Section: eRadHealth Menu

Introduction

Electronic Product Radiation Safety Reporting Form

This software application is intended to automate the hard copy product reporting forms in the effort of the Center for Devices and Radiological Health (CDRH) to become capable of accepting electronic submissions from industry and to improve our review process. This FDA Electronic Submission (eSub) software is the next version of the application developed to allow us to accept all Radiological Health reports and other submissions electronically and improve the ability of CDRH to accomplish its mandated product and industry evaluations in a timely and efficient manner.

All electronic reports and correspondence can either be transferred to CD and mailed to the address below, or can be sent via the FDA Electronic Submissions Gateway to CDRH. If you follow instructions to set up an account with the FDA Gateway, it currently may take several weeks,, but when you submit through it you will receive your acknowledgement email message with Accession Number within minutes! Or, in the interest of faster turn-around for a one-time urgent report of if you submit few reports, you may simply fill out this template creating the submission and then at 'Packaging' follow the instructions to transfer the files to a CD to mail in. This method of submitting your report will be acknowledged by an email with the Accession Number within several days.

Information about the FDA Electronic Submissions Gateway can be found at **www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm**. Please contact the Gateway Helpdesk with your questions about that system.

Electronic submissions on CD should be mailed directly to the Document Control Center at:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Attn: eSubmitter Team
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submissions received in the mail on CD will be processed within a few days of receipt.

Note about eSubmitter software:

Instructions provided in this software briefly summarize the requirements of the regulations under the Federal Food, Drug and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product Radiation Control, that applies to manufacturers of electronic products that emit radiation. The software provides questions relevant to requirements in the performance standards and may include explanations or clarification about the performance, labeling, and informational requirements of the standard. It does not replace the regulations, however, and if there is any conflict between the software and the regulations, the regulations must prevail. Throughout this application, pertinent sections of Title 21, Code of Federal Regulations, Chapter I, Subchapter J, are cited in parentheses. Please consult them before making design or procedural decisions.

Regulatory requirements for radiological products can be found at **http://www.fda.gov/Radiation-EmittingProducts/default.htm** and for medical devices are located at **www.fda.gov/M/devaDvices/default.htm**. If you have specific questions about the regulations, please contact us at: **DSMICA@fda.hhs.gov**.

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

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

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

Definitions

Definitions for Rad Health Products

Manufacturers

Manufacturer is any person or organization engaged in the business of manufacturing, assembling, or importing of electronic products (21 CFR1000.3(n)). Manufacturers of electronic products subject to 21CFR1000-1050 must:

- Design and manufacture their products to be in compliance with applicable performance standards;
- Test their products to assure compliance;
- Certify compliance of their products;
- Maintain test and distribution records and a file of correspondence concerning radiation safety, safety complaints, and inquiries;
- Use the published reporting forms or electronic software application to submit reports to CDRH, including Product reports describing the manner of compliance of the product design and testing program and Annual Reports summarizing their compliance testing;
- Report accidental radiation occurrences (i.e., possible, suspected,or known exposures);
- Report any radiation defects or noncompliances; and
- Recall (i.e., repair, replace, or refund the purchase price of) defective or noncompliant products.

Importers

Importer is any person of organization engaged in the business of importing electronic products. An importer is considered to be a manufacturer. The requirements for Manufacturers given above also apply to importers if the requirements have not been done by the foreign manufacturer.

United States Agent for Foreign Manufacturers

Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer`s agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 536(d) of the Radiation Control for Health and Safety Act of 1968 (21U.S.C. 360mm(d)) and this section. The agent maybe an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

From The Federal Food, Drug, and Cosmetic ActSec 536 [21 U.S.C. 360mm](d) Designation of agent for purposes of service

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It shall be the duty of every manufacturer offering an electronic product for importation into the United States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this part or any standards prescribed pursuant to this part may be made by posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

Sec. 531 [21 U.S.C. 360hh] (1) the term **''electronic product radiation''**means:
(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or
(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.
Sec. 531 [21 U.S.C. 360hh](2) the term **''electronic product''**means:
(A) any manufactured or assembled product which, when in operation,(i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or
(B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effect

Role

What is your role?	[L]
Note:	If you are acting as an agent of the actual manufacturer, please select your role as, for example, perhaps an Importer or Consultant. Later in the report, under Manufacturer Data, you will be prompted to enter both manufacturer and submitter information.

Information:	The following screen provides several options for you to accurately define what type of eSubmission you intend to create for FDA. Below are explanations of your options. Please feel free to review this screen, advance to the next screen and view the picklists, but if you're confused, come back to read this screen again to be certain you are selecting the correct report or correspondence type you want to create.

Submission Information

Use the radio buttons to identify the type of submission you are preparing. (Supplements should be prepared using the same document type as the original submission.) [QUESTION TYPE NOT YET IMPLEMENTED: HEADER STEP]	
What Type of Submission is this? (Supplements should be submitted selecting the same document type as the original report.)	( ) Radiation Safety Report (Product) Report (21 CFR 1002.10) ( ) Annual Report (21 CFR 1002.13) ( ) Laser Light Show Documents (all relevant documents) (21 CFR 1040.11(c)) ( ) Correspondence ( ) Variance Request (General, not Laser Light Show) (21 CFR 1010.4)

	( ) Laser Original Equipment/Component Manufacturer Registration (21 CFR 1040.10(a)(3)(ii)) ( ) Abbreviated Report (21 CFR 1002.12)

After answering the Submission Type question above, one of the questions below may become active and required (see the blue dot to the right of the question). If there is an active question, select the appropriate product area or document type from the question's pick list. [QUESTION TYPE NOT YET IMPLEMENTED: HEADER STEP]
What Type of Product is this Radiation Safety Report about?
[L]
What Type of Product is this Annual Report about?
[L]
What Laser Light Show Document are you filing?
[L]
What Type of Correspondence is this?
[L]
What Type of Product is this Variance Request about?
[L]

FDA or State Inspector

Abbreviated Report Applicability

OEM Laser Applicability

Section: Manufacturer Data

General Information

General Information for Radiological Health Products

Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product Radiation Control are required to furnish various reports to the Center for Devices and Radiological Health (CDRH).

The Radiological Health staff, CDRH developed this software application for the Product and Annual reports. This application will assist manufacturers of electronic products that emit radiation in providing adequate reporting of radiation safety testing and compliance with federal performance standards. Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 specify Reporting and Notification requirements 1,2,3.

Reports submitted on radiation safety of electronic products must follow the appropriate form (21 CFR 1002.7). This software application serves the same report responsibility, so long as the submitter or manufacturer prints out the cover letter and sends it in along with the CD containing the report files. The submitter of the report will receive an acknowledgment letter (or email message) with the accession number that CDRH assigns to the report. Please reference this accession number in the future when providing

additional information about this model family in either a supplement or the annual report. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database.

CDRH DOES NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with all applicable standards (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. Prior to the shipment of products in interstate commerce, 21 CFR 1002 requires the manufacturer to submit the product and Annual Reports and to comply with all applicable importation requirements (21CFR 1005). If there are deficiencies, CDRH may disapprove the firm's quality control and testing program, determine that the product contains a radiation defect, or determine that the product fails to comply with a standard. CDRH will notify the manufacturer if we make such a determination. CDRH may require the manufacturer to cease introduction into U.S. commerce until deficiencies are corrected, and to initiate a corrective action program (21CFR 1003 - 1004) for products already introduced into commerce.

CDRH can now accept and process 'CeSub' electronic submissions at this time, if all attachments are PDF files only, and the cover letter is printed out and included with a real signature. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy (save a copy to your hard drive) of the completed report in your records.

Regulatory information is available on the Internet under **www.fda.gov/Radiation-EmittingProducts/default.htm**. No copyright exists for these forms.

Reproduce these forms as needed. If you would like to comment on the reporting forms, website, or future electronic submissions, you may direct the comments to **cdrhesub@cdrh.fda.gov**.

A complete Product Report is required for each product model or model family. Product Reports are now more generally referred to as Radiation Safety Reports to distinguish the Radiological Health submissions from medical device submissions. CDRH suggests that a complete report on one model of a family be submitted, with a separate Supplemental Report for each of the other models in the family. The Supplemental Report should respond in detail to the parts of the form where there are differences to report, referencing the number of the affected item. Items that are unchanged will still appear in the supplement from the original report.

When new models of a product are introduced, if the models satisfy the criteria for an established reporting exemption or if the new models do not involve changes in radiation emission or performance requirements, then the manufacturer need not report the models prior to introduction into commerce. Rather, the manufacturer is only required to identify them in the annual report, or in quarterly updates to the annual report. Quarterly updates to annual reports may be submitted using the Annual Report software included in this application. [See 21 CFR 1002.13(c).]

