SYSTEM	MS AND SUBSYSTEMS	
Are there c	components certifi	ed by this repo	ort marketed by you as a system or subsystem of components?	[L]
2.8 PAR	T 2: COMPL	ETE SYSTI	EMS AND SUBSYSTEMS	
Item: 1 (co	ould contain up t	o 20 items wit	h none required)	
	0.1	]		
-	Subsystem Desig	nation:		
Componen	т туре.			
Item 2				
Item 3				
Model Desi	ignation:			
Manufactur	rer:			
Item 1				
Item 2				
Item 3				
Accession	Number:			
Item 1				
Item 2				
Item 3	<u> </u>			

Note: Please input your data into the following tables in the same order for each model, component type and accession number.

# 2.9 ASSEMBLER INFORMATION

Note:	Attach "Information to Assembers" (1020.30 (g)) as a separate file. Include each of the following as separate files: (a.) Assembly and testing instructions necessary for assuring compliance to the Performance Standard and (b.) Compatibility specifications referenced in 21 CFR 1020.30(g).		
Attach Compatibility S	Specifica	ations referenced in 21 CFR 1020.30 (g) as a separate file.	
File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details [HTML Text]			
Are there assembly and testing instructions necessary at the installation site for assuring compliance to the federal standards?			
Attach Assembly and Testing Instructions necessary for assuring compliance to the Performance Standard as a separate file.			
File Attachment [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
Details [HTML Text]		[HTML Text]	
Note:	If no acts by the assembler will cause failure to comply with the federal standards and all that is necessary is to plug the system in to an adequate power socket, then theuser manual should specify that no assembly instructions or testing is necessary for compliant use of the equipment other than proper power connection. As such no assembly manual will be needed.		

# 2.10 USER INFORMATION

Note: Attach "Information to Users" (1020.30(h)) as separate files. (PDF searchable files are acceptable.) Include each of the following as a separate file:

- (a.) Operating Instructions
- (b.) Maintenance Schedule
- (c.) Picture or drawing of product
- (d.) Product Specifications and Tolerances
- (e.) Cautionary Statements for 21 CFR 1020.32(a)(1) and (f) if applicable
- (f.) Leakage Technique Factors and Tube Rating Charts if applicable

Attach for each model, system or subsystem (as appropriate) the above information in a separate file. Click on the plus sign below to attach any supporting files.

[HTML Text]

File Attachment [Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

# 2.11 ADDITIONAL INFORMATION

Note: Additional information is needed for each model beam-limiting device, HV generator and x-ray control(or combination containing such components) that are being certified by this report.

# 2.11.1 BEAM LIMITING DEVICE (BLD)

Note:	Answer the questions in 2.11.1 if certifying a beam-limiting device in this submission.	

Use and Type of Collimation	Is this report intended for the certification of a beam limiting device (either seperately or in combination)?			[L]	
Model Designation:  Max kVP: Indicate the type of collimation.  If you selected Other, specify type:  Select all uses for which each model family is intended.  Item 1 Item 2 Item 3  If you selected Other, specify use:  2.11.2 HV GENERATOR  Note:  Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  [L]  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP: Indicate the type of generator.  If you selected Other, specify type:  Select all uses for which each model family is intended.	Use and Type of Collimation				
Max kVP: Indicate the type of collimation.  If you selected Other, specify type:  Select all uses for which each model family is intended.  Item 1 Item 2 Item 3  If you selected Other, specify use:  2.11.2 HV GENERATOR  Note: Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  It you selected Other, specify use:  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP: Indicate the type of generator.  If you selected Other, specify type:  Select all uses for which each model family is intended.	Item: 1 (could contain up to 15 items with r	none required)			
Max kVP: Indicate the type of collimation.  If you selected Other, specify type:  Select all uses for which each model family is intended.  Item 1 Item 2 Item 3  If you selected Other, specify use:  2.11.2 HV GENERATOR  Note: Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  It you selected Other, specify use:  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP: Indicate the type of generator.  If you selected Other, specify type:  Select all uses for which each model family is intended.					
Indicate the type of collimation.  If you selected Other, specify type:  Select all uses for which each model family is intended.  Item 1 Item 2 Item 3  If you selected Other, specify use:  2.11.2 HV GENERATOR  Note: Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  [L]  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  [L]  If you selected Other, specify type:	Model Designation:				
Select all uses for which each model family is intended.  Item 1 Item 2 Item 3 If you selected Other, specify use:  2.11.2 HV GENERATOR  Note: Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  [L]  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  If you selected Other, specify type:	Max kVP:				
Select all uses for which each model family is intended.  Item 1  Item 2  Item 3  If you selected Other, specify use:  2.11.2 HV GENERATOR  Note: Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  [L]  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  [L]  If you selected Other, specify type:	Indicate the type of collimation.		[L]		
Item 1 Item 2 Item 3 If you selected Other, specify use:  2.11.2 HV GENERATOR  Note: Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  [L]  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  If you selected Other, specify type:	If you selected Other, specify type:				
Item 2 Item 3  If you selected Other, specify use:  2.11.2 HV GENERATOR  Note: Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  [L]  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  If you selected Other, specify type:  Select all uses for which each model family is intended.	Select all uses for which each model family is	intended.			
It you selected Other, specify use:  2.11.2 HV GENERATOR  Note: Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  [L]  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  [L]  If you selected Other, specify type:	Item 1				
If you selected Other, specify use:  2.11.2 HV GENERATOR  Note: Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  [L]  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  [L]  If you selected Other, specify type:	Item 2				
2.11.2 HV GENERATOR  Note: Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  [L]  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  [L]  If you selected Other, specify type:	Item 3				
Note: Answer the following questions if certifying a High Voltage Generator in this submission.  Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  [L]  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  [L]  If you selected Other, specify type:	If you selected Other, specify use:				
Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?  [L]  Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  [L]  If you selected Other, specify type:	2.11.2 HV GENERATOR				
Use and Type  Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  [L]  If you selected Other, specify type:	Note: Answer the following qu	Note: Answer the following questions if certifying a High Voltage Generator in this submission.			
Item: 1 (could contain up to 15 items with none required)  Model Designation:  Max kVP:  Indicate the type of generator.  [L]  If you selected Other, specify type:  Select all uses for which each model family is intended.	Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?				
Model Designation:  Max kVP:  Indicate the type of generator.  If you selected Other, specify type:  Select all uses for which each model family is intended.	Use and Type				
Model Designation:  Max kVP:  Indicate the type of generator.  If you selected Other, specify type:  Select all uses for which each model family is intended.					
Max kVP:  Indicate the type of generator.  [L]  If you selected Other, specify type:  Select all uses for which each model family is intended.	Item: 1 (could contain up to 15 items with r	none required)			
Indicate the type of generator.  [L]  If you selected Other, specify type:  Select all uses for which each model family is intended.	Model Designation:				
If you selected Other, specify type:  Select all uses for which each model family is intended.	Max kVP:				
Select all uses for which each model family is intended.	Indicate the type of generator. [L]				
	If you selected Other, specify type:				
Item 1	Select all uses for which each model family is	intended.			
	Item 1				
Item 2	Item 2				
Item 3	Item 3				
If you selected Other, specify use:	If you selected Other, specify use:				

# 2.11.3 X-RAY CONTROL

Note:	Answer the following questions if certifying an X-Ray control in this submission.	
Is this report intended	Is this report intended for the certification of an x-ray control (either separately or in combination)?	

Use, Maximum kVp, and Fluoroscopic Control

Item: 1 (could contain up to 15 items with none required)

Model Des	ignation:		
Max kVP:			
Select all u	uses for which each model family	is intended.	
Item 1			
Item 2			
Item 3			
If you selected Other, specify use:			
For Fluoros	scopic Controls, is there a high-l	evel control?	[L]

#### Maximum Deviation from Indicated Value

For each model x-ray control certified in this report, list in an attached table, maximum deviation from the indicated value as given in the user technical specifications (models with identical specifications may be grouped together).

Note:

See the three sample tables below for the required format. Three levels of operation are provided in the sample tables for mid level, low level, and high level techniques. The selection of the mid level has been provided. If the unit is not capable of operating at the specified value, then choose a value as close to that listed as possible. For any techniqes that are fixed, use the same level for all three levels. The sample tables are also separated into three kVp ranges. If the control only operates on one range then leave the other ranges blank and state that the maximum deviations shall be listed as +/- values in units of the technique value (e.g., kVp, mAs, mA, mS). If the controls only operate in one of the kVp ranges then only that column should have values listed in it.

\*Click on the HTML editor box in the supporting details section to create the tables or copy the sample tables into a new document, enter the appropriate values and attach the file below.

	EXAMPLE of Mid-level specifications DESIGNED kVp OPERATING RANGE						
	BELOW 51 kVp		51 TO 70 kVp		ABOVE 70 kVp		
	INDICATED	MAXIMUM DEVIATION	INDICATED	MAXIMUM DEVIATION	INDICATED	MAXIMUM DEVIATION	
kVp	30	+/-2	60	+/-3	90	+/-4.5	
mAS	50	+/-3	60	+/-3	80		
Or							
mA	100		100	+/-2	200	+/-4	
TIME	500		600	+/-6	400	+/-5	

mS									
	EXAMPLE of Low-level specifications DESIGNED kVp OPERATING RANGE								
	BELOV	V 51 kVp	51 TO	51 TO 70 kVp		E 70 kVp			
	INDICATED	MAXIMUM DEVIATION	INDICATED	MAXIMUM DEVIATION	INDICATED	MAXIMUM DEVIATION			
kVp	20	+/-2	56	+/-3	80	+/-4			
mAS	10	+/-2	20	+/-3					
Or									
mA			50	+/-2	100	+/-2			
TIME mS			400	+/-4	100	+/-3			
				n-level specifica PERATING RA					
	BELOV	V 51 kVp	51 TO	70 kVp	ABOVE	70 kVp			
	INDICATED	MAXIMUM DEVIATION	INDICATED	MAXIMUM DEVIATION	INDICATED	MAXIMUM DEVIATION			
kVp	40	+/-3	68	+/-3	120	+/-6			
mAS	80	+/-4	140	+/-3					
Or									
mA			200	+/-4	600	+/-6			
TIME mS			700	+/-7	800	+/-6			
Click on the	he plus sign below to	attach the appropriate f	iles.						
[HTML Te	ext]								
File Attack	hment [M	ultiple File Attachments	s (.pdf, .jpg, .gif, .tif, .a	vi, .wmv, .xpt, .xml, .dtc	d, .sgml, .mol, .xls, .csv	/, .zip)]			
Section	n: Compone	ent Description							
Occin	oni oonipone	THE DESCRIPTION							
201.0 T	UBE HOUSING	ASSEMBLY							
	<b>1</b>					Aliantian P. C. C.			
Note:		on should be complete 5 that contains a tube I		•	ection 2.4 and any com	ibination listed in			
Is this rep	ort intended for the ce	ertification of a tube hou	using assembly or con	nbination containing a t	ube housing assembly	? [L]			
201.1 T	ube Housing As	sembly Informatio	on						
l									

Item: 1 (could contain up to 20 items with 1 required)							
Model Designation:							
List the Max kVp:							
Are any of the models intended for use on a general purpose x-ray system? [L]							
For each model intended for use on a general purpose x-ray system, cite the specific paragraph(s) in your instructions to assemblers that list compatible tube stands, beam limiting devices, and/or other equipment necessary for indication (as required under 21 CFR1020.31(e)(1), (h) (2), and 1020.32(b)(1)(ii), (b)(2)(iii)).							
File Attachment	[Single File	Attachment (.pdf, .jpg, .gif, .tif, .avi, .wn	ıv, .xpt, .xml, .d	td, .sgml, .mol, .xls, .csv, .zip)]			
[HTML Text]							
Also specify where to indicator.	o find information ad	dressing the perpendicularity of the bea	am axis to the ir	nage receptor, and information on t	he SID		
File Attachment	[Single File	Attachment (.pdf, .jpg, .gif, .tif, .avi, .wm	ıv, .xpt, .xml, .d	td, .sgml, .mol, .xls, .csv, .zip)]			
[HTML Text]							
Do you reload tube h	nousing assemblies?				[L]		
Describe how you re certification label).	move, deface, or co	ver the original labels on the assembly	and replace the	m with your own labels (including re	<b>∋</b> -		
File Attachment	[Single File	Attachment (.pdf, .jpg, .gif, .tif, .avi, .wm	ıv, .xpt, .xml, .d	td, .sgml, .mol, .xls, .csv, .zip)]			
[HTML Text]							
202.0 BEAM-LI	MITING DEVIC	ES					
Note:		I be completed for each beam-limiting on tains a beam-limiting device as an inte ection 203.0					
Is this report intende	d for the certification	of a beam limiting device or combination	on containing a	beam limiting device?	[L]		
Is the beam limiting of	device designed for i	ntraoral dental?			[L]		
202.1 Dental Bl	202.1 Dental BLD (intraoral)						
Item: 1 (could contain up to 20 items with 1 required)							
Model Designation:							
Note:	-	e appropriate model indicated, please ( e identification label.	go to question 2	2.4 MODEL DESIGNATION to enter	the model		
Minimum source-to-s	skin distance (SSD)	in cm:					
Geometric configura	tion of x-ray field is:			[L]			
X-ray field size dimensions at minimum SSD: ( cm x cm)							

202.2 Part 1: General Purpose Radiographic BLD			
General Purpose Radiographic BLD - mobile and stationary (excluding mammographic, spo	ot-film devices,	and dental units)	
s the BLD designed for general purpose radiography?		[	[L]
Are any beam-limiting device(s) equipped with a light localizer?		<u> </u>	[L]
202.2 Part 2: General Purpose Radiographic BLD			_
tem: 1 (could contain up to 20 items with 1 required)			
General Purpose Radiographic BLD - mobile and stationary (excluding mammographic, spo	ot-film devices,	and dental units)	
Model Designation:			
What is the minimum source to skin distance (SSD) in cm?			
What is the minimum x-ray field size at 100 centimeters SID (or maximum SID if less than 100 cm)	):		
s the adjustment for the size of the x-ray field stepless?	[L]		
Is the beam-limiting device(s) equipped with a light localizer?			
202.3 Part 1: Stationary General Purpose Radiographic			
Are any model BLDs designed as a Stationary General Purpose Radiographic BLD?		[L]	
Are any of the reported BLD models you are certifing designed for positive beam limitation (PBL)?		[L]	
202.3 Part 2: Stationary General Purpose Radiographic BLD			
tem: 1 (could contain up to 20 items with 1 required)			
Model Designation:			
Are means provided to indicate when the beam axis (both vertical and horizontal) is perpendicular to the plane of the image receptor?			
Describe the means to indicate when the beam axis is perpendicular to the plane of the image rece	eptor?		
Multi-Line Plain Text]			
What is the designed minimum SID? (either cm or in)			
· · · · · · · · · · · · · · · · · · ·			

Provide a drawing or pic	cture of the indicator on the beam-limiting device that show	s the relationship of the field size dimensions to SID.
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv,	, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]		
Is the BLD designed for	positive beam limitation (PBL)?	[L]
What is the horizontal S	SID PBL operating range? (either cm or in)	
What is the verticle SID	PBL operating range? (either cm or in)	
Does the PBL operate to positions?	hroughout the range listed above continuously or in discre	te steps or [L]
	rcuit diagram and interlock mechanism that prevents the p designed to operate and/or when an improper cassette is in	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv,	.xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]		
Is the PBL cassette tray	designed for only certain cassette sizes?	[L]
Provide a copy of the ci	rcuit diagram and interlock mechanism that prevents the p	roduction of x-rays when an improper cassette is inserted
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv,	, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]		
List the applicable casse	ette sizes as labeled on the cassette along withthe model r	number identifying each cassette.
Item 1		
Item 2		
Item 3		
	the conserve Calabia	rı 1
The PBL adjustment of	tne x-ray field is:	[L]
•	the x-ray field is: rcuit diagram and interlock mechanism that prevents the p	
•		roduction of x-rays until such adjustment is completed.
Provide a copy of the ci	rcuit diagram and interlock mechanism that prevents the p	roduction of x-rays until such adjustment is completed.
Provide a copy of the ci	rcuit diagram and interlock mechanism that prevents the p	roduction of x-rays until such adjustment is completed.
Provide a copy of the ci File Attachment [HTML Text]	rcuit diagram and interlock mechanism that prevents the p	roduction of x-rays until such adjustment is completed.  , .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Provide a copy of the ci File Attachment [HTML Text]  Can the PBL x-ray field  When the PBL x-ray fiel	rcuit diagram and interlock mechanism that prevents the p  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv,	roduction of x-rays until such adjustment is completed.  , .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] e receptor?  [L]
Provide a copy of the ci File Attachment  [HTML Text]  Can the PBL x-ray field  When the PBL x-ray fiel coverage occur when ei	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, be adjusted to dimensions smaller than those of the image ld is adjusted to dimensions smaller than the image receptor.	roduction of x-rays until such adjustment is completed.  , xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  e receptor?  [L]  or, does full  [L]

Does the PBL system have	a bypass mode?		[L]				
Specify all conditions under which the bypass mode is activated, and state whether the bypass mode is activated under conditions other than: (1) when radiography is conducted that does not use the cassette trayor permanently mounted vertical cassette holder; (2) when either the beam axis ortable angulation is not within 30 of the horizontal or vertical during any part of the exposure; (3) during stereoscopic radiography; (4) when the image receptor length or width is greater than 50 cm; (5) when the SID is not between 90 to 130 cm vertically or is not between							
90 to 205 cm horizontally.							
[HTML Text]	HTML Text]						
Specify how the system will	automatically return to the PBL mode						
[HTML Text]							
Does the PBL system have	a service switch and/or capture key or	verride?	[L]				
Describe each service switch	ch and/or capture key override availabl	e with the PBL system.					
[HTML Text]							
Attach a drawing or picture	showing the location of each PBL over	rride switch.					
File Attachment	[Single File Attachment (.pdf, .jpg, .gi	if, .tif, .avi, .wmv, .xpt, .xml, .dt	d, .sgml, .mol, .xls, .csv, .zip)]				
[HTML Text]							
Provide circuit diagrams and	d description of function for each PBL	bypass and override circuit.					
File Attachment	[Multiple File Attachments (.pdf, .jpg,	.gif, .tif, .avi, .wmv, .xpt, .xml,	.dtd, .sgml, .mol, .xls, .csv, .zip)]				
[HTML Text]							
202.4 Part 1: Beam L	imiting Device used with Spe	ot Film					
Is the beam-limiting device	designed to be used with Spot Film Ra	adiography or Digital Spot Rec	cording?	[L]			
000 4 Dart 0: Daars I	inition Device weed with Co	-4 Eiles					
202.4 Part 2: Beam L	202.4 Part 2: Beam Limiting Device used with Spot Film						
Item: 1 (could contain up	to 20 items with 1 required)						
Beam-Limiting Device Use	ed with Spot Film Radiography or D	igital Spot recording (exclud	ding therapy simulators).				
Model Designation:							
Describe how reduction of timage receptor.	he x-ray field is accomplished when th	e fluoroscopic x-ray field is lar	ger than the recorded selected portion	n of the			
[Multi-Line Plain Text]							
Describe how the enlargem image receptor.	ent of the x-ray field is accomplished v	when the fluoroscopic x-ray fie	ld is smaller than the selected portion	of the			
[HTML Text]							
Describe the means availab	ole to adjust the x-rayfield to a size sma	aller than the selected portion	of the image receptor.				
[HTML Text]							
				I			

List the applicable image cm and format: 4 on 1	receptor sizes (for film use as labeled on the cassette) and the available formats. For example, size: cr	m x					
Item 1							
Item 2							
Item 3							
What is the minimum x-ra limiting device is designed	y field at the greatest SID for tube housings for which the beam- d? (cm xcm)						
Provide a drawing or picture of the location of the beam limiting device with respect to the patient and the image receptor when it is assembled in a fluoroscopic system.							
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
[HTML Text]		_					
Are means provided for s	ystem failure override?	[L]					
Describe each service sw	itch and/or capture key:						
[HTML Text]							
Describe the label advisir	g need for repair in the event of system failure. Please attach a copy of the label.						
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
Details	[HTML Text]						
Describe the visual indica	tion of the override condition at the fluoroscopist position:						
[HTML Text]							
202.5 Part 1: Beam	Limiting Device used for Fluoroscopy						
Is the BLD designed for fl	uoroscopy use?	[L]					
Are any of the beam-limiting device(s) designed for use in image-intensified fluoroscopy, other than radiation therapy simulation?							
202.5 Part 2: Beam Limiting Device used for Fluoroscopy							
Item: 1 (could contain u	p to 20 items with 1 required)						
Model Designation:							
Which of the following is t	he geometric configuration of x-ray field: [L]						
If you chose "other" for th	e above question, please attach a description:						
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
[HTML Text]							
What is the minimum x-ra	y field at the greatest SID for tube housings for which the beam-						

lir	limiting device is designed? (cm x cm) or (in x in)						
Is	the BLD designed for non	nimage intens	ified fluoroscopy?	[L]			
D	escribe the means for limit	ting the x-ray	field within the visible area of the image receptor:				
[Ի	HTML Text]						
W	/hat is the minimum SSD ι	under normal	fluoroscopy? (cm)				
Is	Is the beam-limiting device/system combination designed for special surgical procedures?  [L]						
Is	there a removable spacer	r?		[L]			
W	/hat is the minimum SSD v	with spacer re	moved? (cm)				
A	re means provided for syst	tem failure ov	verride?	[L]			
	escribe each service switc			1			
[ -	HTML Text]						
D	escribe the label advising	need for repa	ir in the event of system failure.				
File Attachment [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]							
D	etails	[HTML Text					
D	escribe the visual indicatio	on of the over	ride condition at the fluoroscopist position:				
[Ի	HTML Text]						
2	02.6 Part 1: X-Ray 9	Systems [	Designed for One SID				
Is	the BLD designed to be u	used with syst	ems with one SID and one Image receptor size?		[L]		
	o any of the beam-limiting	devices have	e a light field that defines the perimeter of the x-ray fie	ld?	[L]		
			igned for fixed SID/image receptor size?		[L]		
2	02.6 Part 2: X-Ray \$	Systems [	Designed for One SID				
Ite	em: 1 (could contain up t	to 20 items v	vith 1 required)				
М	lodel Designation:						
TI	he design SID (either cm o	or in):					
TI	he image receptor size in t	both (in x in)	as well as (cm x cm):				
D	escribe the means for limit	ting and/or ce	entering the x-ray field.				
ľ							

[HTML Text]						
202.7 Part 1: Beam Limiting Devices Designed for Mammography						
Is the BLD designed for mammography?		[L]				
Does the beam-limiting device have a light field that defines the perimeter of the x-ray field?						
202.7 Part 2: Beam Limiting Devices Designed for Mammography						
Item: 1 (could contain up to 20 items with 1 required)						
State the maximum design SID and x-ray field size for each model BLD:						
Model Designation:						
SID (either cm or in):						
Field Size (either cm x cm or in x in):						
Does the beam-limiting device have a light field that defines the perimeter of the x-ray field?	[L]					
Provide an exact replica of all labels that show the maximum design SID and image receptor siz	re:					
File Attachment [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dte	d, .sgml, .mol, .xls, .csv, .zip)]					
[HTML Text]						
Is the image receptor support device changed when the image receptor is changed?	[L]					
Is there an interlock to assure proper image receptor selection with properaperture BLD?	[L]					
202.8 Part 1: Other Radiographic X-Ray Systems						
Is the BLD designed for other radiographic systems?		[L]				
Does the beam-limiting device have a light field that defines the perimeter of the x-ray field?		[L]				
Does the x-ray field extend beyond the edge of the image receptor?		[L]				
202.8 Part 2: Other Radiographic X-Ray Systems						
Item: 1 (could contain up to 20 items with 1 required)						
Other Radiographic X-Ray Systems (e.g., extraoral dental, podiatric, and cephalometric)						
ıl I						

