OMB N	o. 0910-0025; Exp. May 31, 2010
Section:	: eRadHealth Menu
Role	
What is your i	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	on Information
FDA or Sta	ate Inspector
Abbreviate	ed Report Applicability
OEM Lase	er Applicability
Section:	: Manufacturer Data
Introduction	

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 www.fda.gov/esg. 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 www.fda.gov/cdrh/radhealth/ and medical devices available at www.fda.gov/cdrh/devadvice/. If you have specific questions about the regulations, please contact us at: DSMICA@fda.hhs.gov.

If you have specific questions regarding this software, please contact the eSub team by email at: eSubmitter@fda.hhs.gov.

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

Thank you for your continued support of the FDA Electronic Submission Program (eSub).

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 www.fda.gov/cdrh/radhealth/. 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		
Email Address		
Establishment Informa	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 0	Official f	from Contact Address book:
Contact Information:		
Contact Name		
Occupation Title		
Email Address		
Establishment Informa	ation:	
Establishment Name		
Division Name		
Physical Location:		
Address		
Telephone Number		
Fax Number		
Mailing Location:		
Address		
Report Submitte	r	
Note:		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

	docume	entation.	
Select the Submitter from	om the	Contact Address book:	
Contact Information:			
Contact Name			
Occupation Title			
Email Address			
Establishment Informat	tion:		
Establishment Name			
Division Name			
Physical Location:			
Address			
Telephone Number			
Fax Number			
Mailing Location:			
Address			
Comments:			
Internal Reference Nun	mber:		
Parent Establishn	nent		
Is there a parent establ	lishmer	12	[L]
is there a parent establish			
Select the Parent Estab	blishme	nt and Contact from the Contact Address book:	
Contact Information:			
Contact Name			
Occupation Title			
Email Address			
Establishment Informat	tion:		
Establishment Name			
Division Name			
Physical Location:			
Address			
Telephone Number			
Fax Number			
Mailing Location:			

Address					
Manufacturar Designated United States Agent					
Manufacturer Designated United States Agent					
Note:	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 contain	in up to	10 items with none required)			
	1				
Note:		of the required responses below do not apply to your designated agent, enter 'NOT APF	PLICABLE' or 'NA.'		
	d Agent	from the Contact Address book:			
Contact Information:					
Contact Name					
Occupation Title					
Email Address					
Address					
Establishment Name Division Name					
	Address				
Telephone Number Fax Number					
	Fax Number Attach a copy of written agreement with the designated U.S. agent:				
[Multi-Line Plain Text]		sherit with the designated 0.5. agent.			
		[Single File Attachment (ndf ing gif tif avi wmv ynt yml dtd sgml mol yls	csv zin)]		
The Attachment	File Attachment [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Importer					
Item: 1 (could contain up to 10 items with none required)					
Select the Importer from the Contact Address book:					
Contact Information:					
Contact Name					
Occupation Title					
Email Address					
l					

Establishment Inform	ation:				
Establishment Name					
Division Name	Division Name				
Physical Location:	Physical Location:				
Address					
Telephone Number					
Fax Number					
Mailing Location:					
Address					
Additional Manu	factur	ing Locations			
Item: 1 (could conta	in up to	100 items with none required)			
Note:	Produc codes proced	If any of the products certified in this report are manufactured at locations other than listed in the Manufacturer Responsible for 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 Manufactur	rer Addı	ess from the Establishment Address book:			
Establishment Inform	ation:				
Establishment Name	Establishment Name				
Division Name					
Home Page					
Physical Location:					
Address					
Telephone Number					
Fax Number					
Mailing Location:					
Address	Address				
Comments:	Comments:				
Code used on identification labels:					
•					
Section: Pro	Section: Product Data				
Product and Mod	Product and Model Identification				
. 75 dast and Wo					

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?	[L]	
A request for an exemption from notification?	[L]	
Corrective action plans you may be conducting?	[L]	
A description of any design changes that correct noncompliances for future production?	[L]	
Provide an explanation:		
[Multi-Line Plain Text]		

Exemption Requests

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

Variance Requests

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

File Attachment		[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Stop:	For all The eletthe Me U.S. F. Center Attn: e Docum 10903 Silver Addition Food a Divisio 5630 F	Variance requests, two submissions must be made to the FDA. ectronic 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 or for Devices and Radiological Health Submitter Team nent Mail Center - W066-0609 New Hampshire Avenue Spring, MD 20993-0002 ponally, 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
	Rockvi	ille, 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 information or additional comments that would help expedite the review of this submission? Click the plus sign below to		
attach any supporting files.		
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	

Private Labeling

Is the product sold by other companies under different brand names?	[L]
---	-----

Private Labeling-Table				
Item: 1 (could contain up to 20 items with 1 required)				
Total Community to 20 none min				
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):			
Enter brand names and/or m	odel designations in the following table by clicking on the Add button. If	you prefer to attach a file please click on the		
	"See File Attachment" as the first table entry.	you prefer to attach a file, please click on the		
Item 1				
Item 2				
Item 3				
List of Brand Names and/or N	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 r	nodel designations:		
[Multi-Line Plain Text]				
Medical Devices				
Provide the premarket 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one of these numbers has been assigned by				
FDA yet. [Multi-Line Plain Text]				
If it has not been assigned yet, provide an explanation and submit it as soon as you receive such a filing number.				
[Multi-Line Plain Text]				
Γ				

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	DESIGN	NOITAN
-------------	--------	--------	--------

Item: 1 (could contain up to 500 items with 1 required)			
Component Type:	[L]		
Model Designation:			

2.5 INDIVISIBL	E COMBINATIO	N OF COMPONENTS	
	•		
Note:	labeled components within tube housing and x-ray controls v single certification la	ony of these components are sold separately, they cannot be listed as single labeled. Examples are high voltage generators contained within tube housing assemblies, beam-limiting devices assemblies, beam-limiting devices which are integral parts of tube housings, and high voltage which are inseparable and housed jointly. These are the combinations that may be combined unabel. Other combinations may be authorized by the Center for Devices and Radiological Health manufacturer. Authorization for single labeling may be granted only for inseparable combination	contained generators nder a upon
	components that are	e contained within a single housing.	
			<u> </u>
Do you combine cor	nponents under a sing	le certification label pursuant to 21 CFR 1020.30(c)?	[L]
2.5.1 COMBINA	ATION OF COME	PONENTS	
Item: 1 (could cont	ain up to 10 items wi	th none required)	
	T		
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 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	tion:		
[L]			
Model Designation:			
2.6 OTHER NA	MES OR LABEL	S	
Are any of the mode	els you manufacture re	ported 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 cont	ain up to 10 items wi	th none required)	
Component Type?		[L]	
Model Designation:			
Other Company Unc	der Whose Name The	Model Is Sold?	
Model Name Sold U	nder Other Company?		

2.7 LABEL DESCRIPTION

Note:	in		ed under 2.4, 2.5 and 2.6, provide an exact replica of all labels filled out as they would be when in the copies of the labels and the requested information. The label should include the following as	ntroduced
2. 7 3. 7 4. 7 5. 7 6. I	The name a sold) The date an above, there model The manufin addition o view wh	nd place of mean the code used designation acturer, mode, the standard en the produ	ent of the manufacturer (or the individual or company under whose name anufacture. 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 to the fully assembled for use. Provide a drawing or photograph of ea and/or combination showing where the attached label is located.	2 er 1.8 able sible
Attach a fi	le that contains	a replica of labels	s for every model listed under 2.4, 2.5 and 2.6. Click on the plus sign below to attach files.	
[HTML Te	xt]			
File Attach	nment	[Multiple File	Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
2.8 Par	t 1: COMPL	ETE SYSTEN	MS AND SUBSYSTEMS	
Are there	components ce	ertified by this repo	rt marketed by you as a system or subsystem of components?	[L]
2.8 PAF	RT 2: COMI	PLETE SYSTI	EMS AND SUBSYSTEMS	
Item: 1 (c	ould contain ι	ıp to 20 items wit	h none required)	
System or	· Subsystem De	esignation:		
Compone	nt Type:			
Item 1				
Item 2	1			
Item 3				
Model Des	signation:			
Manufactu	ırer:			
Item 1				
Item 2				
Item 3				
Accession	Number:			
Item 1	tem 1			
Item 2	_			
Item 3				

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]		[HTML Text]		
Are there assembly a	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)]		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
Details		[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.		3		

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.	

Is this report intended for the certification of a beam limiting device (either seperately or in combination)?			
Use and Type of Collimation			
Item: 1 (could contain up to 15 items with none required)			
Model Designation:			
Max kVP:			
Indicate the type of collimation.	[L]		
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		l	
Is this report intended for the certification of an x-ray high voltage generator (either separatel	y 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:			
Select all uses for which each model family is intended.			
Item 1			
Item 2			
Item 3			
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	for the certification of an x-ray control (either separately or in combination)?	[L]

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	ses 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							
	BELOV	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							
	BELOW	7 51 kVp	51 TO 70 kVp		ABOVE 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		
	EXAMPLE of High-level specifications DESIGNED kVp OPERATING RANGE							
	BELOV	V 51 kVp	51 TO	70 kVp	ABOVE	70 kVp		
	INDICATED	MAXIMUM DEVIATION	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 t	he plus sign below to a	attach the appropriate f	ïles.					
[HTML Te	ext]							
File Attac	hment [M	ultiple File Attachments	s (.pdf, .jpg, .gif, .tif, .a	vi, .wmv, .xpt, .xml, .dto	d, .sgml, .mol, .xls, .csv	/, .zip)]		
Section	on: Compone	nt Descriptio	n					
201 D T	UBE HOUSING	ASSEMBLY						
		, .OOLIVIDE I						
Note:	Note: This section should be completed for each tube housing assembly listed in section 2.4 and any combination listed in section 2.5 that contains a tube housing assembly as an integral partthereof.							
Is this rep				nbination containing a t	ube housing assembly	? [L]		
						•		
201.1 T	ube Housing As	sembly Information	on					
I								

Item: 1 (could contain up to 20 items with 1 required)						
Model Designation:						
List the Max kVp:						
Are any of the mode	ls intended for use o	n a general purpose x-ray system?	•	[L]		
	nds, beam limiting de	neral purpose x-ray system, cite the specific p vices, and/or other equipment necessary for				
File Attachment	[Single File	Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt	t, .xml, .dtd, .sgml, .mol, .xls, .csv,	.zip)]		
[HTML Text]						
Also specify where to indicator.	o find information ad	dressing the perpendicularity of the beam axis	s to the image receptor, and inform	nation on the SID		
File Attachment	[Single File	Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt	t, .xml, .dtd, .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 re	place them with your own labels (including re-		
File Attachment	File Attachment [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
[HTML Text]						
202.0 BEAM-LI	MITING DEVIC	ES				
Note:		be completed for each beam-limiting device ntains a beam-limiting device as an integral pa ection 203.0				
Is this report intende	d for the certification	of a beam limiting device or combination con	staining a beam limiting device?	[L]		
Is the beam limiting	device designed for	ntraoral dental?		[L]		
202.1 Dental Bl	_D (intraoral)					
Item: 1 (could cont	ain up to 20 items v	vith 1 required)				
Model Designation:						
Note:	_	e appropriate model indicated, please go to q e identification label.	uestion 2.4 MODEL DESIGNATIO	ON to enter the model		
Minimum source-to-	skin distance (SSD)	n 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: Genera	al Purpose	Radiographic BL	.D				
General Purpose Radiogr	aphic BLD -	mobile and stationary	/ (excluding mammogra	aphic, spot-	film device:	s, and dental	units)
Is the BLD designed for ger	neral purpose	radiography?					[L]
Are any beam-limiting device	ce(s) equippe	d with a light localizer?					[L]
202.2 Part 2: Genera	al Purpose	Radiographic BL	.D				
Item: 1 (could contain up	to 20 items v	with 1 required)					
General Purpose Radiogr	aphic BLD -	mobile and stationary	/ (excluding mammogra	aphic, spot-	film device:	s, and dental	units)
Model Designation:							
What is the minimum sourc	e to skin dista	ance (SSD) in cm?					
What is the minimum x-ray	field size at 1	00 centimeters SID (or	maximum SID if less that	an 100 cm):			
Is the adjustment for the siz	e of the x-ray	field stepless?			[L]		
Is the beam-limiting device((s) equipped v	with a light localizer?			[L]		
202.3 Part 1: Station	ary Gener	al Purpose Radio	ographic				
Are any model BLDs design	ned as a Stati	onary General Purpose	e Radiographic BLD?			[L]	
Are any of the reported BLD) models you	are certifing designed	for positive beam limitation	on (PBL)?		[L]	
202.3 Part 2: Station	ary Gener	al Purpose Radio	ographic BLD				
Item: 1 (could contain up	to 20 items v	with 1 required)					
Model Designation:							
Are means provided to indic perpendicular to the plane of		`	cal and horizontal) is	[L]			
Describe the means to indic	cate when the	beam axis is perpend	icular to the plane of the	image recep	tor?		
[Multi-Line Plain Text]							
What is the designed minim	num SID? (eit	her cm or in)					

Provide a drawing or pic	cture of the indicator on the beam-limiting device that shows	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 discrete	e steps or [L]
	rcuit diagram and interlock mechanism that prevents the pr lesigned 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 pr	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 casso	ette sizes as labeled on the cassette along withthe model n	number identifying each cassette.
Item 1		
Item 2		
Item 3		
The PBL adjustment of	the x-ray field is:	[L]
Provide a copy of the cir	rcuit diagram and interlock mechanism that prevents the pr	roduction of x-rays until such adjustment is completed.
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv,	.xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	•	
Can the PBL x-ray field	be adjusted to dimensions smaller than those of the image	e receptor? [L]
When the PBL x-ray fiel	be adjusted to dimensions smaller than those of the image d is adjusted to dimensions smaller than the image receptor the image receptor or SID is changed?	
When the PBL x-ray fiel coverage occur when ei	d is adjusted to dimensions smaller than the image receptor	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]					
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 o	verride?	[L]		
Describe each service switch	ch and/or capture key override availab	le with the PBL system.	'		
[HTML Text]					
Attach a drawing or picture	showing the location of each PBL ove	rride switch.			
File Attachment	[Single File Attachment (.pdf, .jpg, .g	if, .tif, .avi, .wmv, .xpt, .xml, .dt	td, .sgml, .mol, .xls, .csv, .zip)]		
[HTML Text]					
Provide circuit diagrams and	d description of function for each PBL	bypass and override circuit.			
File Attachment	File Attachment [Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
[HTML Text]	_				
202 4 Part 4: Page 1	incition Device weed with Co	ot Film			
202.4 Part 1: Beam L	Limiting Device used with Sp	Ot Film			
Is the beam-limiting device	designed to be used with Spot Film Ra	adiography or Digital Spot Rec	cording?	[L]	
202.4 Part 2: Beam L		ot Film			
	- g				
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 the image receptor.	he x-ray field is accomplished when the	ne fluoroscopic x-ray field is la	rger than the recorded selected portion	n of the	
[Multi-Line Plain Text]					
Describe how the enlargement 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	le to adjust the x-rayfield to a size sm	aller than the selected portion	of the image receptor.		
[HTML Text]					
l					

List the applicable image of cm and format: 4 on 1	receptor sizes (for film use as labeled on the cassette) and the available formats. For example, size: cr	n 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 pictuassembled in a fluoroscop	are of the location of the beam limiting device with respect to the patient and the image receptor when it is oic 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 sy	/stem failure override?	[L]
Describe each service sw	itch and/or capture key:	
[HTML Text]		
Describe the label advisin	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 flu	uoroscopy use?	[L]
Are any of the beam-limiti	ng device(s) designed for use in image-intensified fluoroscopy, other than radiation therapy simulation?	[L]
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 the	he geometric configuration of x-ray field: [L]	
If you chose "other" for the	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-	

limiting device is designed?	(cm x cm) or (in x in)	
Is the BLD designed for nor	nimage intensified fluoroscopy?	[L]
Describe the means for limi	ting the x-ray field within the visible area of the image receptor:	
[HTML Text]		
What is the minimum SSD	under normal fluoroscopy? (cm)	
Is the beam-limiting device/	system combination designed for special surgical procedures?	[L]
Is there a removable space	r?	[L]
What is the minimum SSD	with spacer removed? (cm)	
Are means provided for sys	tem failure override?	[L]
Describe each service switch	ch and/or capture key:	
[HTML Text]		
Describe the label advising	need for repair 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)]
Details	[HTML Text]	
	on of the override condition at the fluoroscopist position:	
[HTML Text]		
202.6 Part 1: X-Ray	Systems Designed for One SID	
Is the BLD designed to be u	used with systems with one SID and one Image receptor size?	[L]
Do any of the beam-limiting	devices have a light field that defines the perimeter of the x-ray fie	ld? [L]
Are any of the beam-limiting	g devices designed for fixed SID/image receptor size?	[L]
202.6 Part 2: X-Ray	Systems Designed for One SID	
Item: 1 (could contain up	to 20 items with 1 required)	
Model Designation:		
The design SID (either cm of	or in):	
The design SID (either cm o	or in): both (in x in) as well as (cm x cm):	