All symbols, units, and unusual terms in the report must be adequately defined and consistently used. Please use the terms as defined in Section 1040.10(b) and in the IEEE Standard Dictionary of Electrical and Electronic Terms (IEEE Std. 1001972 and ANSI C42.1001972).

Burden to Industry

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing, and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

Manufacturer and Report Information

Confirmation:	This Manufacturer section of this report requests names, addresses, phone numbers, etc. for your firm, various officials of your firm, consultants who may assist in preparing the report, parent firm (if any), importer and designated agent (for foreign firms). Some of this information is mandatory and its absence will prevent you from completing the report submission. Because some of these entries may be redundant, utilize the 'Contact Address Book' feature so you can save your data and reselect the entries later and in the future. (See the upload/download buttons in upper right corner of the screens). You can check for missing data at any time using the "Missing Data Report" from the "Output" menu across the top of this application. The Missing Data Report lists all missing responses that are required (that have the blue dot).

Information:	Attention: Variance Applicants If you are acting as an agent or consultant for, or on behalf of, or filing for, a company that will be manufacturing or producing a Class IIIb or IV projector or laser light show or both which require an approved variance, the following explanations may provide further clarification. Manufacturer: This is the firm or company who is requesting the variance, will certify the product or show, and will be the holder and owner of the variance. This is not the agent or consultant who may be filing this report or Variance request for the manufacturer; that agent may be the submitter, identified in a later screen. Responsible Individual: This person works for the Manufacturer and is responsible for compliance of the projector and/or show. In the case of laser light shows, he or she may be the company president, CEO, or the laser light show head operator or a manager who oversees the shows. Reporting Official: This person works for the Manufacturer and is responsible for reports, recordkeeping, and submitting FDA required documents and correspondence.

Manufacturer Responsible for Product Compliance

Note:	This is the firm that takes responsibility for certification that the product meets the performance standard. This firm develops and maintains the quality control and testing program that is the basis for the certification of this product. Additionally, this firm usually is the owner of the product design and manufacturing process design. Be sure to enter address information for each tab below:

Select the Manufacturer's address from the Establishment Address book: [QUESTION TYPE NOT YET IMPLEMENTED: ESTABLISHMENT COMPLEX]

Responsible Individual

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

Select the Responsible Individual from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

Manufacturer's Reporting Official

Note:	This is the person at the manufacturing facility that is knowledgeable and responsible for addressing all aspects of the testing and quality control procedures for certification as reported to FDA in the product report. Documentation of changes intesting and quality control procedures submitted to FDA must be signed by this individual.
Select the Reporting Official from Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]	

Report Submitter

Note:	The submitter may be a consulting individual or firm providing assistance in report preparation and maintenance. Documents or submissions such as this one that are prepared by the submitter must have an accompanying authorization letter from the manufacturer's reporting official for authenticity.
Select the Submitter from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]	
Internal Reference Number:	

Parent Establishment

Is there a parent establishment?	[L]

Select the Parent Establishment and Contact from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

Manufacturer Designated United States Agent

Note:	Manufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.

Is there a United States agent that has been designated by the manufacturer?	[L]

Written Agreement

Item: 1 (could contain up to 10 items with none required)

Note:	The manufacturer who is certifying the product being reported is the manufacturer of record. If this firm is not in the United States, please identify your current Importer(s).

Note:	If any of the required responses below do not apply to your designated agent, enter 'NOT APPLICABLE' or 'NA.'
Select the Designated Agent from the Contact Address book:	
Contact Name	
Occupation Title	

Email Address	
Establishment Name	
Division Name	
Address	
Telephone Number	
Fax Number	
Attach a copy of written agreement with the designated U.S. agent:	
[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Importer

Item: 1 (could contain up to 10 items with none required)

Select the Importer from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

Additional Manufacturing Locations

Item: 1 (could contain up to 100 items with none required)

Note:	If any of the products certified in this report are manufactured at locations other than listed in the Manufacturer Responsiblefor Product Compliance section, then the names, addresses, and FDA registration numbers should be provided. In addition any codes used on labels to identify a manufacturing location must be provided. Each factory location must assure all production procedures are followed identically step by step as provided in this report.If the procedures are not the same then separate reports should be filed.
Select the Manufacturer Address from the Establishment Address book: [QUESTION TYPE NOT YET IMPLEMENTED: ESTABLISHMENT COMPLEX]	
Code used on identification labels:	

Section: Product Data

Product and Model Identification

Attention - Information about this section

In this section you'll be asked to identify several required or optional things which will help FDA/CDRH staff to prioritize their reviews. You'll be asked to consider the following aspects:

(1) Identify your product's radiation type and the CDRH Product Code.

(2) Enter an Accession number if this will be a report supplment. If you are preparing a supplement, you'll see that after entering a valid 7-digit Accession number many questions will no longer be required (they will either be disabled or will be optional, meaning they will no longer have the blue dot).

(3) You will also have several questions that are of high significance for FDA/CDRH - why you might be submitting this report or

correspondence. Please read these questions carefully, referring to the 21 CFR regulations on the website www.FDA.gov if you are unsure if the question is relevant to your firm's situation.
(4) If you find that you have more information that you want the FDA/CDRH to read but it doesn't seem to fit under other questions, we have a final "***Additional Information***" question in this section which invites you to add comments and/or attach a file that provides further information from your firm about this submission. This is the place to add that extra information.

Product Type Reported

Note:	Each product that CDRH regulates is assigned a product code by CDRH.

What is the product code?

To select the three letter product code,

- Click the plus sign. You will see a product code filter dialog box.
- Select the appropriate category name from the pick list. You will be provided a list of product codes from which to choose.
- Select the best match to your product.
- The remaining fields will be filled in for you when you select your product code. [QUESTION TYPE NOT YET IMPLEMENTED: RH SINGLE PRODUCT CODE]

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

Examples of X-Ray Products

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

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

Report Information

Is this the first time you've submitted a report on the particular type of product selected in the Product Type Reported section?	[L]
Since this is not the first time you've reported on this type of product, then is this a report supplement to a previously reported model family?	[L]
Provide the Accession Number of the original report for which this is a supplement: (Note: Do not enter any Device Premarket Application or Notification document number here, such as PMAs, 510(k)s, IDEs, etc. See Accession number description below.)	

Are you requesting a new variance, a renewal, extension or amendment to a previous variance?	[L]

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If you are requesting a renewal, extension, or amendment, please provide the variance number that was issued by CDRH.	
Stop:	If you are requesting a new variance, renewal, extension, or amendment, you must file a Variance Request separate from this report. To do this, open a new report (File > New) and select either "Laser Light Show Variance Request" or "Variance Request (General, not Laser Light Show)" as your Type of Submission in the Submission Information Screen. If you select "Variance Request (General, not Laser Light Show)r" you must select the product for which you are requesting a variance with the pick list in the bottom section of the screen.

Special Considerations

Note:	Check all items in this section that may apply to this submission.

Information:	If this product will require a formally approved Variance from a certain performance requirement, you will need to complete two Reports for FDA, both (1) this Radiation Safety Report (RSR) on this product, and (2) a Variance Request report. This eSubmitter software application package includes a general Variance Request form as well as the specific Laser Light Show Variance Request form. Both the Product RSR file and the appropriate Variance Request Correspondence file must be submitted to CDRH following the regular files packaging procedures in this application. Both may be transferred to the same CD or submitted via the FDA ESG to submit to the FDA/CDRH. In addition, any Variance Request form must be printed out and the signed hard-copy sent to FDA's Division of Dockets Management at: Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane Rockville, MD 20852 NOTE: There is no need to send a copy of the CD to Division of Dockets Management.

Noncompliances or Defects

Does this document or any of its attachments contain:	
A notification of noncompliance or defect?	[L]
You may provide an explanation and/or attach a document here:	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Responses to Noncompliances or Defects

Does this document or any of its attachments contain any of these responses concerning noncompliances or defects?	
A refutation of noncompliances or defects identified to your firm?	[L]
A request for an exemption from notification to purchasers (see 21 CFR 1003.21 and 1003.30)?	[L]
Corrective action plans you intend to implement to correct noncompliances or defects discovered in past or current production?	[L]

Note:	If you are submitting a Corrective Action Plan (CAP) following 21 CFR 1004 and information on design changes for future production, the design change information must be submitted in a Radiation Safety (Product) Report or supplemental report. Both the proposed CAP and the design changes may be submitted in one document if you prepare a product report and choose to include the CAP in it as a file attachment. Alternatively, you may create a separate eSubmission for the CAP using the "Correspondence" type template and selecting "Follow-up correspondence to FDA."