Model Designation:			
Describe the means for limit	ting and/or cer	ntering the x-ray field for this model BLD.	
File Attachment	[Single File A	ttachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[HTML Text]			
Provide an exact replica of e	each label or n	narking that shows the SID and image receptor size.	
File Attachment	[Single File A	ttachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[HTML Text]			
List the model and SID and	d field size at	that SID.	
SID (either cm or in):			
Field Size (either cm x cm o	r in x in):		
			1
202.9 Part 1: Variable	e Filtration		
Does the beam-limiting devi	ce have varial	ole filtration selection?	[L]
2000 tilo 200iii iiiiiiiig uu i	es nave rana.		[-]
202.9 Part 2: Variable	e Filtration		
Item: 1 (could contain up t	to 20 items w	ith 1 required)	
Model Designation:	П		
-	ring the prese	nce of the required minimum filtration in the beam before the tube can be activated.	
[HTML Text]	9 p		
Is an interlock system used	with the filtrati	on?	[L]
Provide circuit diagrams of t	he interlock tie	ed to the kilo voltage selector that is part of the beam-limiting device.	,
File Attachment	[Single File A	ttachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]		
Describe the electrical and r	mechanical ch	aracteristics of the interlock system.	
File Attachment	[Single File A	ttachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]		
202.10 Capacitor Sto	orage X-Ra	y Systems	
Is any model beam-limiting of	device intende	d to be used on capacitor storage x-ray systems?	[L]
List each model that is design	gned for capac	citor storage units.	
Item 1			

Item 2
Item 3
203.0 X-RAY CONTROLS
Note:  This section should be completed for each x-ray control listed in section 2.4 and any combination listed in section 2.5 that contains an x-ray control as an integral part thereof. If this report is not certifying an x-ray control then go to section 204.0.
Is this report intended for the certification of an x-ray control or combination containing an x-ray control?
203.1 Warning Label
Provide a replica of the warning label affixed to the control panel and specify where the label is located with respect to the main power switch.
[Multi-Line Plain Text]
File Attachment [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
203.2 Part 1: Battery Powered Generator
Is the x-ray control used with a battery powered generator? [L]
203.2 Part 2: Battery Powered Generator
Item: 1 (could contain up to 20 items with 1 required)
Model Designation:
Describe the visual means provided to indicate whether or not the battery is in a state of charge adequate for proper operation.
[Multi-Line Plain Text]
203.3 Part 1: Radiography
Radiography (x-ray controls used for radiography, i.e., recording of static images viewed after termination of exposure)
Is the x-ray control designed to operate in the radiographic mode?
203.3 Part 2: Radiography
Item: 1 (could contain up to 20 items with 1 required)
Model Designation:

The type of kV displa	ıv.		[L]				
The type of mA displa							
The type of Time disp							
			1				
The type of mAs disp		de la constant de la	[L]				
	ne mari	rings on the technique factor indicators.					
Details [Multi-Line Plain Text]  File Attachment / pdf inc			tal complement rule controll				
File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .di	ia, .sgmi, .moi, .xis, .csv, .zip)j				
<u> </u>	oicture o	of the preindicators of technique factors to the operator.					
Details		[Multi-Line Plain Text]					
File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .di					
	oicture t	hat illustrates the proximity of any exposure switch to the preindicat	ted technique factors.				
Details		[Multi-Line Plain Text]					
File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
Attach a drawing or p	oicture o	of the indicator of x-ray production.					
Details		[Multi-Line Plain Text]					
File Attachment		ple File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
Attach a description of	of the a	udible signal used to indicate exposure termination.					
Details		Multi-Line Plain Text]					
File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dr					
Note:		ite" or "remote stations" are certifiable componentsand must compl controls.	y with all applicable requirements pertaining to				
• •		tion, state the applicable criteria that defines the technique factors, at to a certain percentage of the voltage waveform.	e.g., thebeginand end points of exposure time				
Details		[Multi-Line Plain Text]					
File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dr	td, .sgml, .mol, .xls, .csv, .zip)]				
Are two or more tube	housin	g assemblies controlled by the same radiographicexposure switch?	[L]				
Describe the pre-exp	osure t	ube selection indicator on the control panel and the provisions for in	ndication on the diagnostic source assemblies.				
[Multi-Line Plain Text	t]						
		s)for initiating and terminating x-ray production. Include each methonit switches, or exposure to the image receptor).	od by which x-ray exposure is terminated (e.g.,				
[Multi-Line Plain Text	t]						
Describe the method	by whi	ch the operator can terminate an exposure or series of exposures t	hat last longer than one-half second.				
[Multi-Line Plain Text	t]						
Describe the method	by whi	ch termination of the exposure causes automatic resetting of thetim	er to its initial setting or to zero.				

[Multi-Line Plain Text]				
Is a "zero" or "off" position	provided?			[L]
Is x-ray production prevent	ted when the tir	ner is set to either position?		[L]
Does the x-ray control inco	orporate an auto	omatic exposure control?		[L]
Provide a drawing or pictul exposure has been terminal		icator for automatic exposure control selection and (2 kup safety device.	) the visible signal that indicates when a	an
[Multi-Line Plain Text]				
File Attachment	[Single File A	uttachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .d	ltd, .sgml, .mol, .xls, .csv, .zip)]	
If the exposure has been to procedures.	erminated by th	e backup safety device during automatic exposure co	ontrol operation, describe the manual re	setting
[Multi-Line Plain Text]				
203.4 Part 1: Fluoro	scopy			
Fluoroscopy (x-ray contr	ols used for g	enerating x-ray images instantaneously and conti	nuously to display dynamic procedu	ıres)
Is the x-ray control designe	ed to operate in	the fluoroscopic mode?		[L]
203.4 Part 2: Fluoro	scopy			
Item: 1 (could contain up	to 20 items w	ith 1 required)		
Model Designation:				
For each fluoroscopic exposis not in position to interce		escribe the method employed to prevent the production eful beam.	on of x rays when the primary protective	: barrier
[Multi-Line Plain Text]				
Note: There	apy simulator s	ystems with remote control are exempt from this requ	uirement.	
Describe each control devi	ice (e.g., norma	Il fluoroscopy, cine, and test mode) for initiating and n	naintaining fluoroscopic x-ray production	n.
[Multi-Line Plain Text]				
How many minutes is the r	maximum cumu	lative on-time prior to an audible signal?		
Can this time interval be pr	reset?			[L]
Give the range limit in minu	utes.			
For each fluoroscopic cont beyond the completion of a		cribe the method of providing an audible signal that in ulative on-time.	dicates to the fluoroscopist x-ray produc	ction
[Multi-Line Plain Text]				
File Attachment	[Single File A	uttachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .d	ltd, .sgml, .mol, .xls, .csv, .zip)]	
Is there a display of total p	atient irradiatio	n time?		[L]

Is there an active display o	f patient irradiation exposure rate or air kerma rate (AKR)?	[L]
Explain how this is comput	ed in an attached file.	
Details	[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Is there a display of total pa	atient irradiation exposure or air kerma?	[L]
Explain how this is comput	ed in an attached file.	
Details	[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
For each x-ray and remote fluoroscopy.	controlpanel, provide a drawing or picture of the indicators that allow continuous monitoring of kVp and m	A during
Details	[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	tomatic exposure rate control mode that initiates exposure without the permanent recording of fluoroscope maximum values of fluoroscopic entrance AKR limited by your specifications. ( either mGy/min or mR/m	
Details	[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Does this model have high	level control?	[L]
For each manual and/or au	tomatic exposure rate control mode, describe any special means provided for activation of the high-level	control.
Details	[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
For each high-level control employed.	, describe the continuous audible signal that indicates to the fluoroscopist that the high-level control is bei	ng
Details	[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
For each high-level control specifications. (mG/min OF	mode that initiates exposure without the permanent recording of fluoroscopic entrance AKR limited by yo R mR/min)	ur
[Multi-Line Plain Text]		
Describe the method by wh	nich the fluoroscopist can initiate and/or terminate the recording of fluoroscopic images.	
[Multi-Line Plain Text]		
204.0 HIGH VOLTA	GE GENERATORS	
2.5 th	item should be completed for each high-voltage generator listed in section 2.4 and any combination listed nat contains a high-voltage generator as an integral part thereof. If this report is not certifying a high-voltage rator then go to section 205.0	
Is this report intended for the generator?	ne certification of an x-ray high-voltage generator of combination containing an x-ray high-voltage	[L]

20 any moderniy	h-voltage	generators co	ontain a thermionic diode valve?			[L]
ist each model th	hat has a t	hermionic dic	ode.			
em 1						
em 2						
em 3						
205.0 SPOT	FILM D	EVICES A	ND IMAGE INTENSIFIERS			
Note:	any co	ombination lis	I be completed for each conventional spot- sted in section 2.5 that contains such compo n device or image intensifier then go to sec	onents as a		
s this report inter	nded for th	e certification	n fo a spot film device or combination contain	ning a spot	film device?	[L]
205.1 Spot Fi	ilm Devi	ce				
tem: 1 (could co	ontain up	to 20 items v	with 1 required)			
Model spot film de	evice:					
lote:			ne appropriate model indicated, please go to	o question 2	2.4 MODEL DESIGNATION to en	ter the mod
	as it a	ppears on the	e identification label.			
s the spot film de			e identification label. le fluoroscopic systems?		[L]	
-	evice desig	ned for mobil			[L]	[L]
s the spot film de For each model s whenever the prin	evice desig evice desig pot-film de mary prote	ned for mobil ned for image evice and ima ctive barrier is	le fluoroscopic systems? e intensified systems? ge intensifier, describe the means to prevers not in position to intercept the entire useful		oscopic tube from producing x rad	liation
s the spot film de or each model s rhenever the prin nechanical chara	evice desig evice desig pot-film de mary prote	ned for mobil ned for imago evice and ima ctive barrier is and provide c	le fluoroscopic systems? e intensified systems? ge intensifier, describe the means to prevers not in position to intercept the entire useful	ıl beam. If t	oscopic tube from producing x rad here is an interlock, describe its e	liation
s the spot film de For each model s whenever the prin nechanical chara	evice desig evice desig pot-film de mary prote	ned for mobil ned for imago evice and ima ctive barrier is and provide c	le fluoroscopic systems? e intensified systems? ge intensifier, describe the means to prevers not in position to intercept the entire useful circuit diagrams.  Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .x	ıl beam. If t	oscopic tube from producing x rad here is an interlock, describe its e	liation
s the spot film de For each model s whenever the prin mechanical chara File Attachment Details	evice desig evice desig pot-film de mary prote acteristics a	ned for mobilined for image evice and imactive barrier is and provide c [Single File	le fluoroscopic systems? e intensified systems? ge intensifier, describe the means to prever sonot in position to intercept the entire useful circuit diagrams.  Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .sel.)	ıl beam. If t	oscopic tube from producing x rad here is an interlock, describe its e	liation
s the spot film de	evice designorment of the potential of t	ned for mobilined for image evice and imactive barrier is and provide configuration [Single File] [HTML Text	le fluoroscopic systems? e intensified systems? ge intensifier, describe the means to prevel s not in position to intercept the entire usefu- circuit diagrams.  Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .x	ıl beam. If t	oscopic tube from producing x rad here is an interlock, describe its e	liation
s the spot film de For each model s whenever the prin mechanical chara File Attachment Details	evice designot-film demany protenteristics and que Factoristic portain up	ned for mobilined for image evice and imactive barrier is and provide configuration [Single File] [HTML Text	le fluoroscopic systems? e intensified systems? ge intensifier, describe the means to prevel s not in position to intercept the entire usefu- circuit diagrams.  Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .x	ıl beam. If t	oscopic tube from producing x rad here is an interlock, describe its e	liation
s the spot film de For each model s whenever the prin nechanical chara File Attachment Details 205.2 Technic tem: 1 (could co	evice designor-film demany protecteristics and the contain up to t	ned for mobilined for imagined for imagined for imagined imagine for imagined provide of the control of the con	le fluoroscopic systems? e intensified systems? ge intensifier, describe the means to prevel s not in position to intercept the entire usefu- circuit diagrams.  Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .x	ul beam. If t	oscopic tube from producing x rad here is an interlock, describe its e	liation
s the spot film de For each model s whenever the prin nechanical chara File Attachment Details 205.2 Technic tem: 1 (could co	evice designor-film demany protestacteristics and protestacteristics and protestacteristics are contain up to the contai	ined for mobilined for image evice and imactive barrier is and provide configuration [Single File [HTML Text extor Adjust to 20 items versimage intension in mage in mage in tension in mage in mage in tension in mage i	le fluoroscopic systems? e intensified systems? ge intensifier, describe the means to prever sonot in position to intercept the entire useful circuit diagrams.  Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .sel)  tment  with 1 required)	ul beam. If t	oscopic tube from producing x rad here is an interlock, describe its e td, .sgml, .mol, .xls, .csv, .zip)]	liation

205.3 Part 1:	lmane l	ntensifier		
200.5 T alt 1.	illiage	THE HOLLING		
Is this report inter	nded for the	e certification	of an image intensifier or combination containing an image intensifier?	[L]
005.0.0.1.0	1			
205.3 Part 2:	Image I	ntensifier		
Item: 1 (could co	ontain up t	o 20 items w	vith 1 required)	
		ſ		
Model Image Inte				
	•		scopic tube from producing x radiation whenever the primary protective barrier is not in posi s an interlock, describe its electrical and mechanical characteristics and provide circuit diag	
File Attachment		[Single File A	Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details		[HTML Text]		
Does this image	intensifier p	ermit or conti	rol technique factor adjustment? [L]	
Message:	If "Yes	" has been se	elected above, the following note applies:	
Note:	addres	ss applicable	device or image intensifier controls x-ray output, it is considered an x-ray control and you m questions in section 203.0, PART 200.Section 2.5 should list the combination of image intered x-ray control.	
	-7			
206.0 TABLE	S, CAS	SETTE HO	OLDERS, FILM CHANGERS AND CRADLES	
Note:	any co certifyi	mbination list ing a table, ca	be completed for each table, cassette holder*, film changer and/or cradle listed in section 2 ted in section 2.5 that contains such components as an integral part thereof. If this report is assette holder, film changer and/or cradle then go to section 207.0* Applicable only to casse	not
Is this report inter	nded for the	e certification	of a cassette holder, film changer, x-ray table, and/or a cradle?	[L]
206.1 Subjec	t Compo	nent Cap	abilities	
Do any of the south	in at a a man a	nanta allaur fa		T <sub>n,1</sub>
•			or operator adjustment of technique factors?  e limit switches that automatically preempt the preset exposure time of the master control	[L]
panel?	,		, , , , , , , , , , , , , , , , , , , ,	[L]
Message:	If "Yes	" has been se	elected for either of the above questions, the following note applies:	
Note:		ons in section	omponent controls x-ray output, it is considered an x-ray control and you must address app n 203.0, PART 200. Section 2.5.1 should list the combination of appropriate component and	
000 0 D 11	. N. 4. 1. 1. T	-:l O!		
206.2 Part 1:	iviodel F	·ıım Chanç	ger	
Is this report for t	he certificat	tion of a film o	changer?	[L]

206.2 Part 2: Model F	Film Changer	
Item: 1 (could contain up	to 20 items with 1 required)	
Model Film Changer:		
Is there a film changer built	into the stationary radiographic table?	[L]
Explain how beam limitation	n is accomplished for serial radiography.	
[HTML Text]		
For each model film change than one-half second.	er, explain the provision(s) enabling the operator to terminate an exposure or series of exposures that	last longer
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
206.3 X-Ray Tables		
Is this report for the certifica	ation of an x-ray table?	[L]
206.4 Model X-Ray T	Table Characteristics	
Item: 1 (could contain up	to 20 items with 1 required)	
Model x-ray table:		
For each model x-ray table,	identify its appropriate characteristics from the following:	
Item 1		
Item 2		
Item 3		
If "other", please describe fu	urther.	
[HTML Text]		
assemblers that lists compa	use on a general purpose x-ray system, cite the specific paragraph(s) (page number) in your instruction atible tube stands and/or other equipment necessary for indication (as required under 21 CFR 1020.31 o)(2)(iii)) of the perpendicularity of the beam axis to the image receptor and the SID.	ons to (e)(1)(i), (g)
	/(Z)(III)) of the perpendiculantly of the beam axis to the image receptor and the Sib.	
[HTML Text]		
206.5 Verticle Casse	tte Holder	
Is this report for the certifica	ation of a verticle cassette holder?	[L]
For each model verticle cas	ssette is the verticle cassette holder equipped with cassette size sensors?	[L]

206 6 Imaga	Pagantar Sizaa							
206.6 image i	Receptor Sizes							
Item: 1 (could co	ntain up to 20 items v	with 1 req	uired)					
Model Designation	n.							
-		( in	in X					
Cassette Sizes: (	cm xcm ) OR (	(in x _	in )					
207.0 CEPHA	LOMETRIC DEV	/ICES						
Note:	This section should cephalometric devi	•	•	nalometric dev	rice listed in s	section 2.4. If the	is report is not	certifying a
Is this report inten	ded for the certification			e?				[L]
207.1 Cephal	ometric Device In	ncluding	a Beam-Limi	ting Device	)			
Item: 1 (could co	ntain up to 20 items v	with 1 req	uired)					
Model Designation	n:							
	n: metric device include a	a beam-lim	iting device as an	integral desig	n feature?			[L]
		g device is	not sold seperate	ly answer the	applicable qu	estions in secti e and beam lim	on 202.0, PAR iting device as	T 200 if not
Does the cephalor	metric device include a  If the beam limiting already done. Sect	g device is tion 2.5 sh	not sold seperate	ly answer the ination cephal	applicable qu	iestions in secti e and beam lim	on 202.0, PAR iting device as	T 200 if not
Does the cephalor  Note:  207.2 Cephalor	If the beam limiting already done. Sect inseparable part.	g device is tion 2.5 sh	not sold seperate ould list the comb a Cassette H	ly answer the ination cephal	applicable qu	estions in secti e and beam lim	on 202.0, PAR iiting device as	T 200 if not
Does the cephalor  Note:  207.2 Cephalor	If the beam limiting already done. Sect inseparable part.	g device is tion 2.5 sh	not sold seperate ould list the comb a Cassette H	ly answer the ination cephal	applicable qu	estions in secti e and beam lim	on 202.0, PAR iiting device as	T 200 if not
Does the cephalor  Note:  207.2 Cephalor	If the beam limiting already done. Sect inseparable part.  ometric Device In the part of t	g device is tion 2.5 sh	not sold seperate ould list the comb a Cassette H	ly answer the ination cephal	applicable qu	estions in secti e and beam lim	on 202.0, PAR iiting device as	T 200 if not
Does the cephalor  Note:  207.2 Cephalor  Item: 1 (could co	If the beam limiting already done. Sect inseparable part.  ometric Device In the part of t	g device is tion 2.5 sh ncluding	not sold seperate could list the comb.  a Cassette Huired)	ly answer the ination cephal	applicable qu	e and beam lim	on 202.0, PAR iting device as	T 200 if not
Does the cephalor  Note:  207.2 Cephalor  Item: 1 (could co  Model Designation  Does the cephalor	If the beam limiting already done. Sect inseparable part.  ometric Device In the interior of t	g device is tion 2.5 sh	not sold seperate could list the comb.  a Cassette Huired)	ly answer the ination cephal	applicable quometric devid	e and beam lim	iting device as	T 200 if not can integral
Does the cephalor  Note:  207.2 Cephal  Item: 1 (could co  Model Designation  Does the cephalor	If the beam limiting already done. Sect inseparable part.  ometric Device In the sect inseparable part.  ometric Device In the sect inseparable part.	g device is tion 2.5 sh	a Cassette Huired)	ly answer the ination cephalicolder	applicable quometric devid	n feature?	SYSTEMS	T 200 if not ean integral
Does the cephalor  Note:  207.2 Cephalor  Item: 1 (could co  Model Designation  Does the cephalor	If the beam limiting already done. Sect inseparable part.  ometric Device In the interior of the include a	g device is tion 2.5 sh  ncluding  with 1 req  a cassette	a Cassette Huired)  DEVICES FOr each image	ly answer the ination cephalical	applicable quometric devicentegral design	n feature?	SYSTEMS	T 200 if not ean integral
Does the cephalor  Note:  207.2 Cephalor  Item: 1 (could co  Model Designation  Does the cephalor  208.0 IMAGE	If the beam limiting already done. Sect inseparable part.  Ometric Device In the interior of t	g device is tion 2.5 sh  ncluding  with 1 req  a cassette  IPPORT  d be comp	a Cassette Huired)  DEVICES FOr each imaupport device there	ly answer the ination cephalical	applicable quometric devicentegral design	n feature?	SYSTEMS	T 200 if not ean integral
Does the cephalor  Note:  207.2 Cephal  Item: 1 (could co  Model Designation  Does the cephalor  208.0 IMAGE  Note:  Is this report inten	If the beam limiting already done. Sect inseparable part.  Ometric Device In the interior of t	g device is tion 2.5 sh  ncluding  with 1 req  a cassette  IPPORT  d be comp receptor so	a Cassette Huired)  DEVICES FOr each image property device there e receptor support	ly answer the ination cephalical	applicable quometric devicentegral design	n feature?	SYSTEMS	[L]

Does	s the image rec	eptor support	device include a cassette holder with a front panel as an integral part?	[L]				
Se	ction: Qu	ality Co	ntrol Testing					
301	.0 Leakage	Radiation	from the Diagnostic Source					
Note	e:		following questions if certifying a beam-limiting device or tube housing assembly in this submission lected for question 2.4 (a),(b), 2.5 (a), (b), (c) or (d)).	(i.e., if				
Req	uirement:							
Mes	sage:	source shall tube is ope	e radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction in the line of 1 meter in any direction in the second of 1 meters of 1 mete	the x-ra				
Арр	licability:							
Mes	sage:	device). Sin	ement is applicable to the diagnostic source assembly (tube housing assembly combined with a bear milar models of a single component type may be grouped for presentation of test results applicable to t when the technical basis for this grouping is clearly stated in the description of prototype testing (so Testing (a)).	o this				
Criti	cal Parameters	s and "Worst	t Case" Conditions:					
A.	Message:		he test results must include data representative of each compatible combination of tube housing assembly and eam-limiting device.					
B.	Message:		s a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be ifficiently restrictive to assure compliance with the standard.					
C.	Message:		o assure the use of maximum rated peak tube potential and continuous tube current, the test method(s) must ovide the procedure for periodic calibration of technique factors.					
D.	Message:		ny test using a scan of the diagnostic source assembly, the rate of scan specified in the test method unt for the response time of the radiation instrumentation.	s) must				
Prot	otype Testing:	1						
			full production phase and thus the testing and quality control procedures may not be the same as e testing apply?	[L]				
A.	Describe the o		thod (i.e., one that actuallymeasures x radiation) employed in testing and measuring each model wit	h respe				
	[HTML Text]							
B.	3. Identify the instrument(s) used for the test by manufacturer and model number.							
	[HTML Text]							
C.	Attach a samp	ole of raw test	data.					
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details		[HTML Text]					
D.	Is the actual c	omplianceval	ue calculated from the raw test data?	[L]				
E.	Attach a comp	ole of calculate	ed compliance values complete with an explanation of any correction factors employed.					