[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?		[L]
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 size	ze:	
File Attachment [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dt	td, .sgml, .mol, .xls, .csv, .zip)]	
[HTML Text]	<u> </u>	
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)		

Model Designation:		1
Describe the means for limi	iting and/or centering the x-ray field for this model BLD.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[HTML Text]		
Provide an exact replica of	each label or marking that shows the SID and image receptor size.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[HTML Text]		
List the model and SID an	nd field size at that SID.	
SID (either cm or in):		
Field Size (either cm x cm c	or in x in):	
202.9 Part 1: Variabl	e Filtration	
Does the beam-limiting dev	rice have variable filtration selection?	[L]
202.9 Part 2: Variabl	e Filtration	
Item: 1 (could contain up	to 20 items with 1 required)	
Model Designation:		
Describe the means of assu	uring the presence of the required minimum filtration in the beam before the tube can be activated.	
[HTML Text]		
Is an interlock system used	with the filtration?	[L]
Provide circuit diagrams of	the interlock tied to the kilo voltage selector that is part of the beam-limiting device.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
Describe the electrical and	mechanical characteristics of the interlock system.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
202.10 Capacitor Sto	orage X-Ray Systems	
Is any model beam-limiting	device intended to be used on capacitor storage x-ray systems?	[L]
List each model that is desi	igned for capacitor 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 disp	lay:		[L]	
The type of mA dis	play:		[L]	
The type of Time di	splay:		[L]	
The type of mAs dis	splay:		[L]	
Attach the range of	the mar	kings on the technique factor indicators.	•	
Details	Details [Multi-Line Plain Text]			
File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .d	td, .sgml, .mol, .xls, .csv, .zip)]	
Attach a drawing or	picture	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, .d	td, .sgml, .mol, .xls, .csv, .zip)]	
Attach a drawing or	picture	that illustrates the proximity of any exposure switch to the preindicar	ted technique factors.	
Details		[Multi-Line Plain Text]		
File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .d	td, .sgml, .mol, .xls, .csv, .zip)]	
Attach a drawing or	picture	of the indicator of x-ray production.		
Details		[Multi-Line Plain Text]		
File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .d	td, .sgml, .mol, .xls, .csv, .zip)]	
Attach a description	n of the a	audible signal used to indicate exposure termination.		
Details		[Multi-Line Plain Text]		
File Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
Note:		lite" or "remote stations" are certifiable componentsand must compl controls.	y with all applicable requirements pertaining to	
-	•	ation, state the applicable criteria that defines the technique factors, ct 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, .d	td, .sgml, .mol, .xls, .csv, .zip)]	
Are two or more tub	oe housir	ng assemblies controlled by the same radiographicexposure switch?	[L]	
Describe the pre-ex	oposure t	tube selection indicator on the control panel and the provisions for in	ndication on the diagnostic source assemblies.	
[Multi-Line Plain Te	xt]			
		(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 Te	xt]			
Describe the metho	od by wh	ich the operator can terminate an exposure or series of exposures t	hat last longer than one-half second.	
[Multi-Line Plain Te	xt]			
Describe the metho	od by wh	ich termination of the exposure causes automatic resetting of thetim	ner to its initial setting or to zero.	
İ				

[Multi-Line Plain Text]				
Is a "zero" or "off" position	provided?			[L]
Is x-ray production preven	ted when the time	r is set to either position?		[L]
Does the x-ray control inco	orporate an autom	atic exposure control?		[L]
Provide a drawing or pictu exposure has been termin		tor for automatic exposure control selection and (2 p safety device.) the visible signal that indicates when a	an
[Multi-Line Plain Text]				
File Attachment	[Single File Atta	chment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .d	ltd, .sgml, .mol, .xls, .csv, .zip)]	
If the exposure has been t procedures.	erminated by the	packup 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	rols used for gen	erating x-ray images instantaneously and conti	nuously to display dynamic procedu	res)
Is the x-ray control design	ed to operate in th	e fluoroscopic mode?		[L]
203.4 Part 2: Fluoro	scopy			
Item: 1 (could contain up	to 20 items with	1 required)		
Model Designation:				
For each fluoroscopic exposition to interce		ribe the method employed to prevent the production lbeam.	on of x rays when the primary protective	barrier
[Multi-Line Plain Text]				
Note: Ther	apy simulator sys	ems with remote control are exempt from this requ	uirement.	
Describe each control dev	ice (e.g., normal f	uoroscopy, cine, and test mode) for initiating and n	naintaining fluoroscopic x-ray production	n.
[Multi-Line Plain Text]				
How many minutes is the	maximum cumula	ive on-time prior to an audible signal?		
Can this time interval be p	reset?			[L]
Give the range limit in min	utes.			
For each fluoroscopic con-		e the method of providing an audible signal that in tive on-time.	dicates to the fluoroscopist x-ray produ	ction
[Multi-Line Plain Text]				
File Attachment	[Single File Atta	ichment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .d	ltd, .sgml, .mol, .xls, .csv, .zip)]	
Is there a display of total p	atient irradiation t	me?		[L]

Is there an active display	of patient irradiation exposure rate or air kerma rate (AKR)?	[L]
Explain how this is compu	ted 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 p	patient irradiation exposure or air kerma?	[L]
Explain how this is compu	ited 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.	e controlpanel, provide a drawing or picture of the indicators that allow continuous monitoring of kVp and n	nA 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)]	
	utomatic exposure rate control mode that initiates exposure without the permanent recording of fluoroscopy we 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	n level control?	[L]
For each manual and/or a	utomatic 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.	ol, describe the continuous audible signal that indicates to the fluoroscopist that the high-level control is bei	ing
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 O	ol mode that initiates exposure without the permanent recording of fluoroscopic entrance AKR limited by you R mR/min)	our
[Multi-Line Plain Text]		
Describe the method by w	which the fluoroscopist can initiate and/or terminate the recording of fluoroscopic images.	
[Multi-Line Plain Text]		
204.0 HIGH VOLTA	AGE GENERATORS	
2.5 t	item should be completed for each high-voltage generator listed in section 2.4 and any combination listed that contains a high-voltage generator as an integral part thereof. If this report is not certifying a high-voltage gerator then go to section 205.0	

Do any model higl	h-voltage generators	contain a thermionic diode valve?		[L]
List each model th	at has a thermionic o	diode.		
Item 1				
Item 2				
Item 3				
205 0 CDOT I	TII M DEVICES	AND IMAGE INTENCIFIEDS		
205.0 5POT 1	-ILINI DEVICES	AND IMAGE INTENSIFIERS		
Note:	any combination	uld be completed for each conventional s listed in section 2.5 that contains such c ilm device or image intensifier then go to	omponents as an integral part thereof.	
Is this report inten	ded for the certification	on fo a spot film device or combination c	ontaining a spot film device?	[L]
205.1 Spot Fi	Im Device			
	201.00			
ltem: 1 (could co	ntain up to 20 items	with 1 required)		
Model spot film de				
Note:	1	the appropriate model indicated, please the identification label.	go to question 2.4 MODEL DESIGNA.	TION to enter the mode
ls the spot film de	vice designed for mo	bile fluoroscopic systems?	[L]	
ls the spot film de	vice designed for ima	age intensified systems?		[L]
whenever the prin		nage intensifier, describe the means to parties in a position to intercept the entire circuit diagrams.		
File Attachment	[Single Fil	e Attachment (.pdf, .jpg, .gif, .tif, .avi, .wi	mv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .cs	sv, .zip)]
Details	[HTML Te	xt]		
205.2 Technic	que Factor Adju	stment		
ltem: 1 (could co	ntain up to 20 items	s with 1 required)		
		1		
Model Designation	ո։			
Does the spot-film	device or image inte	ensifier permit or control technique factor	adjustment? [L]	
Message:	If "Yes" has been	selected above, the following note appl	ies:	
Note:		m device or image intensifier controls x-ı	ray output, it is considered an x-ray cor D.Section 2.5 should list the combination	

205 3 Part 1: I	mage Intensifier		
200.51 ait 1.1	mage intensiller		
Is this report intend	led for the certification	of an image intensifier or combination containing an image intensifier?	[L]
205 3 Part 2: I	mage Intensifier		
200.01 art 2.1	mage intensiler		
Item: 1 (could con	ntain up to 20 items v	vith 1 required)	
Model Image Inten	sifier:		
	·	escopic tube from producing x radiation whenever the primary protective barrier is not in posit is an interlock, describe its electrical and mechanical characteristics and provide circuit diagr	
File Attachment	[Single File	Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text	1	
Does this image int	tensifier permit or cont	trol technique factor adjustment? [L]	
Message:	If "Yes" has been s	elected above, the following note applies:	
Note:		device or image intensifier controls x-ray output, it is considered an x-ray control and you mu questions in section 203.0, PART 200.Section 2.5 should list the combination of image inten d x-ray control.	
206.0 TABLES	S, CASSETTE H	OLDERS, FILM CHANGERS AND CRADLES	
Note:	any combination lis certifying a table, ca	I be completed for each table, cassette holder*, film changer and/or cradle listed in section 2. sted in section 2.5 that contains such components as an integral part thereof. If this report is reassette holder, film changer and/or cradle then go to section 207.0* Applicable only to casset ended for permanent verticle mounting and/or contain a front panel.	not
Is this report intend	led for the certification	of a cassette holder, film changer, x-ray table, and/or a cradle?	[L]
206.1 Subject	Component Cap	vabilities	
Do any of thesubie	ct components allow f	or operator adjustment of technique factors?	[L]
<u> </u>	· ·	le limit switches that automatically preempt the preset exposure time of the master control	[L]
Message:	If "Yes" has been s	elected for either of the above questions, the following note applies:	
Note:		component controls x-ray output, it is considered an x-ray control and you must address appli In 203.0, PART 200. Section 2.5.1 should list the combination of appropriate component and i	
206.2 Part 1: N	Model Film Chan	ger	
Is this report for the	e certification of a film	changer?	[L]

206.2 Part 2: Model	Film Changer	
Item: 1 (could contain up	to 20 items with 1 required)	
Model Film Changer:		
Is there a film changer built	t 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 th	at 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 certification	ation of an x-ray table?	[L]
206.4 Model X-Ray	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 f	further.	
[HTML Text]		
assemblers that lists compa	r use on a general purpose x-ray system, cite the specific paragraph(s) (page number) in your instru atible tube stands and/or other equipment necessary for indication (as required under 21 CFR 1020	actions to 0.31(e)(1)(i), (g)
	b)(2)(iii)) of the perpendicularity of the beam axis to the image receptor and the SID.	
[HTML Text]		
206.5 Verticle Casse	ette Holder	
Is this report for the certification	ation of a verticle cassette holder?	[L]
For each model verticle cas	ssette is the verticle cassette holder equipped with cassette size sensors?	[L]

200 0 1 2 2 2 2	December Cines			
206.6 Image	Receptor Sizes			
Item: 1 (could co	ontain up to 20 items v	n 1 required)		
Model Designation	on:			
Ū	cm xcm) OR (_in xin)		
207.0 CEPH	ALOMETRIC DE\	CES		
Note:		e completed for eachcephalometric device lis then go to section 208.0	sted in section 2.4. If this r	report is not certifying a
Is this report inte	nded for the certification	the cephalometric device?		[L]
207.1 Cepha	lometric Device Ir	uding a Beam-Limiting Device		
Item: 1 (could co	ontain up to 20 items	n 1 required)		
Model Designation	on:			
		eam-limiting device as an integral design feat	ure?	[L]
	ometric device include a	eam-limiting device as an integral design feat evice is not sold seperately answer the applic 2.5 should list the combination cephalometr	able questions in section	202.0, PART 200 if not
Does the cephalo	If the beam limiting already done. Sections inseparable part.	evice is not sold seperately answer the applic	able questions in section	202.0, PART 200 if not
Does the cephalo Note: 207.2 Cepha	If the beam limiting already done. Sections inseparable part.	evice is not sold seperately answer the applic 2.5 should list the combination cephalometr uding a Cassette Holder	able questions in section	202.0, PART 200 if not
Does the cephalo Note: 207.2 Cepha Item: 1 (could co	If the beam limiting already done. Sections inseparable part. Ilometric Device Inseparation on tain up to 20 items in the beam limiting already done. Section in the beam limiting already done. Section in the beam limiting already done.	evice is not sold seperately answer the applic 2.5 should list the combination cephalometr uding a Cassette Holder	able questions in section	202.0, PART 200 if not
Does the cephalo Note: 207.2 Cepha Item: 1 (could co	If the beam limiting already done. Sections inseparable part. Illometric Device Inseparation up to 20 items on:	evice is not sold seperately answer the application 2.5 should list the combination cephalometrical should lis	rable questions in section ic device and beam limitin	202.0, PART 200 if not ng device asan integral
Does the cephalo Note: 207.2 Cepha Item: 1 (could could could could decould decou	If the beam limiting already done. Sections inseparable part. Illometric Device Inseparation up to 20 items on:	evice is not sold seperately answer the applic 2.5 should list the combination cephalometr uding a Cassette Holder	rable questions in section ic device and beam limitin	202.0, PART 200 if not
Does the cephalo Note: 207.2 Cepha Item: 1 (could could could could be could be cephalo Does the cephalo	If the beam limiting already done. Sections inseparable part. Illometric Device Inseparable part. Inseparable part. Illometric Device Inseparable part. Inseparable part.	evice is not sold seperately answer the application 2.5 should list the combination cephalometrical should lis	rable questions in section ic device and beam limiting device and beam	202.0, PART 200 if not ng device asan integral
Does the cephalo Note: 207.2 Cepha Item: 1 (could could could could be could be cephalo Does the cephalo	If the beam limiting already done. Section should be already done.	evice is not sold seperately answer the application 2.5 should list the combination cephalometrical uding a Cassette Holder In 1 required) In 1 required is settle holder with a front panel as an integral	rable questions in section ic device and beam limiting device and beam limiting all design feature? RAPHIC X-RAY SY	202.0, PART 200 if not
Does the cephalo Note: 207.2 Cepha Item: 1 (could could could could be cephalo Does the cephalo 208.0 IMAGE	If the beam limiting already done. Section should certifying a image of the beam limiting already done. Section should certifying a image of the beam limiting already done. Section should certifying a image of the beam limiting already done. Section should certifying a image of the beam limiting already done.	evice is not sold seperately answer the application 2.5 should list the combination cephalometrical department of	rable questions in section ic device and beam limiting device and beam limiting all design feature? RAPHIC X-RAY SY	202.0, PART 200 if not
Does the cephalo Note: 207.2 Cepha Item: 1 (could could could could be could be cephalo 208.0 IMAGE Note: Is this report interests	If the beam limiting already done. Section should certifying a image of the beam limiting already done. Section should certifying a image of the beam limiting already done. Section should certifying a image of the beam limiting already done. Section should certifying a image of the beam limiting already done.	evice is not sold seperately answer the application 2.5 should list the combination cephalometrical device is not sold seperately answer the application 2.5 should list the combination cephalometrical devices. Should list the combination cephalometrical devices the folder with a front panel as an integral device septor support device then go to section 300.00 a image receptor support device?	rable questions in section ic device and beam limiting device and beam limiting all design feature? RAPHIC X-RAY SY	202.0, PART 200 if not

Doe	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 shal tube is oper	e radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction to the sceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgens (mR) exposure) in 1 hour when rated at its leakage technique factors. Compliance shall be determined by measurements averaged square centimeters with no linear dimension greater than 20 centimeters (1020.30(k)).	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	and "Worst	: Case" Conditions:	
A.	Message:		est results must include data representative of each compatible combination of tube housing assemb -limiting device.	oly and
B.	Message:		result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test muliently restrictive to assure compliance with the standard.	ıst be
C.	Message:		sure the use of maximum rated peak tube potential and continuous tube current, the test method(s) de the procedure for periodic calibration of technique factors.	must
D.	Message:		ny test using a scan of the diagnostic source assembly, the rate of scan specified in the test method Int for the response time of the radiation instrumentation.	s) must
Prot	otype Testing:			
			full production phase and thus the testing and quality control procedures may not be the same as e testing apply?	[L]
A.	Describe the control to this requirer		hod (i.e., one that actuallymeasures x radiation) employed in testing and measuring each model with	h respec
	[HTML Text]			
B.	Identify the ins	strument(s) us	sed for the test by manufacturer and model number.	
	[HTML Text]			
C.	Attach a samp	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		[HTML Text]	
D.	Is the actual c	omplianceval	ue calculated from the raw test data?	[L]
	1			