A description of any design changes that correct noncompliances for future production?	[L]

Note:	If you are submitting information on product design changes for future production due to a discovery of noncompliances or defects in current production, you must use the Radiation Safety (Product) Report template to create the report . Correspondence templates may be used to submit other information such as a proposed corrective action plan pertaining to a noncompliance or defect.

You may add an explanation and/or attach a document here:	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Exemption Requests

Does this document or any of its attachments contain:	
Exemption of a product for government use from a standard (21 CFR 1010.5)?	[L]
Exemption for products for government use from reporting and recordkeeping (21 CFR 1002.51)?	[L]
Special exemption of products from reporting and/or recordkeeping (21 CFR 1002.50)?	[L]
Request for approval of alternate labeling?	[L]
Application for alternate test procedures (21 CFR 1010.13)?	[L]
You may provide an explanation and/or attach any relevant documents here:	
[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Variance Requests

Information:	Please note: in addition to responding to these questions below, a separate General Variance Request or Laser Light Show Variance Request form must be completed and submitted to CDRH, with a hard copy sent to FDA's Division of Dockets Management as instructed below for any variance request. The information requested on this screen does not constitute the full structured content of the variance request. The 2 types of Variance forms can be created in eSubmitter by selecting the appropriate Variance submission type under the eRad Health Menu section of this application.
Message:	Click the plus sign to list the requirements from which you are requesting a variance.

This submission includes an application for a variance from certain requirements.	
Item 1	
Item 2	
Item 3	
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	

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Details	[HTML Text]
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Stop:	For all Variance requests, two submissions must be made to the FDA. The electronic version should be submitted following the Packaging Files for Submission instructions located under Output in the Menu bar, and explained in subsection 4.3 of the User Manual. If sending a CD & submittal letter, please mail to: U.S. Food and Drug Administration Center for Devices and Radiological Health Attn: eSubmitter Team Document Mail Center - WO66-0609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002 Additionally, a paper version (hard-copy) of the signed Variance request document should be submitted to: Food and Drug Administration Division of Dockets Management (HFA-305) 5630 Fishers Lane, Room 1061 Rockville, MD 20857

Responses to Communications from FDA

Does this document or any of its attachments contain:	
A response to an FDA inspection?	[L]
What was the date of the inspection?	[Date]
A response to a Warning letter or a Notification of Noncompliance or Defect from the FDA?	[L]
What was the date of the Warning Letter or other notification letter?	[Date]
A response to a report review inquiry from the CDRH (the inquiry may have been in the form of a letter, email, or phone call)?	[L]
What was the date of the inquiry?	[Date]
A response to any other communication from FDA?	[L]
What was the date of the communication?	[Date]
Provide an explanation:	
[Multi-Line Plain Text]	

Additional Information

Here's your opportunity to add anything else to this submission that you want to tell the FDA! Is there any other relevant information or additional comments that would help expedite the review of this submission? Click the plus sign below to attach any supporting files.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv,

	.zip)]
Details	[HTML Text]

Private Labeling

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

Private Labeling-Table

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

Give the name and address of the manufacturer:	
Establishment Name	
Division Name	
Email Address	
Address	
Telephone Number	
Fax Number	
Give the firm establishment registration number of the manufacturer listed above (if known):	

Enter brand names and/or model designations in the following table by clicking on the Add button. If you prefer to attach a file, please click on the Add button and enter the text "See File Attachment" as the first table entry.	
Item 1	
Item 2	
Item 3	
List of Brand Names and/or Model Designations	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

The Original Equipment Manufacturer (OEM) accession number (if known):	

Explain how the brand names and model designations correspond with your own brand names and model designations:
[Multi-Line Plain Text]

Medical Devices

Provide the premarket 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one of these numbers has been assigned by FDA yet.
[Multi-Line Plain Text]

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If it has not been submitted yet, or if your device is exempt from premarket clearance or approval, please provide an explanation. The device regulations can be found in 21 CFR 807 - device manufacturer registration and device listing.
[Multi-Line Plain Text]

Note:	See also http://www.fda.gov/MedicalDevices/default.htm for more information on medical device premarket clearance procedures.

Section: 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. Eachtime 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 certifiedcomponents 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 certifed 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 orcoordinated 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 abovean 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 cumulativeair 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 ofrotations 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 maximumin 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 linepotential; that is,Percent line-voltage regulation = 100(Vn -Vi)/Viwhere:Vn = No-load line potential andVi = 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 productionof 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 tothe 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 ofan 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, electricalprotective 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 in1020.30, 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			
Item 1		Item 2	

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 DESIGNATION

3626 Diagnostic X-Ray Product Rpt (OMB 0910-0025)

Item: 1 (could contain up to 500 items with 1 required)

Component Type:	[L]
Model Designation:	

2.5 INDIVISIBLE COMBINATION OF COMPONENTS

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.

Do you combine components under a single certification label pursuant to 21 CFR 1020.30(c)?	[L]

2.5.1 COMBINATION OF COMPONENTS

Item: 1 (could contain up to 10 items with none required)

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.

Certifiable Combination:	
[L]	
Model Designation:	

2.6 OTHER NAMES OR LABELS

Are any of the models you manufacture reported in 2.4 and/or 2.5 sold under name(s) other than the certifying manufacturer?	[L]

2.6.1 Names or Labels

Item: 1 (could contain up to 10 items with none required)

Component Type?	[L]
Model Designation:	
Other Company Under Whose Name The Model Is Sold?	

Model Name Sold Under Other Company?

2.7 LABEL DESCRIPTION

Note:	For every model listed under 2.4, 2.5 and 2.6, provide an exact replica of all labels filled out as they would be when introduced into commerce. Attach copies of the labels and the requested information. The label should include the following as applicable:

1. The certification statement
2. The name and address of the manufacturer (or the individual or company under whose name it is sold)
3. The date and place of manufacture. If the place of manufacturer is not the address in item 2 above, then the code used on the label to identify the location of manufacture as listed under 1.8
4. The model designation and sample serial number
5. The manufacturer, model designation and sample serial number of the tube insert if applicable
6. In addition, the standard requires that the labels be permanently affixed, legible, and accessible to view when the product is fully assembled for use. Provide a drawing or photograph of each certifiable component and/or combination showing where the attached label is located.

Attach a file that contains a replica of labels for every model listed under 2.4, 2.5 and 2.6. Click on the plus sign below to attach files.	
[HTML Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

2.8 Part 1: COMPLETE SYSTEMS AND SUBSYSTEMS

Are there components certified by this report marketed by you as a system or subsystem of components?	[L]

2.8 PART 2: COMPLETE SYSTEMS AND SUBSYSTEMS

Item: 1 (could contain up to 20 items with none required)

System or Subsystem Designation:	
Component Type:	
Item 1	
Item 2	
Item 3	

Model Designation:	
Manufacturer:	
Item 1	
Item 2	
Item 3	
Accession Number:	
Item 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 Specifications referenced in 21 CFR 1020.30 (g) as a separate file.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Are there assembly and testing instructions necessary at the installation site for assuring compliance to the federal standards?	[L]
Attach Assembly and Testing Instructions necessary for assuring compliance to the Performance Standard as a separate file.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Note:	If no acts by the assembler will cause failure to comply with the federal standards and all that is necessary is to plug the system in to an adequate power socket, then theuser manual should specify that no assembly instructions or testing is necessary for compliant use of the equipment other than proper power connection. As such no assembly manual will be needed.

2.10 USER INFORMATION

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

(a.) Operating Instructions

(b.) Maintenance Schedule

(c.) Picture or drawing of product

(d.) Product Specifications and Tolerances

(e.) Cautionary Statements for 21 CFR 1020.32(a)(1) and (f) if applicable

(f.) Leakage Technique Factors and Tube Rating Charts if applicable	
Attach for each model, system or subsystem (as appropriate) the above information in a separate file. Click on the plus sign below to attach any supporting files.	
[HTML Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

2.11 ADDITIONAL INFORMATION

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

2.11.1 BEAM LIMITING DEVICE (BLD)

Note:	Answer the questions in 2.11.1 if certifying a beam-limiting device in this submission.	
Is this report intended for the certification of a beam limiting device (either seperately or in combination)?		[L]

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 in this submission.	
Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?		[L]

Use and Type

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

Model Designation:	

Max kVP:	
Indicate the type of generator.	[L]
If you selected Other, specify type:	

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 Designation:	
Max kVP:	
Select all uses for which each model family is intended.	
Item 1	
Item 2	
Item 3	
If you selected Other, specify use:	
For Fluoroscopic Controls, is there a high-level 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.