	File Attachment	[Sin	ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[НТ	ML Text]				
Expl	ain how complian	nce is established	i.				
[Mul	ti-Line Plain Text]						
Proc	duction Testing:						
A.	Does the test in	volve a direct tes	st of the performance parameter?				
B.			in testing of each model with respect to this requirement. If reference is made to a test protocol attachment for documentation.				
	File Attachment	[Sin	igle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[НТ	ML Text]				
C.	If any test used this requirement	-	liance does not actually measure x radiation, explain why it is an accurate indication of compliance with				
	[HTML Text]						
D.	Submit the tech	nical data that su	upports the use of the test in question (C.)				
	File Attachment	[Sin	igle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[НТ	ML Text]				
Ε.	Attach a copy of	Attach a copy of the detailed instructions for performing each test.					
	File Attachment	[Sin	igle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details [HT		[HTML Text]				
F.	Identify the instr	rument(s) used fo	or each test by manufacturer and model number.				
	File Attachment	[Sin	igle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[НТ	ML Text]				
G.	For each test me rejection limits a		uestion (B.) under Production Testing, attach the detailed instructions for performing the test where the				
	File Attachment	[Sin	ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[НТ	ML Text]				
H.	For each test m	ethod listed in qu	uestion (B.), please attach sample raw test data.				
	File Attachment	[Sin	igle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[НТ	ML Text]				
l.	Is the actual cor	mpliance value ca	alculated from the raw test data? [L]				
	- Please att	ach a sample of	calculated compliancevalues complete with an explanation of any correction factors employed.				
	File Attach	nment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				

J. Is this performance parameter tested on 100 percent of the produced models?  Assembler Testing:  Does assembler testing apply?  A. Does the test involve a direct test of the performance parameter?  B. Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as anattachment for documentation.  File Attachment [Single File Attachment (pdf, jpg, glf, slf, avi, wmv, xpt, xml, dtd, sgml, mol, xls, csv, zip)]  Details [HTML Text]  D. Submit the technical data that supports the use of the test in question (C.)  File Attachment [Single File Attachment (pdf, jpg, glf, slf, avi, wmv, xpt, xml, dtd, sgml, mol, xls, csv, zip)]  Details [HTML Text]  C. Attach a sample of raw test data.  File Attachment [Single File Attachment (pdf, jpg, glf, slf, avi, wmv, xpt, xml, dtd, sgml, mol, xls, csv, zip)]  Details [HTML Text]  F. Identify the instrument(s) used for each test by manufacturer and model number.  File Attachment [Single File Attachment (pdf, jpg, glf, slf, avi, wmv, xpt, xml, dtd, sgml, mol, xls, csv, zip)]  Details [HTML Text]  G. For each test method listed in question (B.) under Assembler Testing, attach the detailedinstructions for performing the test where the rejection limits are specified.  File Attachment [Single File Attachment (pdf, jpg, glf, slf, avi, wmv, xpt, xml, dtd, sgml, mol, xls, csv, zip)]  Details [HTML Text]  H. For each test method listed in question (B.) please attach sample raw test data.  File Attachment [Single File Attachment (pdf, jpg, glf, slf, avi, wmv, xpt, xml, dtd, sgml, mol, xls, csv, zip)]  Details [HTML Text]  H. For each test method listed in question (B.), please attach sample raw test data.  File Attachment [Single File Attachment (pdf, jpg, glf, slf, avi, wmv, xpt, xml, dtd, sgml, mol, xls, csv, zip)]  Details [HTML Text]  H. Is the actual compliance value calculated from the raw test data?  For vide a copy of the pages in the user manual that specifies no assembly or installation	[Mult	i-Line Plain Text]		
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Details [HTML Text]				ed to
	File A	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
000 0 D Ovelite	Deta	ils	[HTML Text]	
1000 0 Dears Ovella				
302.0 Beam Quality	302	.0 Beam Quality		

Note	e:		e following questions if certifying a beam-limiting device or tube housing assembly in this submission elected for question 2.4 (a), (b), 2.5 (a), (b), (c) or (d)).	(i.e., if				
Req	luirement:							
Mes	ssage:		alue layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in nostic x-ray standard (see 1020.30(m)).	in Table				
Арр	olicability:							
Mes	ssage:	device con	rement is applicable to the tube housing assembly or the diagnostic source assembly if the beam-limit tainsfiltration. Similar models of a single component type may be grouped for presentation of test res to this requirement when the technical basis for this grouping is clearly stated (see (a) under Prototyp	ults				
Criti	ical Parameter	s and "Wors	et Case" Conditions:					
Α.	Message:		test results must include data representative of each compatible combination of tubehousing assemb n-limiting device.	ly and				
В.	Message:		result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test mu ciently restrictive to assure compliance with the standard.	ıst be				
C.	Message:	I	e the peak tube potential has a critical effect on determining the half-value layer, the test method(s) mide the procedure for periodic calibration of tube potential.	nust				
D.	Message:		inimize the sources of scatter radiation, the x-rayfield specified in the test method(s) must be just larg gh to cover the sensitive volume of the detector.	ge				
Pro	totype Testing	:						
			o full production phase and thus the testing and quality control procedures may not be the same as be testing apply?	[L]				
A.	Describe the respect to this		ethod (i.e., one that actually measures x radiation) employed in testing and measuring each model wit	th				
	[HTML Text]							
B.	Identify the in	strument(s) u	sed for the test by manufacturer and model number.					
	[HTML Text]		, , , , , , , , , , , , , , , , , , ,					
	C. Attach a sample of raw test data.							
C.	Attach a sam	ole of raw tes	t data.					
C.	Attach a samp	·	t data.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
C.		·	1					
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D.	File Attachme Details Is the actual of	compliance va	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]	[L]				
D.	File Attachme Details Is the actual of	ent compliance va ple of calcula	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] alue calculated from the raw test data?	[L]				
D.	File Attachme Details Is the actual of	ent compliance va ple of calcula	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  alue calculated from the raw test data?  ted compliance values complete with an explanation of any correction factors employed.	[L]				
D. E.	File Attachme Details Is the actual of Attach a samp	ent compliance va ple of calcula	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] alue calculated from the raw test data?  ted compliance values complete with an explanation of any correction factors employed.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]	[L]				
D. E.	File Attachme Details Is the actual of Attach a samp File Attachme Details	compliance value of calcula ent	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] alue calculated from the raw test data?  ted compliance values complete with an explanation of any correction factors employed.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]	[L]				
[Mul	File Attachme Details Is the actual of Attach a samp File Attachme Details Iain how compli	compliance va ple of calcula ent ance is estab	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] alue calculated from the raw test data?  ted compliance values complete with an explanation of any correction factors employed.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]	[L]				

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	Details	[HTML Text]	172				
C.	If any test used to mo this requirement.	onitor compliance does not actually measure x radiation, explain why it is an accurate indication of cor	mpliance with				
	[HTML Text]						
D.	Submit the technical	data that supports the use of the test in question (C.)					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi	ip)]				
	Details	[HTML Text]					
E.	Attach a copy of the c	detailed instructions for performing each test.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi	ip)]				
	Details	[HTML Text]					
F.	Identify the instrumen	nt(s) used for each test by manufacturer and model number.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi	ip)]				
	Details	[HTML Text]					
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[HTML Text]					
П	Foreach test method listed in question (B.), please attach sample raw test data.						
H.	1 oreaen test metries	(-7, )-1					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi	ip)]				
		<u> </u>	ip)]				
i.	File Attachment  Details	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi	ip)]				
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l.	File Attachment  Details  Is the actual compliar  Please attach a	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi  [HTML Text]  nce value calculated from the raw test data?  a sample of calculated compliance values complete with an explanation of any correction factors emplification [Multi-Line Plain Text]	[L]				
I.	File Attachment  Details  Is the actual complian  Please attach a  Details	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi  [HTML Text]  nce value calculated from the raw test data?  a sample of calculated compliance values complete with an explanation of any correction factors emple  [Multi-Line Plain Text]  t [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .cd	[L]				
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I.  Explaining the second of t	File Attachment  Details  Is the actual compliar  Please attach a Details  File Attachment  ain how compliance is  ii-Line Plain Text]  Is this performance page	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi  [HTML Text]  nce value calculated from the raw test data?  a sample of calculated compliance values complete with an explanation of any correction factors emple  [Multi-Line Plain Text]  t [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .ce established.	[L] oyed.				
I.  Explaining [Multiple of the content of the cont	File Attachment  Details  Is the actual complian  Please attach a Details  File Attachment  ain how compliance is  ii-Line Plain Text]  Is this performance possible Testing:  s assembler testing applications.	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi  [HTML Text]  nce value calculated from the raw test data?  a sample of calculated compliance values complete with an explanation of any correction factors emple  [Multi-Line Plain Text]  t [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .ce established.	[L] oyed. esv, .zip)]				

	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
C.			or compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with				
	[HTML Text]	[HTML Text]					
D.	Submit the tec	hnical data	a that supports the use of the test in question (C.)				
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
E.	Attach a copy	of the deta	ailed instructions for performing each test.				
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	Details		[HTML Text]				
G.	For each test rejection limits		ed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the ied.				
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
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	Details		[HTML Text]				
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File	Attachment	[S	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Det	ails	[⊢	HTML Text]				
30	3.0 Aluminur	n Equiva	alence				
		A	the fellowing questions if entitions a second to be less with a few towards of the second sec				
Not	e:		the following questions ifcertifying a cassette holder with a front panel or the device you are certifying includes a holder as an integral part (i.e., if yes was selected for question 2.4 (I), 207.2, or 208.1).				
Red	quirement:						
Me	ssage:		ninum equivalent of the frontpanels of cassette holders and film changers, tabletops, and cradles that are used the patient and image receptorshall not exceed the limits indicated in Table II of the diagnostic x-ray standard 0.30(n)).				
Apı	olicability:						
Me	ssage:	This requ	uirement is applicable to cassetteholders, film hangers, tables and cradles. Similar models of a single				

		mponent type may be groupedfor. presentation of test results applicable to this requirement when the technical bat this grouping is clearly stated in the description of prototype testing (see 303.4(a)).				
Criti	ical Parameters an	d "Worst Case" Conditions:				
A.	Message:	As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.				
В.	Message:	Since the peak tube potential has a critical effect on determining the aluminum equivalent, the test method(s) is provide the procedure for periodic calibration of tube potential.				
С.	Message:	Since compliance will be measured at 100 kVp and 2.7 millimeters of aluminum half-value layer, test data resultion of the conditions must be extrapolated to the value at the specified conditions.				
Prot	otype Testing:					
		p prior to full production phase and thus the testing and quality control procedures may not be the same as prototype testing apply?				
۸.	Describe the direct to this requirement	testmethod (i.e., one that actually measures x radiation) employed in testing and measuring each model with response.				
	[HTML Text]					
١.	Identify the instrun	nent(s) used for the test by manufacturer and model number.				
	[HTML Text]					
<b>)</b> .	Attach a sample o	raw test data.				
	Details	[Multi-Line Plain Text]				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
).	Is the actual comp	liance value calculated from the raw test data?				
	Attach a sample o	calculated compliance values complete with an explanation of any correction factors employed.				
	Details	[Multi-Line Plain Text]				
	File Attachment	File Attachment [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
xpl	ain how compliance	is established.				
Mul	ti-Line Plain Text]					
Proc	duction Testing:					
١.	Does the test invo	ve a direct test of the performance parameter?				
3.		ds employed in testing of each model with respect to this requirement. If reference is made to a test protocol a copy as an attachment for documentation.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
С.	If any test used to this requirement.	monitor compliance does not actually measure x radiation, explain why it is an accurate indicationof compliance w				
	[HTML Text]					
Э.	Submit the technic	al data that supports the use of the test in question (C.)				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				

	Deta	ils	[HTI	ML Text]				
E.	Attac	ch a copy of the detai	led insti	ructions for performing each test.				
	Deta	ils	[Mul	[Multi-Line Plain Text]				
	File Attachment [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]							
F.	Identify the instrument(s) used for each test by manufacturer and model number.							
	File	Attachment	[Sing	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTN	ML Text]				
G.		each test method liste tion limits are specifi	-	estion (B.) under Production Testing, attach the detailed instructions for performing the test when	nere the			
	File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTN	ML Text]				
Н.	For e	each test method liste	ed in qu	estion (B.), please attach sample raw test data.				
	File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTN	ML Text]				
I.	Is the	e actual compliance v	/alue ca	lculated from the raw test data?	[L]			
	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.							
	File Attachment			[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
		Details		[HTML Text]				
Ехр	lain ho	w compliance is esta	blished					
[Mul	lti-Line	Plain Text]						
J.	Is thi	s performance paran	neter tes	sted on 100 percentof the produced models?	[L]			
Ass	emble	r Testing:						
Doe	s asse	mbler testing apply?			[L]			
A.	Does	s the test involve a di	rect test	of the performance parameter?	[L]			
B.	1	•	-	n testing of each model with respect to this requirement. If reference is madeto a test protocol attachment for documentation.				
	File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTN	ML Text]				
C.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indicationof compliance with this requirement.							
	[HTN	/IL Text]						
_	Subr	mit the technical data	that su	pports the use of the test in question (C.)				
υ.	File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
D.	File /							

E.	Attach a copy	of the deta	ailedinstructions for performing each test.		
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
	Details		[HTML Text]		
F.	Identify the ins	strument(s	sed for each test by manufacturer and model number.		
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
	Details		[HTML Text]		
G.	For each test rejection limits		ted in question (B.) under Assembler Testing, attach the detailed instructions for performing the test wher ified.	e the	
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
	Details		[HTML Text]		
Н.	For each test i	method lis	sted in question (B.), please attach sample raw test data.		
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
	Details		[HTML Text]		
I.	Is the actual c	ompliance	value calculated from the raw test data?	[L]	
			n the user manual that specifies no assembly or installation instructions are necessary and all that is need the power cord into the wall socket.	led to	
File	Attachment	[5	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
		HTML Text]			
304	1.0 Standby	Radiation	on from Capacitor Energy Storage Equipment		
Req	uirement:	5 " "		6000	
Mes	ssage:	microgra	on emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of aysor 0.03 mR in 1 minute at 5 centimeters from any accessible surface of the diagnostic source assembles m-limiting device fully open and 0.88 mGy or 100 mR in1 hour 100 centimeters from the source (see 1020)	y, with	
Арр	licability:	•			
Mes	ssage:	of a sing	uirement is applicable to the diagnostic source assembly of capacitor energy storage equipment. Similar gle component type may be grouped for presentation of test results applicable to this requirement when the last for this grouping is clearly stated in the description of prototype testing (see 304.4(a)).		
Criti	ical Parameters	s and "Wo	orst Case" Conditions:		
A.	Message:		ne test results must include data representative of each compatible combination of tube housing assembly eam-limiting device.	and	
В.	Message:	I	s a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must officiently restrictive to assure compliance with the standard.	be	
C.	Message:		o test for the maximum standby radiation, the beam-limiting device must be fully open and the highest ava eak tube potential must be used. These conditions must bespecified in the test method(s).	ilable	
D.	Message:		or any test using a scan of the diagnostic source assembly, the rate of scan specified in the test method(s, ke into account the response time of the radiation instrument.	must	
Prof	totype Testing:				

	duction testing. Does protot	ype testing apply?  ethod (i.e., one that actually measures x radiation) employedin testing and measuring each model with	[L]					
A.	to this requirement.	strice (i.e., one that accounty incastrics x radiation) employeean testing and measuring each model with	тоороо					
	[HTML Text]							
B.	Identify the instrument(s) used for the test by manufacturer and model number.							
	[HTML Text]							
C.	Attach a sample of raw te	est data.						
	Details	[Multi-Line Plain Text]						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
D.	Is the actual compliance	value calculated from the raw test data?	[L]					
E.	Attach a sample of calcul	ated compliance values complete with an explanation of any correction factors employed.						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
	Details	[HTML Text]						
Exp	lain how compliance is esta	ablished.						
[Mul	lti-Line Plain Text]							
Pro	duction Testing:							
A.	Does the test involve a di	irect test of the performance parameter?	[L]					
B.		ployed in testing of each model with respect to this requirement. If reference is made to a test protocol vas an attachment for documentation.						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
	Details	[HTML Text]						
C.	If any test used to monito this requirement.	or compliance does not actually measure x radiation, explain why it is an accurate indication of complian	nce with					
	[HTML Text]							
	1							
D.		that supports the use of the test in question (C.)						
D.		that supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
D.	Submit the technical data							
D. E.	Submit the technical data File Attachment Details	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
	Submit the technical data File Attachment Details	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]						
	Submit the technical data File Attachment Details Attach a copy of the deta	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  iled instructions for performing each test.						
	Submit the technical data File Attachment Details Attach a copy of the deta File Attachment Details	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  illed instructions for performing each test.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
E.	Submit the technical data File Attachment Details Attach a copy of the deta File Attachment Details	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  [Indicate the standard of the sta						

l								
	File A	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Deta	ils	[HTML Text]					
H.	For each test method listed in question (B.), pleaseattach sample raw test data.							
	File Attachment [Si		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Deta	ils	[HTML Text]					
l.	Is the actual compliance value calculated from the raw test data?							
	-	Please attach a samp	ole of calculated compliance values complete with an explanation of anycorrection factors employed.					
		File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	zip)]				
		Details	[HTML Text]					
Expla	ain ho	w compliance is estab	lished.					
[Mult	i-Line	Plain Text]						
J.	Is thi	s performance parame	eter tested on 100 percent of the produced models?	[L]				
Asse	emble	r Testing:		*				
Does	asse	mbler testing apply?		[L]				
A.	Does	the test involve a dire	ct test of the performance parameter?	[L]				
B.		•	byed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.					
	File A	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Deta	ils	[HTML Text]					
C.		test used to monitor of the desirement.	compliance does not actually measure x radiation, explain why it is an accurateindication of compliar	ice with				
	[HTN	IL Text]						
D.	Subn	nit the technical data t	nat supports the use of the test in question (C.)					
	File A	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Deta	ils	[HTML Text]					
E.	Attac	h acopy of the detailed	d instructions for performing each test.					
	File A	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Deta	ils	[HTML Text]					
F.	Ident	ify the instrument(s) u	sed for each test by manufacturer and model number.					
	File A	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Deta	ils	[HTML Text]					
G.		each test method listed	in question (B.) under Assembler Testing, attach the detailed instructions for performing the test wh	ere the				

	ı			1
	File A	ttachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Detail	ls		[HTML Text]
٦.	For ea	ach test meth	od listed	d in question (B.), please attach sample raw test data.
	File A	ttachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Detail	ls		[HTML Text]
	Is the	actual compl	iance va	alue calculated fromthe raw test data?
			•	ne user manual that specifies no assembly or installation instructions are necessary and all that is needed to power cord into the wall socket.
File Attachment		[Sin	igle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Deta	ils		[HT	ML Text]
_				
305	5.0 Fu	ıoroscopic	Entra	nce Exposure Rate
	uireme			
	1		1	
	Messa	age:	Fluor	roscopic equipment manufactured prior to May 19,1995.  Equipment with automatic exposure rate control shall not be operable at any combination of tube potential
				and current that will result in am exposure rate in excess of 2.58x 10-3 C/kg per minute or 10 roentgens per minute at the point where the center of the useful beam entersthe patient, except:(a) during recording of fluoroscopic images, or(b)when an optional high-level control is provided. When so provided, the equipments shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.29x 10-3 C/kg per minute (5 R/min) at the point where the center of the useful beam enters the ???
3.		Message:		Fluoroscopic equipment that is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.29x 10-3 C/per minute (5 R/min) at the point where the center of the usefulbeam enters the patient, except:(a) during recording of fluoroscopic images, or(b) when an optional high-level control isactivated (see 1020.32(d)).
C.		Message:		Fluoroscopic equipment that is provided with both automatic exposure rate control and manual control sha not be operable at any combination of tube potential and current that will result in an exposure rate in except 1.29x 10-3 C/kg per minute (5 R/min) in the mode containing high-level control and 2.58x 10-3 C/kg per minute or 10 roentgens per minute at the point where the center of theuseful beam enters the patient, except:(a) during recording of fluoroscopic images, or(b) when an optional high-level control is activated (s 1020.32(d)).(c) when a mode without high level option is activated in which case the exposure rate is limite to 2.58x 10-3 C/kg per minuteor 10 roentgens per minute at the point where the center of the useful beam enters the patient.
2.	Messa	age:	Fluor	roscopic equipment manufactured on or after May 19,1995.
١.		Message:		Equipment which can operate above 44 mGy/min (5 R/min) must have automatic exposure rate control.
В.		Message:		Equipment shall not be operable at any combination of tube potential and current that will result in an air kerma rate (AKR) in excess of 88 mGy/min or 10 roentgens per minute at the point where the center of the usefulbeam enters the patient, except:(a) during recording of fluoroscopic images, or(b) when an optional high-level control (HLC) is activated. When theHLC is activated, it shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 176 mGy/min or 20 roentgens per minute at the point where the center of the useful beam enters the patient unless the high-level control activated.
Арр	licabili	ity:		
Mes	sage:	cor	mponen	rement is applicable to fluoroscopic and automatic exposure rate x-ray controls. Similar models of a single t type may be grouped for presentation of test results applicable to this requirement when the technical basi uping is clearly stated in the description of prototype testing (see 305.4(a)).