Describe all methods emplo locument, provide a copy a file Attachment Details f any test used to monitor conis requirement. HTML Text]	[HTML Text] ct test of the performance parameter? [L] byed in testing of each model with respect to this requirement. If reference is made to a 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 compliance with that supports the use of the test in question (C.)			
ction Testing: Does the test involve a direct Doescribe all methods emplotocument, provide a copy a Cille Attachment Details Frany test used to monitor conis requirement. HTML Text] Submit the technical data the	ct test of the performance parameter? [L] byed in testing of each model with respect to this requirement. If reference is made to a 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 compliance with			
Does the test involve a direct Does the test involve a direct Doescribe all methods employ document, provide a copy a direct Doescribe Attachment Doescribe Attachment Doescribe Test and test used to monitor conis requirement. HTML Text]	byed in testing of each model with respect to this requirement. If reference is made to a 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 compliance with			
Does the test involve a direct constraint of the	byed in testing of each model with respect to this requirement. If reference is made to a 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 compliance with			
Describe all methods emplo locument, provide a copy a file Attachment Details f any test used to monitor conis requirement. HTML Text] Submit the technical data th	byed in testing of each model with respect to this requirement. If reference is made to a 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 compliance with			
ocument, provide a copy a file Attachment Details any test used to monitor conis requirement. HTML Text] Submit the technical data th	[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 compliance with			
Details any test used to monitor conis requirement. HTML Text] Submit the technical data th	[HTML Text] compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with			
any test used to monitor conis requirement. HTML Text] Submit the technical data th	compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with			
nis requirement. HTML Text] Submit the technical data th				
Submit the technical data th	nat supports the use of the test in question (C.)			
	nat supports the use of the test in question (C.)			
ile Attachment				
*	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
Details	[HTML Text]			
Attach a copy of the detailed instructions for performing each test.				
ile Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
Details	[HTML Text]			
dentify the instrument(s) used for each test by manufacturer and model number.				
ile Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
) etails	[HTML Text]			
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.				
ile Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
Details	[HTML Text]			
or each test method listed	in question (B.), please attach sample raw test data.			
ile Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
Petails	[HTML Text]			
s the actual compliance val	lue calculated from the raw test data? [L]			
Please attach a sampl	le of calculated 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]			
n how compliance is establi	ished.			
	etails ttach a copy of the detaile le Attachment etails entify the instrument(s) us le Attachment etails or each test method listed jection limits are specified le Attachment etails or each test method listed jection limits are specified le Attachment etails or each test method listed preach test method listed le Attachment etails the actual compliance va Please attach a samp File Attachment Details			

[Mul	ti-Line Plain Text]					
J.	Is this performance pa	rameter tested on 100 percent of the produced models?	[L]			
Ass	embler Testing:					
Doe	s assembler testing app	ly?	[L]			
A.	Does the test involve	a direct test of the performance parameter?	[L]			
В.	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, .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 technical of	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]				
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	[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 detailedinstructions for performing the test where edified.	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 complian	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 neede g the power cord into the wall socket.	ed to			
File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Deta	ails	[HTML Text]				
302	2.0 Beam Quality					

Note					
	ə <i>:</i>		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	uirement:				
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 Tabl	
Арр	licability:				
Mes	ssage:	device con	ement 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	t Case" Conditions:		
۹.	Message:		est results must include data representative of each compatible combination of tubehousing assemb n-limiting device.	ly and	
3.	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	
C.	Message:		e the peak tube potential has a critical effect on determining the half-value layer, the test method(s) made 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	
Prof	totype Testing				
This	section is for s	tart 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 crespect to this		thod (i.e., one that actually measures ${\sf x}$ radiation) employed in testing and measuring each model wit .	:h	
	[HTML Text]				
B.	Identify the in:				
	[HTML Text]				
	[HTML Text]	strument(s) u	sed for the test by manufacturer and model number.		
C.	[HTML Text] Attach a samp				
C.		ole of raw test			
C.	Attach a samp	ole of raw test	t data.		
C. D.	Attach a samp File Attachme Details	ple of raw test	t data. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	[L]	
D.	Attach a samp File Attachme Details Is the actual of	ont compliance va	t data. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]	[L]	
D.	Attach a samp File Attachme Details Is the actual of	ple of raw test	t data. [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.	Attach a samp File Attachme Details Is the actual of	ple of raw test	t data. [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.	Attach a samp File Attachme Details Is the actual of Attach a samp File Attachme	ple of raw test ent compliance va ple of calculat	t data. [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.	Attach a samp File Attachme Details Is the actual of Attach a samp File Attachme Details	pole of raw test	t data. [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. Expl	Attach a samp File Attachme Details Is the actual of Attach a samp File Attachme Details lain how compli	compliance value of calculatent	t data. [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]	

	File Attachment	copy as an attachment for documentation. [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 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 instrumer	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)]					
	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.	Foreach test method	Foreach test method listed in question (B.), please attach sample raw test data.					
	l=1 A	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	File Attachment		[HTML Text]				
	Details	[HTML Text]					
I.	Details	[HTML Text] nce value calculated from the raw test data? [Line is a second or continuous continuo	L]				
I.	Details Is the actual complian	<u>, </u>	L]				
l.	Details Is the actual complian	nce value calculated from the raw test data?	L]				
I.	Details Is the actual complian Please attach a	nce value calculated from the raw test data? [Lasample of calculated compliance values complete with an explanation of any correction factors employed. [Multi-Line Plain Text]					
I.	Details Is the actual complian Please attach a Details	nce value calculated from the raw test data? [In sample of calculated compliance values complete with an explanation of any correction factors employed. [Multi-Line Plain Text] [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details Is the actual compliant Please attach at Details File Attachment	nce value calculated from the raw test data? [In sample of calculated compliance values complete with an explanation of any correction factors employed. [Multi-Line Plain Text] [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details Is the actual compliant Please attach at Details File Attachment ain how compliance is ti-Line Plain Text]	nce value calculated from the raw test data? [It is sample of calculated compliance values complete with an explanation of any correction factors employed. [Multi-Line Plain Text] [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] established.					
[Mult	Details Is the actual compliant Please attach at Details File Attachment ain how compliance is ti-Line Plain Text]	nce value calculated from the raw test data? [It is sample of calculated compliance values complete with an explanation of any correction factors employed. [Multi-Line Plain Text] [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] established.]				
[Mult J.	Details Is the actual compliant Please attach at Details File Attachment ain how compliance is ti-Line Plain Text] Is this performance p	nce value calculated from the raw test data? [It is sample of calculated compliance values complete with an explanation of any correction factors employed. [Multi-Line Plain Text] [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] established. [It is ample of calculated compliance values complete with an explanation of any correction factors employed. [Multi-Line Plain Text] [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] established.]				
[Mult J.	Details Is the actual compliant Please attach at Details File Attachment ain how compliance is ti-Line Plain Text] Is this performance purembler Testing: s assembler testing ap	nce value calculated from the raw test data? [It is sample of calculated compliance values complete with an explanation of any correction factors employed. [Multi-Line Plain Text] [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] established. [It is ample of calculated compliance values complete with an explanation of any correction factors employed. [It is ample of calculated compliance values complete with an explanation of any correction factors employed. [It is ample of calculated compliance values complete with an explanation of any correction factors employed. [It is ample of calculated compliance values complete with an explanation of any correction factors employed. [It is ample of calculated compliance values complete with an explanation of any correction factors employed. [It is ample of calculated compliance values complete with an explanation of any correction factors employed. [It is a place of calculated compliance values complete with an explanation of any correction factors employed. [It is a place of calculated compliance values complete with an explanation of any correction factors employed. [It is a place of calculated compliance values complete with an explanation of any correction factors employed. [It is a place of calculated compliance values complete with an explanation of any correction factors employed. [It is a place of calculated complete values complete with an explanation of any correction factors employed. [It is a place of calculated complete values	l Lj				

lı	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.				
	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		ted in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the fied.				
	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 i		ted 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	value calculated from the raw test data? [L]				
			the user manual that specifies no assembly or installation instructions are necessary and all that is needed to he power cord into the wall socket.				
File	Attachment	[5	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 Equiv	alence				
		•					
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:						
Mes	ssage:	between	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 (20.30(n)).				
Арр	olicability:						
Mes	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)).	sis			
Criti	cal 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) reprovide the procedure for periodic calibration of tube potential.	nu			
Э.	Message:	Since compliance will be measured at 100 kVp and 2.7 millimeters of aluminum half-value layer, test data result from other conditions must be extrapolated to the value at the specified conditions.	ıltir			
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?				
١.	Describe the direct to this requirement	testmethod (i.e., one that actually measures x radiation) employed in testing and measuring each model with res	ре			
	[HTML Text]					
-	Identify the instrun	nent(s) used for the test by manufacturer and model number.				
	[HTML Text]					
) .	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 compliance value calculated from the raw test data? [L]					
Ē.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.					
	Details	[Multi-Line Plain Text]				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Expl	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]				
Э.	If any test used to this requirement.	monitor compliance does not actually measure x radiation, explain why it is an accurate indicationof compliance w	/ith			
	[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	[HTML Text]						
E.	Attac	ch a copy of the detail	led instructions for performing each test.						
	Deta	ils	[Multi-Line Plain Text]						
	File /	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
F.	Ident	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)]						
	Deta	ils	[HTML Text]						
G.	1	each test method liste tion limits are specifie	ed in question (B.) under Production Testing, attach the detailed instructions for performing the test whe ed.	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 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)]						
	Deta	ils	[HTML Text]						
l.	Is the	e actual compliance v	value calculated 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, .z	.ip)]					
		Details	[HTML Text]						
Ехр	lain ho	w compliance is estal	blished.						
[Mu	lti-Line	Plain Text]							
J.	Is thi	s performance param	neter tested on 100 percentof the produced models?	[L]					
Ass	emble	r Testing:							
Doe	s asse	mbler testing apply?		[L]					
A.	Does	the test involve a dir	rect test of the performance parameter?	[L]					
B.	1	•	ployed in testing of each model with respect to this requirement. If reference is madeto 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 '	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]							
	Submit the technical data that supports the use of the test in question (C.)								
D.	Subr								
D.		Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						

E.	Attach a copy of the d		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 instrument(s) us) 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 method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.				
	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	method lis	ted 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	e 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.	ed to	
File	Attachment	[5	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
Deta	ails	[HTML Text]		
304	1.0 Standby	Radiation	on from Capacitor Energy Storage Equipment		
Req	uirement:	5 " "			
Mes	ssage:	microgra	tion emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 0.26 graysor 0.03 mR in 1 minute at 5 centimeters from any accessible surface of the diagnostic source assembly, wit pam-limiting device fully open and 0.88 mGy or 100 mR in1 hour 100 centimeters from the source (see 1020.31(I)		
Арр	licability:	•			
Mes	sage:	of a sing	uirement is applicable to the diagnostic source assembly of capacitor energy storage equipment. Similar nate of the 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 am-limiting device.	and	
В.	Message:	I	s a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must fficiently restrictive to assure compliance with the standard.	be	
C.	Message:		test for the maximum standby radiation, the beam-limiting device must be fully open and the highest available tube potential must be used. These conditions must bespecified in the test method(s).	lable	
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:				
			•		

A.	Describe the directtes to this requirement.	t method (i.e., one that actually measures x radiation) employedin testing and measuring each model with	respec					
	[HTML Text]							
В.	Identify the instrument	Identify the instrument(s) used for the test by manufacturer and model number.						
	[HTML Text]							
C.	Attach a sample of rav	v 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)]						
D.	Is the actual complian	ce value calculated from the raw test data?	[L]					
E.	Attach a sample of cal	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]						
Ехр	lain how compliance is e	established.						
[Mu	lti-Line Plain Text]							
Pro	duction Testing:							
A.	Does the test involve a	a direct test of the performance parameter?	[L]					
B.		Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, providea 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 complia	nce wit					
	[HTML Text]							
D.	Submit the technical d	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.	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)]						
	Details	[HTML Text]						

	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xp	t xml dtd saml mol xls csv zin)]			
	Details	[HTML Text]				
Н.	1					
	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]	t, .xiii, .dd, .sgiii, .iioi, .xis, .ssv, .2ip/j			
		value calculated from the raw test data?	[L]			
۱.	<u> </u>	mple of calculated compliance values complete with an expla				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wm	<u></u>			
	Details	[HTML Text]	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
Evn	lain how compliance is e	<u> </u>				
	ti-Line Plain Text]	aunonou.				
J.		meter tested on 100 percent of the produced models?	[L]			
		meter tested on 100 percent or the produced models?	[L]			
	embler Testing:					
Doe	Es assembler testing apply?					
Α.	Does the test involve a direct test of the performance parameter? [L]					
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 an attachment for documentation.					
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xp	t, .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 technical da	a that supports the use of the test in question (C.)				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xp	t, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]				
E.	Attach acopy of the de	iled instructions for performing each test.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xp	t, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]				
	Identify the instrument(s) used for each test by manufacturer and model number.					
F.	identity the instrument	1				
F.	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xp	t, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
F.		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xp [HTML Text]	t, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			

	File F	Attachment		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Detai	ils		[HTML Text]	
H.	For e	ach test meth	hod 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)]	
	Details			[HTML Text]	
I.	Is the actual compliance value calculated fromthe raw test data?				
		., .	•	ne user manual that specifies no assembly or installation instructions are necessary and all that is needed to epower cord into the wall socket.	
File /	Attach	ment	[Sin	ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Deta	ils		[HT	ML Text]	
305	.0 Fu	Joroscopio	c Entra	nce Exposure Rate	
_					
Requ	uireme	ent:	$\overline{}$		
1.	Mess	sage:	Fluor	roscopic equipment manufactured prior to May 19,1995.	
Α.		Message:		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 equipment 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 ???	
B.				any combination of tube potential and current that will result in an exposure rate in excess of per minute (5 R/min) at the point where the center of the usefulbeam enters the patient, exceptions are supported by the content of the usefulbeam enters the patient, exceptions are supported by the content of the usefulbeam enters the patient, exceptions are supported by the content of the usefulbeam enters the patient, exceptions are supported by the content of the usefulbeam enters the patient, exceptions are supported by the content of the usefulbeam enters the patient, exceptions are supported by the content of the usefulbeam enters the patient, exceptions are supported by the content of the usefulbeam enters the patient, exceptions are supported by the content of the usefulbeam enters the patient, exceptions are supported by the content of the usefulbeam enters the patient, exceptions are supported by the content of the usefulbeam enters the patient of the usefulbeam enters the usefulbea	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/kg 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 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) 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 (see 1020.32(d)).(c) when a mode without high level option is activated in which case the exposure rate is limited 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.	Mess	sage:	Fluor	roscopic equipment manufactured on or after May 19,1995.	
A.		Message:		Equipment which can operate above 44 mGy/min (5 R/min) must have automatic exposure rate control.	
В.	inessage.			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 is activated.	
Appl	licabil	lity:			
Mess	sage:	со	omponent	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 basis 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 mus sufficiently restrictive to assure compliance with the standard.	t be			
В.	Message:	Message: To test for the maximum entrance exposure rate, the beam-limiting device must be fully open. This condition must be specified in the test method(s).				
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) in 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			
Pro	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 rement.	1			
	[HTML Text]					
В.	Identify the instrur	ent(s) used 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 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]				
Ехр	lain how compliance	s established.				
[Mul	ti-Line Plain Text]					
Pro	duction Testing:					
A.	Does the test invo	e a direct test of the performance parameter?	[L]			
B.	1	Is 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	ice wit			
	1					