Click on the plus sign below to attach the appropriate files.
[HTML Text]

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

Section: Component Description

201.0 TUBE HOUSING ASSEMBLY

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 report intended for the certification of a tube housing assembly or combination containing a tube housing assembly?	[L]

201.1 Tube Housing Assembly Information

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

Model Designation:	
List the Max kVp:	

Are any of the models intended for use on a general purpose x-ray system?	[L]
For each model intended for use on a general purpose x-ray system, cite the specific paragraph(s) in your instructions to assemblers that lists compatible tube stands, beam limiting devices, and/or other equipment necessary for indication (as required under 21 CFR1020.31(e)(1), (h)(2), and 1020.32(b)(1)(ii), (b)(2)(iii)).	

File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	
Also specify where to find information addressing the perpendicularity of the beam axis to the image receptor, and information on the SID indicator.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	
Do you reload tube housing assemblies?	[L]
Describe how you remove, deface, or cover the original labels on the assembly and replace them with your own labels (including re-certification label).	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	

202.0 BEAM-LIMITING DEVICES

Note:	This section should be completed for each beam-limiting device listed in section 2.4 and any combination listed in section 2.5 that contains a beam-limiting device as an integral part thereof. If this report is not certifying a beam limiting device then go to section 203.0

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Is this report intended for the certification of a beam limiting device or combination containing a beam limiting device?	[L]

Is the beam limiting device designed for intraoral dental?	[L]

202.1 Dental BLD (intraoral)

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

Model Designation:		
Note:	If you do not see the appropriate model indicated, please go to question 2.4 MODEL DESIGNATION to enter the model as it appears on the identification label.	
Minimum source-to-skin distance (SSD) in cm:		
Geometric configuration of x-ray field is:		[L]
X-ray field size dimensions at minimum SSD: (__ cm x __ cm)		

202.2 Part 1: General Purpose Radiographic BLD

General Purpose Radiographic BLD - mobile and stationary (excluding mammographic, spot-film devices, and dental units)	
Is the BLD designed for general purpose radiography?	[L]

Are any beam-limiting device(s) equipped with a light localizer?	[L]

202.2 Part 2: General Purpose Radiographic BLD

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

General Purpose Radiographic BLD - mobile and stationary (excluding mammographic, spot-film devices, and dental units)		
Model Designation:		
What is the minimum source to skin distance (SSD) in cm?		
What is the minimum x-ray field size at 100 centimeters SID (or maximum SID if less than 100 cm):		
Is the adjustment for the size of the x-ray field stepless?		[L]
Is the beam-limiting device(s) equipped with a light localizer?		[L]

202.3 Part 1: Stationary General Purpose Radiographic

Are any model BLDs designed as a Stationary General Purpose Radiographic BLD?	[L]
Are any of the reported BLD models you are certifing designed for positive beam limitation (PBL)?	[L]

202.3 Part 2: Stationary General Purpose Radiographic BLD

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

Model Designation:	
Are means provided to indicate when the beam axis (both vertical and horizontal) is perpendicular to the plane of the image receptor?	[L]
Describe the means to indicate when the beam axis is perpendicular to the plane of the image receptor?	
[Multi-Line Plain Text]	

What is the designed minimum SID? (either cm or in)	
Describe the means provided to indicate each design SID:	
[HTML Text]	

Provide a drawing or picture of the indicator on the beam-limiting device that shows 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 SID PBL operating range? (either cm or in)	
What is the verticle SID PBL operating range? (either cm or in)	

Does the PBL operate throughout the range listed above continuously or in discrete steps or positions?	[L]
Provide a copy of the circuit diagram and interlock mechanism that prevents the production of x rays when the PBL system is positioned at SID's at which it is not designed to operate and/or 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]	

Is the PBL cassette tray designed for only certain cassette sizes?	[L]
Provide a copy of the circuit diagram and interlock mechanism that prevents the production 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 cassette sizes as labeled on the cassette along withthe model 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 circuit diagram and interlock mechanism that prevents the production 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 receptor?	[L]

When the PBL x-ray field is adjusted to dimensions smaller than the image receptor, does full coverage occur when either the image receptor or SID is changed?	[L]
State how the beam-limiting device returns to positive beam limitation upon a change in image receptor or SID:	
[HTML Text]	

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 override?	[L]
Describe each service switch and/or capture key override available with the PBL system.	
[HTML Text]	
Attach a drawing or picture showing the location of each PBL override switch.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	
Provide circuit diagrams and description of function for each PBL bypass and override circuit.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	

202.4 Part 1: Beam Limiting Device used with Spot Film

Is the beam-limiting device designed to be used with Spot Film Radiography or Digital Spot Recording?	[L]

202.4 Part 2: Beam Limiting Device used with Spot Film

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

Beam-Limiting Device Used with Spot Film Radiography or Digital Spot recording (excluding therapy simulators).	
Model Designation:	
Describe how reduction of the x-ray field is accomplished when the fluoroscopic x-ray field is larger than the recorded selected portion of the image receptor.	
[Multi-Line Plain Text]	
Describe how the enlargement of the x-ray field is accomplished when the fluoroscopic x-ray field is smaller than the selected portion of the image receptor.	
[HTML Text]	
Describe the means available to adjust the x-rayfield to a size smaller than the selected portion of the image receptor.	
[HTML Text]	
List the applicable image receptor sizes (for film use as labeled on the cassette) and the available formats. For example, size: ___ cm x ___ cm and format: 4 on 1	
Item 1	
Item 2	
Item 3	
What is the minimum x-ray field at the greatest SID for tube housings for which the beam-limiting device is designed? (__cm x __cm)	
Provide a drawing or picture of the location of the beam limiting device with respect to the patient and the image receptor when it is assembled in a fluoroscopic system.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	
Are means provided for system failure override?	[L]
Describe each service switch and/or capture key:	
[HTML Text]	
Describe the label advising 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 indication 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 fluoroscopy use?	[L]

Are any of the beam-limiting device(s) designed for use in image-intensified fluoroscopy, other than radiation therapy simulation?	[L]

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202.5 Part 2: Beam Limiting Device used for Fluoroscopy

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

Model Designation:	
Which of the following is the geometric configuration of x-ray field:	[L]
If you chose "other" for the 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-ray 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 nonimage intensified fluoroscopy?	[L]
Describe the means for limiting 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 spacer?	[L]
What is the minimum SSD with spacer removed? (cm)	

Are means provided for system failure override?	[L]
Describe each service switch 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]
Describe the visual indication 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 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 field?	[L]
Are any of the beam-limiting devices designed for fixed SID/image receptor size?	[L]

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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 or in):	
The image receptor size in both (in x in) as well as (cm x cm):	
Describe the means for limiting and/or centering the x-ray field.	
[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:	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	
Is the image receptor support device changed when the image receptor is changed?	[L]
Is there an interlock to assure proper image receptor selection with properaperture BLD?	[L]

202.8 Part 1: Other Radiographic X-Ray Systems

Is the BLD designed for other radiographic systems?	[L]

Does the beam-limiting device have a light field that defines the perimeter of the x-ray field?	[L]
Does the x-ray field extend beyond the edge of the image receptor?	[L]

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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:	
Describe the means for limiting 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 and field size at that SID.	
SID (either cm or in):	
Field Size (either cm x cm or in x in):	

202.9 Part 1: Variable Filtration

Does the beam-limiting device have variable filtration selection?	[L]

202.9 Part 2: Variable Filtration

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

Model Designation:	
Describe the means of assuring 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 Storage 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 designed 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?	[L]

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?	[L]

203.3 Part 2: Radiography

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

Model Designation:	
The type of kV display:	[L]

The type of mA display:	[L]
The type of Time display:	[L]
The type of mAs display:	[L]
Attach the range of the markings on the technique factor indicators.	
Details	[Multi-Line Plain Text]
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Attach a drawing or 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, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Attach a drawing or picture that illustrates the proximity of any exposure switch to the preindicated technique factors.	
Details	[Multi-Line Plain Text]
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Attach a drawing or 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, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Attach a description of the 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:	"Satellite" or "remote stations" are certifiable componentsand must comply with all applicable requirements pertaining to x-ray controls.
For each accuracy specification, state the applicable criteria that defines the technique factors, e.g., thebeginand end points of exposure time could be defined with respect to a certain percentage of the voltage waveform.	
Details	[Multi-Line Plain Text]
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Are two or more tube housing assemblies controlled by the same radiographicexposure switch?	[L]
Describe the pre-exposure tube selection indicator on the control panel and the provisions for indication on the diagnostic source assemblies.	
[Multi-Line Plain Text]	
Describe the control device(s)for initiating and terminating x-ray production. Include each method by which x-ray exposure is terminated (e.g., preset time, mAs, pulses, limit switches, or exposure to the image receptor).	
[Multi-Line Plain Text]	
Describe the method by which the operator can terminate an exposure or series of exposures that last longer than one-half second.	
[Multi-Line Plain Text]	
Describe the method by which termination of the exposure causes automatic resetting of thetimer to its initial setting or to zero.	