A.	Message:	As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must sufficiently restrictive to assure compliance with the standard.	t be		
В.	Message:	To test for the maximum entrance exposure rate, the beam-limiting device must be fully open. This condition be specified in the test method(s).	on mus		
C.	Message:	For equipment without automatic exposure rate control, the test results must include data for "worst case" combinations of peak tube potentials and tube currents (e.g., maximum kVp and mA).			
D.	Message:	For equipment with automatic exposure rate control, the technique factors specified in the test method(s) method driven to the maximum design limits for this test.	nust be		
E.	Message:	For automatic exposure rate control equipment using direct viewing optics, the test must be performed with suppressed ambient light conditions.	1		
Prof	totype Testing:				
		prior to full production phase and thus the testing and quality control procedures may not be the same as prototype testing apply?	[L]		
A.	Describe the direct respect to this req	test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with irement.	1		
	[HTML Text]				
В.	Identify the instrur	ent(s) used for the test by manufacturer and model number.			
	[HTML Text]				
C.	Attach a sample o	raw test data.			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[Multi-Line Plain Text]			
D.	Is the actual comp	ance value calculated from the raw test data?	[L]		
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[Multi-Line Plain Text]			
Expl	lain how compliance	s established.			
[Mul	ti-Line Plain Text]				
Pro	duction Testing:				
A.	Does the test invo	re a direct test of the performance parameter?	[L]		
B.	1	ds employed in testing of each model with respect to this requirement. If reference is made to a test protocol a copy as an attachment for documentation.			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]			
C.	If any test used to this requirement.	nonitor compliance does not actually measure x radiation, explain why it is an accurate indication of complian	ce wit		

	Subr		T		
		Attachment	╫	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	uls	[HIN	ML Text]	
E.	Attac	ch a copy of the detai	led instr	ructions for performing each test.	
	File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	iils	[HTN	ML Text]	
F.	Iden	tify the instrument(s)	used fo	r each test by manufacturer and model number.	
	File	Attachment	[Sino	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	iils	[HTN	ML Text]	
G.		each test method liste		estion (B.) under Production Testing, attach the detailed instructions for performing the test wh	ere the
	File	Attachment	[Sino	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	iils	[HTM	ML Text]	
H.	For 6	each test method liste	d in que	estion (B.), please attach sample raw test data.	
	File	Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	iils	[HTM]	ML Text]	
	Is the	e actual compliance v	alue ca	alculated from the raw test data?	[L]
	-	Please attach a san	ple of c	calculated compliance values complete withan explanation of any correctionfactors employed.	
		File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	:ip)]
		Details		[Multi-Line Plain Text]	
Ехр	ain ho	w compliance is esta	blished.		
[Mul	ti-Line	Plain Text]			
J.	Is th	is performance paran	neter tes	sted on 100 percent of the produced models?	[L]
Ass	*	er Testing:			•
Doe	s asse	embler testing apply?			[L]
A.	Does	s the test involve a di	ect test	t of the performance parameter?	[L]
B.	Desc	cribe all methods emp	oloyed ir	n testing of each model with respect to this requirement. If reference is made to a test protocol attachment for documentation.	
		Attachment	Т	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	nils	[HTN	ML Text]	
C.		y test used to monitor		iance doesnot actually measure xradiation, explain why it is an accurate indication of compliance	ce with
Ο.		//L Text]			
<b>.</b>	[HTN	NE TOXI			

	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details		[HTML Text]
E.	Attach a copy of	of the detaile	d instructions for performing each test.
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details		[HTML Text]
F.	Identify the inst	trument(s) us	sed for each test by manufacturer and model number.
	File Attachmen	. ,	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details		[HTML Text]
G.	For each test n		in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the d.
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details		[HTML Text]
Н.	For each test n	nethod listed	in question (B.), please attach sample raw test data.
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details		[HTML Text]
I.	Is the actual co	mpliance va	lue calculated from the raw test data? [L]
			e user manual that specifies no assembly or installation instructions are necessary and all that is needed to power cord into the wall socket.
File A	Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Deta	ils	[HTI	VIL Text]
306	.0 Primary F	Protective	Barrier Transmission
ltem:	: 1 (could conta	ain up to 15	items with none required)
Mode	el Number of the	e device:	
Regu	uirement:		
	sage:	radiation fro milliroentge	ure rate due to transmission through the barrier with the attenuation block in theuseful beam combined with om the image intensifier, if provided, shall not exceed 3.34x 10-3 percent of the entrance exposure rate (or 2 cms per hour for each roentgen per minute of entrance exposure rate) at 10 centimeters from any accessible ne fluoroscopic imaging assembly beyond the plane of the imagereceptor (see 1020.32(a)(i)).
Appl	icability:		
Mess	sage:	device; ima for presenta	ement is applicable to fluoroscopic imaging assemblies or the following component parts thereof: spot-film ge intensifier; and fluoroscopic screen assembly. Similar models of asingle component type may be grouped ation of test results applicable to this requirement when the technical basis for this grouping is clearly stated ription of prototype testing (see 306.4(a)).
Critic	cal Parameters	and "Worst	t Case" Conditions:
Α.	Message:	The to	est results mustinclude data representative of each compatible combination of components that comprise the

B.	Message:	As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must sufficiently restrictive to assure compliance with the standard.	t be
C.	Message:	For any test using a scan of the fluoroscopic imaging assembly, the rate of scan specified in the test method must take into account the response time of the radiation instrument.	d(s)
D.	Message:	To test for the transmission of radiation through the primary protective barrier, the beam-limiting devicemus fully open and the highest available peak tube potential must be used. These conditions must be specified in test method(s).	
E.	Message:	If an oblique fluoroscopic capability is provided, the radiation transmitted through the primary protective barn must be measured at the maximum oblique fluoroscopic angles.	rier
F.	Message:	If the fluoroscopic beam-limiting device is equipped with an override capability, the radiation transmitted thro the primary protective barrier must be measured at the largest x-ray field setting.	ough
Prot	otype Testing:		
	•	prior to full production phase and thus the testing and quality control proceduresmay not be the same as prototype testing apply?	[L]
A.	Describe the direct t respect to this require	est method (i.e., one that actually measures ${\sf x}$ radiation) employed in testing and measuring each model with rement.	
	[HTML Text]		
B.	Identify the instrume	ent(s) used for the test by manufacturer and model number.	
	[HTML Text]		
C.	Attach a sample of r	aw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[Multi-Line Plain Text]	
D.	Is the actual complia	ance value calculated from the raw test data?	[L]
E.	Attach a sample of c	calculated compliance values complete with an explanation of any correction factorsemployed.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[Multi-Line Plain Text]	
F.	Explain how complia	ance is established.	
	[HTML Text]		
Prod	luction Testing:		
A.	Does the test involve	e a direct test of the performance parameter?	[L]
B.		s employed in testing of each model with respect to this requirement. If reference is made to a test protocol copy as an attachment for documentation.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
C.	If any test used to m this requirement.	onitor compliance does not actually measure x radiation, explain why it is an accurate indication of complianc	ce with
	[HTML Text]		

Ì	l <u>.</u>	A 1	In	
		Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta		[HTML Text]	
E.	$\vdash$	.,	d instructions for performing each test.	
	$\vdash$	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ils	[HTML Text]	
F.	Iden	tify the instrument(s) us	sed for each test by manufacturer and model number.  I	
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta		[HTML Text]	
G.	1	each test method listed etion limits are specified	in question (B.) under Production Testing, attach the detailed instructions for performing the test whole.	ere the
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ils	[HTML Text]	
H.	For e	each test method listed	in question (B.), please attach sample raw test data.	
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ils	[HTML Text]	
I.	Is the	e actual compliance val	lue calculated from the raw test data?	[L]
	-	Please attach a samp	elle of calculated compliance values complete with an explanation of any correction factors employed.	
		File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	tip)]
		Details	[HTML Text]	
	-	Explain how complian	ice isestablished.	
		[HTML Text]		
J.	Is thi	is performance parame	ster tested on 100 percent of the produced models?	[L]
Ass	emble	er Testing:		
Doe	s asse	embler testing apply?		[L]
A.	Does	s the test involve a dire	ct test of the performance parameter?	[L]
В.	1	•	byed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.	
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
1	_			
	Deta	ils	[HTML Text]	
C.	If an		[HTML Text] compliance does not actually measurex radiation, explain why it is an accurate indication of complian	ce with
C.	If an	y test used to monitor o	I' '	ce with
C.	If any	y test used to monitor or requirement. //L Text]	I' '	ce with

	Details		[HTML Text]	
E.	Attach a copy	of the detail	ed instructions for performing each test.	
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details			[HTML Text]	
F.	Identify the ins	strument(s) ı	used for each test by manufacturer and model number.	
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
G.	For each test rejection limits		d in question (B.) under Assembler Testing,attach the detailed instructionsfor performing the test where	e the
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
Н.			d in question (B.), please attachsample raw test data.	
File Attachment		nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
I.	Is the actual c	ompliance v	alue calculated from the raw test data?	[L]
			he user manual that specifies no assembly or installation instructions are necessary and all that is need e power cord into the wall socket.	ded to
File	Attachment	[Sii	ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Deta	ails	[H]	TML Text]	
30	7.0 Reprodu	cibility an	nd Linearity	
	quirement: ssage:	coefficient factors, ar the numbe product (n	x-ray unit is operated on an adequate power supply as specified by the manufacturer;(1) the estimated of variation of radiation exposure shall not be greater than 0.05 for any specific combination of technique where: s=Estimated standard deviation X = Mean value of the sample Xi = ith observation of the same of observations sampled(2) the average ratios of exposure to the indicated tube current exposure times, obtained at any two consecutive tube current settingsshall not differ by more than 0.10 times their and X2 = the average mR/mAs values obtained at each of two consecutive tube current settings. (see a) and (c)).	que nple N = ne
App	olicability:			
Mes	ssage:	componer	rement is applicable to radiographic x-ray controls and high-voltage generators. Similar models of a sin nt type may be grouped for presentation of test results applicable to this requirement when the technica puping is clearly stated in the description of prototype testing (see 307.4(a)).	
Crit	ical Parameters	and "Wors	st Case"Conditions:	
Α.	Message:		result of inherent inaccuracies of the test methodand instrumentation, rejection limits for any test must ciently restrictive to assure compliance with the standard.	t be
В.	Message:	"wor	assure compliance with the reproducibility and linearity requirements, the test results must include data set case" combinations of technique factors and supplyline conditions (e.g., low kVp,high mA, low-line vehighest allowed line-voltage regulation).	
		To a	letermine compliance, variable controls for technique factors shall be adjusted to alternate settings and	reset

C.	Message:	to the test setting between measurements.	
Prot	otype Testing:		
	section is for startup production testing. Does pro		L]
A.	Describe the directtes to this requirement.	t method (i.e., one that actually measures x radiation) employed in testing and measuring each model with re	espect
	[HTML Text]		
B.	Identify the instrument	t(s) used for the test by manufacturer and model number.	
	[HTML Text]		
C.	Attach a sample of rav	w test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[Multi-Line Plain Text]	
D.	Is the actual complian	ce value calculated from the raw test data?	L]
E.	Attach a sample of ca	lculated compliance values complete with an explanation of any correction factors employed.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Expl	ain how compliance is	established.	
[Mul	ti-Line Plain Text]		
Proc	duction Testing:		
A.	Does the test involve	a direct test of the performance parameter?	L]
B.		employed in testingof each model with respect to this requirement. If reference is made to a test protocol copy as an attachment for documentation.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
C.	If any test used to more this requirement.	nitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance	with
	[HTML Text]		
D.	Submit the technical d	data that supports the use of the test in question (C.)	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
E.	Attach a copy of the d	etailed instructions for performing each test.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
F.	Identify the instrument	t(s) used for each test by manufacturer and model number.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
ı			

	Deta	ails	[HTML Text]	
G.	1	each test method listed ction limits are specifie	d in question (B.) under Production Testing,attach the detailed instructions for performing the test who	ere the
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ails	[HTML Text]	
Н.	For e	each test method listed	d in question (B.), please attach sample raw test data.	
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ails	[HTML Text]	
I.	Is the	e actual compliance va	alue calculated from the raw test data?	[L]
	_	Please attach a samp	ole of calculated compliance values complete with an explanation of any correction factors employed	
		File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	zip)]
		Details	[HTML Text]	
Expl	ain ho	ow compliance is estab	lished.	
[Mul	ti-Line	Plain Text]		
J.	Is thi	is performance parame	eter tested on 100 percent of the produced models?	[L]
Ass	emble	er Testing:		-
Does	s asse	embler testing apply?		[L]
A.	Does	s the test involve a dire	ect test of the performance parameter?	[L]
B.	ı	•	oyed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.	
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ails	[HTML Text]	
C.	I '	y test used to monitor requirement.	compliance does not actually measurex radiation, explain why it is an accurate indication of compliar	nce with
	[HTN	ML Text]		
D.	Subr	mit the technical data t	hat supports the use of the test in question (C.)	
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ails	[HTML Text]	
E.	Attac	ch a copy of the detaile	ed instructions for performing each test.	
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	nils	[HTML Text]	
F.	Iden	tify the instrument(s) u	sed for each test by manufacturerand model number.	
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
		nils	[HTML Text]	

G.	For each test m		d in question (B.) under Assembler Testing, attach the detailed instructions for performing theted.	est where the
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .:	zip)]
	Details		[HTML Text]	
Н.	For each test m	nethod listed	d inquestion (B.), please attach sample raw test data.	
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .:	zip)]
	Details		[HTML Text]	
I.	Is the actual co	mpliance va	alue calculated from the raw test data?	[L]
		. •	e user manual that specifies no assembly or installation instructions are necessary and all that power cord into the wall socket.	is needed to
File	Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[Mu	lti-Line Plain Text	t]		
	. ,		ne user manual that specifies no assembly or installation instructions are necessary and all that power cord into the wall socket.	t is needed to
File	Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Deta	ails	[НТІ	ML Text]	
			mponents other than the Diagnostic Source Assembly  items with none required)	
Mod	del Number of the	dovices		
Note	Note.			
		If you do no	ot see the appropriate model indicated, please go to question 2.4 MODEL DESIGNATION to earls on the identification label.	nter the model
Req	quirement:	If you do no		nter the model
	quirement: ssage:	If you do not as it appear		erograys (2
Mes	-	If you do not as it appear	on emitted by a component other than the diagnostic source assembly shall not exceed 18 mices in 1 hour at 5 centimeters from any accessible surface of the component when it is operate.	erograys (2
Mes App	ssage:	If you do not as it appear The radiation milliroentge assembled  This require tubes), and	on emitted by a component other than the diagnostic source assembly shall not exceed 18 mices) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated x-ray system under any conditionsfor which it was designed (see 1020.30(1)).  The ement is applicable to x-ray controls, high-voltage generators that contain thermionic diode valuing intensifiers. Similar models of a single component type may be grouped for presentation to this requirement when the technical basis for this grouping is clearly stated in the description	erograys (2 ed in an ves (valve n of test results
Mes Mes	osage:  blicability:  ssage:	The radiation milliroentge assembled  This require tubes), and applicable testing (see	on emitted by a component other than the diagnostic source assembly shall not exceed 18 mices) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated x-ray system under any conditionsfor which it was designed (see 1020.30(1)).  The ement is applicable to x-ray controls, high-voltage generators that contain thermionic diode valuing intensifiers. Similar models of a single component type may be grouped for presentation to this requirement when the technical basis for this grouping is clearly stated in the description	erograys (2 ed in an ves (valve n of test results
Mes App Mes	osage:  blicability:  ssage:	This require tubes), and applicable and "Wors"	on emitted by a component other than the diagnostic source assembly shall not exceed 18 micens) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated x-ray system under any conditionsfor which it was designed (see 1020.30(1)).  The ement is applicable to x-ray controls, high-voltage generators that contain thermionic diode value image intensifiers. Similar models of a single component type may be grouped for presentation to this requirement when the technical basis for this grouping is clearly stated in the description a 308.4(a)).	erograys (2 ed in an ves (valve n of test results n of prototype
Mes Mes	olicability: esage:	This require tubes), and applicable testing (see and "Wors"  As a suffice For a	on emitted by a component other than the diagnostic source assembly shall not exceed 18 micens) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated x-ray system under any conditionsfor which it was designed (see 1020.30(1)).  The ement is applicable to x-ray controls, high-voltage generators that contain thermionic diode value image intensifiers. Similar models of a single component type may be grouped for presentation to this requirement when the technical basis for this grouping is clearly stated in the description as 308.4(a)).  The Case Conditions:  The example of the test method and instrumentation, rejection limits for any test the contain the recommendation of the test method and instrumentation, rejection limits for any test the contains the result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test the contains the result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test that contains the contai	erograys (2 ed in an ves (valve n of test results n of prototype

Prot	totype Testing:					
		full production phase and thus the testing and quality control procedures may not be the same as	[L]			
proc	duction testing. Does prototyp					
A.	respect to this requirement.	thod (i.e., one that actually measures x radiation) employed in testing and measuring each model with	1			
[HTML Text]						
B.	Identify the instrument(s) us	sed for the test by manufacturer and model number.				
	[HTML Text]					
C.	Attach a sample of raw test	data.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[Multi-Line Plain Text]				
D.	Is the actual compliance va	lue calculated from the raw test data?	[L]			
E.	Attach a sample of calculate	ed compliance values complete with an explanation of any correction factors employed.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
F.	Explain how compliance is	established.				
	[HTML Text]					
Pro	duction Testing:					
	adonon roomig.					
A.	1	ct test of the performance parameter?	[L]			
А. В.	Does the test involve a dire	ct test of the performance parameter?  byed in testing of each model with respect to this requirement. If reference is made toa test protocol as an attachment for documentation.	[L]			
	Does the test involve a dire	byed in testing of each model with respect to this requirement. If reference is made to atest protocol	[L]			
	Does the test involve a direct Describe all methods emplodocument, provide a copy a	byed in testing of each model with respect to this requirement. If reference is made toa test protocol as an attachment for documentation.	[L]			
	Does the test involve a direct Describe all methods employed document, provide a copy at File Attachment Details	byed in testing of each model with respect to this requirement. If reference is made toa test protocol as an attachment for documentation.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
В.	Does the test involve a direct Describe all methods employed document, provide a copy at File Attachment Details  If any test used to monitor of the direct Does the test involve a direct Details	byed in testing of each model with respect to this requirement. If reference is made to atest protocol as an attachment for documentation.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]				
В.	Does the test involve a direct Describe all methods employed document, provide a copy at File Attachment Details  If any test used to monitor of this requirement.  [HTML Text]	byed in testing of each model with respect to this requirement. If reference is made to atest protocol as an attachment for documentation.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]				
В.	Does the test involve a direct Describe all methods employed document, provide a copy at File Attachment Details  If any test used to monitor of this requirement.  [HTML Text]	byed in testing of each model with respect to this requirement. If reference is made toa test protocol as an attachment for documentation.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  compliance does not actually measure x radiation, explain why it is an accurate indication of complian				
В.	Does the test involve a direct Describe all methods employed document, provide a copy at File Attachment Details  If any test used to monitor of this requirement.  [HTML Text]  Submit the technical data the	byed in testing of each model with respect to this requirement. If reference is made toa test protocol as an attachment for documentation.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  compliance does not actually measure x radiation, explain why it is an accurate indication of complian that supports the use of the test in question (C.)				
В.	Does the test involve a direct Describe all methods employed document, provide a copy at File Attachment  Details  If any test used to monitor of this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details	byed in testing of each model with respect to this requirement. If reference is made toa test protocol as an attachment for documentation.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  compliance does not actually measure x radiation, explain why it is an accurate indication of complian that supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
B.	Does the test involve a direct Describe all methods employed document, provide a copy at File Attachment  Details  If any test used to monitor of this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details	byed in testing of each model with respect to this requirement. If reference is made toa test protocol as an attachment for documentation.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  compliance does not actually measure x radiation, explain why it is an accurate indication of complian that supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]				
B.	Does the test involve a direct Describe all methods employed document, provide a copy at File Attachment  Details  If any test used to monitor of this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details  Attach a copy of the detailed	byed in testing of each model with respect to this requirement. If reference is made toa test protocol as an attachment for documentation.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  compliance does not actually measure x radiation, explain why it is an accurate indication of complian at supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  d instructions for performing each test.				
B.	Does the test involve a direct Describe all methods employed document, provide a copy at File Attachment  Details  If any test used to monitor of this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details  Attach a copy of the detailer File Attachment  Details	byed in testing of each model with respect to this requirement. If reference is made toa test protocol as an attachment for documentation.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  compliance does not actually measure x radiation, explain why it is an accurate indication of complian at supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  d instructions for performing each test.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
B. C.	Does the test involve a direct Describe all methods employed document, provide a copy at File Attachment  Details  If any test used to monitor of this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details  Attach a copy of the detailer File Attachment  Details	byed in testing of each model with respect to this requirement. If reference is made toa test protocol as an attachment for documentation.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  compliance does not actually measure x radiation, explain why it is an accurate indication of complian that supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  d instructions for performing each test.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]				

	File	Attachment	[Single F	File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ails	[HTML 1				
Н.	For e	each test method listed	in questio	n (B.), please attach sample raw test data.			
	$\vdash$	Attachment	Ī	File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ails	1	[HTML Text]			
l.	Is the actual compliance value calculated from the raw test data?						
	-	Please attach a samp	le of calcu	ue calculated from the raw test data?  [L]  e of calculated compliance values complete with an explanation of any correction factors employed.			
		File Attachment	[Si	ingle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv,	zip)]		
		Details	[H:	TML Text]			
	-	Explain how complian	nce is esta	ablished.			
		[HTML Text]					
J.	Is th	is performance parame	eter tested	on 100 percent of the produced models?	[L]		
Ass	emble	er Testing:			•		
Doe	s asse	embler testing apply?			[L]		
A.	Does the test involve a direct test of the performance parameter?						
_	Does the test involve a direct test of the performance parameter?  Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.						
B.		•	-		l .		
В.	docu	•	s an attac		l .		
В.	docu	ument,provide a copy a	s an attac	hment for documentation.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	ı		
В. С.	File Deta	ument,provide a copy a Attachment	S an attac	hment for documentation.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	File A	Attachment ails y test used to monitor	S an attac	hment for documentation.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext]			
C.	File A Deta If an this I	Attachment  Attachment  ills  y test used to monitor requirement.  ML Text]	[Single F	hment for documentation.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext]			
	Deta  If any this I	Attachment  Attachment  ills  y test used to monitor requirement.  ML Text]	[Single F	hment for documentation.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext]  e does not actually measure x radiation, explain why it is an accurate indication of compliance.			
C.	Deta  If any this I	Attachment alls y test used to monitor or requirement.  ML Text] mit the technical data to Attachment	[Single F	chement for documentation.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext]  e does not actually measure x radiation, explain why it is an accurate indication of compliants the use of the test in question (C.)  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
C.	File A Deta If an this I [HTM Subr File A Deta	Attachment alls y test used to monitor or requirement.  ML Text] mit the technical data to Attachment	[Single F [HTML 1] compliance  [Single F [HTML 1]	chement for documentation.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext]  e does not actually measure x radiation, explain why it is an accurate indication of compliants the use of the test in question (C.)  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
C.	File And This I	Attachment alls y test used to monitor or requirement.  ML Text] mit the technical data to Attachment	[Single F [HTML 1] compliance [Single F [HTML 1] compliance [Single F [HTML 1]	Text]  The Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Text]  Text does not actually measure x radiation, explain why it is an accurate indication of compliants the use of the test in question (C.)  Tile Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Text does not actually measure x radiation, explain why it is an accurate indication of compliants the use of the test in question (C.)			
C.	File And This I	Attachment ails y test used to monitor or requirement.  ML Text] mit the technical data to Attachment ails ch a copy of the detailed	[Single F [HTML 1] compliance [Single F [HTML 1] compliance [Single F [HTML 1]	chement for documentation.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext]  e does not actually measure x radiation, explain why it is an accurate indication of compliants the use of the test in question (C.)  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext]  fons for performing each test.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
D.	File A  Subr  File A  Attac  File A  Deta	Attachment ails  y test used to monitor or requirement.  ML Text]  mit the technical data to the Attachment ails  ch a copy of the detailed Attachment ails	[Single For Example of	chement for documentation.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext]  e does not actually measure x radiation, explain why it is an accurate indication of compliants the use of the test in question (C.)  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext]  fons for performing each test.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
C.	File A  Subr  File A  Attac  File A  Iden	Attachment ails  y test used to monitor or requirement.  ML Text]  mit the technical data to the Attachment ails  ch a copy of the detailed Attachment ails	[Single For Example of	chement for documentation.  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext]  Text]  Text does not actually measure x radiation, explain why it is an accurate indication of compliants the use of the test in question (C.)  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext]  Text does not actually measure x radiation, explain why it is an accurate indication of compliants the use of the test in question (C.)  File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  Fext does not actually measure x radiation, explain why it is an accurate indication of compliants the use of the test in question (C.)			