	D.	Subr	nit the technical data th	nat 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	[НТИ	//L Text]	
	Ε.	Attac	ch a copy of the detaile	d 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	[НТМ	//L Text]	
ı	F.	Ident	tify the instrument(s) us	sed for	r 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)]	
		Deta	ils	[HTN	//L Text]	
Ī	G.		each test method listed tion limits are specified		estion (B.) under Production 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)]	
		Deta	ils	[HTN	//L Text]	
ı	Η.	For e	each test method listed	in que	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	//L Text]	
ļ		Is the	e actual compliance va	lue ca	Iculated from the raw test data?	[L]
		-	Please attach a samp	le 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]	
	Expla	ain ho	w compliance is establ	ished.		
	Mult	i-Line	Plain Text]			
Ŀ	J.	Is thi	s performance parame	ter tes	sted on 100 percent of the produced models?	[L]
	Asse	emble	r Testing:			
	Does	asse	mbler testing apply?			[L]
,	Α.	Does	s the test involve a dire	ct test	of the performance parameter?	[L]
1	В.		•	-	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]	
	C.		y test used to monitor or equirement.	compli	ance doesnot actually measure xradiation, explain why it is an accurate indication of complianc	e with
		[HTN	/IL Text]			
	D.	Subr	nit the technical data th	nat sup	oports the 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		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	-	[HTML Text]
F.	Identify the inst	rument(s) u	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 m		d 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 m	nethod listed	d 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	alue calculated from the raw test data?
I		. •	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 A	Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Detai	ils	[HT	ML Text]
306	.0 Primarv F	rotective	Barrier Transmission
Item:	: 1 (could conta	in up to 15	items with none required)
Mode	el Number of the	device:	
Requ	ıirement:		
Mess	sage:	radiation from 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 ens per hour for each roentgen per minute of entrance exposure rate) at 10 centimeters from any accessible the fluoroscopic imaging assembly beyond the plane of the imagereceptor (see 1020.32(a)(i)).
Appli	icability:		
Mess	sage:	device; ima for present	ement is applicable to fluoroscopic imaging assemblies or the following component parts thereof: spot-film age 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 cription of prototype testing (see 306.4(a)).
Critic	cal Parameters	and "Wors	t Case" Conditions:

В.	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 bard 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 throthe 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	test method (i.e., one that actually measures \boldsymbol{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	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 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]		
Proc	luction Testing:		
A.	Does the test involve	e a direct test of the performance parameter?	[L]
B.		is 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 m this requirement.	nonitor compliance does not actually measure x radiation, explain why it is an accurate indication of complianc	ce with
	[HTML Text]		

1	l	A 1	les centre of the contract of	
		Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
_	Deta		[HTML Text]	
E.		.,	d instructions for performing each test.	
		Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
H	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.		each test method listed ction limits are specified	in question (B.) under Production Testing, attach the detailed instructions for performing the test when the detailed instructions for performing the detailed instructions for the detailed instructions for the detailed instruction for t	ere the
	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Deta	nils	[HTML Text]	
Н.	For 6	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	iils	[HTML Text]	
I.	Is the	e actual compliance val	lue calculated from the raw test data?	[L]
	-	Please attach a samp	ele 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	nce 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.		•	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)]	
	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. ML Text]	I' '	ce with

	Details		[HTML Text]	
E.	Attach a copy	of the detail	ed instructions 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) 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.	For each test	method liste	d in question (B.), please attachsample 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 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 a 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]	「ML Text]	
30	7.0 Reprodu	cibility an	d 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 at 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:	
A.	Message:		result of inherent inaccuracies of the test methodand instrumentation, rejection limits for any test must ciently restrictive to assure compliance with the standard.	be:
B.	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 pluction testing. Does pro		[L]
A.	Describe the directtes to this requirement.	st method (i.e., one that actually measures x radiation) employed in testing and measuring each model with r	espect
L	[HTML Text]		
B.	Identify the instrumen	t(s) used for the test by manufacturer and model number.	
	[HTML Text]		
C.	Attach a sample of ra	w test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
L	Details	[Multi-Line Plain Text]	
D.	Is the actual compliar	nce 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 mo this requirement.	nitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance	e with
L	[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)]	
L	Details	[HTML Text]	
E.	Attach a copy of the c	letailed 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 instrumen	t(s) used for each test by manufacturer and model number.	

	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 wh d.	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.	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)]				
	Deta	ils	[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	l.			
		File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .	zip)]			
		Details	[HTML Text]				
Expl	ain ho	w compliance is estab	lished.				
[Mul	ti-Line	Plain Text]					
J.	Is thi	s performance parame	eter tested on 100 percent of the produced models?	[L]			
Ass	emble	r Testing:					
Doe	s asse	mbler testing apply?		[L]			
A.	Does	s the test involve a dire	ect 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 test 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)]				
	Deta	ils	[HTML Text]				
C.	l '	y test used to monitor equirement.	compliance does not actually measurex radiation, explain why it is an accurate indication of complian	nce with			
	[HTN	/IL Text]					
D.	Subr	nit 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	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.	Ident	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)]				

G.	For each test n		I in question (B.) under Assembler Testing, attach the detailed instructions for performing thetest d.	where the
	File Attachmen	ıt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi	p)]
	Details		[HTML Text]	
H.	For each test n	nethod listed	I inquestion (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, .zi	o)]
	Details		[HTML Text]	
I.	Is the actual co	ompliance va	alue calculated from the raw test data?	[L]
			e user manual that specifies no assembly or installation instructions are necessary and all that is power cord into the wall socket.	needed to
File	Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[Mul	ti-Line Plain Tex	t]		
			e user manual that specifies no assembly or installation instructions are necessary and all that is power cord into the wall socket.	s 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]	
308	3.0 Radiation	from Co	mponents other than the Diagnostic Source Assembly	
			items with none required)	
Item		ain up to 15		
Item	n: 1 (could conta	ain up to 15 e device: If you do no		er the model
Mod Note	n: 1 (could conta	ain up to 15 e device: If you do no	items with none required) ot see the appropriate model indicated, please go to question 2.4 MODEL DESIGNATION to ent	er the model
Mod Note Req	n: 1 (could contained to the let Number of the let)	e device: If you do not as it appea	items with none required) ot see the appropriate model indicated, please go to question 2.4 MODEL DESIGNATION to ent	ograys (2
Mode Note Req	n: 1 (could contained to the let Number of the let)	e device: If you do not as it appea	items with none required) ot see the appropriate model indicated, please go to question 2.4 MODEL DESIGNATION to enters on the identification label. on emitted by a component other than the diagnostic source assembly shall not exceed 18 micropus) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated.	ograys (2
Mode Notes Req Mes	n: 1 (could contained let Number of the let numb	e device: If you do not as it appear The radiation milliroentge assembled This require tubes), and	items with none required) of see the appropriate model indicated, please go to question 2.4 MODEL DESIGNATION to enters on the identification label. on emitted by a component other than the diagnostic source assembly shall not exceed 18 micropens) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated ex-ray system under any conditionsfor which it was designed (see 1020.30(1)). ement is applicable to x-ray controls, high-voltage generators that contain thermionic diode valve 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 of	ograys (2 I in an es (valve of test results
Mode Notes Req Mess	n: 1 (could contained let Number of the let numb	ain up to 15 e device: If you do not as it appea The radiation milliroentge assembled This require tubes), and applicable it testing (see	items with none required) of see the appropriate model indicated, please go to question 2.4 MODEL DESIGNATION to enters on the identification label. on emitted by a component other than the diagnostic source assembly shall not exceed 18 micropens) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated ex-ray system under any conditionsfor which it was designed (see 1020.30(1)). ement is applicable to x-ray controls, high-voltage generators that contain thermionic diode valve 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 of	ograys (2 I in an es (valve of test results
Mode Notes Req Mess	n: 1 (could contained let Number of the let numb	ain up to 15 e device: If you do not as it appea The radiation milliroentge assembled This require tubes), and applicable testing (see and "Wors"	items with none required) of see the appropriate model indicated, please go to question 2.4 MODEL DESIGNATION to enters on the identification label. on emitted by a component other than the diagnostic source assembly shall not exceed 18 micropens) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated ex-ray system under any conditionsfor which it was designed (see 1020.30(1)). ement is applicable to x-ray controls, high-voltage generators that contain thermionic diode valve 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 of a 308.4(a)).	ograys (2 I in an es (valve of test results of prototype
Mode Note Req Mes App	n: 1 (could contained let Number of the let numb	ain up to 15 e device: If you do not as it appear The radiation milliroentge assembled This require tubes), and applicable testing (see and "Wors" As a suffice For a	items with none required) of see the appropriate model indicated, please go to question 2.4 MODEL DESIGNATION to enters on the identification label. on emitted by a component other than the diagnostic source assembly shall not exceed 18 micropus) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated ax-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 valve 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 of a 308.4(a)). It Case" Conditions: Tresult of inherent inaccuracies of the test method and instrumentation, rejection limits for any test	ograys (2 If in an es (valve of test results of prototype must be

Prot	totype Testing:							
		o full production phase and thus the testing and quality control procedures may not be the same as	[L]					
prod	duction testing. Does prototy	pe testing apply? ethod (i.e., one that actually measures x radiation) employed in testing and measuring each model with						
A.	respect to this requirement		•					
	[HTML Text]							
B.								
	[HTML Text]							
C.	Attach a sample of raw tes	st 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	alue calculated from the raw test data?	[L]					
E.	Attach a sample of calcula	ted 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]						
_	Explain how compliance is established.							
۲.	Explain how compliance is	established.						
F.	[HTML Text]	established.						
		established.						
	[HTML Text] duction Testing:	ect test of the performance parameter?	[L]					
Proc	[HTML Text] duction Testing: Does the test involve a direction Describe all methods employed.		[L]					
Prod	[HTML Text] duction Testing: Does the test involve a direction Describe all methods employed.	ect test of the performance parameter? loyed in testing of each model with respect to this requirement. If reference is made toa test protocol	[L]					
Prod	[HTML Text] duction Testing: Does the test involve a direct of the describe all methods employed accomply document, provide a copy	ect test of the performance parameter? loyed in testing of each model with respect to this requirement. If reference is made toa test protocol as an attachment for documentation.	[L]					
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A. B.	[HTML Text] duction Testing: Does the test involve a direct of the describe all methods employed accomply document, provide a copy File Attachment Details If any test used to monitor	ect test of the performance parameter? loyed 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]						
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Proo	[HTML Text] duction Testing: Does the test involve a direct of the describe all methods empty document, provide a copy File Attachment Details If any test used to monitor this requirement. [HTML Text]	ect test of the performance parameter? loyed 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						
Proo	[HTML Text] duction Testing: Does the test involve a direct of the distribution of the service of the distribution of the service of the se	ect test of the performance parameter? loyed 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.)						
Proo	[HTML Text] duction Testing: Does the test involve a direction document, provide a copy File Attachment Details If any test used to monitor this requirement. [HTML Text] Submit the technical data to File Attachment Details	ect test of the performance parameter? loyed 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)]						
A. B.	[HTML Text] duction Testing: Does the test involve a direction document, provide a copy File Attachment Details If any test used to monitor this requirement. [HTML Text] Submit the technical data to File Attachment Details	ect test of the performance parameter? loyed 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]						
A. B.	[HTML Text] duction Testing: Does the test involve a direction document, provide a copy File Attachment Details If any test used to monitor this requirement. [HTML Text] Submit the technical data to File Attachment Details Attach a copy of the detailed	ect test of the performance parameter? loyed 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] ed instructions for performing each test.						
A. B.	[HTML Text] duction Testing: Does the test involve a direction document, provide a copy of the details If any test used to monitor this requirement. [HTML Text] Submit the technical data to File Attachment Details Attach a copy of the details File Attachment Details	ect test of the performance parameter? loyed 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] ed instructions for performing each test. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]						
A. B. C.	[HTML Text] duction Testing: Does the test involve a direction document, provide a copy of the details If any test used to monitor this requirement. [HTML Text] Submit the technical data to File Attachment Details Attach a copy of the details File Attachment Details	ect test of the performance parameter? loyed 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] ed 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	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi	ip)]
	Details	[HTN	ML Text]	
Н.	For each test method	l listedin que	estion (B.), please attach sample raw test data.	
	File Attachment		gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	ip)]
	Details	[HTN]	//L Text]	
I.	Is the actual complian	nce value ca	Iculated from the raw test data?	[L]
	Please attach a	a sample of o	calculated compliance values complete with an explanation of any correction factors empl	oyed.
	File Attachmen	t	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .c	sv, .zip)]
	Details		[HTML Text]	
	- Explain how co	mpliance is	established.	
	[HTML Text]			
J.	Is this performance p	arameter tes	sted on 100 percent of the produced models?	[L]
Ass	sembler Testing:			
Doe	es assembler testing ap	ply?		[L]
Α.	Does the test involve	a direct test	of the performance parameter?	[L]
				1
B.			n testing of each model with respect to this requirement. If reference is made to a test pro ttachment for documentation.	
B.		copy as an a	•	tocol
B.	document,provide a	copy as an a	ttachment for documentation.	tocol
B.	document,provide a d File Attachment Details	copy as an a	ttachment for documentation. gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	tocol
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C.	document,provide a control of the Attachment Details If any test used to most this requirement. [HTML Text]	[Sing [HTM]	ttachment for documentation. gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z ML Text] ance does not actually measure x radiation, explain why it is an accurate indication of cor	ip)] mpliance wit
C.	document,provide a control of the Attachment Details If any test used to most this requirement. [HTML Text] Submit the technical	[Sing	ttachment for documentation. gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z ML Text] ance does not actually measure x radiation, explain why it is an accurate indication of core oports the use of the test in question (C.)	ip)] mpliance wit
C.	document,provide a control of the Attachment of	[Sing [HTN]] data that sup [Sing [HTN]]	ttachment for documentation. gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z ML Text] ance does not actually measure x radiation, explain why it is an accurate indication of cor oports the use of the test in question (C.) gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi	ip)] mpliance wit
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C.	File Attachment Details If any test used to mothis requirement. [HTML Text] Submit the technical File Attachment Details Attach a copy of the office Attachment Details Identify the instrument	copy as an a [Sing [HTM conitor complied data that sup [Sing [HTM detailed instruction [Sing [HTM Int(s) used for	ttachment for documentation. gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z ML Text] ance does not actually measure x radiation, explain why it is an accurate indication of cor oports the use of the test in question (C.) gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z ML Text] ructions for performing each test. gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z ML Text] reach test by manufacturer and model number.	ip)] mpliance wit

1	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 Attachmer		[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]	
	' '	. 0	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 the 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	ment is applicable to fluoroscopic and radiographic x-ray controls and high-voltage generators. Similar single component type may be grouped for presentation of test results applicable to this requirement when albasis for this grouping is clearly stated in the description of prototype testing (see 309.4(a)).		
Criti	cal Parameters	and "Worst	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	
В.	Message:	data t	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:				
			o full production phase and thus the testing and quality control procedures maynot be the same as the testing apply?	[L]	
A.	Describe the d		thod (i.e., one that actually measures x radiation) employed in testing and measuring each modelwith	respect	
	[HTML Text]				
B.	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, .zip	D)]			
	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	٥)]			
	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	ıpliance 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	٥)]			
	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, .zig	o)]			
	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	o)]			
	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, .zig	o)]			
	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, .zig	o)]			
	Details	[HTML Text]				
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	rameter tested on 100 percent of the produced models?	[L]							
Asse	embler Testing:		•							
Does	s assembler testing app	ly?	[L]							
Α.	Does thetest involve a	direct test of the performance parameter?	[L]							
В.		employed in testingof each model with respect to this requirement. If reference is made to a test protocol opy as an attachment of 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.	nitor compliance doesnot actually measure x radiation, explain why it is an accurate indication of complian	ce 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 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)] [HTML Text]								
	Details									
G.	For each test method rejection limits are spe	isted 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]								
H.	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 need 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]								
1	Щ									