[Multi-Line Plain Text]	
Is a "zero" or "off" position provided?	[L]
Is x-ray production prevented when the timer is set to either position?	[L]
Does the x-ray control incorporate an automatic exposure control?	[L]
Provide a drawing or picture of (1) the indicator for automatic exposure control selection and (2) the visible signal that indicates when an exposure has been terminated by the backup safety device.	
[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
If the exposure has been terminated by the backup safety device during automatic exposure control operation, describe the manual resetting procedures.	
[Multi-Line Plain Text]	

203.4 Part 1: Fluoroscopy

Fluoroscopy (x-ray controls used for generating x-ray images instantaneously and continuously to display dynamic procedures)	
Is the x-ray control designed to operate in the fluoroscopic mode?	[L]

203.4 Part 2: Fluoroscopy

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

Model Designation:	
For each fluoroscopic exposure switch, describe the method employed to prevent the production of x rays when the primary protective barrier is not in position to intercept the entire useful beam.	
[Multi-Line Plain Text]	
Note:	Therapy simulator systems with remote control are exempt from this requirement.
Describe each control device (e.g., normal fluoroscopy, cine, and test mode) for initiating and maintaining fluoroscopic x-ray production.	
[Multi-Line Plain Text]	
How many minutes is the maximum cumulative on-time prior to an audible signal?	
Can this time interval be preset?	[L]
Give the range limit in minutes.	
For each fluoroscopic control device, describe the method of providing an audible signal that indicates to the fluoroscopist x-ray production beyond the completion of any preset cumulative on-time.	
[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 patient irradiation time?	[L]
Is there an active display of patient irradiation exposure rate or air kerma rate (AKR)?	[L]

Explain how this is computed 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 patient irradiation exposure or air kerma?	[L]
Explain how this is computed 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 controlpanel, provide a drawing or picture of the indicators that allow continuous monitoring of kVp and mA during fluoroscopy.	
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 manual and/or automatic exposure rate control mode that initiates exposure without the permanent recording of fluoroscopic images, state the respective maximum values of fluoroscopic entrance AKR limited by your specifications. (either mGy/min or mR/min)	
Details	[Multi-Line Plain Text]
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Does this model have high level control?	[L]
For each manual and/or automatic 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, describe the continuous audible signal that indicates to the fluoroscopist that the high-level control is being 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)]
For each high-level control mode that initiates exposure without the permanent recording of fluoroscopic entrance AKR limited by your specifications. (mG/min OR mR/min)	
[Multi-Line Plain Text]	
Describe the method by which the fluoroscopist can initiate and/or terminate the recording of fluoroscopic images.	
[Multi-Line Plain Text]	

204.0 HIGH VOLTAGE GENERATORS

Note:	This item should be completed for each high-voltage generator listed in section 2.4 and any combination listed in section 2.5 that contains a high-voltage generator as an integral part thereof. If this report is not certifying a high-voltage generator then go to section 205.0
Is this report intended for the certification of an x-ray high-voltage generator of combination containing an x-ray high-voltage generator?	[L]

Do any model high-voltage generators contain a thermionic diode valve?	[L]
List each model that has a thermionic diode.	
Item 1	
Item 2	
Item 3	

205.0 SPOT FILM DEVICES AND IMAGE INTENSIFIERS

Note:	This section should be completed for each conventional spot-film device and image intensifier listed in section 2.4 and any combination listed in section 2.5 that contains such components as an integral part thereof. If this report is not certifying a spot film device or image intensifier then go to section 206.0
Is this report intended for the certification fo a spot film device or combination containing a spot film device?	[L]

205.1 Spot Film Device

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

Model spot film device:	
Note:	If you do not see the appropriate model indicated, please go to question 2.4 MODEL DESIGNATION to enter the model as it appears on the identification label.
Is the spot film device designed for mobile fluoroscopic systems?	[L]
Is the spot film device designed for image intensified systems?	[L]
For each model spot-film device and image intensifier, describe the means to prevent the fluoroscopic tube from producing x radiation whenever the primary protective barrier is not in position to intercept the entire useful beam. If there is an interlock, describe its electrical and mechanical characteristics and provide circuit diagrams.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

205.2 Technique Factor Adjustment

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

Model Designation:	
Does the spot-film device or image intensifier permit or control technique factor adjustment?	[L]
Message:	If "Yes" has been selected above, the following note applies:
Note:	Since the spot-film device or image intensifier controls x-ray output, it is considered an x-ray control and you must address applicable questions in section 203.0, PART 200.Section 2.5 should list the combination ofimage intensifier or spot-film device and x-ray control.

205.3 Part 1: Image Intensifier

Is this report intended for the certification of an image intensifier or combination containing an image intensifier?	[L]

205.3 Part 2: Image Intensifier

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

Model Image Intensifier:	
Describe the means to prevent the fluoroscopic tube from producing x radiation whenever the primary protective barrier is not in position to intercept the entire useful beam. If there is an interlock, describe its electrical and mechanical characteristics and provide circuit diagrams.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Does this image intensifier permit or control technique factor adjustment?	[L]
Message:	If "Yes" has been selected above, the following note applies:
Note:	Since the spot-film device or image intensifier controls x-ray output, it is considered an x-ray control and you must address applicable questions in section 203.0, PART 200.Section 2.5 should list the combination of image intensifier or spot-film device and x-ray control.

206.0 TABLES, CASSETTE HOLDERS, FILM CHANGERS AND CRADLES

Note:	This section should be completed for each table, cassette holder*, film changer and/or cradle listed in section 2.4 and any combination listed in section 2.5 that contains such components as an integral part thereof. If this report is not certifying a table, cassette holder, film changer and/or cradle then go to section 207.0* Applicable only to cassette holders that are intended for permanent verticle mounting and/or contain a front panel.
Is this report intended for the certification of a cassette holder, film changer, x-ray table, and/or a cradle?	[L]

206.1 Subject Component Capabilities

Do any of thesubject components allow for operator adjustment of technique factors?	[L]
Do any of the subject components provide limit switches that automatically preempt the preset exposure time of the master control panel?	[L]
Message:	If "Yes" has been selected for either of the above questions, the following note applies:
Note:	Since the relative component controls x-ray output, it is considered an x-ray control and you must address applicable questions in section 203.0, PART 200. Section 2.5.1 should list the combination of appropriate component and x-ray control.

206.2 Part 1: Model Film Changer

Is this report for the 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 into the stationary radiographic table?	[L]
Explain how beam limitation is accomplished for serial radiography.	
[HTML Text]	
For each model film changer, explain the provision(s) enabling the operator to terminate an exposure or series of exposures that last longer than one-half second.	
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 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 further.	
[HTML Text]	
For each table intended for use on a general purpose x-ray system, cite the specific paragraph(s) (page number) in your instructions to assemblers that lists compatible tube stands and/or other equipment necessary for indication (as required under 21 CFR 1020.31(e)(1)(i), (g)(2), and 1020.32(b)(1)(ii), (b)(2)(iii)) of the perpendicularity of the beam axis to the image receptor and the SID.	
[HTML Text]	

206.5 Verticle Cassette Holder

Is this report for the certification of a verticle cassette holder?	[L]
For each model verticle cassette is the verticle cassette holder equipped with cassette size sensors?	[L]

206.6 Image Receptor Sizes

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

Model Designation:	
Cassette Sizes: (___cm x ___cm) OR (___in x ___in)	

207.0 CEPHALOMETRIC DEVICES

Note:	This section should be completed for eachcephalometric device listed in section 2.4. If this report is not certifying a cephalometric device then go to section 208.0
Is this report intended for the certification of the cephalometric device?	[L]

207.1 Cephalometric Device Including a Beam-Limiting Device

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

Model Designation:	
Does the cephalometric device include a beam-limiting device as an integral design feature?	[L]
Note:	If the beam limiting device is not sold seperately answer the applicable questions in section 202.0, PART 200 if not already done. Section 2.5 should list the combination cephalometric device and beam limiting device asan integral inseparable part.