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	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
H.	For each test r	method listed	in question (B.), please attach sample raw test data.	
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
I.	Is the actual co	ompliance va	lue calculated from the raw test data?	[L]
		. •	e user manual that specifies no assembly or installation instructions are necessary and all that is need power cord into the wall socket.	eded to
File	Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Deta	ails	[НТІ	ML Text]	
309	0.0 Peak Tul	oe Potenti	al	
Req	uirement:			
Mes	sage:	exposure, v	acturer shall state the maximum deviation of the peak tube potential from its preindicated value durin when the equipment is connected to an adequate power supply as specified by the manufacturer. The fthe peak tube potential shall not exceed the limits given (see 1020.31(a)(4) and 1020.32(f)).	
Арр	licability:	*		
Mes	sage:	models of a	ement is applicable to fluoroscopic and radiographic x-ray controls and high-voltage generators. Similal single component type may be grouped for presentation of test results applicable to this requiremental basis for this grouping is clearly stated in the description of prototype testing (see 309.4(a)).	
Criti	cal Parameters	and "Wors	t Case" Conditions:	
Α.	Message:		result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test mu iently restrictive to assure compliance with the standard.	st be
B.	Message:	data i	sure compliance with the maximum deviation statements provided to the user, the testresults must in for "worst case" combinations of technique factors and supply line conditions (e.g., highest kW, low linge, and highest allowed line-voltage regulation).	
Prot	otype Testing:	*		
			full production phase and thus the testing and quality control procedures maynot be the same as e testing apply?	[L]
A.	Describe the d		thod (i.e., one that actually measures x radiation) employed in testing and measuring each modelwith	n respect
	[HTML Text]			
В.	Identify theinst	rument(s) us	ed for the test by manufacturer and model number.	
	[HTML Text]			
C.	Attach a samp	le of raw test	data.	
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
D.	Is the actual co	ompliance va	lue calculated from the raw test data?	[L]

	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zij	p)]
	Details	[HTML Text]	
Expl	ain how compliance is e		
[Mul	ti-Line Plain Text]		
Prod	duction Testing:		
A.	Does the test involve a	a direct test of the performance parameter?	[L]
B.		employed in testing of each model with respect to this requirement. If reference is made to a test protopy as an attachment for documentation.	ocol
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zig	p)]
	Details	[HTML Text]	
C.	If any test used to mor this requirement.	nitor compliance does not actually measure x radiation, explain why it is an accurate indication of com	pliance wi
	[HTML Text]		
D.	Submit the technical d	ata that supports the use of the test in question (C.)	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zig	p)]
	Details	[HTML Text]	
E.	Attach a copy of the de	etailed instructions for performing each test.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zij	p)]
	Details	[HTML Text]	
F.	Identify the instrument	(s) used for each test by manufacturer and model number.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zig	p)]
	Details	[HTML Text]	
G.	For each test method I rejection limits are spe	isted in question (B.) under Production Testing, attach the detailed instructions for performing the tes cified.	t where the
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip	p)]
	Details	[HTML Text]	
H.	For each test method I	isted in question (B.), please attach sample raw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip	p)]
	Details	[HTML Text]	7
I.	Is the actual compliand	ce value calculated from the raw test data?	[L]
	Please attach a	sample of calculated compliance values complete with an explanation of any correction factors emplo	yed.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .cs	sv, .zip)]
	Details	[HTML Text]	

Expl	ain how compliance is e	established.				
[Mult	ti-Line Plain Text]					
J.	Is this performance pa	urameter tested on 100 percent of the produced models?	[L]			
Ass	embler Testing:					
Does	s assembler testing app	ly?	[L]			
A.	Does thetest involve a	direct test of the performance parameter?	[L]			
В.		Describe all methods employed in testingof each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment occumentation.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
C.	If any test used to mor this requirement.	nitor compliance doesnot actually measure x radiation, explain why it is an accurate indication of complian	nce with			
	[HTML Text]					
D.	Submit the technical d	ata that supports the use of the test in question (C.)				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
E.	Attach a copy of the detailed instructions for performing each test.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
F.	Identify the instrument	c(s) used for each test by manufacturer and model number.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
G.	For each test method rejection limits are spe	listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test whe cified.	ere the			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
Н.	For each test method	listed in question (B.), please attach sample raw test data.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
I.	Is the actual compliance value calculated from the raw test data?					
		in the user manual that specifies no assembly or installation instructions are necessary and all that is neg g the power cord into the wall socket.	eded to			
File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Deta	ils	[HTML Text]				

Req	uirement:						
Mes	The manufacturer shall state themaximum deviation of the tube current from its preindicated value during an exposition when the equipment is connected to an adequate power supply as specified by the manufacturer. The deviation tube current shall not exceed the limits given (see 1020.31(a)(4) and 1020.32(f)).						
App	olicability:	J					
	ssage:	models o	quirement is applicable to fluoroscopic and radiographic x-ray controls and high-voltage generators. Sim of a single component type may be grouped for presentation of test results applicable to this requireme unical basis for this groupings clearly stated in the description of prototype testing (see 310.4(a)).				
Crit	ical Parameter	s and "Wo	orstCase" Conditions:				
A.	Message:		s a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test mufficiently restrictive to assure compliance with the standard.	ust be			
B.	Message:	da	o assure compliance with the maximum deviation statements provided to the user, the test results must ta for "worst case" combinations of technique factors and supply line conditions (e.g., highest kW, low-loltage, and highest allowed line-voltage regulation).				
Pro	totype Testing	:					
This	s section is for s	tart up prio	or to full production phase and thus the testing and quality control procedures may not be the same ototype testing apply?	[L]			
A.		Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.					
	[HTML Text]	-					
В.	Identify the in	Identify the instrument(s) used for the test by manufacturer and model number.					
	[HTML Text]						
C.	Attach a sam	ple of raw t	test data.				
C.	Attach a samp		test data.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
C.							
	File Attachme	ent	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	[L]			
D.	File Attachme  Details  Is the actual of	ent	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [Multi-Line Plain Text]	[L]			
D.	File Attachme  Details  Is the actual of	compliance	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [Multi-Line Plain Text]  e value calculated from the raw test data?	[L]			
	File Attachme Details Is the actual of	compliance	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [Multi-Line Plain Text]  e value calculated from the raw test data?  ulated compliance values complete with an explanation of any correction factors employed.	[L]			
D. E.	File Attachme Details Is the actual of Attach a samp	compliance ple of calcu	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [Multi-Line Plain Text]  e value calculated from the raw test data?  ulated compliance values complete with an explanation of any correction factors employed.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]	[L]			
D. E.	File Attachmed Details  Is the actual of Attach a sample File Attachmed Details	compliance ple of calcuent	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [Multi-Line Plain Text]  e value calculated from the raw test data?  ulated compliance values complete with an explanation of any correction factors employed.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]	[L]			
D. E. Exp	File Attachmed Details  Is the actual of Attach a sample File Attachmed Details  lain how compliance of the Attachmed Details	compliance ple of calcuent ance is est	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [Multi-Line Plain Text]  e value calculated from the raw test data?  ulated compliance values complete with an explanation of any correction factors employed.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]	[L]			
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D. E. Exp [Mul	File Attachmed Details  Is the actual of Attach a sample File Attachmed Details  Is the actual of Attach a sample File Attachmed Details  Iti-Line Plain Teduction Testin Does the test Describe all metails	compliance ple of calcuent ance is est axt] g: involve a conethods em	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [Multi-Line Plain Text]  e value calculated from the raw test data?  ulated compliance values complete with an explanation of any correction factors employed.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  tablished.	[L]			

	Details	[HTML Text]						
C.	If any test used to me this requirement.	nitor compliance does notactually measure x radiation, explain why it is an accurate indicati	on of compliance with					
	[HTML Text]							
D.	Submit the technical data that supports the use of the test inquestion (C.)							
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls	s, .csv, .zip)]					
	Details	[HTML Text]						
Ε.	Attach a copy of the	etailed instructions for performing each test.						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls	s, .csv, .zip)]					
	Details	[HTML Text]						
F.	Identify the instrume	t(s) used for each test by manufacturer and model number.						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls	s, .csv, .zip)]					
	Details	[HTML Text]						
Э.	For each test method rejection limits are sp	listed in question (B.) under Production Testing, attach the detailed instructions for performing periods.	ng the test where the					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[HTML Text]						
Ⅎ.	For each test method	listed in question (B.), pleaseattach sample raw test data.						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
	Details	[HTML Text]						
	Is the actual complia	ce value calculated from the raw test data?	[L]					
	Please attach a	sample of calculated compliance values complete with an explanation of any correction fac-	tors employed.					
	File Attachmen	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .m	ol, .xls, .csv, .zip)]					
	Details	[HTML Text]						
Expl	ain how compliance is	established.						
Mul	ti-Line Plain Text]							
J.	Is this performance p	arameter tested on 100 percent of the produced models?	[L]					
Ass	embler Testing:							
Doe:	s assembler testing ap	oly?	[L]					
Α.	Does the test involve	adirect test of the performance parameter?	[L]					
В.		employed in testing of each model with respect to this requirement. If reference is made to a copy as an attachment for documentation.	a test protocol					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls	s, .csv, .zip)]					
	Details	[HTML Text]						

	this requireme	nt.					
	[HTML Text]						
D.	Submit the technical data that supports the use of the test in question (C.)						
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip]	)]			
	Details		[HTML Text]				
E.	Attach a copy	of the d	etailed instructions for performing eachtest.				
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)	)]			
	Details		[HTML Text]				
F.	Identify the ins	trument	c(s) used for each test by manufacturer and model number.				
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)	)]			
	Details		[HTML Text]				
G.	For each test r rejection limits		listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test ecified.	where the			
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)	)]			
	Details		[HTML Text]				
Н.	For each test r	nethod	listed in question (B.), please attach sample raw test data.				
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
I.	Is the actual compliance val		ce value calculated from the raw test data?	[L]			
	. ,		in the user manual that specifies no assembly or installation instructions are necessary and all that is g the power cord into the wall socket.	needed to			
File	Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Deta	ills		[HTML Text]				
311	1.0 Tube Current - Exposure Time Product						
Req	uirement:						
Mes	The manufacturer shall state the maximum deviation of the tube current exposure time product (mAs) from its preindicated value during an exposure, when the equipment is connected to an adequate power supply as specified the manufacturer. The deviation of the tube current exposure time product shall not exceed the limits given (solution).						
Арр	licability:	icability:					
Mes	sage:	model	equirement is applicable to radiographic x-ray controls andhigh voltage generators that have mAs setti. Is of a single component type may be grouped for presentation of test results applicable to this requires chnical basis for this grouping is clearly stated in the description of prototype testing (see 311.4(a)).				
Criti	cal Parameters	and "\	Vorst Case" Conditions:				

		sufficiently re	estrictive to assure compliance with the standard.					
B.	Message:	data for "wor	impliance with the maximum deviation statements provided to the user, the test results must in st case" combinations of technique factors and supply line conditions (e.g., highest kW, low linglest allowed line-voltage regulation).	nclude ne				
Prot	otype Testing:							
	•		oduction phase and thus the testing and quality control procedures may not be the same as	[L]				
prod	uction testing. Does p		g apply?  one that actually measures x radiation) employed in testing and measuring each model wit	h				
A.		respect to this requirement.						
	[HTML Text]							
B.	Identify the instrume	nt(s) used for t	the test by manufacturer and model number.					
	[HTML Text]							
C.	Attach a sample of ra	aw test data.						
	File Attachment	[Single	e File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[НТМІ	L Text]					
D.	Is the actual complia	nce value calc	culated from the raw test data?	[L]				
E.	Attach a sample of c	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.						
	File Attachment	[Single	e File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[НТМІ	L Text]					
Expl	ain how compliance is	established.						
[Mul	ti-Line Plain Text]							
Proc	duction Testing:							
A.	1			[L]				
	Does the test involve	a direct test o	of the performance parameter?					
B.	Describe all methods	employed in	of the performance parameter?  testing of each model with respect to this requirement. If reference is made toa test protocol tachment for documentation.	•				
В.	Describe all methods	s employed in to	testing of each model with respect to this requirement. If reference is made toa test protocol					
B.	Describe all methods document, provide a	s employed in to copy as an att	testing of each model with respect to this requirement. If reference is made toa test protocol tachment for documentation.					
B.	Describe all methods document, provide a File Attachment Details	s employed in to copy as an att	testing of each model with respect to this requirement. If reference is made to a test protocol tachment for documentation.  e File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	ce with				
	Describe all methods document, provide a File Attachment  Details  If any test used to m	s employed in to copy as an att	testing of each model with respect to this requirement. If reference is made toa test protocol tachment for documentation.  e File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  L Text]	ce with				
	Describe all methods document, provide a File Attachment Details If any test used to m this requirement.  [HTML Text]	s employed in a copy as an att	testing of each model with respect to this requirement. If reference is made to a test protocol tachment for documentation.  e File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  L Text]	ce with				
C.	Describe all methods document, provide a File Attachment Details If any test used to m this requirement.  [HTML Text]	[Single [HTML] conitor complian	testing of each model with respect to this requirement. If reference is made toa test protocol tachment for documentation.  e File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  L Text]  nce does not actually measure x radiation, explain whyit is an accurate indication of complian	ce with				
C.	Describe all methods document, provide a File Attachment Details  If any test used to m this requirement.  [HTML Text]  Submit the technical	[Single compliant complian	testing of each model with respect to this requirement. If reference is made toa test protocol tachment for documentation.  e File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  L Text]  nce does not actually measure x radiation, explain whyit is an accurate indication of complian ports the use of the test inquestion (C.)	ce with				
C.	Describe all methods document, provide a File Attachment  Details  If any test used to m this requirement.  [HTML Text]  Submit the technical File Attachment  Details	[Single control compliant	testing of each model with respect to this requirement. If reference is made toa test protocol tachment for documentation.  e File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  L Text]  nce does not actually measure x radiation, explain whyit is an accurate indication of complian corts the use of the test inquestion (C.)  e File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	ce with				
C.	Describe all methods document, provide a File Attachment  Details  If any test used to m this requirement.  [HTML Text]  Submit the technical File Attachment  Details	[Single [HTML] [HTML] [HTML]	testing of each model with respect to this requirement. If reference is made toa test protocol tachment for documentation.  e File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  L Text]  nce does not actually measure x radiation, explain whyit is an accurate indication of complian corts the use of the test inquestion (C.)  e File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  L Text]	ce with				

	File A	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
	Detai	ils	[HTML Text]						
G.		For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.							
	File Attachment [S		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
	Detai	ils	[HTML Text]						
Н.	For each test method listed in question (B.), please attach sample raw test data.								
	File A	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
	Detai	ils	[HTML Text]						
l.	Is the	e actual compliance v	alue calculated from the raw test data?	[L]					
	-	Please attach a sam	ple of calculated compliance values complete withan explanation of any correction factors employed	l.					
		File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv,	.zip)]					
		Details	[HTML Text]						
Ехр	lain hov	w compliance is estab	plished.						
ſΜυ	ılti-l ino								
įa	IIII-LIIIE	Plain Text]							
J.			eter tested on 100 percent of the produced models?	[L]					
J.	Is this		eter tested on 100 percent of the produced models?	[L]					
J. <b>Ass</b>	ls this	s performance param	eter tested on 100 percent of the produced models?	[L]					
J. <b>Ass</b>	Is this	s performance param r Testing: mbler testing apply?	eter tested on 100 percent of the produced models?  ect test of the performance parameter?						
J. <b>Ass</b> Doe	Is this sembles es asses Does Desc	s performance param r Testing: mbler testing apply? s the test involve a direction of the control of the contro		[L]					
J. <b>Ass</b> Doe	Is this sembler es asser Does Desc docur	s performance param r Testing: mbler testing apply? s the test involve a direction of the control of the contro	ect test of the performance parameter?  loyed in testing of each model with respect to this requirement. If reference is made to a test protoco	[L]					
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	File Attachment	:	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
	Details		[HTML Text]		
G.	For each test me		ed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where died.		
	File Attachment		Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
	Details		[HTML Text]		
Н.	For each test me	ethod list	ed in question (B.), please attach sample raw test data.		
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
	Details		[HTML Text]		
l.	Is the actual cor	mpliance	value calculated from the raw test data?		
		. •	the user manual that specifies no assembly or installation instructions are necessary and all that is needed ne power cord into the wall socket.		
File	Attachment	[S	ringle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
Deta	ails	[H	ITML Text]		
Do-	uirement:				
ved					
	ssage:	exposure	ufacturer shall state the maximum deviation of the exposure time from its preindicated value during an specified by the manufacturer. The of exposure time shall not exceed the limits given (see 1020.31(a)(4))		
Mes	ssage:	exposure			
Mes App	osage:  blicability:	exposure deviation  This requ compone	e, when the equipment is connected to an adequate power supply as specifiedby the manufacturer. The		
Mes App Mes	osage:  blicability:  ssage:	exposure deviation  This requ compone for this gi	when the equipment is connected to an adequate power supply as specified by the manufacturer. The of exposure time shall not exceed the limits given (see 1020.31(a)(4)).  In the equipment is applicable to a single to the equipment of the equipm		
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App Mes Criti A. B.	blicability:  ssage:  ical Parameters at Message:  Message:  totype Testing: s section is for stars	exposure deviation  This requirement requirement of this grand "Wo sufficient of the	when the equipment is connected to an adequate power supply as specified by the manufacturer. The of exposure time shall not exceed the limits given (see 1020.31(a)(4)).  direment is applicable to adiographic x-raycontrols and high-voltage generators. Similarmodels of a single entitype may be grouped for presentation of test results applicable to this requirement when the technical be trouping is clearly stated in the description of prototype testing (see 312.4(a)).  Test Case Conditions:  a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be ficiently restrictive to assure compliance with the standard.  assure compliance with the maximum deviation statements provided to the user, the test results must include a for "worst case" combinations of technique factors and supply line conditions (e.g., highest kW, low-line).		
App Mes Criti A. B. Prot	blicability: ssage:  ical Parameters a  Message:  Message:  totype Testing: s section is for starduction testing. Do	This requested the second of t	when the equipment is connected to an adequate power supply as specifiedby the manufacturer. The of exposure time shall not exceed the limits given (see 1020.31(a)(4)).  Interpret is applicable toradiographic x-raycontrols and high-voltage generators. Similarmodels of a single that type may be grouped for presentation of test results applicable to this requirement when the technical becoming is clearly stated in the description of prototype testing (see 312.4(a)).  Interpret Case Conditions:  In a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be ficiently restrictive to assure compliance with the standard.  In assure compliance with the maximum deviation statements provided to the user, the test results must include a for "worst case" combinations of technique factors and supply line conditions (e.g., highest kW, low-line tage, and highest allowed line-voltage regulation).  In to full production phase and thus the testing and quality control procedures may not be the same as expected to the user, the test results must include the first of the user of the same and the same		
App Mes Criti A. B. Prot	blicability:  ssage:  ical Parameters a  Message:  Message:  totype Testing: s section is for starduction testing. Do  Describe the dir	This requested the second of t	when the equipment is connected to an adequate power supply as specifiedby the manufacturer. The of exposure time shall not exceed the limits given (see 1020.31(a)(4)).  Interpret is applicable toradiographic x-raycontrols and high-voltage generators. Similarmodels of a single that type may be grouped for presentation of test results applicable to this requirement when the technical becoming is clearly stated in the description of prototype testing (see 312.4(a)).  Interpret Case Conditions:  In a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be ficiently restrictive to assure compliance with the standard.  In assure compliance with the maximum deviation statements provided to the user, the test results must include a for "worst case" combinations of technique factors and supply line conditions (e.g., highest kW, low-line tage, and highest allowed line-voltage regulation).  In to full production phase and thus the testing and quality control procedures may not be the same as expected to the user, the test results must include the first of the user of the same and the same		
Mess App Mess Criti A. B.	ical Parameters a Message:  Message:  totype Testing: s section is for starduction testing. Do Describe the dir respect to this re [HTML Text]	This requested the sequence of	when the equipment is connected to an adequate power supply as specifiedby the manufacturer. The of exposure time shall not exceed the limits given (see 1020.31(a)(4)).  Interpret is applicable toradiographic x-raycontrols and high-voltage generators. Similarmodels of a single that type may be grouped for presentation of test results applicable to this requirement when the technical becoming is clearly stated in the description of prototype testing (see 312.4(a)).  Interpret Case Conditions:  In a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be ficiently restrictive to assure compliance with the standard.  In assure compliance with the maximum deviation statements provided to the user, the test results must include a for "worst case" combinations of technique factors and supply line conditions (e.g., highest kW, low-line tage, and highest allowed line-voltage regulation).  In to full production phase and thus the testing and quality control procedures may not be the same as expected to the user, the test results must include the first of the user of the same and the same		

	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[HTML Text]					
_							
D.		ce value calculated from the raw test data?					
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[HTML Text]					
	ain how compliance is e	stablished.					
[Mul	ti-Line Plain Text]						
Proc	duction Testing:						
A.		direct test of the performance parameter?					
B.		employed in testing of each model with respect to this requirement. If reference is made to a test protocol copy as an attachment for documentation.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[HTML Text]					
C.	If any test used to monitor compliance doesnot actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.						
	[HTML Text]						
D.	Submit the technical da	ata that supports the use of the test in question (C.)					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[HTML Text]					
E.	Attach a copy of the de	etailed instructions for performing each test.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[HTML Text]					
F.	Identify the instrument	(s) used for each test by manufacturer and model number.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[HTML Text]					
G.	For each test method I rejection limits are spe	isted in question (B.) under Production Testing, attach the detailed instructions for performing the test where the cified.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[HTML Text]					
Н.	For each test method I	isted in question (B.), please attach sample raw test data.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details	[HTML Text]					

	<u>,                                      </u>	ce value calculated from the raw test data?	[L]				
		sample of calculated compliance values complete with an explanation of any correction fa					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .r	mol, .xls, .csv, .zip)]				
	Details	[HTML Text]					
xpl	lain how compliance is established.						
Mul	lti-Line Plain Text]						
	Is this performance par	rameter tested on 100 percent of the produced models?	[L]				
SS	embler Testing:						
)oe	s assembler testing appl	iy?	[L]				
١.	Does the test involve a	a direct test of the performance parameter?	[L]				
3.		employed in testing of each model with respect to this requirement. If reference is made to opy as an attachment for documentation.	a test protocol				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .x	ds, .csv, .zip)]				
	Details	[HTML Text]					
Э.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.						
	[HTML Text]						
D.	Submit the technical data that supports the use of the test in question (C.)						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .x	ds, .csv, .zip)]				
	Details	[HTML Text]					
≣.	Attach a copy of the de	etailed instructions for performing each test.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .x	(ls, .csv, .zip)]				
	Details	[HTML Text]					
F.	Identify the instrument(	(s) used for each test by manufacturer and model number.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .x	(ls, .csv, .zip)]				
	Details	[HTML Text]					
G.	For each test method li rejection limits are spec	isted in question (B.) under Assembler Testing, attach the detailed instructions for perforn cified.	ning the test where the				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .x	ds, .csv, .zip)]				
	Details	[HTML Text]					
Н.	For each test method li	isted in question(B.), please attach sample raw test data.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .x	kls, .csv, .zip)]				
	Details	[HTML Text]					
		ce value calculated from the raw test data?	[L]				

File	Attachment	[5	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
Deta	ails	[۱	HTML Text]			
313	3.0 Automati	c Expos	sure Control Limits			
Req	uirement:					
Message: Eithe exposexcep		exposur except v	ne product of peak x-ray tubepotential, current, and exposure time shall be limited to not more than 60 kl e or the product of xray tube current and exposure time shall be limited to not more than 600 mAs per e when the x-ray tube potential is less than 50 kVp in which case the product of x-ray tube current and exp all be limited to not more than 2000 mAs per exposure (see 1020.31(a)(3)(iii)).	xposur		
Арр	licability:	1				
Mes	ssage:	exposur.	uirement is applicable to radiographic x-ray controls and high voltage generators used in systems with a be controls. Similar models of a single component type may be groupedfor presentation of test results ap equirement when the technical basis for this grouping is clearly stated in the description of prototype test 1).	plicable		
Criti	ical Parameters	and "Wo	orst Case" Conditions:			
A.	Message:		a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be ficiently restrictive to assure compliance with the standard.			
B.	Message:		assure compliance with the 60 kWs, 600 mAs, or 2000 mAs limits applicable to this system, the test results st include data for various combinations of technique factors.			
Prot	totype Testing:	•				
			or to full production phase and thus the testing and quality control procedures may not be the same as otype testing apply?	[L]		
A.	Describe the c	irect test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with requirement.				
	[HTML Text]					
В.	Identify the ins	trument(s	) used for the test by manufacturer and model number.			
	[HTML Text]					
C.	Attach a samp	le of raw t	lest data.			
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip			
	Details		[HTML Text]			
D.	Is the actual c	ompliance	ance value calculated from the raw test data?			
E.	Attach a samp	le of calcu	ulated compliance values complete with an explanation of any correction factors employed.			
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details		[HTML Text]			
	lain how complia	nnoo is ost	tablished			

A.	Does	s the test involve a c	lirect test	of the performance parameter?	[L]			
B.				n testing of each model with respectto this requirement. If reference is made to a test protocol attachment for documentation.				
	File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	iils	[HTN	ML Text]				
C.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.							
	[НТЛ	/IL Text]						
Э.	Subr	Submit the technical data that supports the use of the test in question (C.)						
	File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	iils	[НТИ	ML Text]				
≣.	Attac	ch a copy of the deta	ailed instr	ructions for performing each test.				
	File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[НТИ	ML Text]				
=.	Iden	tify the instrument(s)	) used for	r each test by manufacturer and model number.				
	File Attachment [Sin		[Sing	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[НТЛ	HTML Text]				
Э.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.							
	File	Attachment	ent [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Deta	ils	[НТИ	ML Text]				
Ⅎ.	For e	each testmethod list	ed in que	estion (B.), please attach sample raw test data.				
	File	File Attachment [Sing		Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[НТИ	ML Text]				
	Is the	e actual compliance	value ca	lculated from the raw test data?	[L]			
	-	Please attach a sa	mple of c	calculated compliance values complete with an explanation of any correction factors employed.				
		File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	ip)]			
		Details		[HTML Text]				
Ξхр	lain how compliance is established.							
Mu	lti-Line	Plain Text]						
	Is thi	is performance para	meter tes	sted on 100 percent of the produced models?	[L]			
٠.	-	er Testing:						
J. Ass	emble	ii restiriy.						