Kec	quirement:							
Mes	ssage:	when	nanufacturer shall state themaximum deviation ofthe tube current from its preindicated value during an ex the equipment is connected to an adequate power supply as specified by the manufacturer. The deviatio current shall not exceed the limits given (see 1020.31(a)(4) and 1020.32(f)).					
Apr	olicability:							
	ssage:	mode	equirement is applicable to fluoroscopic and radiographic x-ray controls and high-voltage generators. Sin Is of a single component type may be grouped for presentation of test results applicable to this requirement chnical basis for this groupings clearly stated in the description of prototype testing (see 310.4(a)).					
Crit	ical Paramete	rs and "\	WorstCase" Conditions:					
A.	Message:		As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test ma sufficiently restrictive to assure compliance with the standard.	ust be				
В.	Message:	ŀ	To assure compliance with the maximum deviation statements provided to the user, the test results must data for "worst case" combinations of technique factors and supply line conditions (e.g., highest kW, low-voltage, and highest allowed line-voltage regulation).					
Pro	totype Testing	g:						
			rior to full production phase and thus the testing and quality control procedures may not be the same prototype 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.	[HTML Text] Attach a sam	nple of rav	w test data.					
C.	1	·	w test data. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
C.	Attach a sam	·						
	Attach a sam File Attachme	ent	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	[L]				
D.	Attach a sam File Attachme Details Is the actual	ent complian	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [Multi-Line Plain Text]	[L]				
D.	Attach a sam File Attachme Details Is the actual	ent complian	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [Multi-Line Plain Text] ce value calculated from the raw test data?	[L]				
D.	Attach a sam File Attachme Details Is the actual Attach a sam	ent complian	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [Multi-Line Plain Text] ce value calculated from the raw test data? Iculated compliance values complete with an explanation of any correction factors employed.	[L]				
D. E.	Attach a sam File Attachme Details Is the actual Attach a sam File Attachme	ent complian pple of ca	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [Multi-Line Plain Text] ce value calculated from the raw test data? [culated 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.	Attach a sam File Attachme Details Is the actual Attach a sam File Attachme Details	complian uple of ca	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [Multi-Line Plain Text] ce value calculated from the raw test data? [culated 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 [Mu	Attach a sam File Attachme Details Is the actual Attach a sam File Attachme Details Joeanne	ent complian pple of ca ent liance is a	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [Multi-Line Plain Text] ce value calculated from the raw test data? [culated 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 [Mu	Attach a sam File Attachme Details Is the actual Attach a sam File Attachme Details Idain how complete Iti-Line Plain Te	ent complian pple of ca ent liance is of ext]	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [Multi-Line Plain Text] ce value calculated from the raw test data? [culated 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]				
[Mu	Attach a sam File Attachme Details Is the actual Attach a sam File Attachme Details Islain how complete the c	ent complian pple of ca ent diance is a ext] mg: t involve a methods	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [Multi-Line Plain Text] ce value calculated from the raw test data? Iculated 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] established.	[L]				

	Deta	ils	[HTN	//L Text]			
C.		test used to monitor equirement.	compli	ance does notactually measure x radiation, explain why it is an accurate indication of complian	nce with		
	[HTML Text]						
D.	Submit the technical data that supports the use of the test inquestion (C.)						
	File Attachment [S		[Sing	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ils	[НТЛ	ML Text]			
E.	Attac	ch a copy of the detaile	ed 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	[НТЛ	ML Text]			
F.	Ident	ify the instrument(s) u	ised for	r 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)]			
	Deta	ils	[HTN	//L 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 [Sir		[Sing	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details [HTI		[НТЛ	ML Text]			
Н.	For each test method listed in question (B.), pleaseattach sample raw test data.						
	File Attachment [Sin		[Sing	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	Details [HT		[HTML Text]			
l.	Is the actual compliance value ca			lculated from the raw test data?	[L]		
	-	Please attach a sam	ple 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, .zip)]			
		Details		[HTML Text]			
Expl	ain ho	ain how compliance is established.					
[Mult	ti-Line	Plain Text]					
J.	Is thi	s performance param	eter tes	sted on 100 percent of the produced models?	[L]		
Asse	emble	r Testing:			,		
Does	s assembler testing apply?						
A.	Does	the test involve adire	ct test	of the performance parameter?	[L]		
B.	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	гнти	//L Text]			

	[HTML Text]							
D.	. Submit the technical 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 de	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	(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		isted in question (B.) under Assembler Testing, attach the detailed instructions for performing the test wh cified.	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]					
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]					
I.	Is the actual compliance val		ce value calculated from the raw test data?	[L]				
	ide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to ate the system is 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	ails		[HTML Text]					
311	.0 Tube Current - Exposure Time Product							
	uirement:							
Mes	sage: The manufa		anufacturer shall state the maximum deviation of the tube current exposure time product (mAs) from its icated value during an exposure, when the equipment is connected to an adequate power supply as specinufacturer. The deviation of the tube current exposure time product shall not exceed the limits given (see					
Арр	licability:							
	This requirement is applicable to radiographic x-ray controls and high voltage generators that have mAs settings. Simmodels of a single component type may be grouped for presentation of test results applicable to this requirement whether the technical basis for this grouping is clearly stated in the description of prototype testing (see 311.4(a)).							
Mes		the tec	rimour basic for the grouping is sisted in the description of prototype tooling (see of 1.144).					

		sufficiently restrictive to assure compliance with the standard.					
B.	Message:	To assure compliance with the maximum deviation statements provided to the user, the test results must in data for "worst case" combinations of technique factors and supply line conditions (e.g., highest kW, low line voltage, and highest allowed line-voltage regulation).	nclude ne				
Prot	otype Testing:						
	•	prior to full production phase and thus the testing and quality control procedures may not be the same as	[L]				
prod	luction testing. Does prototype testing apply? Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with						
A.	respect to this requir		11				
	[HTML Text]						
В.	Identify the instrume	ent(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	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 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	s established.					
[Mul	ti-Line Plain Text]						
Proc	duction Testing:						
A.	Doos the test involve	Production Testing:					
Describe all methods employed in testing of each model with respect to this requirement. If refer		e a direct test of the performance parameter?					
B.	Describe all methods	s employed in testing of each model with respect to this requirement. If reference is made to a test protocol					
B.	Describe all methods	s employed in testing of each model with respect to this requirement. If reference is made to a test protocol					
B.	Describe all methods document, provide a	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.					
B. C.	Describe all methods document, provide a File Attachment Details	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. [Single 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 testing of each model with respect to this requirement. If reference is made to a test protocol copy as an attachment for documentation. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML 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 testing of each model with respect to this requirement. If reference is made to a test protocol copy as an attachment for documentation. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]	ce with				
C.	Describe all methods document, provide a File Attachment Details If any test used to m this requirement. [HTML Text]	s 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. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] conitor compliance does not actually measure x radiation, explain whyit is an accurate indication of compliance	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	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. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] onitor compliance does not actually measure x radiation, explain whyit is an accurate indication of complian data that supports 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	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. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] onitor compliance does not actually measure x radiation, explain whyit is an accurate indication of complian data that supports the use of the test inquestion (C.) [Single 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	s employed in testing of each model with respect to this requirement. If reference is made toa test protocol a copy as an attachment for documentation. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] conitor compliance does not actually measure x radiation, explain whyit is an accurate indication of compliance data that supports the use of the test inquestion (C.) [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]	ce with				

	File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ails	[HTML Text]			
Э.	1	each test method listed	d in question (B.) under Production Testing, attach the detailed instructions for performing the test whed.	nere the		
	File Attachment [S		[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 sam	ple of calculated compliance values complete withan 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	ow compliance is estab	plished.			
[Mu	lti-Line	e Plain Text]				
J.	Is th	is performance param	eter tested on 100 percent of the produced models?	[L]		
Δςς						
	emble	er Testing:				
		er Testing: embler testing apply?		[L]		
	s asse	embler testing apply?	ect test of the performance parameter?	[L]		
Doe	Does	embler testing apply? s the test involve a direction all methods employed	ect test of the performance parameter? loyed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.	[L]		
Doe A.	Does Desc	embler testing apply? s the test involve a direction all methods employed	loyed in testing of each model with respect to this requirement. If reference is made to a test protocol	[L]		
Doe A.	Does Desc	embler testing apply? s the test involve a direction of the cribe all methods employment, provide a copy Attachment	loyed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation.	[L]		
Doe A.	Described Descri	embler testing apply? s the test involve a direction all methods employment, provide a copy Attachment	loyed in testing of each model with respect to this requirement. If reference is made to a test protocol as an attachment for documentation. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	[L]		
Doe A. B.	Described Descri	embler testing apply? s the test involve a direction of the cribe all methods employment, provide a copy Attachment ails by test used to monitor	loyed in testing of each model with respect to this requirement. If reference is made to a 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]	[L]		
Doe A. B.	Does docu File A Deta If an this I	embler testing apply? s the test involve a direction and the cribe all methods employment, provide a copy. Attachment sails by test used to monitor requirement. ML Text]	loyed in testing of each model with respect to this requirement. If reference is made to a 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]	[L]		
Doe A. B.	Does docu File . Deta If an this i [HTM	embler testing apply? s the test involve a direction and the cribe all methods employment, provide a copy. Attachment sails by test used to monitor requirement. ML Text]	loyed in testing of each model with respect to this requirement. If reference is made to a 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 compliance does.	[L]		
Doe A. B.	Does docu File . Deta If an this i [HTM	embler testing apply? s the test involve a direction of the composition of the test involve a direction of the test involve a copy. Attachment will be a copy of the test used to monitor requirement. ML Text] mitthe technical data the tech	loyed in testing of each model with respect to this requirement. If reference is made to a 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 compliance to the test in question (C.)	[L]		
Doe A. B.	Described Descri	embler testing apply? s the test involve a direction of the cribe all methods employment, provide a copy. Attachment ails y test used to monitor requirement. ML Text] mitthe technical data the characteristics.	loyed in testing of each model with respect to this requirement. If reference is made to a 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 compliance to the test in question (C.) [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	[L]		
A. B.	Described Descri	embler testing apply? s the test involve a direction of the cribe all methods employment, provide a copy. Attachment ails y test used to monitor requirement. ML Text] mitthe technical data the characteristics.	loyed in testing of each model with respect to this requirement. If reference is made to a 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 compliance to the test in question (C.) [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]	[L]		
Doe A. B.	Described Descri	embler testing apply? s the test involve a direction of the control of the contr	loyed in testing of each model with respect to this requirement. If reference is made to a 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 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] ed instructions for performing each test.	[L]		

1	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 specifie		ed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the ed.		
	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 liste	ed 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	value calculated from the raw test data? [L]		
	. ,		the user manual that specifies no assembly or installation instructions are necessary and all that is needed to e power cord into the wall socket.		
File	Attachment	[S	ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]		
Deta	ails	[H	TML Text]		
312.0 Exposure Time					
314					
	quirement:				
Red	quirement: ssage:	exposure	Ifacturer shall state the maximum deviation of the exposure time from its preindicated value during an 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)).		
Req	ssage:	exposure	when the equipment is connected to an adequate power supply as specifiedby the manufacturer. The		
Mes App	-	exposure deviation This required compone	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)). irement is applicable toradiographic x-raycontrols and high-voltage generators. Similarmodels of a single not type may be grouped for presentation of test results applicable to this requirement when the technical basis		
Mes App	ssage:	exposure deviation This required compone	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)). irement is applicable toradiographic x-raycontrols and high-voltage generators. Similarmodels of a single		
Mes App	ssage: plicability: ssage:	exposure deviation This required compone for this grand "Wor	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)). irrement is applicable to adiographic x-ray controls and high-voltage generators. Similar models of a single not type may be grouped for presentation of test results applicable to this requirement when the technical basis outping is clearly stated in the description of prototype testing (see 312.4(a)). st Case" Conditions:		
Mes App	ssage: plicability: ssage:	This required for this grand "Wor	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)). irement is applicable toradiographic x-raycontrols and high-voltage generators. Similarmodels of a single not type may be grouped for presentation of test results applicable to this requirement when the technical basis outping is clearly stated in the description of prototype testing (see 312.4(a)).		
Reco	ssage: plicability: ssage: tical Parameters	This requirements of the second of the secon	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)). irrement is applicable to adiographic x-ray controls and high-voltage generators. Similar models of a single not type may be grouped for presentation of test results applicable to this requirement when the technical basis outping is clearly stated in the description of prototype testing (see 312.4(a)). st Case Conditions: a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be		
Appr Mes Critt A. B.	ssage: plicability: ssage: tical Parameters Message:	This requirements of the second of the secon	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)). irrement is applicable to adiographic x-raycontrols and high-voltage generators. Similarmodels of a single not type may be grouped for presentation of test results applicable to this requirement when the technical basis outping is clearly stated in the description of prototype testing (see 312.4(a)). st Case" Conditions: a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be initiately 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)		
Requirements Approximately Message Critical Actions of the Proof This is a second of the Proof T	ssage: policability: ssage: tical Parameters Message: Message: totype Testing: s section is for sta	This requirement of this grand "Wor and	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)). irrement is applicable to adiographic x-raycontrols and high-voltage generators. Similarmodels of a single not type may be grouped for presentation of test results applicable to this requirement when the technical basis outping is clearly stated in the description of prototype testing (see 312.4(a)). st Case" Conditions: a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be initiately 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)		
Requirements Approximately Message Critical Actions of the Proof This is a second of the Proof T	ssage: plicability: ssage: tical Parameters Message: Message: totype Testing: s section is for staduction testing. Design of the standard	This required compone for this grand "Wor and "Wor and "Wor art up prior oes prototy frect test metalian."	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)). Interpretation of exposure time shall not exceed the limits given (see 1020.31(a)(4)). Interpretation of exposure time shall not exceed the limits given (see 1020.31(a)(4)). Interpretation of the stress of the stress of the test method and instrumentation of the stress of the test method and instrumentation, rejection limits for any test must be inciently restrictive to assure compliance with the standard. Interpretation of the stress of the test method and instrumentation, rejection limits for any test must be inciently restrictive to assure compliance with the standard. Interpretation of the stress of the standard of 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 age, and highest allowed line-voltage regulation). Interpretation of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as population of the same as popu		
Approximately Ap	ssage: plicability: ssage: tical Parameters Message: Message: totype Testing: s section is for staduction testing. Describe the di	This required compone for this grand "Wor and "Wor and "Wor art up prior oes prototy frect test metalian."	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)). Interpretation of exposure time shall not exceed the limits given (see 1020.31(a)(4)). Interpretation of exposure time shall not exceed the limits given (see 1020.31(a)(4)). Interpretation of the stress of the stress of the test method and instrumentation of the stress of the test method and instrumentation, rejection limits for any test must be inciently restrictive to assure compliance with the standard. Interpretation of the stress of the test method and instrumentation, rejection limits for any test must be inciently restrictive to assure compliance with the standard. Interpretation of the stress of the standard of 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 age, and highest allowed line-voltage regulation). Interpretation of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as population of the same as popu		
Requested Message Approximately Message Critical Actions of the Processing Pr	blicability: ssage: tical Parameters Message: Message: totype Testing: s section is for staduction testing. Describe the direspect to this respect to this	This requirement deviation This requirement deviation This requirement deviation This requirement deviation As a sufficient to a sufficient deviation de	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)). Interpretation of exposure time shall not exceed the limits given (see 1020.31(a)(4)). Interpretation of exposure time shall not exceed the limits given (see 1020.31(a)(4)). Interpretation of the stress of the stress of the test method and instrumentation of the stress of the test method and instrumentation, rejection limits for any test must be inciently restrictive to assure compliance with the standard. Interpretation of the stress of the test method and instrumentation, rejection limits for any test must be inciently restrictive to assure compliance with the standard. Interpretation of the stress of the standard of 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 age, and highest allowed line-voltage regulation). Interpretation of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as a population of the stress of the same as population of the same as popu		

C.	Attach a sample of raw tes	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	ralue calculated from the raw test data?					
E.	Attach a sample of calcula	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]					
Expl	ain how compliance is esta	blished.					
[Mult	ti-Line Plain Text]						
Proc	duction Testing:						
A.	Does the test involve a dir	ect test of the performance parameter?					
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)]					
	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 data	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 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 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 liste	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)]					
	Details	[HTML Text]					

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 factor	rs employed.				
	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	established.					
[Mul	lti-Line Plain Text]						
J.	Is this performance pa	arameter tested on 100 percent of the produced models?	[L]				
Ass	embler Testing:						
Doe	s assembler testing app	oly?	[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 topy as an attachment for documentation.	test protocol				
	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 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 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	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)]				
	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 ecified.	g the test where 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]					
	Is the actual compliant	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	[HTML Text]						
313	3.0 Automati	c Expos	sure Control Limits						
Req	uirement:								
Mes	sage:	exposure except w	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	sage:	exposure	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:		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.						
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	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]					
A.	Describe the c		method (i.e., one that actually measures x radiation) employed in testing and measuring each model wit ent.	h					
	[HTML Text]								
В.	Identify the ins	dentify the instrument(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	value calculated from the raw test data?	[L]					
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]						
	ain how complia	noo is ost	tablished						

A.	Does	s the test involve a c	lirect test	of the performance parameter?	[L]			
B.	1			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)]				
	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.							
	[HTN	/IL Text]						
Э.	Subr	mit the technical data	a that sup	pports 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	[HTN	ML Text]				
Ξ.	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	[HTN	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	[HTN	HTML Text]				
Э.	1	each test method list	•	estion (B.) under Production Testing, attach the detailed instructions for performing the test whe	ere the			
	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]				
Ⅎ.	For e	each testmethod list	ed in que	estion (B.), please attach sample raw test data.				
	File	Attachment	[Sing	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	Details [HTN		[HTML 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]				
Ехр	lain ho	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]			
J.	*	u Toetine.						
J. Ass	emble	er resting:						