207.2 Cephalometric Device Including a Cassette Holder

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

Model Designation:	
Does the cephalometric device include a cassette holder with a front panel as an integral design feature?	[L]

208.0 IMAGE RECEPTOR SUPPORT DEVICES FOR MAMMOGRAPHIC X-RAY SYSTEMS

Note:	This section should be completed for each image receptor support device listed in section 2.4. If this report is not certifying a image receptor support device then go to section 300.0
Is this report intended for the certification of a image receptor support device?	[L]

208.1 Cassette Holder with Front Panel

Does the image receptor support device include a cassette holder with a front panel as an integral part?	[L]

Section: Quality Control Testing

301.0 Leakage Radiation from the Diagnostic Source

Note:	Answer the following questions if certifying a beam-limiting device or tube housing assembly in this submission (i.e., if yes was selected for question 2.4 (a),(b), 2.5 (a), (b), (c) or (d)).
Requirement:	
Message:	The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgens (mR) exposure) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters (1020.30(k)).
Applicability:	

Message:	This requirement is applicable to the diagnostic source assembly (tube housing assembly combined with a beam-limiting device). Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see Prototype Testing (a)).	
Critical Parameters and "Worst Case" Conditions:		
A.	Message:	The test results must include data representative of each compatible combination of tube housing assembly and beam-limiting device.
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 the use of maximum rated peak tube potential and continuous tube current, the test method(s) must provide the procedure for periodic calibration of technique factors.
D.	Message:	For any test using a scan of the diagnostic source assembly, the rate of scan specified in the test methods) must account for the response time of the radiation instrumentation.
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?		[L]
A.	Describe the direct test method (i.e., one that actuallymeasures x radiation) employed in testing and measuring each model with respect to this requirement.	
	[HTML Text]	
B.	Identify the instrument(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	[HTML Text]
D.	Is the actual compliancevalue 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	[HTML Text]
Explain how compliance is established.		
[Multi-Line Plain Text]		
Production Testing:		
A.	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, .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 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample 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]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			

Does assembler testing apply?			[L]
A.	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 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 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]	
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 listed in question (B.) under Assembler Testing, attach the detailedinstructions for performing the test where the rejection limits are specified.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .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 value calculated from the raw test data?		[L]
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]		
Details	[HTML Text]		

302.0 Beam Quality

Note:	Answer the following questions if certifying a beam-limiting device or tube housing assembly in this submission (i.e., if yes was selected for question 2.4 (a), (b), 2.5 (a), (b), (c) or (d)).		
Requirement:			
Message:	The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I of the diagnostic x-ray standard (see 1020.30(m)).		
Applicability:			
Message:	This requirement is applicable to the tube housing assembly or the diagnostic source assembly if the beam-limiting device containsfiltration. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated (see (a) under Prototype Testing).		
Critical Parameters and "Worst Case" Conditions:			
A.	Message:	The test results must include data representative of each compatible combination of tubehousing assembly and beam-limiting device.	
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:	Since the peak tube potential has a critical effect on determining the half-value layer, the test method(s) must provide the procedure for periodic calibration of tube potential.	
D.	Message:	To minimize the sources of scatter radiation, the x-rayfield specified in the test method(s) must be just large enough to cover the sensitive volume of the detector.	
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?			[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]		
B.	Identify the instrument(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	[HTML Text]	
D.	Is the actual compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			

Production Testing:			
A.	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, .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 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.	Foreach test method listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
	–	Please 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)]

Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	Does the test involve a direct test of the performance parameter?		[L]
B.	Describe all methods employed intesting 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, .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 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 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 method listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

303.0 Aluminum Equivalence

Note:	Answer the following questions ifcertifying a cassette holder with a front panel or the device you are certifying includes a cassette holder as an integral part (i.e., if yes was selected for question 2.4 (l), 207.2, or 208.1).		
Requirement:			
Message:	The aluminum equivalent of the frontpanels of cassette holders and film changers, tabletops, and cradles that are used between the patient and image receptorshall not exceed the limits indicated in Table II of the diagnostic x-ray standard (see 1020.30(n)).		
Applicability:			
Message:	This requirement is applicable to cassetteholders, film hangers, tables and cradles. Similar models of a single component type may be groupedfor. presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 303.4(a)).		
Critical Parameters and "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.	
B.	Message:	Since the peak tube potential has a critical effect on determining the aluminum equivalent, the test method(s) must provide the procedurefor periodic calibration of tube potential.	
C.	Message:	Since compliance will be measured at 100 kVp and 2.7 millimeters of aluminum half-value layer, test data resulting from other conditions must be extrapolated to the value at the specified conditions.	
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 productiontesting. Does prototype testing apply?			[L]
A.	Describe the direct testmethod (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.		
	[HTML Text]		
B.	Identify the instrument(s) used for the test by manufacturer and model number.		
	[HTML Text]		
C.	Attach a sample of 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)]	
D.	Is the actual compliance 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.		

	Details	[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]			
Production Testing:			
A.	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, .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 indicationof 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.		
	Details	[Multi-Line Plain Text]	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
F.	Identify the instrument(s) used for each test by manufacturer and model number.		
	File Attachment	[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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]

–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percentof the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	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 madeto a test protocol document, provide a copy as an attachment for documentation.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
C.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indicationof 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 detailedinstructions 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 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 method listed in question (B.), please attach sample raw test data.		

	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]		
Details	[HTML Text]		

304.0 Standby Radiation from Capacitor Energy Storage Equipment

Requirement:			
Message:	Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 0.26 micrograysor 0.03 mR in 1 minute at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open and 0.88 mGy or 100 mR in1 hour 100 centimeters from the source (see 1020.31(l)).		
Applicability:			
Message:	This requirement is applicable to the diagnostic source assembly of capacitor energy storage equipment. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 304.4(a)).		
Critical Parameters and "Worst Case" Conditions:			
A.	Message:	The test results must include data representative of each compatible combination of tube housing assembly and beam-limiting device.	
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 test for the maximum standby radiation, the beam-limiting device must be fully open and the highest available peak tube potential must be used. These conditions must bespecified in the test method(s).	
D.	Message:	For any test using a scan of the diagnostic source assembly, the rate of scan specified in the test method(s) must take into account the response time of the radiation instrument.	
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?			[L]
A.	Describe the directtest method (i.e., one that actually measures x radiation) employedin testing and measuring each model with respect to this requirement.		
	[HTML Text]		
B.	Identify the instrument(s) used for the test by manufacturer and model number.		
	[HTML Text]		
C.	Attach a sample of 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)]	
D.	Is the actual compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	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, 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 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 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 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]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of anycorrection factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	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, .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 accurateindication 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 acopy of the detailed instructions for performing each test.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
F.	Identify the instrument(s) used for each test by manufacturer and model number.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
G.	For each test method 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 method listed in question (B.), please attach sample raw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
I.	Is the actual compliance value calculated fromthe raw test data?	[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

305.0 Fuoroscopic Entrance Exposure Rate

Requirement:			
1.	Message:	Fluoroscopic equipment manufactured prior to May 19,1995.	
A.	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.	Message:	Fluoroscopic equipment that is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.29x 10-3 C/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.	Message:	Fluoroscopic 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.	
B.	Message:	Equipment shall not be operable at any combination of tube potential and current that will result in an air kerma rate (AKR) in excess of 88 mGy/min or 10 roentgens per minute at the point where the center of the usefulbeam enters the patient, except:(a) during	

		recording of fluoroscopic images, or(b) when an optional high-level control (HLC) is activated. When theHLC is activated, it shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 176 mGy/min or 20 roentgens per minute at the point where the center of the useful beam enters the patient unless the high-level control is activated.
Applicability:		
Message:	This requirement is applicable to fluoroscopic and automatic exposure rate x-ray controls. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 305.4(a)).	
Critical Parameters and "Worst Case" Conditions:		
A.	Message:	As a result of inherent inaccuracies ofthe test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.
B.	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) must be driven tothe maximum design limits for this test.
E.	Message:	For automatic exposure rate control equipment using direct viewing optics, the test must be performed with suppressed ambient light conditions.
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?		[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]	
B.	Identify the instrument(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 compliance 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]

Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	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, .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 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
	–	Please attach a sample of 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, .zip)]
	Details	[Multi-Line Plain Text]
Explain how compliance is established.		
[Multi-Line Plain Text]		
J.	Is this performance parameter tested on 100 percent of the produced models?	[L]
Assembler Testing:		
Does assembler testing apply?		[L]
A.	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, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
C.	If any test used to monitor compliance doesnot actually measure xradiation, 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 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 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 method listed in question (B.), please attach sample raw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]