Α.	Does thetest in	volve a direc	it test of the performance parameter?	[L]			
B.		•	yed in testing of each model with respect tothis requirement. If reference is made to a test protocol is an attachment for documentation.	•			
	File Attachmen	ıt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
C.	If any test used to monitor compliance does not actually measure x radiation, explain why itis an accurate indication of compliance with this requirement.						
	[HTML Text]						
D.	Submit the tecl	hnical data th	nat supports the use of the test in question (C.)				
	File Attachmen	ıt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
E.	Attach a copy of	of the detaile	d instructions for performing each test.				
	File Attachmen	ıt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
F.	Identify the ins	trument(s) us	sed for each test by manufacturer and model number.				
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.						
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
H.	For each test n	nethod listed	in question (B.), please attach sample raw test data.				
	File Attachmen	ıt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
l.	Is the actual co	ompliance val	ue calculated from the raw test data?	[L]			
			e user manual that specifies no assembly or installation instructions are necessary and all that is nee power cord into the wall socket.	eded to			
File A	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Deta	ils	[HTN	HTML Text]				
314	.0 Automation	c Exposur	e Control Minimum Exposure Time				
Requ	uirement:						
	sage:	equipment i minimum ex	ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission rated for pulsed operation shall be equalto or less than a time interval equivalent to two pulses, andth sposure time for all other equipment shall be equal to or less than 1/60second or a time interval requests, whichever is greater (see 1020.31(a)(3)(ii)).				
		22					

1/00	Thi	is requirer	ment is applicable to radiographic x-ray controls and high-voltage generators used in systems with	
ivies			posure controls. Similar models of a single component type may be grouped for presentation of test this requirement when thetechnical basis for this grouping is clearly stated in the description of prot	
	tes	sting (see :	314.4(a)).	
Criti	cal Parameters and	d "Worst (	Case" Conditions:	
Mes	sage:		f inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be estrictive to assure compliance with the standard.	
Prot	otype Testing:	•		
This	section is for start u	p prior to t	full production phase and thus the testing and quality control procedures may not be the same as	[L]
prod	uction testing. Does	prototype	testing apply?	[-]
A.	Describe the direct respect to this requ		od (i.e., one that actually measures x radiation) employed in testing and measuring each model with	1
	[HTML Text]			
B.	Identify the instrum	nent(s) use	ed for the test by manufacturer and model number.	
	[HTML Text]			
C.	Attach a sample of	raw test o	data.	
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
D.	Is the actual compl	liance valu	ue calculated from the raw test data?	[L]
E.	Attach a sample of	calculated	d compliance values complete with an explanation of any correction factors employed.	
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
Expl	ain how compliance	is establis	shed.	
[Mul	ti-Line Plain Text]			
Proc	duction Testing:			
A.	Does the test involv	ve a direct	t test of the performance parameter?	[L]
B.			yed in testing of each model with respect to this requirement. If reference is made to atest protocol is an attachment for documentation.	
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
C.	If any test used to r this requirement.	monitor co	ompliance does not actually measure x radiation, explain why it is an accurate indication of complian	ce wit
	[HTML Text]			
D.	Submit the technical	al data tha	at supports the use of the test in question (C.)	
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	

		Attachment	+ -	le Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ails	[HTML Te	ext]			
F.	Iden	tify the instrument(s) u	sed for eac	h test by manufacturer and model number.			
	File	Attachment	[Single Fi	ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta		[HTML Te	•			
G.		For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.					
	File	Attachment	[Single Fi	le Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ails	[HTML Te	ext]			
Н.	For e	each test method listed	I in question	n (B.), please attach sample raw test data.			
	File	Attachment	[Single Fi	le Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	nils	[HTML Te	ext]			
l.	Is th	e actual compliance va	ilue calcula	ted from the raw test data?	[L]		
	-	Please attach a samp	ole of calcul	ated compliance values complete with an explanation of any correction factors employe	ed.		
		File Attachment			-:\1		
			[Sin	igle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv,	.zip)]		
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Exp	lain ho	Details ow compliance is estab	[НТ		.zip)j		
			[НТ		.21p)]		
[Mul	lti-Line	ow compliance is estab	[HT		[L]		
[Mul	lti-Line	ow compliance is estab	[HT	ML Text]			
[Mul J. <b>Ass</b>	Iti-Line Is th	ow compliance is estable Plain Text] is performance parame	[HT	ML Text]			
[Mul J. Ass	Is the	ow compliance is estable Plain Text] is performance parameter Testing: embler testing apply?	[HT	ML Text]	[L]		
[Mul	Is the semble as asset Does	ow compliance is estable Plain Text] is performance parameter Testing: embler testing apply? so the test involve a direction all methods employed.	[HT lished.	ML Text] on 100 percent of the produced models?	[L]		
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[Mul J. Ass Doe A.	Is the Is the Is as asset docu.  File Deta	ow compliance is estable Plain Text] is performance parameter Testing: embler testing apply? s the test involve a direction all methods employment, provide a copy at Attachment	eter tested of the coverage of	on 100 percent of the produced models?  The performance parameter?  The performance parameter?  The performance parameter is performent. If reference is made to a test protocomment for documentation.  The Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	[L] [L] [L]		
J.  Ass  Doe  A.	Is the Is the Is as asset docu.  Does docu.  File Deta	ow compliance is estable Plain Text] is performance parameter Testing: embler testing apply? s the test involve a direction and the complexity of the comple	eter tested of the coverage of	on 100 percent of the produced models?  The performance parameter?  The performance parameter?  The performance parameter?  The performance parameter is made to a test protocomment for documentation.  The performance parameter is made to a test protocomment for documentation.  The performance parameter is made to a test protocomment for documentation.  The performance parameter is made to a test protocomment for documentation.  The performance parameter is made to a test protocomment for documentation.  The performance parameter is made to a test protocomment for documentation.	[L] [L] [L]		
J.  Ass  Doe  A.  B.	Is the Is the Is as asset docu.  Does docu.  File Deta If an this Is In It Is Is Is It Is	pow compliance is estable Plain Text]  is performance parameter Testing:  embler testing apply?  s the test involve a directive all methods employment, provide a copy at Attachment wills  y test used to monitor of requirement.	eter tested of the compliance	on 100 percent of the produced models?  The performance parameter?  The performance parameter?  The performance parameter?  The performance parameter is made to a test protocomment for documentation.  The performance parameter is made to a test protocomment for documentation.  The performance parameter is made to a test protocomment for documentation.  The performance parameter is made to a test protocomment for documentation.  The performance parameter is made to a test protocomment for documentation.  The performance parameter is made to a test protocomment for documentation.	[L] [L] [L]		
[Mul J. Ass Doe A. B.	Iti-Line Is th Is	pow compliance is estable Plain Text]  is performance parameter Testing:  embler testing apply?  s the test involve a directive all methods employment, provide a copy at Attachment wills  y test used to monitor of requirement.	eter tested of the compliance that support	on 100 percent of the produced models?  The performance parameter?  The performance parameter?  The performance parameter?  The performance parameter is made to a test protocomment for documentation.  The Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  The attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  The attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  The attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	[L] [L] [L]		
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	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	1
	Details		[HTML Text]	
F.	Identify the ins	trument(s) u	sed for each test by manufacturer and model number.	
	File Attachmer	nt	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		HTML Text]	
G.	For each test r rejection limits		I in question (B.) under Assembler Testing, attach the detailed instructions forperforming the test when d.	nere the
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
Н.	For each test r	method listed	l in question (B.), please attach sample raw test data.	
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
l.	Is the actual co	ompliance va	lue calculated from the raw test data?	[L]
			ne user manual that specifies no assembly or installation instructions are necessary and all that is no power cord into the wall socket.	eded to
File /	Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Deta	ils	[НТ	ML Text]	
315	5.0 Illuminan	ce of Ligh	nt Localizers	
Requ	uirement:			
Mes	sage:	than 160 lu	ht localizer is used to define the perimeter of the x-ray field, it shall provide an average illumination of tx (15 footcandles) at 100 centimeters or at the maximum SID whichever is less. The average illuminated upon measurements madein the approximate center of each quadrantof the light field (see 102 4)(i)).	nation
Арр	licability:			
Mes	sage:	a light loca presentatio	ement is applicable to any beam-limiting devices in a general purpose or other radiographic system lizer to define the perimeter of the x-ray field. Similar models of a single component type may be grown of test results applicableto this requirement when the technical basis for this grouping is clearly station of prototype testing (see (a) under Prototype Testing).	ouped for
Criti	cal Parameters	and "Wors	t Case" Conditions:	
Mes	sage:		of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be restrictive to assure compliance with the standard.	;
Prot	otypeTesting:			
			o full production phase and thus the testing and quality control procedures may not be the same as be testing apply?	[L]
A.	Describe the d respect to this		thod (i.e., one that actually measures $\boldsymbol{x}$ radiation) employed in testing and measuring each model $\boldsymbol{w}$ .	rith
	[HTML Text]			

	identity the instrument	t(s) used for thetest by manufacturer and model number.			
	[HTML Text]				
C.	Attach a sample of rav	w test data.			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]			
D.	Is the actual complian	ce value calculated from the raw test data?	[L]		
E.	Attach a sample of ca	lculated compliance values complete with an explanation of any correction factors employed.			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]			
Exp	lain how compliance is	established.			
[Mul	lti-Line Plain Text]				
Pro	duction Testing:				
A.	Does the test involve	a direct test of the performance parameter?	[L]		
B.	Describeall methods employed in testing of each model with respect to this requirement. If referenceis made to a test protocol document, provide a copy as an attachment for documentation.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]			
C.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.				
C.	1 '	nitor compliance does not actually measure x radiation, explain why it is an accurate indication of complia	ance with		
C.	1 '	nitor compliance does not actually measure x radiation, explain why it is an accurate indication of complia	ance with		
C.	this requirement.  [HTML Text]	nitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance does not actually measure x radiation, explain why it is an accurate indication of compliance does not actually measure x radiation, explain why it is an accurate indication of compliance does not actually measure x radiation, explain why it is an accurate indication of compliance does not actually measure x radiation, explain why it is an accurate indication of compliance does not actually measure x radiation, explain why it is an accurate indication of compliance does not actually measure x radiation.	ance with		
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	this requirement.  [HTML Text]  Submit the technical of	data that supports the use of the test in question (C.)	ance with		
D.	this requirement.  [HTML Text]  Submit the technical of File Attachment  Details	data that supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	ance with		
D.	this requirement.  [HTML Text]  Submit the technical of File Attachment  Details	data that supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]	ance with		
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D. E.	this requirement.  [HTML Text]  Submit the technical of File Attachment  Details  Attach a copy of the difference of the Attachment  Details  Identify the instrument File Attachment  Details  For each test method	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  etailed instructions for performing each test.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  t(s) used for each test by manufacturer and model number.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  [HTML Text]  Ilisted in question (B.) under Production Testing, attach the detailed instructions for performing the test when the state of the stat			
D.	this requirement.  [HTML Text]  Submit the technical of File Attachment  Details  Attach a copy of the difference of the Attachment  Details  Identify the instrument File Attachment  Details  For each test method rejection limits are specified.	data that supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  etailed instructions for performing each test.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  t(s) used for each test by manufacturer and model number.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  listed in question (B.) under Production Testing, attach the detailed instructions for performing the test whereified.			

File Attachment		Attachment	ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wm	ıv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Detai	ils	TML Text]				
I.	Is the	e actual compliance val	calculated from the raw test data?		[L]		
	-	Please attach a samp	f calculated compliance values complete with an	explanation of any correction factors employed.			
		File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .av	ri, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi	ip)]		
		Details	[HTML Text]				
Expl	ain ho	w compliance is establ	d.				
[Mul	ti-Line	Plain Text]					
J.	Is this	s performance parame	ested on 100 percent of the produced models?		[L]		
Ass	emble	r Testing:			•		
Doe	s asse	mbler testing apply?			[L]		
A.	Does	the test involve a dire	est of the performance parameter?		[L]		
B.	1	-	I in testing of each model with respect to this requal attachment for documentation.	uirement. If reference is made to a test protocol			
	File A	Attachment	ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wm	nv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Detai	ils	TML Text]				
C.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.						
	[HTN	[HTML Text]					
D.	Submit the technical data that supports the use of the test in question (C.)						
	Subn	nit the technical data th	supports the use of the test in question (C.)				
	<u> </u>	nit the technical data th Attachment	supports the use of the test in question (C.)	nv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
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I.	Is the actual c	ompliance va	alue calculated from the raw test data?	[L]
			ne user manual that specifies no assembly or installation instructions are necessary and all that is new power cord into the wall socket.	
	Attachment		gle File Attachment (.pdf, .ipg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
_	ails		ML Text]	
Dell	alis	[1	WE TONG	
316	6.0 Alignme	nt of Visua	ally Defined X-Ray Fields	
Rec	quirement:	-		
A.	Message:	all ge respe perce	al fields (including light fields): Means shall be provided for visually defining the perimeter of the x-ray eneral purpose x-ray systems. The total misalignment of the edges of the visually defined field with the excive edges of the x-ray field along either the length or width of the visually defined field shall not exc ent ofthe distance from the source to the center of the visually defined field when the surface upon wh	e ceed 2
	1	<del>- 1</del>	ars is perpendicular to the axis of the x-ray beam (see 1020.31(d)(2)(i)).	
B.	Message:	contra use o	fields: The edge of the light field at 100 centimeters or at themaximum SID, whichever is less, shall the ast ratio, corrected forambient lighting, of not less than 4 in the case of beam-limiting devices designed in stationary general purpose equipment, and a contrast ratio of not less than 3 in the case of beam-lives designed for use on mobilegeneral purpose and other radiographic equipment (see 1020.31(d)(2)(i)).	ed for imiting
App	plicability:	<u>'</u>		
Mes	ssage:	light localize presentation	ement is applicable to any beam-limiting device in a general purpose or other radiographic system the ter to define the perimeter of the x-ray field. Similar models of a single component type may be group on of test results applicable to this requirement when the technical basis for this grouping is clearly sta	ed for
		the descrip	tion of prototype testing (see (b) under Prototype Testing).	
Crit	tical Parameter		t Case" Conditions:	
A.	Message:		result of inherent inaccuracies of the testmethod and instrumentation, rejection limits for any test mustiently Finitly restrictive to assure compliance with the standard.	st be
В.	Message:		esure compliance with the requirement for visually defining the perimeter of the x-ray field, the test re- include data for the range of SID's and image receptor sizes.	sults
Pro	totype Testing:			
			o full production phase and thus the testing and quality control procedures may not be the same as be testing apply?	[L]
A.	Describe the o		thod (i.e., one that actually measures x radiation) employed in testing and measuring each model wit	th
	[HTML Text]			
В.	Identify the ins	strument(s) us	sedfor the test by manufacturer and model number.	
	[HTML Text]			
C.	Attach asamp	le of raw test	data.	
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[Multi-Line Plain Text]	

E.	Attach a sample of ca	culated compliance values complete with an explanation of any correction factors employed.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)	]			
	Details	[HTML Text]				
Expl	ain how compliance is	established.				
[Mul	ti-Line Plain Text]					
Proc	duction Testing:					
A.	Does the test involve	a direct test of the performance parameter?	[L]			
B.		employed intesting of each model with respect to this requirement. If reference is made to a test protocopy as an attachment for documentation.	ol			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)	]			
	Details	[HTML Text]				
C.	If any test used to mo	nitor compliance does not actually measure x radiation, explain why it is an accurate indication of comp	liance with			
	[HTML Text]					
D.	Submit the technical of	lata that supports the use of the test in question (C.)				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)	]			
	Details	[HTML Text]				
E.	Attacha copy of the detailed instructions for performing each test.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)	]			
	Details	[HTML Text]				
F.	Identify the instrument	t(s) used for each test by manufacturer and model number.				
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	Details	[HTML Text]				
G.		For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]				
H.	For each test method	listed in question (B.), please attach sample raw test data.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)				
	Details	[HTML Text]	1			
I.	Is the actual complian	ce value calculated from theraw test data?	[L]			
	Please attach a	sample of calculated compliance values complete with an explanation of any correction factors employ	ed.			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv	, .zip)]			
	Details	[HTML Text]				

Expla	ain how compliance is e	established.				
[Mult	i-Line Plain Text]					
J.	Isthis performance par	rameter tested on 100 percent of the produced models?	[L]			
Asse	embler Testing:		•			
Does	assembler testing app	ly?	[L]			
A.	Does the test involve a	a direct test of the performance parameter?	[L]			
B.		employed in testing of each model with respect to this requirement. If reference is made to a test protocolopy as an attachment for documentation.	I			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
C.	If any test used to mor this requirement.	nitor compliance does not actually measure x radiation, explain whyit is an accurate indication of complia	nce with			
	[HTML Text]					
D.	Submit the technical d	ata that supports the use of the test in question (C.)				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
E.	Attach a copy of the de	etailed instructions for performing each test.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
F.	Identify the instrument	(s) used for each test by manufacturer and model number.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
G.	For each test method rejection limits are spe	listed in question (B.)under Assembler Testing, attach the detailed instructions for performing the test wheelfied.	ere the			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
H.	For each test method	listed in question (B.), please attach sample raw test data.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
l.	Is the actual compliand	ce value calculated from the raw test data?	[L]			
		in the user manual that specifies no assembly or installation instructions are necessary and all that is not get the power cord into the wall socket.	eeded to			
File A	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Deta	ils	[HTML Text]				

Red	quirement:	- 1-			
A. Wessage:			stationary general purpose x-ray systems, the center of the x-ray field shall align with the center of the image ptor to within 2 percent of the SID (see 1020.31(e)(1)).		
B. Message:		For o	other x-ray systems, the center of the x-ray field shall align with the center of the image receptor to within ent of the SID unless means are provided to size and align the x-ray fieldsuch that the x-ray field at the perimage receptor does not extend beyond any edge of the image receptor see 1020.31(f)(2) and (4)).		
Δnı	l plicability:		(/// (///		
	ssage:	systems; ( solely for r applicable	rement is applicable to beam-limiting devices used in radiographic x-ray systems other than (a) mobile x (b) systems for spot filming; (c) systems intended solely for intraoral image receptors; and (d) systems us mammography. Similar models of a single component type may be grouped for presentation of test result to this requirement when thetechnical basis for this grouping is clearly stated in the description of protocol.	sed Its	
		testing (se	ee (a) under Prototype Testing).		
Crit	tical Parameter	s and "Wors	st Case" Conditions:		
A.	Message:		result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must ciently restrictive to assure compliance with the standard.	be	
B.	Message:		ssure compliance with the centering requirement, the testresults must include data for various combinat S and image receptor sizes.	ions	
Pro	ototype Testing	:			
This	s section is for s	tart up prior t	to full production phase and thus the testing and quality control procedures may not be the same as	[L]	
pro	duction testing.	Does prototy	pe testing apply?		
A.	Describe the to this require		ethod (i.e., one that actually measures x radiation) employed in testing and measuring each modelwith r	esp	
	[HTML Text]				
В.	Identify the in	strument(s) u	used for the test by manufacturer and model number.		
	[HTML Text]				
C.	Attach a samp	ole of raw tes	st data.		
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
	Details		[Multi-Line Plain Text]		
D.	Is the actual of	ompliance v	alue calculated from the raw test data?	[L]	
E.	Attach a samp	ole of calcula	ated compliance values complete with an explanation of any correction factors employed.		
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
	Details		[HTML Text]		
Exp	olain how compli	ance is estat	olished.		
[Mu	ılti-Line Plain Te	xt]			
Dro	duction Testin	g:			
A.	Does the test	nvolve a dire	ect test of the performance parameter?		

	document, provide a c	opy as an attachment for documentation.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv	, .zip)]			
	Details	[HTML Text]				
C.	If any test used to mor this requirement.	itor compliance does not actually measure x radiation, explain why it is an accurate indication of	compliance wit			
	[HTML Text]					
D.	Submit the technical d	ata that supports the use of the test in question (C.)				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv	<sup>,</sup> , .zip)]			
	Details	[HTML Text]				
E.	Attach a copy of the de	etailed instructions for performing each test.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv	′, .zip)]			
	Details	[HTML Text]				
F.	Identify the instrument	(s) used for each test by manufacturer and model number.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv	′, .zip)]			
	Details	[HTML Text]				
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv	, .zip)]			
	Details	[HTML Text]				
H.	For each test method	in question (B.), please attach sample raw test data.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv	, .zip)]			
	Details	[HTML Text]				
I.	Is the actual compliand	be value calculated from the raw test data?	[L]			
	Please attach a	sample of calculated compliance values complete with an explanation of any correction factors e	mployed.			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xl	3, .csv, .zip)]			
	Details	[HTML Text]				
Expl	ain how compliance is e	stablished.				
[Mult	ti-Line Plain Text]					
J.	Is this performance pa	rameter tested on 100 percent of the produced models?	[L]			
Ass	embler Testing:					
Does	s assembler testing app	ly?	[L]			
A.	Does the test involve a	direct test of the performance parameter?	[L]			
В.		employed in testing of each model with respect to this requirement. If reference is made to a test opy as an attachment for documentation.	protocol			

li	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details		[HTML Text]
C.			compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with
	[HTML Text]		
D.	Submit the tech	nnical data tl	hat supportsthe use of the test in question (C.)
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details		[HTML Text]
E.	Attach a copy o	of the detaile	ed instructions for performing each test.
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details		[HTML Text]
F.	Identify the inst	trument(s) u	sed for each test by manufacturer and model number.
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
,	Details		[HTML Text]
G.	For each test m		I in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
2	Details		[HTML Text]
Н.	For each test m	nethod listed	l in question (B.), please attach sample raw test data.
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details		[HTML Text]
1.	Is the actual co	mpliance va	alue calculated from the raw test data?
			e user manual that specifies no assembly or installation instructions are necessary and all that is needed to power cord into the wall socket.
File	Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Deta	ils	[НТІ	ML Text]
011	10 D - 11	able V.D	
318	s.u Radiograf	pnic X-Ra	ay Field Size and Image Receptor Size
Req	uirement:		
A.	Message:	plane in inc plane	eral purpose stationary x-ray systems: The beam-limiting device shall numerically indicate the field size in the of the image receptor to which it is adjusted. Indication of field size dimensions and SID's shall be specified the and/or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the of the image receptor that correspond to those indicated by the beam-limiting device to within 2 percent of ID when the beam axis is perpendicular to the plane of the image receptor (see 1020.31(e)(1)(ii) and (iii)).
Арр	licability:	*	
Mes	sage:	stationary of	ement is applicable to beam-limiting devices and permanently mounted cassette holders that are used in general purpose systems. Similar models of a single component type may be grouped for presentation of test licable to this requirement when the technical basis for this grouping is clearly stated in the description of

Criti	cal Parameters an	d "Worst Case" Conditions:	
CHIL	1		accomblica or
۹.	Message:	The test results must include data representative of each compatible combination of tube housing a beam-limiting devices.	issembiles an
3.	Message:	As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any to sufficiently restrictive to assure compliance with the standard.	est must be
С.	Message:	Since the SID is used for calculating the compliance values of this requirement, the accuracy of the measurement must be verified.	SID
Prot	otype Testing:		
		up prior to full production phase and thus the testing and quality control procedures may not be the sames does not apply go to 318.5 for production testing. Does prototype testing apply?	ne as [L]
۹.	Describe the direct respect to this required	t test method (i.e., one that actually measures x radiation) employed in testing and measuring each mo uirement.	odel with
	[Multi-Line Plain To	ext]	
В.	Identify the instrun	nent(s) used for the test by manufacturer and model number.	
	[Multi-Line Plain To	ext]	
C.	Attach a sample of	f raw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .	.zip)]
	Details	[Multi-Line Plain Text]	
D.	Is the actual comp	sliance value calculated from the raw test data?	[L]
Ε.	Attach a sample of	f calculated compliance values complete with an explanation of any correction factors employed.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .	.zip)]
	Details	[HTML Text]	
Expl	ain how compliance	s is established.	
Mul	ti-Line Plain Text]		
Proc	duction Testing:		
۹.	Does the test invol	lve a direct test of the performance parameter?	[L]
В.		ods employed in testing of each model with respect to this requirement. If reference is made to a test prepare a copy as an attachment for documentation.	otocol
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .	zip)]
	Details	[HTML Text]	
С.	If any test used to this requirement.	monitor compliance does not actually measure x radiation, explain why it is an accurate indication of co	ompliance wit
	[HTML Text]		
D.	Submit the technic	cal data that supports the use of thetest in question (C.)	