A.	Does thetest in	nvolve a direc	ct test of the performance parameter?	[L]				
B.			byed in testing of each model with respect tothis requirement. If reference is made to a test protocol as an attachment for documentation.					
	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 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 tec	hnical data th	nat 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 detaile	d 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) 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 r	nethod 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]					
l.	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 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	ils	[HTN]	ML Text]					
314	.0 Automati	c Exposur	re Control Minimum Exposure Time					
Requ	uirement:							
Mess	sage:	equipment 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, and the exposure time for all other equipment shall be equal to or less than 1/60second or a time interval required.					
		aeiiver 5 mi	As, whichever is greater (see 1020.31(a)(3)(ii)).					

automatic e applicable		automatic e.	ment is applicable to radiographic x-ray controls and high-voltage generators used in systems with xposure controls. Similar models of a single component type may be grouped for presentation of test to this requirement when thetechnical basis for this grouping is clearly stated in the description of prote 314.4(a)).			
Criti	ical Parameters a	and "Worst	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:					
	section is for star luction testing. Do	• •	full production phase and thus the testing and quality control procedures may not be the same as e testing apply?	[L]		
A.	Describe the dir		hod (i.e., one that actually measures x radiation) employed in testing and measuring each model with	1		
	[HTML Text]					
В.	Identify the instr	ument(s) us	ed 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		[HTML Text]			
D.	Is the actual cor	npliance val	ue calculated from the raw test data?	[L]		
Ε.	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 complian	ce is establi	ished.			
[Mul	ti-Line Plain Text]					
Prod	duction Testing:					
Α.	Does the test in	volve a dired	ct test of the performance parameter?	[L]		
B.	1	Describe all methods employed in testing of each model with respect to this requirement. If reference is made toa 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 this requirement		ompliance does not actually measure x radiation, explain why it is an accurate indication of complian	ce with		
	[HTML Text]					
D.	Submit the tech	nical data th	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	1	File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ails	[HTML T	ext]			
F.	lden	tify the instrument(s) u	sed for ead	ch test by manufacturer and model number.			
	File	Attachment	[Single F	File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ails	[HTML T	ext]			
G.	1	each test method listed ction limits are specifie		on (B.) under Production Testing, attach the detailed instructions for performing the test w	here the		
	File	Attachment	[Single F	File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ails	[HTML T	ext]			
H.	For	each test method listed	d in questio	on (B.), please attach sample raw test data.			
	File	Attachment	[Single F	File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ails	[HTML T	ext]			
l.	Is th	e actual compliance va	alue calcula	ated from the raw test data?	[L]		
	-	Please attach a samp	ole of calcu	ulated compliance values complete with an explanation of any correction factors employe	d.		
		File Attachment	1	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details		[Sii	ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv,	.zip)]		
		Details		ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, TML Text]	.zip)j		
Ехр	lain ho	Details ow compliance is estab	[H ¹		.zip)]		
		ļ.	[H ¹		.zip)j		
[Mu	lti-Line	ow compliance is estab	[H]		[L]		
[Mul	lti-Line	ow compliance is estab	[H]	TML Text]			
[Mul	Iti-Line Is th	ow compliance is estable Plain Text] is performance parame	[H]	TML Text]			
[Mul J. Ass	Is th	ow compliance is estable Plain Text] is performance parameter Testing: embler testing apply?	[H7	TML Text]	[L]		
J.	Is the semble as asset Does	ow compliance is estable Plain Text] is performance parameter Testing: embler testing apply? s the test involve a direction all methods emple	eter tested	TML Text] on 100 percent of the produced models?	[L] [L]		
[Mul J. Ass Doe A.	Is the semble as asset Does docu	ow compliance is estable Plain Text] is performance parameter Testing: embler testing apply? s the test involve a direction all methods emple	eter tested ect test of the oyed in test as an attack	on 100 percent of the produced models? the performance parameter? sting of each model with respect to this requirement. If reference is made to a test protoco	[L] [L]		
[Mul	Is the semble as asset Does docu	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 a	eter tested ect test of the oyed in test as an attack	on 100 percent of the produced models? the performance parameter? sting of each model with respect to this requirement. If reference is made to a test protocochment fordocumentation. File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	[L] [L]		
[Mul J. Ass Doe A.	Is the semble as asset docu	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 attachment	eter tested ect test of the oyed in test as an attact [Single F	on 100 percent of the produced models? the performance parameter? sting of each model with respect to this requirement. If reference is made to a test protocochment fordocumentation. File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	[L] [L]		
J. Ass Doe A.	Is the semble as asset docu	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 attachment ails	eter tested ect test of the oyed in test as an attact [Single F	on 100 percent of the produced models? the performance parameter? sting of each model with respect to this requirement. If reference is made to a test protocochment fordocumentation. File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] Fext]	[L] [L]		
[Mul J. Ass Doe A. B.	Is the semble as asset docu	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 attachment ails by test used to monitor requirement. ML Text]	eter tested eter tested oved in testas an attact [Single F [HTML T compliance	on 100 percent of the produced models? the performance parameter? sting of each model with respect to this requirement. If reference is made to a test protocochment fordocumentation. File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] Fext]	[L] [L]		
[Mul J. Ass Doe A. B.	Iti-Line Is th Is th Is th Is semble Is asset In this Itinity If an this Itinity Itini	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 attachment ails by test used to monitor requirement. ML Text]	eter tested ect test of the oyed in test as an attact [Single Figure 1] [HTML Tompliance] hat support	on 100 percent of the produced models? the performance parameter? sting of each model with respect to this requirement. If reference is made to a test protocochment fordocumentation. File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] Fext] e does not actuallymeasure x radiation, explain why it is an accurate indication of compliance.	[L] [L]		
[Mul J. Ass Doe A. B.	Iti-Line Is th Is th Is th Is semble Is asset In this Itinity If an this Itinity Itini	ow compliance is estable Plain Text] is performance parameter Testing: embler testing apply? so the test involve a directive all methods employment, provide a copy of Attachment ails by test used to monitor requirement. ML Text] mit the technical data to Attachment	eter tested ect test of the oyed in test as an attact [Single Figure 1] [HTML Tompliance] hat support	on 100 percent of the produced models? the performance parameter? sting of each model with respect to this requirement. If reference is made to a test protocochment fordocumentation. File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] Text] e does not actuallymeasure x radiation, explain why it is an accurate indication of compliance to the test in question (C.) File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	[L] [L]		

1	File Attachme	nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	ĺ
	Details		[HTML Text]	
F.	Identify the ins	strument(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 rejection limits		ted in question (B.) under Assembler Testing, attach the detailed instructions forperforming the test who fied.	ere 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	method lis	ted 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	e 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 ne the power cord into the wall socket.	eded to
File	Attachment	[3	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Deta	ails	[1	HTML Text]	
315	5.0 Illuminar	nce of Li	ght Localizers	
Req	uirement:			
Mes	ssage:	than 160	light localizer is used to define the perimeter of the x-ray field, it shall provide an average illumination o Dlux (15 footcandles) at 100 centimeters or at the maximum SID whichever is less. The average illumin based upon measurements madein the approximate center of each quadrantof the light field (see 1020 (f)(4)(i)).	ation
Арр	licability:			
Mes	ssage:	a light lo	uirement is applicable to any beam-limiting devices in a general purpose or other radiographic system to ocalizer to define the perimeter of the x-ray field. Similar models of a single component type may be groution of test results applicableto this requirement when the technical basis for this grouping is clearly stated that the properties of prototype testing (see (a) under Prototype Testing).	uped for
Criti	ical Parameters	s and "Wo	orst Case" Conditions:	
Mes	ssage:		cult of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be titly restrictive to assure compliance with the standard.	
Prof	totypeTesting:			
			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 crespect to this		method (i.e., one that actually measures x radiation) employed in testing and measuring each model wi	th
	[HTML Text]			

	Identify 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 cal	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]			
Exp	lain how compliance is e	established.			
[Mul	lti-Line Plain Text]				
Pro	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 referenceis 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 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	nce 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.	nce with		
	this requirement. [HTML Text]		ance with		
	this requirement. [HTML Text] Submit the technical d	lata that supports the use of the test in question (C.)	ance with		
D.	this requirement. [HTML Text] Submit the technical difference of the control of	lata 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 difference of the control of	[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.	this requirement. [HTML Text] Submit the technical difference of the Attachment Details Attach a copy of the difference of the Attachment Details	[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)]	ance with		
D.	this requirement. [HTML Text] Submit the technical difference of the Attachment Details Attach a copy of the difference of the Attachment Details	lata 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]	ance with		
D.	this requirement. [HTML Text] Submit the technical difference of the Attachment Details Attach a copy of the difference of the Attachment Details Identify the instrument	lata 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.	ance with		
	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	[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] [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]			
D. E.	this requirement. [HTML Text] Submit the technical defile Attachment Details Attach a copy of the defile 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] [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]			
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.	[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] [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [Itml Text] [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] [Isted in question (B.) under Production Testing, attach the detailed instructions for performing the test wherefied.			

	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	e value calculated from the raw test data?	[L]			
	Please attach a sa	ample 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 es	stablished.				
[Mul	ti-Line Plain Text]					
J.	Is this performance para	ameter tested on 100 percent of the produced models?	[L]			
Ass	embler Testing:					
Doe	s assembler testing apply	y?	[L]			
A.	Does the test involve 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 protopy as an attachment for documentation.				
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip	p)]			
	Details	[HTML Text]				
C.	If any test used to monit	itor compliance does not actually measure x radiation, explain why it is an accurate indication of com	pliance 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 det	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	D)]			
	Details	[HTML Text]				
F.	Identify the instrument(s	s) used 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))]			
	Details	[HTML Text]				
G.	For each test method lis rejection limits are spec	sted in question (B.) under Assembler Testing, attach the detailed instructions for performing the test cified.	t where the			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Details	[HTML Text]				
_	For each test method lis	sted in question (B.), please attach sample raw test data.				
Н.	Tor each test method ha	questie (2.), predes anastr campio rain tost anas				

	lo the petual a		live coloulated from the year test date?	n 1
Orov		•	lue calculated from the raw test data? e user manual that specifies no assembly or installation instructions are necessary and all that is necessary.	[L]
	. ,	. 0	power cord into the wall socket.	eueu i
File	Attachment	[Sing	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Deta	ails	[HTN	ML Text]	
316	6.0 Alignme	nt of Visua	ally Defined X-Ray Fields	
Rec	uirement:			
Α.	Message:	all gei respe perce	If fields (including light fields): Means shall be provided for visually defining the perimeter of the x-ray neral purpose x-ray systems. The total misalignment of the edges of the visually defined field with the ctive edges of the x-ray field along either the length or width of the visually defined field shall not exent of the distance from the source to the center of the visually defined field when the surface upon what is perpendicular to the axis of the x-ray beam (see 1020.31(d)(2)(i)).	e ceed 2
		- ''	fields: The edge of the light field at 100 centimeters or at themaximum SID, whichever is less, shall I	20/0 2
B.	Message:	contra use o	ast ratio, corrected forambient lighting, of not less than 4 in the case of beam-limiting devices design n stationary general purpose equipment,and a contrast ratio of not less than 3 in the case of beam-li es designed for use on mobilegeneralpurpose and other radiographic equipment (see 1020.31(d)(2)(ed for miting
App	licability:	•		
Mes	ssage:	light localize	ement is applicable to any beam-limiting device in a general purpose or other radiographic system th er to define the perimeter of the x-ray field. Similar models of a single component type may be group n of test results applicable to this requirement when the technical basis for this grouping is clearly sta	ed for
		the descript	tion of prototype testing (see (b) under Prototype Testing).	
Crit	ical Parameter	s and "Worst	t Case" Conditions:	
A.	Message:		result of inherent inaccuracies of the testmethod and instrumentation, rejection limits for any test must iently restrictive to assure compliance with the standard.	st be
В.	Message:		sure 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 the testing apply?	[L]
A.	Describe the o		thod (i.e., one that actually measures x radiation) employed in testing and measuring each model wit	:h
	[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]	
	ī	_		

E.	Attach a sample of ca	alculated compliance values complete with an explanation ofany correction factors employed.			
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	p)]		
	Details	[HTML Text]			
Expl	ain how compliance is	established.			
[Mul	ti-Line Plain Text]				
Prod	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 prot copy as an attachment for documentation.	ocol		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	p)]		
	Details	[HTML Text]			
C.	If any test used to mo this requirement.	nitor compliance does not actually measure x radiation, explain why it is an accurate indication of cor	mpliance with		
	[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, .z	p)]		
	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, .z	p)]		
	Details	[HTML Text]			
F.	Identify the instrumen	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, .z	p)]		
	Details	[HTML Text]			
G.	For each test method rejection limits are spe	listed in question (B.) under Production Testing, attach the detailed instructions for performing the te ecified.	st where the		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	p)]		
	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, .z	p)]		
	Details	[HTML Text]			
I.	Is the actual complian	nce value calculated from theraw test data?	[L]		
	Please attach a	sample of calculated compliance values complete with an explanation of any correction factors empl	oyed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .c	sv, .zip)]		
	Details	[HTML Text]			

Expl	ain how compliance is e	established.				
[Mult	ti-Line Plain Text]					
J.	Isthis performance par	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	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 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 morthis requirement.	nitor compliance does not actually measure x radiation, explain whyit is an accurate indication of complian	ce 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 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(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 ecified.	re 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 complian	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 need go 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]				

	_						
Red	quirement:	1 -					
A.	Message:		stationary general purpose x-ray systems, the center of the x-ray field shall align with the center of the in otor to within 2 percent of the SID (see 1020.31(e)(1)).	nag			
В.	Message:	For c	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; (i solely for ri 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 proton	sed ılts			
		testing (se	e (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	:					
				[L]			
pro			pe testing apply?				
A.	to this require		ethod (i.e., one that actually measures x radiation) employed in testing and measuring each modelwith research	esp			
	[HTML Text]						
B.	Identify the in	Identify the instrument(s) used for the test by manufacturer and model number.					
	[HTML Text]						
C.	Attach a sam	ole of raw tes	at 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 o	compliance va	alue calculated from the raw test data?	[L]			
E.	Attach a sam	ole of calcula	ted 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]				
Eyr	olain how compli	ance is estab	plished.				
	ılti-Line Plain Te	xt]					
_							
[Mu	duction Testin	g:					

	docu	ment, provide a copy	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.	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	IL Text]					
D.	Subn	nit the technical data t	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	ITML Text]				
≣.	Attac	h a copy of the detaile	structions for performing each test.				
	File A	Attachment	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .x	xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
	Deta	ils	tTML Text]				
÷.	Ident	ify the instrument(s) u	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]				
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 A	Attachment	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .>	xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
Details [HTML Text]							
٦.	For each test method listed in question (B.), please attach 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	ITML Text]				
	Is the	e actual compliance va	calculated from the raw test data?	[L]			
-	-	Please attach a samp	of calculated compliance values complete with an exp	lanation of any correction factors employed.			
		File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .w	/mv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
		Details	[HTML Text]				
Expla	ain ho	w compliance is estab	ed.				
[Mult	i-Line	Plain Text]					
J.	Is this	s performance parame	tested on 100 percent of the produced models?	[L]			
Asse	embler Testing:						
		mbler testing apply?		[L]			
Α.			est of the performance parameter?	[L]			
В.			d in testing of each model with respect to this requirer	<u> </u>			
		mont provide a conv	in attachment for documentation.				

li	File Attachmen	ŧ	[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 of	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	rument(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)]
	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	nils	[НТ	ML Text]
046	0 0 D - di	ahia V Da	
318	3.0 Radiograp	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 thes 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	The test results must include data representative of each compatible combination of tube housing	a accompliae or
Α.	Message:	beam-limiting devices.	j assemblies an
В.	Message:	As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any sufficiently restrictive to assure compliance with the standard.	y test must be
Э.	Message:	Since the SID is used for calculating the compliance values of this requirement, the accuracy of to measurement must be verified.	he SID
Prot	otype Testing:		
		up prior to full production phase and thus the testing and quality control procedures may not be the sas does not apply go to 318.5 for production testing. Does prototype testing apply?	ame as [L]
۹.	Describe the direct respect to this requ	It test method (i.e., one that actually measures ${\sf x}$ radiation) employed in testing and measuring each ruirement.	nodel 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]	
Э.	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	liance 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	e 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 e a copy as an attachment for documentation.	protocol
	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	compliance wit
	[HTML Text]		
D.	Submit the technic	cal data that supports the use of thetest in question (C.)	
	I	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv	