I.	Is the actual compliance value calculated from the raw test data?	[L]
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]	
Details	[HTML Text]	

306.0 Primary Protective Barrier Transmission

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

Model Number of the device:		
Requirement:		
Message:	The exposure rate due to transmission through the barrier with the attenuation block in theuseful beam combined with radiation from the image intensifier, if provided, shall not exceed 3.34x 10-3 percent of the entrance exposure rate (or 2 milliroentgens per hour for each roentgen per minute of entrance exposure rate) at 10 centimeters from any accessible surface ofthe fluoroscopic imaging assembly beyond the plane of the imagereceptor (see 1020.32(a)(i)).	
Applicability:		
Message:	This requirement is applicable to fluoroscopic imaging assemblies or the following component parts thereof: spot-film device; image intensifier; and fluoroscopic screen assembly. Similar models of asingle component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 306.4(a)).	
Critical Parameters and "Worst Case" Conditions:		
A.	Message:	The test results mustinclude data representative of each compatible combination of components that comprise the fluoroscopic imaging assembly.
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:	For any test using a scan of the fluoroscopic imaging assembly, the rate of scan specified in the test method(s) must take into account the response time of the radiation instrument.
D.	Message:	To test for the transmission of radiation through the primary protective barrier, the beam-limiting devicemust be fully open and the highest available peak tube potential must be used. These conditions must be specified in the test method(s).
E.	Message:	If an oblique fluoroscopic capability is provided, the radiation transmitted through the primary protective barrier must be measured at the maximum oblique fluoroscopic angles.
F.	Message:	If the fluoroscopic beam-limiting device is equipped with an override capability, the radiation transmitted through the primary protective barrier must be measured at the largest x-ray field setting.
Prototype Testing:		
This section is for start up prior to full production phase and thus the testing and quality control proceduresmay not be the same as production testing. Does 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]		
B.	Identify the instrument(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 compliance value calculated from the raw test data?		[L]
E.	Attach a sample of 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 compliance is established.		
	[HTML Text]		
Production Testing:			
A.	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, .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 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
–	Explain how compliance isestablished.		
	[HTML Text]		
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	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, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
C.	If any test used to monitor compliance does not actually measurex 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 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 Assembler Testing,attach the detailed instructionsfor 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 listed in question (B.), please attachsample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]		
Details	[HTML Text]		

307.0 Reproducibility and Linearity

Requirement:		
Message:	Whenthe x-ray unit is operated on an adequate power supply as specified by the manufacturer;(1) the estimated coefficient of variation of radiation exposure shall not be greater than 0.05 for any specific combination of technique factors, and where: s=Estimated standard deviation X = Mean value of the sample Xi = ith observation of the sample N = the number of observations sampled(2) the average ratios of exposure to the indicated tube current exposure time product (mAs) obtained at any two consecutive tube current settingsshall not differ by more than 0.10 times their sum, or where X1 and X2 = the average mR/mAs values obtained at each of two consecutive tube current settings. (see 1020.31(b) and (c)).	
Applicability:		
Message:	This requirement is applicable to radiographic x-ray controls and high-voltage generators. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 307.4(a)).	
Critical Parameters and "Worst Case"Conditions:		
A.	Message:	As a result of inherent inaccuracies of the test methodand instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.
B.	Message:	To assure compliance with the reproducibility and linearity requirements, the test results must include data for "worst case" combinations of technique factors and supplyline conditions (e.g., low kVp,high mA, low-line voltage, and highest allowed line-voltage regulation).

C.	Message:	To determine compliance, variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting between measurements.	
Prototype Testing:			
This section is for startup 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?			[L]
A.	Describe the directtest method (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.		
	[HTML Text]		
B.	Identify the instrument(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 compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	Does the test involve a direct test of the performance parameter?		[L]
B.	Describe all methods employed in testingof each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment 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 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)]	
	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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	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 copyas 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 measurex 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 instrument(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 listed in question (B.) under Assembler Testing, attach the detailed instructions for performing thetest 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 listed inquestion (B.), please attach sample raw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
I.	Is the actual compliance value calculated from the raw test data?	[L]

Providea copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
[Multi-Line Plain Text]	
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

308.0 Radiation from Components other than the Diagnostic Source Assembly

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

Model Number of the device:	
Note:	If you do not see the appropriate model indicated, please go to question 2.4 MODEL DESIGNATION to enter the model as it appears on the identification label.
Requirement:	
Message:	The radiation emitted by a component other than the diagnostic source assembly shall not exceed 18 micrograys (2 milliroentgens) in 1 hour at 5 centimeters from any accessible surface of the component

	when it is operated in an assembled x-ray system under any conditionsfor which it was designed (see 1020.30(1)).		
Applicability:			
Message:	This requirement is applicable to x-ray controls, high-voltage generators that contain thermionic diode valves (valve tubes),and image intensifiers. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 308.4(a)).		
Critical Parameters and "Worst Case" Conditions:			
A.	Message:	As a result of inherent inaccuracies ofthe test method andinstrumentation, rejection limits for any test must be sufficientlyrestrictive to assure compliance with the standard.	
B.	Message:	For any test using a scan of the subject components, the rate of scan specified in the test method(s) must takeinto account the response time of the radiation instrument.	
C.	Message:	To test for the maximumleakage radiationfrom the subject component, the highest available peak tube potential must be used. This condition must be specified in test method(s).	
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?			[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]		
B.	Identify the instrument(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 compliance 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	[HTML Text]	
F.	Explain how compliance is established.		
	[HTML Text]		
Production Testing:			
A.	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 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 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 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 listedin question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
–	Explain how compliance is established.		
	[HTML Text]		
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			

Does assembler testing apply?			[L]
A.	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, .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 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 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 method listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

309.0 Peak Tube Potential

Requirement:			
Message:	The manufacturer shall state the maximum deviation of the peak tube potential from its preindicated value during an exposure, when the equipment is connected to an adequate power supply as specified by the manufacturer. The deviation of the peak tube potential shall not exceed the limits given (see 1020.31(a)(4) and 1020.32(f)).		
Applicability:			
Message:	This requirement is applicable to fluoroscopic and radiographic x-ray controls and high-voltage generators. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technicalbasis for this grouping is clearly stated in the description of prototype testing (see 309.4(a)).		
Critical Parameters and "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.	
B.	Message:	To assure compliance with the maximum deviation statements provided to the user, the testresults must include 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).	
Prototype Testing:			
This section is for start up prior to full production phase and thus the testing and quality control procedures maynot be the same as production testing. Does prototype testing apply?			[L]
A.	Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each modelwith respect to this requirement.		
	[HTML Text]		
B.	Identify theinstrument(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	[HTML Text]	
D.	Is the actual compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	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, .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 ofthe test in question (C.)		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
E.	Attach a copy of the detailed instructions for performing each test.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
F.	Identify the instrument(s) used for each test by manufacturer and model number.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
G.	For each test method 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			

Does assembler testing apply?			[L]
A.	Does thetest involve a direct test of the performance parameter?		[L]
B.	Describe all methods employed in testingof each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an 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 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 that supports the use of the test in question (C.)		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
E.	Attach a copy of the detailed instructions for performing each test.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
F.	Identify the instrument(s) used for each test by manufacturer and model number.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.		
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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 value calculated from the raw test data?		[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

310.0 Tube Current

Requirement:			
Message:	The manufacturer shall state themaximum deviation ofthe tube current from its preindicated value during an exposure, when the equipment is connected to an adequate power supply as specified by the manufacturer. The deviation of the tube current shall not exceed the limits given (see 1020.31(a)(4) and 1020.32(f)).		
Applicability:			
Message:	This requirement is applicable to fluoroscopic and radiographic x-ray controls and high-voltage generators. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this groupings clearly stated in the description of prototype testing (see 310.4(a)).		
Critical Parameters and "WorstCase" 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.	
B.	Message:	To assure compliance with the maximum deviation statements provided to the user, the test results must include 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).	
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 asproduction testing. Does 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]		
B.	Identify the instrument(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 compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	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, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
C.	If any test used to monitor compliance does notactually measure x radiation, explain why it is an accurate indication of compliance with this requirement.		
	[HTML Text]		
D.	Submit the technical data that supports the use of the test inquestion (C.)		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
E.	Attach a copy of the detailed instructions for performing each test.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
F.	Identify the instrument(s) used for each test by manufacturer and model number.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
G.	For each test method 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 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]	
I.	Is the actual compliance 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, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			