	Deta	ils	[HTML Text]			
E.	Attac	ch a copy of the detaile	ed instructions for performing each test.			
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ils	[HTML Text]			
F.	Iden	tify the instrument(s) u	used for each test by manufacturer and model number.			
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ils	[HTML Text]			
G.		each test method listed tion limits are specifie	d in question (B.) under Production Testing, attach the detailed instructions for performing the test whole.	ere the		
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ils	[HTML Text]			
Н.	For e	each test method listed	d in question (B.), please attach sample raw test data.			
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ils	[HTML Text]	•		
l.	Is the	e actual compliance va	alue calculated from the rawtest data?	[L]		
	-	Please attach a sam	ple of calculated compliance values complete with an explanation of any correction factors employed.			
		File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
		Details	[Multi-Line Plain Text]			
Ехр	lain ho	w compliance is estab	blished.			
[Mu	lti-Line	Plain Text]				
J.	Is thi	s performance param	eter tested on 100 percent of the produced models?	[L]		
Ass	emble	r Testing:				
Doe	s asse	embler testing apply?		[L]		
A.	Does	s the test involve a dire	ect test of the performance parameter?	[L]		
B.		•	loyed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.	•		
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ils	[HTML Text]			
C.	1	y test usedto monitor o equirement.	compliance does not actually measure x radiation, explain why it is an accurate indication of complian	ce with		
	[HTN	/IL Text]				
		mit the technical data t	that supports the use of the test in question (C.)			
D.	Subr	ilit tile technical data t				
D.		Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			

E.	Attach a copy	he detailed instructions for performing each test.			
	File Attachme	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]			
F.	Identify the ins	ment(s) used for each test by manufacturer andmodelnumber.			
	File Attachme	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]			
G.	For each test rejection limits	hod listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the especified.			
	File Attachme	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]			
Н.	For each test i	hod listed in question (B.), please attach sample raw test data.			
	File Attachme	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]			
l.	Is the actual c	Diance value calculated from the raw test data?			
		ages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to plug the power cord into the wall socket.			
File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
Deta	ils	[HTML Text]			
319	0.0 X-Ray Fi	Size Determination for Fixed SID/Image Receptor Size Equipment			
Requ	uirement:				
Mes	sage:	adiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit be field at the plane of the image receptor to dimensions no greater than those of the image receptor, or shall be rovided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor ones not extend beyond any edge of the image receptor (see 1020.31(f)(2)).			
Арр	licability:				
Mes	sage:	his requirement is applicable to beam-limiting devices. Similar models of a single component type may be grouped for resentation of test results applicable to this requirement when the technicalbasis for this grouping is clearly stated in the description of prototype testing (see 319.4(a)).			
Crisi	aal Baramatare	nd "Worst Case" Conditions:			
		s a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be			
ivies	sage:	ufficiently restrictive to assure compliance with the standard.			
Prot	otype Testing:				
		up prior to full production phase and thus the testing and quality control procedures may not be the same as [L] s prototype testing apply?			
A.		ct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with uirement.			
respect to this requirement.  [HTML Text]					

i	identify the instrument(s) us	sed for the test by manufacturer and model number.	
	[HTML Text]		
C.	Attach a sample of raw test	data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[Multi-Line Plain Text]	
D.	Is the actual compliance va	lue calculated from the raw test data?	[L]
E.	Attach a sample of calculate	ed compliance values complete with an explanation of any correction factors employed.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Expl	ain how compliance is establ	lished.	
[Mul	ti-Line Plain Text]		
Prod	duction Testing:		
A.	Does the testinvolve a direct	ct test of the performance parameter?	[L]
B.	·	byed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
	l .	[ITTML TEXT]	
C.	If any test used to monitor of this requirement.	compliance does not actually measure x radiation, explain why it is an accurate indication of complian	nce with
C.	· ·	ļ. ·	nce with
C.	this requirement.  [HTML Text]	ļ. ·	nce with
	this requirement.  [HTML Text]	compliance does not actually measure x radiation, explain why it is an accurate indication of complian	nce with
	this requirement.  [HTML Text]  Submit the technical data the	compliance does not actually measure x radiation, explain why it is an accurate indication of compliant supports the use of the test in question (C.)	nce with
	this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details	compliance does not actually measure x radiation, explain why it is an accurate indication of compliant supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	nce with
D.	this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details	compliance does not actually measure x radiation, explain why it is an accurate indication of compliant supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]	nce with
D.	this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details  Attach a copy of the detaile	compliance does not actually measure x radiation, explain why it is an accurate indication of compliant supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  d instructions for performing each test.	nce with
D.	this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details  Attach a copy of the detaile File Attachment  Details	compliance does not actually measure x radiation, explain why it is an accurate indication of compliant supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  Id instructions for performing each test.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	nce with
D.	this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details  Attach a copy of the detaile File Attachment  Details	compliance does not actually measure x radiation, explain why it is an accurate indication of compliant supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  Id instructions for performing each test.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]	nce with
D.	this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details  Attach a copy of the detailer File Attachment  Details  Identify the instrument(s) us	compliance does not actually measure x radiation, explain why it is an accurate indication of compliant supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  Id instructions for performing each test.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  [HTML Text]  Seed for each test by manufacturer and model number.	nce with
D.	this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details  Attach a copy of the detailed File Attachment  Details  Identify the instrument(s) use File Attachment  Details	compliance does not actually measure x radiation, explain why it is an accurate indication of compliant supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  In the compliant of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  Seed for each test by manufacturer and model number.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  In question (B.) under Production Testing, attach the detailed instructions for performing the test who	
D. E.	this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details  Attach a copy of the detailed File Attachment  Details  Identify the instrument(s) use File Attachment  Details  For each test method listed	compliance does not actually measure x radiation, explain why it is an accurate indication of compliant supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  In the compliant of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  Seed for each test by manufacturer and model number.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  In question (B.) under Production Testing, attach the detailed instructions for performing the test who	
D. E.	this requirement.  [HTML Text]  Submit the technical data the File Attachment  Details  Attach a copy of the detailed File Attachment  Details  Identify the instrument(s) use File Attachment  Details  For each test method listed rejection limits are specified.	compliance does not actually measure x radiation, explain why it is an accurate indication of compliance does not actually measure x radiation, explain why it is an accurate indication of compliance and supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  [In question (B.) under Production Testing, attach the detailed instructions for performing the test who is.	

	Details	[HTN	ML Text]				
l.	Is the actual complian	ce value ca	alculated from the rawtest data?	[L]			
	- Please attach a	sample of c	calculated compliance values complete with an explanation of any correction factors employed.				
	File Attachment	· · ·	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi	ip)]			
	Details		[HTML Text]				
Expl	lain how compliance is e	established.					
[Mul	lti-Line Plain Text]						
J.	Is this performance pa	rameter tes	sted on 100 percent of the produced models?	[L]			
Ass	embler Testing:						
Doe	s assembler testing app	lv?		[L]			
Α.	1		t of the performance parameter?	[L]			
В.			n testing of each model with respect to this requirement. If reference is made to a test protocol	1-3			
	document,provide a co	opy as an a	attachment for documentation.				
	File Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		ML Text]				
C.	If any test used to monitor compliance does notactually measure x radiation, explain why it is an accurate indication of compliance with this requirement.						
	[HTML Text]						
D.	Submit the technical d	ubmit the technical data that supports the use of the test in question (C.)					
	File Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTN	ML Text]				
E.	Attach a copy of the d	etailed instr	ructions for performing each test.				
	File Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTN	ML Text]				
F.	Identifythe instrument	s) used for	each test by manufacturer and model number.				
	File Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTN	ML Text]				
G.	For each test method rejection limits are spe		estion (B.) under Assembler Testing, attach the detailed instructions for performing the test whe	ere the			
	File Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTN	ML Text]				
Н.	For each test method	listed in que	estion (B.), please attach sample raw test data.				
			gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				

	Details		[HTML Text]				
l.	Is the actual c	ompliance va	alue calculated from the rawtest data?	[L]			
			ne user manual that specifies no assembly or installation instructions are necessary and all that is new power cord into the wall socket.	eded to			
File	Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Details		[HTI	HTML Text]				
320	0.0 Alignmer	nt of the X	-Ray Field and Spot-Film Cassette				
Rec	uirement:						
A. Message:		recep for fu witho	total misalignment of the edges of the x-ray field with the respective edges of the selected portion of to total along the length or width dimensions of the x-ray field in the plane of the image receptor, when a fill coverage of the selected portion of the image receptor, shall not exceed 3 percent of the SID. The tructure to sign of the misalignment along any two orthogonal dimensions shall not exceed 4 percentages and the second s	djusteď sum			
В.	Message:		center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion	of the			
		film to	o within 2 percent of the SID (see 1020.31(h)(3)).				
App	olicability:						
			ement is applicable to beam-limiting devices and spot-film devices. Similar models of a single compo e grouped for presentation of test results applicable to this requirement when the technical basis for				
		grouping is	clearly stated in the description of prototype testing (see 320.4(a)).				
Crit	ical Parameters	and"Worst	Case" Conditions:				
A.	Message:		est results must include data representative of each compatible combination of beam-limiting devices film devices.	s and			
B.	Message:		As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.				
C.	Message:		ssure compliance with the spot-film x-ray field limitation requirement, the test results must include dat e of SID's and applicable spot-film formats for each image receptor size.	a for the			
Pro	totype Testing:	<u> </u>					
This	s section is for st	art up prior to	o full production phase and thus the testing and quality control procedures may not be the same as the testing apply?	[L]			
A.	Describe the o		thod (i.e., onethat actually measures x radiation) employed in testing and measuring each model with	n respec			
	[HTML Text]						
В.	Identify the ins	strument(s) u	sed for the test by manufacturer and model number.				
	[HTML Text]						
C.	Attach a samp	le of raw test	t data.				
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	1		1				
	Details		[HTML Text]				

E.	Attach a sample of cald	culated compliance values complete with an explanation of any correction factors employed.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
Expl	ain how compliance is e	stablished.				
[Mul	ti-Line Plain Text]					
Proc	duction Testing:					
A.	Does thetest involve a	direct test of the performance parameter?	[L]			
B.		employed in testing of each model with respect to this requirement. If reference is made to a test protocopy as an attachment fordocumentation.	ol			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
C.	If any test used to mon this requirement.	itor compliance does not actuallymeasure x radiation, explain why it is an accurate indication of compli	ance with			
	[HTML Text]					
D.	Submit the technical da	ata that supports the use of the test in question (C.)				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
E.	Attach a copy of the de	Attach a copy of the detailed instructions for performing each test.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
F.	Identify the instrument(	dentify the instrument(s) used for each test by manufacturer and model number.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
G.		For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
H.	For each test method li	isted in question (B.), please attach sample raw test data.	n question (B.), please attach sample raw test data.			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]	î			
l.	Is the actual compliand	ce value calculated from the raw test data?	[L]			
	Please attach a s	sample of calculated compliance values complete with an explanation of any correction factors employe	ed.			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv	.zip)]			
	Details	[HTML Text]				

Expl	ain how compliance is e	stablished.				
[Mult	ti-Line Plain Text]					
J.	Is this performance pa	rameter tested on 100 percent of the produced models?	[L]			
Asse	embler Testing:					
Does	s assembler testing app	ly?	[L]			
Α.	Does the test involve a	direct test of the performance parameter?	[L]			
В.		employed in testing of each model with respect to this requirement. If reference is made to a testprotocol opy as anattachment for documentation.	•			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
C.	If any test used to mor this requirement.	itor compliance does not actually measure x radiation, explain why it is an accurate indication of complia	nce with			
	[HTML Text]					
D.	Submitthe technical da	ata that supports the use of the test in question (C.)				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
E.	Attach a copy of the detailed instructions for performing each test.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
F.	Identify the instrument	(s) used for each test by manufacturer and model number.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
G.	For each test method rejection limits are spe	isted in question (B.) under Assembler Testing, attach the detailed instructions for performing the test wh cified.	ere the			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
Н.	For each test method	isted in question (B.), please attach sample raw test data.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
l.	Is the actual compliand	ce value calculated from the raw test data?	[L]			
		in the user manual that specifies no assembly or installation instructions are necessary and all that is near the power cord into the wall socket.	eded to			
File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Deta	ils	[HTML Text]				
ı						

Req	uirement:					
Mes	sage:	For nonii	image intensified fluoroscopy, the x-ray field shall not extend beyond the visible area of the image recep	otor.		
		For imag	ge intensified fluoroscopy:			
٨.	Message:	red per inte	total misalignment of the edges of the x-ray field with the respective edges of the visible area of the image programment of the visually defined field in the plane of the image receptor shall not exceed 3 sent of the SID. The sum, without regard to sign, of the misalignmentalong any two orthogonal dimensions resecting at the center of the visible area of the image receptor shall not exceed 4 percent of the SID.			
3.	Message:	the	or rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined to length and width dimensions of the x-ray field that pass through the center of the visible area of the impreperor (see 1020.32(b)(2)(ii)).	along nage		
٩рр	licability:	,				
Mes	sage:	type may	uirement is applicable to beam-limiting devices and image intensifiers. Similar models of a single comp y be grouped for presentation of test results applicable to this requirement when the technical basis for g is clearly stated in the description of prototype testing (see 321.4(a)).			
Crit	ical Parameters	and "Wo	orst Case" Conditions:			
A.	Message:		e test results must include data representative of each compatible combination of beam-limiting devices ar age intensifiers.			
В.	Message:		result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be ciently restrictive to assure compliance with the standard.			
C.	Message:	the	ssure compliance with the fluoroscopic x-ray field limitation requirement, the test results must include data range of SID's and available magnification modes that result in different visual areas on the input phosphor mage intensifier.			
Prof	totype Testing:					
			or to full production phase and thus the testing and quality controlprocedures may not be the sameas otype testing apply?	[L]		
A.	Describe the o		method (i.e., one that actually measures x radiation) employed in testing and measuring eachmodel wit	h resp		
	[HTML Text]					
В.	Identify the ins	strument(s)	) used for the test by manufacturer and model number.			
	[HTML Text]					
Э.	Attach a samp	le of raw te	est data.			
	File Attachme					
	Details		[HTML Text]			
<b>)</b> .	Is the actual c	ompliance	value calculated from the raw test data?	[L]		
<u> </u>	Attach a samp	le of calcu	ulated compliance values complete with an explanation of any correction factors employed.			
	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	1					

Proc	ductio	n Testing:					
Α.	Does	s the test involve a	direct test	of the performance parameter?	[L]		
3.	1			n testing of each model with respect to this requirement. If reference is made to a test protocol attachment for documentation.			
	File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ils	[HTN	//L Text]			
<b>)</b> .		If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.					
	[HTN	//L Text]					
).	Subr	mit the technical da	ta that sup	oports the use of the test in question (C.)			
	File /	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ils	[HTN	//L Text]			
Ē.	Attac	ch a copy of the det	ailed instr	ructions for performing each test.			
	File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	Details [HTI		HTML Text]			
	Identify the instrument(s) used for each test by manufacturer and model number.						
	File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details [HTM		[HTN	HTML Text]			
3.	1	each test method listion limits are spec	•	estion (B.) under Production Testing, attach the detailed instructions forperforming the test whe	re the		
	File	Attachment	[Sing	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	Details [HTML Text		//L Text]			
Ⅎ.	For e	each test method lis	ted in que	estion (B.), please attach sample raw test data.			
	File /	Attachment	[Sing	ringle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	iils	[HTN	[HTML Text]			
	Is the actual compliance value calculated from the raw test data?				[L]		
	-	Please attach a sa	ample of c	calculated compliance values complete with an explanation of any correction factors employed.			
		File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	ip)]		
		Details		[HTML Text]			
xpl	ain ho	w compliance is es	tablished.				
Mul	ti-Line	Plain Text]					
	Is thi	is performance para	ameter tes	sted on 100 percent of the produced models?	[L]		
sse	emble	er Testing:					

Does	s assembler testing	apply?		[L]			
A.	Does the test invo	olve a dire	ct test of the performance parameter?	[L]			
B.			byed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.				
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
C.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.						
	[HTML Text]						
D.	Submit the technic	cal data th	nat supports the use of the test in question (C.)				
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
E.	Attach a copy of the	he detaile	d instructions for performing each test.				
	File Attachment		Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
F.	Identify the instrument(s) used foreach test by manufacturer and model number.						
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
G.	For each test method listed in question(B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.						
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
Н.	For each test met	hod listed	in question (B.), please attach sample raw test data.				
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details		[HTML Text]				
l.	Is the actual comp	oliance val	lue calculated from the raw test data?	[L]			
		-	e user manual that specifies no assembly or installation instructions are necessary and all that is nee power cord into the wall socket.	eded to			
File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Deta	ails	[HTN	TML Text]				
322	2.0 X-Ray Field	d Size D	Petermination for Dental Equipment				
Req	uirement:						
Mes	ra m	ny beamsu ninimum S	ic equipment designed for use with an intraoral image receptor shall be provided with means to limit ich that if the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the SD shall be containable in a circle having a diameter of no more than 7 centimeters; or if the minimum 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diamete	m SSD			

		more than	6 centimeters (see 1020.31(f)(1)(i) and (ii)).			
Арр	licability:					
Mes	sage:	presentatio	ement is applicable to beam-limiting devices. Similar models of a single component type may be grou n of test results applicable to this requirement when the technical basisfor this grouping is clearly stat of prototype testing (see (a) under Prototype testing below).			
Criti	cal Parameters	and "Wors	t Case" Conditions:			
Mes	sage:		of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be restrictive to assure compliance with the standard.			
Prot	otype Testing:					
		• •	o full production phase and thus the testing and quality control procedures may not be the same type testing apply?	[L]		
A.	Describe the d respect to this		thod (i.e., one that actually measures ${\sf x}$ radiation) employed in testing and measuring each model with .	า		
	[HTML Text]					
В.	Identify the ins	trument(s) u	sed for the test by manufacturer and model number.			
	[HTML Text]					
Э.	Attach a sampl	e of raw test	data.			
	File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details		[HTML Text]			
Э.	Is the actual co	mpliance va	pliance value calculated from the raw test data?			
Ε.	Attach a sampl	sample of calculated compliance values complete with an explanation of any correction factors employed.				
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details		[HTML Text]			
Expl	ain how complia	nce is estab	lished.			
Mul	ti-Line Plain Tex	t]				
Proc	duction Testing	:				
Α.	Does the test in	nvolve a dire	ct test of the performance parameter?	[L]		
В.			byed intesting of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.			
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details		[HTML Text]			
C.	If any test used this requirement		compliance does not actually measure x radiation, explain why it is an accurate indication of complian	ice with		
	[HTML Text]					
D.	Submit the tecl	nnical data t	nat supports the use of the test in question (C.)			
	File Attachmen		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			

	Deta	ils	[HTML Text]				
E.	Attac	ch a copy of the detaile	ed instructions for performing each test.				
	File A	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTML Text]				
F.	Ident	tify the instrument(s) u	used for each test by manufacturer and model number.				
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTML Text]				
G.	1	each test method listed tion limits are specifie	d in question (B.) under Production Testing, attach the detailed instructions for performing the test whd.	ere the			
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTML Text]				
Н.	For e	each test method listed	d in question (B.), please attach sample raw test data.				
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTML Text]				
l.	Is the	eactual compliance va	llue calculated from the raw test data?	[L]			
	-	Please attach a sam	ple of calculated compliance values complete with an explanation of any correction factors employed.				
		File Attachment	le Attachment [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .cs				
		Details	[HTML Text]				
Ехр	lain ho	w compliance is estat	blished.				
[Mu	lti-Line	Plain Text]					
J.	Is thi	s performance param	eter tested on 100 percent of the produced models?	[L]			
Ass	emble	r Testing:					
Doe	s asse	mbler testing apply?		[L]			
Α.	Does	s the test involve a dire	ect test of the performance parameter?	[L]			
B.	1	•	loyed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.				
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTML Text]				
	1 '	y test used to monitor equirement.	compliance does not actually measure x radiation, explain why it is an accurate indication of complian	nce wit			
C.	this r	[HTML Text]					
C.		/IL Text]					
	[HTM	-	that supports the use of the test in question (C.)				
C. D.	[HTM	-	that supports the use of the test in question (C.)  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				