	Deta	ils	[HTML Text]				
E.	Attac	ch 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)]				
	Deta	ils	[HTML Text]				
F.	Ident	tify the instrument(s) ι	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.	1	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where th rejection limits are specified.					
	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	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)]				
	Deta	ils	[HTML Text]				
I.	Is the	e actual compliance v	alue calculated from the rawtest 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, .z	ip)]			
		Details	[Multi-Line Plain Text]				
Ехр	lain ho	w compliance is estat	olished.				
[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.	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]				
C.	1	y test usedto monitor (equirement.	compliance does not actually measure x radiation, explain why it is an accurate indication of compliance	ce with			
	[HTN	/IL Text]					
		wit the technical data	that supports the use of the test in question (C.)				
D.	Subr	nit the technical data					
D.		Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				

E.	Attach a copy	of the detaile	ed 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) us	sed for each test by manufacturer andmodelnumber.				
	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		in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the l.				
	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	nethod listed	d 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	alue calculated from the raw test data?	[L]			
		. •	ne user manual that specifies no assembly or installation instructions are necessary and all that is neede e power cord into the wall socket.	ed to			
File /	Attachment [Sin		gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
Deta	ils	[НТІ	//L Text]				
319	.0 X-Ray Fi	eld Size D	Determination for Fixed SID/Image Receptor Size Equipment				
Requ	uirement:	1					
Mess	the field at provided w		hic equipment designed for only one image receptor size at a fixed SID shall be provided with means to the plane of the image receptor to dimensions no greater than those of the image receptor, or shall be rith means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor xtend beyond any edge of the image receptor (see 1020.31(f)(2)).				
Appl	licability:						
Mess	sage:	presentatio	rement is applicable to beam-limiting devices. Similar models of a single component type may be grouped for on of test results applicable to this requirement when the technicalbasis for this grouping is clearly stated in otion of prototype testing (see 319.4(a)).				
Critic	cal Parameters	and "Worst	t Case" Conditions:				
Mess	essage: As a result		of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be restrictive to assure compliance with the standard.				
Prote	otype Testing:						
This	section is for sta	art up prior to	o full production phase and thus the testing and quality control procedures may not be the same as be testing apply?	[L]			
This	section is for stauction testing. D	art up prior to loes prototyp	be testing apply? Sthod (i.e., one that actually measures x radiation) employed in testing and measuring each model with	[L]			

	[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.		nce value calculated from the raw test data?	[L]			
	· · · · · · · · · · · · · · · · · · ·		[[-]			
E.		Iculated compliance values complete with an explanation of any correction factors employed.				
	File Attachment Details	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]				
F						
	lain how compliance is	established.				
_	Iti-Line Plain Text]					
	duction Testing:					
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 protoco copy as an attachment for documentation.	DI .			
	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.					
	this requirement.	Third compliance does not actually measure x radiation, explain why it is an accurate indication of compli	ance wit			
	this requirement. [HTML Text]	Third compliance does not actually measure x radiation, explain why it is an accurate indication of compl	ance wit			
	[HTML Text]	data that supports the use of the test in question (C.)	ance wit			
	[HTML Text]		ance wit			
	[HTML Text] Submit the technical of	data that supports the use of the test in question (C.)	ance wit			
D.	[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 wit			
D.	[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 wit			
D.	[HTML Text] Submit the technical of File Attachment Details Attach a copy of the december 1.5 copy of the december 2.5	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] letailed instructions for performing each test.	ance wit			
D.	[HTML Text] Submit the technical of File Attachment Details Attach a copy of the difference of the 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] letailed instructions for performing each test. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	ance wit			
D.	[HTML Text] Submit the technical of File Attachment Details Attach a copy of the difference of the Attachment Details	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] [letailed instructions for performing each test. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]	ance wit			
D.	[HTML Text] Submit the technical of File Attachment Details Attach a copy of the difference of File Attachment Details Identify the instrument	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] [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.	ance wit			
D.	[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	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] letailed 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 w				
D. E.	[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	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] letailed 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 w				
D.	[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 spec	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] [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] [Isted in question (B.) under Production Testing, attach the detailed instructions for performing the test vecified.				

	Details		[HTML Text]	
	Is the actu	ual compliance val	ue calculated from the rawtest data?	[L]
	- Plea	ase attach a sampl	le of calculated compliance values complete with an explanation of any correction factors employed.	<u> </u>
		Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .z	
	Deta	ails	[HTML Text]	
Expl	ain how co	mpliance is establi	shed.	
[Mul	ti-Line Plair	n Text]		
J.	Is this per	formance paramet	ter tested on 100 percent of the produced models?	[L]
Ass	embler Tes	sting:		
Doe	s assemble	er testing apply?		[L]
A.	Does the	test involve a direc	ct test of the performance parameter?	[L]
В.	1	•	yed in testing of each model with respect to this requirement. If reference is made to a test protocol an attachment for documentation.	
	File Attacl	hment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
C.	If any test this requir		ompliance does notactually measure x radiation, explain why it is an accurate indication of complian	ce with
	[HTML Te	ext]		
D.	Submit the	e technical data th	at supports the use of the test in question (C.)	
	File Attacl	hment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
E.	Attach a c	copy of the detailed	d instructions for performing each test.	
	File Attacl	hment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details		[HTML Text]	
		e instrument(s) use	ed for each test by manufacturer and model number.	
F.	Identifythe		ed for each test by manufacturer and model number.	
F.	File Attacl	` '	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
F.	<u> </u>	` '	·	
F. G.	File Attacl Details For each	hment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] in question (B.) under Assembler Testing, attach the detailed instructions for performing the test when	ere the
	File Attacl Details For each	hment test method listed limits are specified	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] in question (B.) under Assembler Testing, attach the detailed instructions for performing the test when	ere the
	File Attacl Details For each rejection I	hment test method listed limits are specified	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] in question (B.) under Assembler Testing, attach the detailed instructions for performing the test whe	ere the
	File Attack Details For each rejection I File Attack Details	hment test method listed limits are specified hment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] in question (B.) under Assembler Testing, attach the detailed instructions for performing the test when. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	ere the

	Details		[HTML Text]	1			
l.	Is the actual co	ompliance va	llue calculated from the rawtest 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)]				
Det	tails	[HTM]	ML Text]				
32	0.0 Alignmer	nt of the X	-Ray Field and Spot-Film Cassette				
Red	quirement:						
A.	Message:	recep for ful withou	The total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the imag receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, shall not exceed 3 percent of the SID. The sum without regard to sign of the misalignment along any two orthogonal dimensions shall not exceed 4 percent of the SID (see 1020.31(h)(2)).				
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			
	Annlicability		o within 2 percent of the SID (see 1020.31(h)(3)).				
Ap	plicability:						
Me	ssage:		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)).				
Cri	tical Parameters	and"Worst	Case" Conditions:				
A.	Message:		The test results must include data representative of each compatible combination of beam-limiting devices and spot-film devices.				
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:		To assure compliance with the spot-film x-ray field limitation requirement, the test results must include data for range of SID's and applicable spot-film formats for each image receptor size.				
Pro	totype Testing:						
Thi			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 d		thod (i.e., onethat actually measures x radiation) employed in testing and measuring each model with	n respe			
	[HTML Text]						
В.	Identify the ins	trument(s) us	sed for the test by manufacturer and model number.				
	[HTML Text]						
	Attach a samp	le of raw test	data.				
C.		nt	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
C.	File Attachmer						
C.	File Attachmer Details		[HTML Text]				

E.	Attach a sample of ca	alculated 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 thetest 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 protocol copy as an attachment fordocumentation.						
	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 this requirement.	nitor compliance does not actuallymeasure x radiation, explain why it is an accurate indication of complian	nce with					
	[HTML Text]	[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)]						
	Details	[HTML Text]						
E.	Attach a copy of the d	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 instrumen	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)]						
	Details	[HTML Text]						
G.	For each test method rejection limits are spe	listed in question (B.) under Production 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]						
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 complian	nce value calculated from the raw test data?	[L]					
	Please attach a	sample of calculated compliance values complete with an 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]						

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]				
Asse	embler Testing:		•				
Does	s assembler testing app	ly?	[L]				
A.	Does the test involve a	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 copy 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.	nitor 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	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 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 neg 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]					

	quirement:						
Mes	ssage:	For nonir	mage intensified fluoroscopy, the x-ray field shall not extend beyond the visible area of the image recep	otor.			
Message: A. Message:		For imag	ge intensified fluoroscopy:				
A.			The total misalignment of the edges of the x-ray field with the respective edges of the visible area of the image receptor along any dimension of the visuallydefined field in the plane of the image receptor shall not exceed 3 percent of the SID. The sum, without regard to sign, of the misalignmentalong any twoorthogonal dimensions intersecting at the center of the visible area of the image receptor shall not exceed 4 percent of the SID.				
В.	the		ctangular x-ray fields used with circular image receptors, the error in alignment shall be determined along ngth and width dimensions of the x-ray field that pass through the center of the visible area of the image tor (see 1020.32(b)(2)(ii)).				
Αрр	plicability:						
Mes	ssage:	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 is clearly stated in the description of prototype testing (see 321.4(a)).				
Crit	tical Parameter	s and "Wo	orst Case" Conditions:				
Α.	Message:		e test results must include data representative of each compatible combination of beam-limiting device age intensifiers.	test results must include data representative of each compatible combination of beam-limiting devices and go 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	nssure compliance with the fluoroscopic x-ray field limitation requirement, the test results must include data fr range of SID's and available magnification modes that result in different visual areas on the input phosphor of Image intensifier.				
	*						
Pro	totype Testing	:					
This	s section is for s	tart up prioi	r to full production phase and thus the testing and quality controlprocedures may not be the sameas type testing apply?	[L]			
This	s section is for s duction testing.	tart up prior Does protot direct test n					
This	s section is for s duction testing.	tart up prior Does protot direct test n	type testing apply?				
This oroo	Describe the to this require	tart up prior Does protot direct test n ment.	type testing apply?				
This oroo	Describe the to this require	tart up prior Does protot direct test n ment.	type testing apply? method (i.e., one that actually measures x radiation) employed in testing and measuring eachmodel wit				
This prod A.	Describe the to this require [HTML Text] Identify the in [HTML Text]	tart up prior Does protot direct test n ment. strument(s)	type testing apply? method (i.e., one that actually measures x radiation) employed in testing and measuring eachmodel wit of the test by manufacturer and model number.				
This oroo	Describe the to this require [HTML Text] Identify the in	tart up prior Does protot direct test n ment. strument(s)	type testing apply? method (i.e., one that actually measures x radiation) employed in testing and measuring eachmodel wit used for the test by manufacturer and model number. est data.				
This prod A.	Describe the to this require [HTML Text] Identify the in [HTML Text] Attach a same	tart up prior Does protot direct test n ment. strument(s)	type testing apply? method (i.e., one that actually measures x radiation) employed in testing and measuring eachmodel wit of the test by manufacturer and model number.				
This proo A.	Describe the to this require [HTML Text] Identify the in [HTML Text] Attach a sample File Attachmed Details	tart up prior Does protot direct test n ment. strument(s)	type testing apply? method (i.e., one that actually measures x radiation) employed in testing and measuring eachmodel with a subject of the test by manufacturer and model number. est data. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]	h resp			
This prod A. B.	Describe the to this require [HTML Text] Identify the in [HTML Text] Attach a sample File Attachmed Details Is the actual of	tart up prior Does protot direct test n ment. strument(s) pole of raw te	type testing apply? method (i.e., one that actually measures x radiation) employed in testing and measuring eachmodel with a used for the test by manufacturer and model number. est data. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text] value calculated from the raw test data?				
This proo A.	Describe the to this require [HTML Text] Identify the in [HTML Text] Attach a sample File Attachmed Details Is the actual of	tart up prior Does protot direct test n ment. strument(s) pole of raw te ent compliance	type testing apply? method (i.e., one that actually measures x radiation) employed in testing and measuring eachmodel with a subject of the test by manufacturer and model number. est data. [Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]	h resp			

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]				
) .		y test used to monit equirement.	or compli	ance does not actually measure x radiation, explain why it is an accurate indication of compliar	nce wit			
	[HTN	[HTML Text]						
).	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	ils	[HTN	//L Text]				
Ξ.	Attach a copy of the detailed instructions 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		//L Text]				
	Identify the instrument(s) used for each test by manufacturer and model number.							
	File Attachment [Sing		[Sing	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTN	//L Text]				
€.	1	each test method lis tion limits are spec	•	estion (B.) under Production Testing, attach the detailed instructions forperforming the test whe	re the			
	File	Attachment	[Sinç	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTN	TML Text]				
Ⅎ.	For e	each test method lis	ted in que	estion (B.), please attach sample raw test data.				
	File	Attachment	[Sing	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
	Deta	ils	[HTN	[HTML Text]				
	Is the	e actual compliance	value ca	Iculated 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	s performance para	ameter tes	sted on 100 percent of the produced models?	[L]			
sse	emble	r Testing:						

Does	s assembler test	ting apply?		[L]		
A.	Does the test i	nvolve a d	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 y as an attachment for documentation.			
	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 requirement		or compliance does not actually measure x radiation, explain why it is an accurate indication of complian	ice 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]			
Ε.	Attach a copy of the detaile		iled 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]			
=.	Identify the ins	trument(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]			
١.	For each test r	nethod list	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]			
	Is the actual co	ompliance	value calculated from the raw test data?	[L]		
		. •	the user manual that specifies no assembly or installation instructions are necessary and all that is need no power cord into the wall socket.	ded to		
File	Attachment	[S	ingle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
Deta	ils	[H	ITML Text]			
322	2.0 X-Ray Fi	eld Size	Determination for Dental Equipment			
Req	uirement:					
Mes	sage:	ray beam minimum	phic equipment designed for use with an intraoral image receptor shall be provided with means to limit issuch that if the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the SSD shall be containable in a circle having a diameter of no more than 7 centimeters; or if the minimum an 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diamete	n 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:				
			ofull production phase and thus the testing and quality control procedures may not be the same type testing apply?	[L]	
A.	Describe the di respect to this		thod (i.e., one that actually measures x radiation) employed in testing and measuring each model with	า	
	[HTML Text]				
B. Identify the instrument(s) used for the test by manufacturer and model number.		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]		
D.	Is the actual co	mpliance va	lue calculated from the raw test data?	[L]	
Ε.	Attach a sampl	e of calculat	ed 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	ished.		
Mult	i-Line Plain Tex	t]			
Proc	luction Testing	:			
Α.	Does the test in	nvolve a dire	ct test of the performance parameter?	[L]	
В.	1	•	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 requiremen		compliance does not actually measure x radiation, explain why it is an accurate indication of complian	nce with	
	[HTML Text]				
D.	Submit the tecl	nnical data th	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	ised 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.	1	each test method listed	${\sf d}$ in question (B.) under Production Testing, attach the detailed instructions for performing the test wh ${\sf d}$.	ere the						
	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 e	each test method listed	d 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)]							
	Deta	ils	[HTML Text]							
I.	Is the	eactual compliance va	lue calculated 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, .z	zip)]						
		Details	[HTML Text]							
Ехр	lain ho	w compliance is estab	blished.							
[Mu	lti-Line	Plain Text]								
J.	Is thi	s performance parame	eter tested on 100 percent of the produced models?	[L]						
Ass	emble	r Testing:								
Doe	s asse	mbler testing apply?		[L]						
A.	Does	s the test involve a dire	ect test of the performance parameter?	[L]						
В.		•	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 A	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]							
	Deta	ils	[HTML Text]							
	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.	this r									
C.				[HTML Text]						
	[HTM	/IL Text]	that supports the use of the test in question (C.)							
C.	[HTM	/IL Text]	hat 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 instrument(s)use		s)used 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]		
Э.	For each test rejection limit		sted in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where tified.		
	File Attachme	ent	[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 lis	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	compliance	e value calculated from the raw test data?		
Pro	vide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to rate the system is to plug the power cord into the wall socket.				
ope	erate the system	is to plug	the power cord into the wall socket.		
_	Attachment	Ī	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)] HTML Text]		
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 ammographic 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] e Determination for Mammographic Equipment ammographic 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		
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 ammographic 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. ammographic 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] e Determination for Mammographic Equipment ammographic 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. ammographic 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 large receptor at any designated SID by more than 2 percent of the SID. Tent, clearly legible markings shall indicatethe image receptor size and maximum SID for which each aperture.		
File Deta 323 Rec A.	Attachment ails 3.0 X-Ray F quirement: Message: Message:	Field Siz Musin W In Permar designe	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] HTML Text] e Determination for Mammographic Equipment ammographic 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. ammographic 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 large receptor at any designated SID by more than 2 percent of the SID. Tent, clearly legible markings shall indicatethe image receptor size and maximum SID for which each aperture.		
File Det: 323 Rec A. B.	Attachment ails 3.0 X-Ray F quirement: Message: Message: plicability: ssage:	Field Siz Musin W In Permar designe This rec present the des	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] HTML Text] e Determination for Mammographic Equipment ammographic 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. ammographic 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 large receptor at any designated SID by more than 2 percent of the SID. Lent, clearly legible markings shall indicatethe image receptor size and maximum SID for which each apertured (see 1020.31(f)(3)). Lent of the size of this spouling is clearly stated at the technical basis for this grouping is clearly stated.		
File Detr 32: Rec A. Mes	Attachment ails 3.0 X-Ray F quirement: Message: Message: plicability: ssage:	This recogned the designative	Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] HTML Text] The Determination for Mammographic Equipment o 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 large receptor at any designated SID by more than 2 percent of the SID. The Determination for Mammographic 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 large receptor at any designated SID by more than 2 percent of the SID. The Determination for Mammographic Equipment in Determination for which each aperture of the SID. The Determination for Mammographic Equipment type may be grouped attended to be an applicable to be an Imiting devices. Similar models of a single component type may be grouped attended to this requirement when the technical basis for this grouping is clearly stated cription of prototype testing (see 323.4(a)).		

C.	Message:	measurement must be verified.			
Prot	otype Testing:				
	section is for start up puction testing. Does pr	orior to full production phase and thus the testing and quality control procedures may not be the same as ototype testing apply?			
A.	Describe the direct te to this requirement.	st method (i.e., one that actuallymeasures x radiation) employed in testing and measuring each model with respec			
	[HTML Text]				
В.	Identify the instrumen	t(s) used for the test by manufacturer and model number.			
	[HTML Text]				
C.	Attach a sample of ra	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	nce value calculated from the raw test data?			
E.	Attach a sample of ca	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]				
Prod	duction Testing:				
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 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 mother 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	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 thed	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 instrumer	et(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)]			

	Deta	ils	[HTML Text]	
G.	1	each test method listed tion limits are specified	I 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]	
H.	For e	each test method listed	I 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 va	slue 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, .:	zip)]
		Details	[HTML Text]	
Expl	ain ho	w compliance is estab	lished.	
[Mul	ti-Line	Plain Text]		
J.	Is thi	s performance parame	eter tested 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	ect 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 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.	l '	test used to monitor equirement.	compliance does not actually measure x radiation, explain why it is an accurate indication of complia	nce witl
	[HTN	IL Text]		
D.	Subr	nit 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	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.	Ident	ify 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 m		d in question (B.) under Assembler Testing, attach the detailed instructions for performing the test v	vhere 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 m	ethod liste	d in question (B.), please attachsample raw testdata.			
	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 co	mpliance 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 repower cord into the wall socket.	eeded to		
File	Attachment	[Sir	ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]			
Deta	ails	[НТ	TML Text]			
324	4.0 X-Ray Fie	ld Size I	Determination for Radiographic Equipment not in 318 - 323			
Reg	quirement:					
Mes	ssage:	receptor si image receptor si image recependict dimension align the x	ic x-ray systems otherthan: (a) stationary general purpose systems; (b) systems designed for one image to and SID; (c) spot-film devices; (d) mobile equipment; and (e) equipment designed for use with intraoral stors shall be provided with means to limit the x-ray beam such that when the axis of the x-ray beam is far to the plane of the image receptor, the dimensions of the x-ray field shall not exceed the corresponding of the image receptor by more than 2 percent of the SID, or shall be provided with means to bothsize and ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the otor (see 1020.31(f)(4)).			
Арр	plicability:					
Mes	ssage:	presentaito	rement is applicable to beam-limiting devices. Similar models of a single component type may be gron of test results applicable to this requirement when the technical basis for this grou ing is clearly solion of prototype testing (see 324.4(a)).	•		
Crit	ical Parameters	and "Wors	st Case" Conditions:			
A.	Message:		result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test reciently restrictive to assure compliance with the standard.	nust be		
B.	Message:	The	test results must include data for each aperture size.			
C.	Message:		ethe SID is used for calculating the compliance values of this requirement, the accuracy of the SID surement must be verified.			
	ototype Testing:					
Prof	totype Testing:					
This	,, ,		o full production phase and thus the testing and quality controlprocedures may not be the same as the testing apply?	[L]		
This	s section is for sta	pes prototy rect test me	pe testing apply? ethod (i.e., one that actually measures x radiation) employed in testing and measuring each model v			
This	s section is for sta duction testing. Do Describe the di	pes prototy rect test me	pe testing apply? ethod (i.e., one that actually measures x radiation) employed in testing and measuring each model v			
This	Describe the direspect to this r	pes prototy rect test me equiremen	pe testing apply? ethod (i.e., one that actually measures x radiation) employed in testing and measuring each model v			

	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 cal	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	established.			
[Mult	ti-Line Plain Text]				
Proc	duction Testing:				
A.	Does the test involve a	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 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 morthis requirement.	nitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance wit			
	[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 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)]			
		[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	i.
	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 mon this requirement.	itor compliance does not actually measure x radiation, explain why itis an accurate indication of complian	nce with
	[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 who ified.	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	e Attachment [Sir		Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
Deta			ML Text]					
325	5.0 Transmi	ssion Limit	for Image Receptor Support Devices for Mammographic Syst					
Req	uirement:							
Mes	ssage:	system sha	ission of the primary beam throughany image receptor support provided with the mammographicx-ray Il be limited suchthat the exposure 5 centimeters from any accessible surface beyond the plane of the pporting device does not exceed 0.88 micrograys (or 0.1 milliroentgen) for each activation ofthe tube (1/3)).	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 technica uping is clearly stated in the description of prototype testing (see325.4(a)).	l basis				
Crit	ical Parameter	s and "Worst	t Case" Conditions:					
Mes	ssage:		ofinherent inaccuracies of the test method and instrumentation, rejection limits for any testmust be suf- o assure compliance with the standard.	ficienti				
Pro	rototype Testing:							
			o full production phase and thus the testing and quality control procedures may not be the same as 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	strument(s) us	sed forthe test by manufacturer and model number.					
	[HTML Text]							
C.	Attach a sam	ple of 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]					
D.	Is the actual of	compliance va	lue calculated from the raw test data?	[L]				
E.	Attach a sam	ple of calculate	ed compliance values complete with an explanation of any correction factors employed.					
	File Attachme		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
	Details		[HTML Text]					
Ехр	lain how compl	ance is establ	ished.					
[Mu	lti-Line Plain Te	xt]						
Pro	ductionTesting	g:						

	Details	[Mul	lti-Line Plain Text]	
	File Attachment	[Sin-	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
С.	If any test used t	•	iance does not actually measure x radiation, explain why it is an accurate indication of comp	oliance wit
	[HTML Text]			
Э.	Submit the techr	nical data that su	pports the use of the test in question (C.)	
	File Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[НТІ	ML Text]	
E.	Attach a copy of	the detailed inst	ructions for performing each test.	
	File Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[НТІ	ML Text]	
F.	Identify the instru	ument(s) used fo	or each test by manufacturer and model number.	
	File Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[НТІ	ML Text]	
G.	For each test me rejection limits a	-	estion (B.)under Production Testing, attach the detailed instructions for performing the test	where the
	File Attachment	[Sin	gle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[НТІ	ML Text]	
H.	For each test me	thod listed in qu	nestion (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)]
	Details	[НТ]	ML Text]	
	Is the actual com	npliance value ca	alculated from the raw test data?	[L]
l.	- Please atta	ach a sample of o	calculated compliance values complete with an explanation of any correction factors employ	ed.
l.			[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv	/, .zip)]
l.	File Attach	ment	1	
I.	File Attach	ment	[HTML Text]	
I. Expl			J	
	Details		J	
	Details ain how compliand	ce is established	J	[L]
[Mul	Details ain how compliand	ce is established	J	[L]
J.	Details ain how compliand ti-Line Plain Text] Is this performan	ce is established	J	[L]
J.	Details ain how compliant ti-Line Plain Text] Is this performar embler Testing: s assembler testin	ce is established nce parameter tea	J	

	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 this requiremen		compliance 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 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)]
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E.	Attach a copy o	f 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 insti	rument(s) ι	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 m rejection limits a		d in question (B.) under Assembler 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 m	ethod liste	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)]
	Details		[HTML Text]
l.	Is the actual cor	mpliance v	alue calculated from the raw test data? [L]
l			he user manual that specifies no assembly or installation instructions are necessary and all that is needed to e power cord into the wall socket.
File /	Attachment	[Sir	ngle File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Deta	ils	[H]	TML Text]
326	.0 Radiograp	hic PBL	Field Size and Image Receptor Size Differences
Note	:	Answer th	e following questions if certifying a beam-limiting device that is designed for PBL.
Requ	uirement:		
Mes	sage:	manually a receptor b be no grea	with positive beam limitation: The x-ray field size in the plane of the image receptor, whether automatically or adjusted shall be such that neither the length nor the width of the x-ray field differs from that of the image y greater than 3 percent of the SID and that the sum of the length and width differences without regard to sign ater than 4 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane or receptor (see 1020.31(g)(1)(i) and (ii)).
Арр	licability:		

Critical Parameters and "Worst Case" Conditions: A. Message: The test results must include data representative of each compatible combination of tube housing assembleam-limiting devices. B. Message: As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test missufficiently restrictive to assure compliance with the standard. C. Message: To assure compliance with the positive beam limitation requirements, the test results must include data in horzontal and verifical ranges of SID's and image receptor sizes and (2) the ± 3° range of angulation relation perpendicular to the plane of the image receptor sizes and (2) the ± 3° range of angulation relation perpendicular to the plane of the image receptor. D. Message: Since the SID is used for calculating the compliance values of this requirement, the accuracy of the SID measurement must be verified. Prototype Testing: This section is for start up prior to full production phase and thus the testing and quality control procedures may not be the same as production testing. Does prototype testing apply? A. Describe the direct lest method (i.e., one that actually measures x radiation) employed in testing and measuring each model wire respect to this requirement. [Multi-Line Plain Text] B. Identify the instrument(s) used forthe test by manufacturer and model number. [HTML Text] C. Attach a sample of 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)] Explain how compliance value calculated from the raw test data? E. Attach a sample of calculated compliance values complete with an explanation of any correction factors employed. [Multi-Line Plain Text] File Attachment [Single File Attachment (.pdf., jpg., .gif., .tif., .avi., .wmv, .xpt., .xml., .dtd., .sgml., .mol., .xls, .csv, .zip)] Explain how compliance is established. [Multi-Line Plain Text] File Attachment [Single File Attachment (.	re used in be grouped clearly stated					
beam-limiting devices. B. Message: As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test mis sufficiently restrictive to assure compliance with the standard. C. Message: To assure compliance with the positive beam limitation requirements, the test results must include data for horizontal and vertical ranges of SID's and image receptor sizes and (2) the ± 3° range of angulation relative horizontal and vertical ranges of SID's and image receptor. D. Message: Since the SID is used for calculating the compliance values of this requirement, the accuracy of the SID measurement must be verified. Prototype Testing: This section is for start up prior to full production phase and thus the testing and quality control procedures may not be the same as production testing. Does prototype testing apply? A. Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model wirespect to this requirement. [Multi-Line Plain Text] B. Identify the instrument(s) used forthe test by manufacturer and model number. [HTML Text] C. Altach a sample of raw test data. [Multi-Line Plain Text] File Attachment [Single File Attachment (.pdfjpggiftifavi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xis, .csv, .zip)] Explain how compliance value calculated from the raw test data? E. Altach as ample of calculated compliance values complete with an explanation of any correction factors employed. [Multi-Line Plain Text] File Attachment [Single File Attachment (.pdfjpggiftifavi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xis, .csv, .zip)] Explain how compliance is established. [Multi-Line Plain Text] Froduction Testing: 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 an attachment (.pdfjpggiftifavi, .wmv, .xpt, .xml, .dt						
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Interesting Interest Intere	st must be					
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If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance	ip)]					
this requirement.	mpliance wit					

D.	Submit the technical dat	ta that supports the use of the test in question (C.)	
	[Multi-Line Plain Text]		
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≣.	Attach a copy of the deta	ailed instructions for performing each test.	
	[Multi-Line Plain Text]		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Identify the instrument(s	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)]	
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	[Multi-Line Plain Text]		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
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	[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 compliance	value calculated from the raw test data?	[L]
	Please attach a sa	ample of calculated compliance values complete with an explanation of any correction factors employed.	
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	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zi	p)]
xpl	ain how compliance is es	tablished.	
Mul	ti-Line Plain Text]		
	Is this performance para	ameter tested on 100 percent of the produced models?	[L]
SS	embler Testing:		
)oe:	s assembler testing apply	?	[L]
١.	Does the test involve a	direct test of the performance parameter?	[L]
3.		inployed in testing of each model with respect to this requirement. If reference is made to a test protocol by as an attachment for documentation.	
	[Multi-Line Plain Text]		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Э.	If any test used to monit this requirement.	or compliance does not actually measure x radiation, explain why it is an accurate indication of complian	ce wit

	Odbinit the technical c	data that supports the use of the test in question (C.)				
	[Multi-Line Plain Text]					
	File Attachment	[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 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 instrumen	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 wheelified.	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)]				
l.	Is the actual complian	ice 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 ne og the power cord into the wall socket.	eded to			
	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]					
File	Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]				
File Deta		[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)] [HTML Text]				
Deta	ails	[HTML Text]				
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Se	ails	[HTML Text] On Aspects				
Se 401	ection: Commo	[HTML Text] On Aspects				
Se 401	ection: Commo	[HTML Text] On Aspects	[L]			
See 401 Rad Do a Dessinstr	1.0 Instrumentation liation Measurement: any of the test protocols cribe each radiation merument is commercially a	n Aspects	if the			
See 401 Rad Do a Descinstr	1.0 Instrumentation liation Measurement: any of the test protocols cribe each radiation merument is commercially a	[HTML Text] On Aspects In 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			
See 401 Rad Do a Descinstrate	ails ction: Commo 1.0 Instrumentatio liation Measurement: any of the test protocols cribe each radiation merument is commercially a dependence; ranges; a	[HTML Text] On Aspects In a use Radiation Measuring instruments? assurement 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; and effective measurement area.	if the			
Se 401 Rad Do a Dessinstr rate File Deta	ails cetion: Common 1.0 Instrumentatio liation Measurement: any of the test protocols cribe each radiation merument is commercially a dependence; ranges; a Attachment	[HTML Text] On Aspects In a 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; and 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	t Measurement:
Do any of the test protocol	s measure Illuminance and/or Contrast? [L]
	and/or contrast measurement instrument that you refer toin Part 300, giving the following: manufacturer and model 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 u	sed 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:	
model number if the instrui commercially available inst ranges, response time, and	easurement instrument that you referred to in Part 300, giving the following:type of instrument; manufacturer and ment is commercially available; rated accuracy; precision; ranges; and response time. If anynumber of truments withcertain basic characteristics may be used, it is sufficient to state the minimum accuracy, precision, d so forth, of the class of instruments that will be used. If any instrument is unique or of special manufacture then lel 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]
	sed for calibration of each instrument including the interval of time between calibrations.
[HTML Text]	sed to calibration of each instrument including the interval of time between calibrations.
,	ent listed in the above question under Electrical Measurement is connected during testing with the use of a
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Other Measurement:	
thefollowing: type of instrui ranges. If any number of co minimum accuracy, precisi	ent instrument (other than radiation, illuminance and contrast, or electrical)that you refer to in Part 300, giving ment; manufacturer and model number if the instrument is commercially available; rated accuracy; precision; and commercially available instruments with certain basic characteristics may be used, it is sufficient to state the on ranges, and so forth, of the class of instruments that will be used. If any instrument is unique or of special on 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 u	sed for calibration of each instrument including the interval of time between calibrations.
[HTML Text]	
402.0 Sampling	

Are any performance parameters tested other than 100 percent? List each performance parameter test that is sampled.			
[HTML Text]			
Describe the sampling pla	n used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample s n the Add button below to attach files.	size,	
[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.			
(5) The acceptable (6) The lottolerand (7)Theproducer's (8) Theconsumer's (9) The operating (10) The average	te (n) bl number (c) uble sampling plan (S or D) e quality level (AQL) ce percent defective (LTPD) risk		
Describe the procedure us	sed 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]			
corre mak	have reached the end of this report. Please verify that all PDFs that are to be included in this submission are ectly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Cle sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirme is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.	neck to	
wessage:	n FDA 3626 A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major opponents (03/06)		
Document Key: Specialized	Response content is defined within straight brackets []; Special code: [L] List of Values.		