E.	1			
	File Attachme	ent	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
F.	Identify the in	nstrument(	ed for each test by manufacturer and model number.	
	File Attachme	ent	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
G.	For each test rejection limit		sted in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where t ified.	
	File Attachme	ent	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
Ⅎ.	For each test	method li	sted in question (B.), please attach sample raw test data.	
	File Attachme	ent	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
l.	Is the actual of	complianc	e value calculated from the raw test data? [L]	
Pro			n the user manual that specifies no assembly or installation instructions are necessary and all that is needed	
ope	erate the system	is to plug	the power cord into the wall socket.	
_	Attachment	T	the power cord into the wall socket.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
File Deta	Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
File Deta	Attachment ails 3.0 X-Ray F	Field Siz	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  e Determination for Mammographic Equipment  lammographic equipment manufactured prior to September 30,1999, shall be provided with means to limit the	
File Deta	Attachment ails 3.0 X-Ray F	Field Siz	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]  e Determination for Mammographic Equipment	
File Deta	Attachment ails 3.0 X-Ray F	Field Siz	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  The Determination for Mammographic Equipment  The Determination for Mammographic	
File Deta	Attachment ails  3.0 X-Ray F  quirement:  Message:	Field Siz	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  e Determination for Mammographic Equipment  fammographic equipment manufactured prior to September 30, 1999, shall be provided with means to limit the seful beam such that the x-ray field at the plane of the image receptor doesnot extend beyond any edge of the large receptor at any designated SID except theedge of the image receptor designed to be adjacent to the chall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID.  fammographic equipment manufactured after September 30, 1999, shall be provided with means to limit the seful beam such that the x-ray field at the plane of the image receptor does not extend beyond anyedge of the	
File Deta	Attachment ails  3.0 X-Ray F  quirement:  Message:  Message:	Field Siz	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  The Determination for Mammographic Equipment  The Determination for Mammographic	
File Deta 323 Rec A.	Attachment ails  3.0 X-Ray F  quirement:  Message:  Message:	Permar designed  This recognises	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  The Determination for Mammographic Equipment  The Determination for Mammographic	
File Det: 323 Rec A. B.	Attachment ails  3.0 X-Ray F  quirement:  Message:  Message:  plicability:  ssage:	Perman designed  This recognished the designed	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]  The Determination for Mammographic Equipment  Image receptor doesnot extend beyond any edge of the large receptor doesnot extend beyond any edge of the large receptor at any designated SID except theedge of the image receptor designed to be adjacent to the chall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID by more than 2 percent of the SID.  Image receptor at any designated SID for which each aperture and (see 1020.31(f)(3)).	
File Detr 32: Rec A.  Mes	Attachment ails  3.0 X-Ray F  quirement:  Message:  Message:  plicability:  ssage:	Permar designed  This represent the des	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  The Determination for Mammographic Equipment  Tammographic equipment manufactured prior to September 30, 1999, shall be provided with means to limit the seful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the large receptor at any designated SID except theedge of the image receptor designed to be adjacent to the chall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID.  Tammographic equipment manufactured after September 30, 1999, shall be provided with means to limit the seful beam such that the x-ray field at the plane ofthe image receptor does not extend beyond anyedge of the mage receptor at any designated SID by more than 2 percent of the SID.  The seful perceptor at any designated SID by more than 2 percent of the SID.  The seful perceptor at any designated SID by more than 2 percent of the SID.  The seful perceptor at any designated SID by more than 2 percent of the SID.  The seful perceptor at any designated SID by more than 2 percent of the SID.  The seful perceptor at any designated SID by more than 2 percent of the SID.  The seful perceptor at any designated SID by more than 2 percent of the SID.  The seful perceptor at any designated SID by more than 2 percent of the SID.  The seful perceptor at any designated SID by more than 2 percent of the SID.  The seful perceptor at any designated SID by more than 2 percent of the SID.  The seful perceptor at any designated SID by more than 2 percent of the SID.  The seful perceptor at any designated SID by more than 2 perceptor size and maximum SID for which each aperture and seful perceptor size and maximum SID for which each aperture and seful perceptor size and maximum SID for which each aperture and seful perceptor size and maximum SID for which each aperture and seful perceptor size and maximum SID for which each aperture and seful perceptor	

C.	Message:	measurement must be verified.
Prot	otype Testing:	
		prior to full production phase and thus the testing and quality control procedures may not be the same as rototype testing apply?
A.	Describe the direct to this requirement.	est method (i.e., one that actuallymeasures x radiation) employed in testing and measuring each model with respect
	[HTML Text]	
B.	Identify the instrume	nt(s) used for the test by manufacturer and model number.
	[HTML Text]	
C.	Attach a sample of ra	aw test data.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
D.	Is the actual complia	nce value calculated from the raw test data?
E.	Attach a sample of c	alculated compliancevalues complete with an explanation of any correction factors employed.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
Expl	ain how compliance is	established.
[Mul	ti-Line Plain Text]	
Proc	duction Testing:	
A.	Does the test involve	a direct test of the performance parameter?
В.		employed in testing of each model with respect to this requirement. If reference is made to a test protocol copy as an attachmentfor documentation.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
C.	If any test used to methis requirement.	onitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with
	[HTML Text]	
D.	Submit the technical	data that supports the use of the test in question (C.)
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
E.	Attach a copy of the	detailed instructions for performing each test.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
F.	Identify the instrume	nt(s) used for each test by manufacturer and model number.
1		

	Deta	ails	[HTML Text]	
G.	1	each test method listed ction limits are specified	${\sf I}$ in question (B.) under Production Testing, attach the detailed instructions for performing the test wh d.	ere the
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ails	[HTML Text]	
Н.	For e	each test method listed	d in question (B.), please attach sample raw test data.	
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ails	[HTML Text]	
I.	Is the	e actual compliance va	alue calculated from the raw test data?	[L]
	_	Please attach a samp	ole of calculated compliance values complete with an explanation of any correction factors employed.	
		File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	ːip)]
		Details	[HTML Text]	
Expl	ain ho	w compliance is estab	lished.	
[Mul	ti-Line	Plain Text]		
J.	Is thi	is performance parame	eter tested on 100 percent of the produced models?	[L]
Ass	emble	er Testing:		
Doe	s asse	embler testing apply?		[L]
A.	Does	s the test involve a dire	ect test of the performance parameter?	[L]
B.	ı	•	oyed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.	
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ails	[HTML Text]	
C.	I '	y test used to monitor or requirement.	compliance does not actually measure x radiation, explain why it is an accurate indication of complian	nce with
	[HTN	ML Text]		
D.	Subr	mit the technical data t	hat supports the use of the test in question (C.)	
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ails	[HTML Text]	
E.	Attac	ch a copy of the detaile	ed instructions for performing each test.	
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	ails	[HTML Text]	
F.	Iden	tify the instrument(s) u	sed for each test by manufacturer and model number.	
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	

G.	For each test n		isted in question (B.) under Assembler Testing, attach the detailed instructions for performing the test w cified.	here the
	File Attachmen	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
Н.	For each test n	nethod li	sted in question (B.), please attachsample raw testdata.	
	File Attachmen	ıt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
I.	Is the actual co	mplianc	e value calculated from the raw test data?	[L]
	. ,		in the user manual that specifies no assembly or installation instructions are necessary and all that is n the power cord into the wall socket.	eeded to
File	Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Deta	ails		[HTML Text]	
324	1.0 X-Ray Fi	eld Siz	re Determination for Radiographic Equipment not in 318 - 323	
_				
Req	uirement:	Γ <u>.</u>		
Mes	sage:	receptorimage in perpendimens align th	praphic x-ray systems otherthan: (a) stationary general purpose systems; (b) systems designed for one par size and SID; (c) spot-film devices; (d) mobile equipment; and (e) equipment designed for use with interceptors shall be provided with means to limit the x-ray beam such that when the axis of the x-ray beat dicular to the plane of the image receptor, the dimensions of the x-ray field shall not exceed the correstions of the image receptor by more than 2 percent of the SID, or shall be provided with means to boths are x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any expreceptor (see 1020.31(f)(4)).	traoral m is conding size and
Арр	licability:			
Mes	sage:	present	quirement is applicable to beam-limiting devices. Similar models of a single component type may be gr taiton of test results applicable to this requirement when the technical basis for this grou ing is clearly s scription of prototype testing (see 324.4(a)).	
Criti	ical Parameters	and "W	/orst Case" Conditions:	
Α.	Message:	- 1	is a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test nufficiently restrictive to assure compliance with the standard.	nust be
В.	Message:	7	he test results must include data for each aperture size.	
C.	Message:	- 1	Sincethe SID is used for calculating the compliance values of this requirement, the accuracy of the SID neasurement must be verified.	
Prot	totype Testing:			
			or to full production phase and thus the testing and quality controlprocedures may not be the same as totype testing apply?	[L]
A.	Describe the d respect to this		t method (i.e., one that actually measures $x$ radiation) employed in testing and measuring each model $t$ nent.	vith
	[HTML Text]			
В.	Identify the ins	trument(	s) used for the test by manufacturer and model number.	
	[HTML Text]			
	ſ			

C.	Attach a sample of raw te	st data.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
D.	Is the actual compliance v	value calculated from the raw test data? [L]
E.	Attach a sample of calcula	ated compliance values complete with an explanation of any correction factors employed.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
Expl	ain how compliance is esta	blished.
[Mult	ti-Line Plain Text]	
Proc	duction Testing:	
A.	Does the test involve a di	rect test of the performance parameter? [L]
B.	·	ployed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
C.	If any test used to monitor this requirement.	compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with
	[HTML Text]	
D.	Submit the technical data	that supports the use of the test in question (C.)
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
E.	Attach a copy of the detai	led instructions for performing each test.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
F.	Identify the instrument(s)	used for each test by manufacturer and model number.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
G.	For each test method lister rejection limits are specific	ed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the ed.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
Н.	For each test method liste	ed in question (B.), please attach sample raw test data.
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]

	<u> </u>	e value calculated from theraw test data?	[L]			
	Please attach a s	ample of calculated compliance values complete with an explanation of any correction factors employed	<u>.                                    </u>			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv,	zip)]			
	Details	[HTML Text]				
Expl	lain how compliance is e	stablished.				
Mul	lti-Line Plain Text]					
J.	Is this performance par	ameter tested on 100 percent of the produced models?	[L]			
Ass	embler Testing:					
Doe	s assembler testing appl	y?	[L]			
١.	Doesthe test involve a	direct test of the performance parameter?	[L]			
3.		mployed in testing of each model with respect to this requirement. If reference ismade to a test protocol ppy as an attachment for documentation.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
C.	If any test used to monitor compliance does not actually measure x radiation, explain why itis an accurate indication of compliance with this requirement.					
	[HTML Text]					
D.	Submit the technicalda	ta that supports the use of the test in question (C.)				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
Ε.	Attach a copy of the de	tailed instructions for performing each test.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
F.	Identify the instrument(	s) used for each test by manufacturer and model number.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
G.	For each test method li rejection limits are spec	sted in question (B.) under Assembler Testing, attach the detailed instructions for performing the test wholified.	ere the			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
H.	For each test method li	sted in question (B.), please attach sample raw test data.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Details	[HTML Text]				
	Is the actual complianc		[L]			

File	Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Deta	ails	[НТІ	ML Text]	
32	5.0 Transmi	ssion Limi	t for Image Receptor Support Devices for Mammographic Syst	
Req	quirement:			
Mes	ssage:	system sha	nission of the primary beam throughany image receptor support provided with the mammographicx-ray will be limited suchthat the exposure 5 centimeters from any accessible surface beyond the plane of the supporting device does not exceed 0.88 micrograys (or 0.1 milliroentgen) for each activation ofthe tube (\$\( \)(3)).	imag
App	olicability:			
Mes	ssage:	component	ement is applicable to mammographic image receptor supporting devices. Similar models of a single type may be grouped for presentation of test results applicable to this requirement when the technical uping is clearly stated in the description of prototype testing (see325.4(a)).	basis
Crit	ical Parameter	s and "Wors	t Case" Conditions:	
Mes	ssage:		ofinherent inaccuracies of the test method and instrumentation, rejection limits for any testmust be suffice of assure compliance with the standard.	icient
Pro	totype Testing	:		
			o full production phase and thus the testing and quality control procedures may not be the same as be testing apply?	[L]
A.	Describe the respect to this		thod (i.e., one that actually measures x radiation) employed in testing and measuring each model with	
	[HTML Text]	requirement		
В.	Identify the in	strument(s) us	sed forthe test by manufacturer and model number.	
	[HTML Text]			
C.	Attach a sam	ole of raw test	t data.	
	File Attachme	ent	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
D.	Is the actual of	compliance va	slue calculated from the raw test data?	[L]
E.	Attach a sam	ole of calculat	ed compliance values complete with an explanation of any correction factors employed.	
	File Attachme	ent	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
Ехр	lain how compli	ance is estab	lished.	
[Mu	lti-Line Plain Te	xt]		
Pro	ductionTesting	j:		

	Details	[Multi-Line Plain Text]						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip	)]					
C.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.							
	[HTML Text]							
D.	Submit the technical of	data that supports the use of the test in question (C.)						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip	p)]					
	Details	[HTML Text]						
E.	Attach a copy of the c	detailed instructions for performing each test.						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip	p)]					
	Details	[HTML Text]						
F.	Identify the instrumen	nt(s) used for each test by manufacturer and model number.						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip	p)]					
	Details	[HTML Text]						
G.	For each test method listed in question (B.)under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.							
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip	p)]					
	Details	[HTML Text]						
Н.	For each test method	d listed in question (B.), please attach sample raw test data.						
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip	p)]					
	Details	[HTML Text]						
	Is the actual complian	nce value calculated from the raw test data?	[L]					
I.	Please attach a	a sample of calculated compliance values complete with an explanation of any correction factors emplo	yed.					
l.		t [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .cs	sv, .zip)]					
l.	File Attachment							
I.	File Attachment Details	[HTML Text]						
I.		l						
	Details	l						
	Details  Ilain how compliance is  Ilti-Line Plain Text]	l	[L]					
[Mu J.	Details  Ilain how compliance is  Ilti-Line Plain Text]	established.	[L]					
[Mu J. <b>Ass</b>	Details  Ilain how compliance is  Ilti-Line Plain Text]	established.  parameter tested on 100 percent of the produced models?	[L]					
[Mu J.	Details	established.  parameter tested on 100 percent of the produced models?	1					

1	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
C.	If any test used this requireme		r compliance does not actually measure x radiation, explain why it is an accurate indication of complian	nce with
	[HTML Text]			
D.	Submit the tec	hnical data	that supports the use of the test in question (C.)	
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
E.	Attach a copy	of the detai	lled instructions for performing each test.	
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
F.	Identify the ins	trument(s)	used for each test by manufacturer and model number.	
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
G.	For each test r rejection limits		ed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test whed.	ere the
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
Н.	For each test r	nethod liste	ed in question (B.), please attach sample raw test data.	
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
,	Details		[HTML Text]	
l.	Is the actual co	ompliance v	value calculated from the raw test data?	[L]
		. •	the user manual that specifies no assembly or installation instructions are necessary and all that is nea be power cord into the wall socket.	eded to
File /	Attachment	[Si	ingle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Deta	ils	[H	TML Text]	
326	.0 Radiogra	phic PB	L Field Size and Image Receptor Size Differences	
Note	e.	Answer th	ne following questions if certifying a beam-limiting device that is designed for PBL.	
Requ	uirement:			
Mes	sage:	manually receptor k be no gre	with positive beam limitation: The x-ray field size in the plane of the image receptor, whether automatic adjusted shall be such that neither the length nor the width of the x-ray field differs from that of the image greater than 3 percent of the SID and that the sum of the length and width differences without regarkater than 4 percent of the SID when the equipment indicates that the beam axis is perpendicular to the perceptor (see 1020.31(g)(1)(i) and (ii)).	age d to sign
App	licability:	<u> </u>		
		1		

Mess	sage:	stationa for pres	quirement is applicable to beam-limiting devices and permanently mounted cassette holders that are use any general purpose systems with PBL collimators. Similar models of a single component type may be gr sentation of test results applicable to this requirement when the technical basis for this grouping is clearly lescription of prototype testing (see 326.4(a)).	ouped
Critic	cal Parameters	and "W	orst Case" Conditions:	
Α.	Message:		he test results must include data representative of each compatible combination of tube housing assemb eam-limiting devices.	lies and
B.	Message:		s a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test mu ufficiently restrictive to assure compliance with the standard.	st be
C.	Message:	h	to assure compliance with the positive beam limitation requirements, the test results must include data for orizontal and vertical ranges of SID's and image receptor sizes and (2) the $\pm$ 3° range of angulation relating perpendicular to the plane of the image receptor.	
D.	Message:		ince the SID is used for calculating the compliance values of this requirement, the accuracy of the SID neasurement must be verified.	
Prote	otype Testing:			
			or to full production phase and thus the testing and quality control procedures may not be the same as otype testing apply?	[L]
Α.	Describe the d		method (i.e., one that actually measures x radiation) employed in testing and measuring each model witnent.	h
	[Multi-Line Pla	in Text]		
B.	Identify the ins	trument(	s) used forthe test by manufacturer and model number.	
	[HTML Text]			
C.	Attach a samp	le of raw	test data.	
	[Multi-Line Pla	in Text]		
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
D.	Is the actual co	omplianc	e value calculated from the raw test data?	[L]
E.	Attach a samp	le of calc	culated compliance values complete with an explanation of any correction factors employed.	•
	[Multi-Line Pla	in Text]		
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Expla	ain how complia	ance is es	stablished.	
[Mult	i-Line Plain Tex	ct]		
Prod	uction Testing	j:		
A.	Does the test i	nvolve a	direct test of the performance parameter?	[L]
В.			mployed in testing of each model with respect to this requirement. If reference is made to a test protocol appy as an attachment for documentation.	•
	[Multi-Line Pla	in Text]		
	File Attachmer	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
C.	If any test used this requireme		itor compliance does not actually measure x radiation, explain why it is an accurate indication of complian	nce with

	[НТМ	L Text]							
D.	Subm	nit the technical data th	nat supports the use of the test in question (C.)						
[Multi-Line Plain Text]									
	File A	uttachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls,	.csv, .zip)]					
E.	Attach a copy of the detailed instructions for performing each test.								
	[Multi-	-Line Plain Text]	<u>,                                      </u>						
	File A	ttachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls,	.csv, .zip)]					
F.	Identi	fy the instrument(s) us	sed for each test by manufacturer and model number.						
	[Multi-	-Line Plain Text]							
	File A	ttachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls,	.csv, .zip)]					
G.	ı	ach test method listed ion limits are specified	in question (B.) under Production Testing, attach the detailed instructions for performind.	g the test where the					
	[Multi-	-Line Plain Text]							
	File A	ttachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls,	.csv, .zip)]					
Н.	For ea	ach test method listed	inquestion (B.), please attach sample raw test data.						
	[Multi-Line Plain Text]								
	File A	uttachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls,	.csv, .zip)]					
l.	Is the	actual compliance va	lue calculated from the raw test data?	[L]					
	-[	Please attach a samp	ele of calculated compliance values complete with an explanation of any correction factor	ors employed.					
		[Multi-Line Plain Text]							
		File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mo	ıl, .xls, .csv, .zip)]					
Expl	ain hov	v compliance is establ	ished.						
[Mult	ti-Line I	Plain Text]							
J.	Is this	s performance parame	eter tested on 100 percent of the produced models?	[L]					
Ass	embler	Testing:		·					
Does	s asser	mbler testing apply?		[L]					
A.	Does	the test involve a dire	ct test of the performance parameter?	[L]					
B.	1	•	oyed in testing of each model with respect to this requirement. If reference is made to a as an attachment for documentation.						
	[Multi-	-Line Plain Text]							
	File A	uttachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls,	.csv, .zip)]					
C.	1	test used to monitor of test used to monitor of test and test and test are test as the test are test a	compliance does not actually measure x radiation, explain why it is an accurate indication	on of compliance wit					

	[Multi-Line Plain Text]							
<u></u>	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
E.	E. Attach a copy of the detailed instructions for performingeach test.							
	[Multi-Line Plain Text]							
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
F.	Identify the instrument	t(s) used for each test by manufacturer and model number.						
	[Multi-Line Plain Text]							
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
G.	For each test method rejection limits are spe	listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test wi ecified.	nere the					
	[Multi-Line Plain Text]							
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
Н.	For each test method	listed in question (B.), please attach sample raw test data.						
	[Multi-Line Plain Text]							
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
I.	Is the actual complian	ce value calculated from the raw test data?	[L]					
	.,	s in the user manual that specifies no assembly or installation instructions are necessary and all that is no	eded to					
-,-5.	rate the system is to plu	g the power cord into the wall socket.						
	rate the system is to plu Attachment	g the power cord into the wall socket.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
	Attachment	<u> </u>						
File Deta	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]						
File Deta	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]						
File Deta	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]						
File Deta	Attachment ails ection: Commo	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]  On Aspects						
File Deta	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]  On Aspects						
File Deta	Attachment ails ection: Commo	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]  On Aspects						
File Deta	Attachment  ails  cction: Commo	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]  On Aspects	[L]					
File Deta	Attachment  ails  ction: Commo	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]  On Aspects  n	if the					
File Deta	Attachment  ails  ction: Commo	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  On Aspects  use Radiation Measuring instruments?  asurement instrument that you refer to in Part 300, giving the following: manufacturer and model number available; type of instrument; precision; accuracy; response time; energy dependence; angularresponse;	if the					
File Deta	Attachment  ails  Cotion: Commo  1.0 Instrumentation  iation Measurement:  any of the test protocols cribe each radiation merument is commercially a dependence; ranges; a  Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  On Aspects  use Radiation Measuring instruments?  asurement instrument that you refer to in Part 300, giving the following: manufacturer and model number available; type of instrument; precision; accuracy; response time; energy dependence; angularresponse; nd effective measurement area.	if the					
File Deta  See  401  Rad Do a Dessinstr rate File Deta	Attachment  ails  ction: Commo  1.0 Instrumentation  iation Measurement:  any of the test protocols cribe each radiation merument is commercially a dependence; ranges; a  Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]  [HTML Text]  On Aspects  use Radiation Measuring instruments?  asurement instrument that you refer to in Part 300, giving the following: manufacturer and model number available; type of instrument; precision; accuracy; response time; energy dependence; angularresponse; nd effective measurement area.  [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	if the					

How do you assure proper day-to-day operation of each instrument?	
[HTML Text]	
Illuminance and Contrast Measurement:	
Do any of the test protocols measure Illuminance and/or Contrast? [L]	
Describe each illuminance and/or contrast measurement instrument that you refer toin Part 300, giving the following: manufacturer and model number if theinstrument is commercially available; type of measuring instrument; precision; accuracy; and ranges.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
[HTML Text]	
How do you assure proper day-to-day operation of each instrument?	
[HTML Text]	
Electrical Measurement:	
Describe each electrical measurement instrument that you referred to in Part 300, giving the following:type of instrument; manufacturer and model number if the instrument is commercially available; rated accuracy; precision; ranges; and response time. If anynumber of commercially available instruments withcertain basic characteristics may be used, it is sufficient to state the minimum accuracy, precision, ranges, response time, and so forth, of the class of instruments that will be used. If any instrument is unique or of special manufacture then the manufacturer and model number should be stated.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
[HTML Text]	
Show where each instrument listed in the above question under Electrical Measurement is connected during testing with the use of a schematicdiagram.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Other Measurement:	
Describe each measurement instrument (other than radiation, illuminance and contrast, or electrical)that you refer to in Part 300, giving thefollowing: type of instrument; manufacturer and model number if the instrument is commercially available; rated accuracy; precision; and ranges. If any number of commercially available instruments with certain basic characteristics may be used, it is sufficient to state the minimum accuracy, precision ranges, and so forth, of the class of instruments that will be used. If any instrument is unique or of special manufacture, however, then the manufacturer and model number should be stated. Please attachanymanuals for the testing instruments.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
[HTML Text]	
402.0 Sampling	
Γ	<del>.</del>

[L] Are any performance parameters tested other than 100 percent? List each performance parameter test that is sampled. [HTML Text] Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Click on the Add... button below to attach files. [HTML Text] File Attachment [Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] Provide the following parameters in an attachment above. (1) The lot size (N) (2) The sample size (n) (3) The reject level number (c) (4) A single or double sampling plan (S or D) (5) The acceptable quality level (AQL) (6) The lottolerance percent defective (LTPD) (7)Theproducer's risk (8) Theconsumer's risk (9) The operating characteristic (OC) curve (10) The average outgoing quality level (AOQL) (11) The procedures for segregation of the lot until sampling allow the lot to be released. Describe the procedure used for selecting the sample and indicate how randomness is assured. [HTML Text] Describe the action taken if the sampling plan leads to a rejection decision. [HTML Text] You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are Stop: 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. Form FDA 3626 A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Message: Components (03/06) Document Key: Specialized Response content is defined within straight brackets []; Special code: [L] List of Values.