Does assembler testing apply?			[L]
A.	Does the test involve adirect 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, .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 eachtest.		
	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 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 method listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

311.0 Tube Current - Exposure Time Product

Requirement:			
Message:	The manufacturer shall state the maximum deviation of the tube current exposure time product (mAs) from its preindicated value during an exposure, when the equipment is connected to an adequate power supply as specified by the manufacturer. The deviation of the tube current exposure time product shall not exceed the limits given (see1020.31(a)(4)).		
Applicability:			
Message:	This requirement is applicable to radiographic x-ray controls andhigh voltage generators that have mAs settings. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 311.4(a)).		
Critical Parameters and "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.	
B.	Message:	To assure compliance with the maximum deviation statements provided to the user, the test results must include 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).	
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?			[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]		
B.	Identify the instrument(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	[HTML Text]	
D.	Is the actual compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	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 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 to monitor compliance does not actually measure x radiation, explain whyit is an accurate indication of compliance with this requirement.		
	[HTML Text]		
D.	Submit the technical data that supports the use of the test inquestion (C.)		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
E.	Attach a copy ofthe detailed instructions for performing each test.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
F.	Identify the instrument(s) used for each test by manufacturer and model number.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
G.	For each test method 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample 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]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			

Does assembler testing apply?			[L]
A.	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, .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.	Submitthe 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)]	
	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 method listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

312.0 Exposure Time

Requirement:			
Message:	The manufacturer shall state the maximum deviation of the exposure time from its preindicated value during an exposure, when the equipment is connected to an adequate power supply as specifiedby the manufacturer. The deviation of exposure time shall not exceed the limits given (see 1020.31(a)(4)).		
Applicability:			
Message:	This requirement is applicable toradiographic x-raycontrols and high-voltage generators. Similarmodels of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 312.4(a)).		
Critical Parameters and "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.	
B.	Message:	To assure compliance with the maximum deviation statements provided to the user, the test results must include 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).	
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?			[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]		
B.	Identify the instrument(s) used for the test by manufacturer andmodel 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 compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	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, .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 that supports the use of the test in question (C.)		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
E.	Attach a copy of the detailed instructions for performing each test.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
F.	Identify the instrument(s) used for each test by manufacturer and model number.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
G.	For each test method 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			

Does assembler testing apply?			[L]
A.	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, .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 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 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 method listed in question(B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

313.0 Automatic Exposure Control Limits

Requirement:			
Message:	Either the product of peak x-ray tubepotential, current, and exposure time shall be limited to not more than 60 kWs per exposure or the product of xray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure (see 1020.31(a)(3)(iii)).		
Applicability:			
Message:	This requirement is applicable to radiographic x-ray controls and high voltage generators used in systems with automatic exposure controls. Similar models of a single component type may be groupedfor presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 313.4(a)).		
Critical Parameters and "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.	
B.	Message:	To assure compliance with the 60 kWs, 600 mAs, or 2000 mAs limits applicable to this system, the test results must include data for various combinations of technique factors.	
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?			[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]		
B.	Identify the instrument(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	[HTML Text]	
D.	Is the actual compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	Does the test involve a direct test of the performance parameter?		[L]
B.	Describe all methods employed in testing of each model with respectto 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, .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 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 testmethod listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			

Does assembler testing apply?			[L]
A.	Does thetest involve a direct test of the performance parameter?		[L]
B.	Describe all methods employed in testing of each model with respect tothis 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, .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 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)]	
	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 method listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

314.0 Automatic Exposure Control Minimum Exposure Time

Requirement:		
Message:	When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equalto or less than a time interval equivalent to two pulses, andthe minimum exposure time for all other equipment shall be equal to or less than 1/60second or a time interval required to deliver 5 mAs, whichever is greater (see 1020.31(a)(3)(ii)).	
Applicability:		
Message:	This requirement is applicable to radiographic x-ray controls and high-voltage generators used in systems with automatic exposure controls. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when thetechnical basis for this grouping is clearly stated in the description of prototype testing (see 314.4(a)).	
Critical Parameters and "Worst Case" Conditions:		
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.	
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?		[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]	
B.	Identify the instrument(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	[HTML Text]
D.	Is the actual compliance 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	[HTML Text]
Explain how compliance is established.		
[Multi-Line Plain Text]		
Production Testing:		
A.	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 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 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 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			

Does assembler testing apply?			[L]
A.	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 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 monitor compliance does not actuallymeasure x radiation, explain why it is an accurate indication of compliancewith 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 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 Assembler Testing, attach the detailed instructions forperforming 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

315.0 Illuminance of Light Localizers

Requirement:		
Message:	When a light localizer is used to define the perimeter of the x-ray field, it shall provide an average illumination of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID whichever is less. The average illumination shall be based upon measurements madein the approximate center of each quadrantof the light field (see 1020.31(d)(2)(ii) and (f)(4)(i)).	
Applicability:		
Message:	This requirement is applicable to any beam-limiting devices in a general purpose or other radiographic system that uses a light localizer to define the perimeter of the x-ray field. Similar models of a single component type may be grouped for presentation of test results applicableto this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see (a) under Prototype Testing).	
Critical Parameters and "Worst Case" Conditions:		
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.	
PrototypeTesting:		
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?		[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]	
B.	Identify the instrument(s) used for thetest 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 compliance 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	[HTML Text]
Explain how compliance is established.		
[Multi-Line Plain Text]		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	[L]
B.	Describeall methods employed in testing of each model with respect to this requirement. If referenceis made to a test protocol document, provide a copy as an attachment for documentation.	

	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
C.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.		
	[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)]	
	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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			

Does assembler testing apply?			[L]
A.	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, .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 instrument(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 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 method listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

316.0 Alignment of Visually Defined X-Ray Fields

Requirement:		
A.	Message:	Visual fields (including light fields): Means shall be provided for visually defining the perimeter of the x-ray field for all general purpose x-ray systems. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent ofthe distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam (see 1020.31(d)(2)(i)).
B.	Message:	Light fields: The edge of the light field at 100 centimeters or at themaximum SID, whichever is less, shall have a contrast ratio, corrected forambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary general purpose equipment,and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobilegeneralpurpose and other radiographic equipment (see 1020.31(d)(2)(iii) and (f)(4)(i)).
Applicability:		
Message:	This requirement is applicable to any beam-limiting device in a general purpose or other radiographic system that uses a light localizer to define the perimeter of the x-ray field. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see (b) under Prototype Testing).	
Critical Parameters and "Worst Case" Conditions:		
A.	Message:	As a result of inherent inaccuracies of the testmethod and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.
B.	Message:	To assure compliance with the requirement for visually defining the perimeter of the x-ray field, the test results must include data for the range of SID's and image receptor sizes.
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?		[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]	
B.	Identify the instrument(s) usedfor the test by manufacturer and model number.	
	[HTML Text]	
C.	Attach asample of raw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[Multi-Line Plain Text]
D.	Is the actual compliance value calculated from the raw test data?	[L]
E.	Attach a sample of calculated 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, .zip)]
	Details	[HTML Text]

Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	Does the test involve a direct test of the performance parameter?		[L]
B.	Describe all methods employed intesting 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, .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.	Attacha copy of the detailed instructions for performing each test.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
F.	Identify the instrument(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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from theraw test data?		[L]
	–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	

	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
Explain how compliance is established.		
[Multi-Line Plain Text]		
J.	Isthis performance parameter tested on 100 percent of the produced models?	[L]
Assembler Testing:		
Does assembler testing apply?		[L]
A.	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, .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 whyit 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 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 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 method listed in question (B.), please attach sample raw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]

I.	Is the actual compliance value calculated from the raw test data?	[L]
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]	
Details	[HTML Text]	

317.0 Alignment of the Center of the Radiographic X-Ray Field

Requirement:		
A.	Message:	For stationary general purpose x-ray systems, the center of the x-ray field shall align with the center of the image receptor to within 2 percent of the SID (see 1020.31(e)(1)).
B.	Message:	For other x-ray systems, the center of the x-ray field shall align with the center of the image receptor to within 2 percent of the SID unless means are provided to size and align the x-ray fieldsuch that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor see 1020.31(f)(2) and (4)).
Applicability:		
Message:	This requirement is applicable to beam-limiting devices used in radiographic x-ray systems other than (a) mobile x-ray systems; (b) systems for spot filming; (c) systems intended solely for intraoral image receptors; and (d) systems used solely for mammography. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when thetechnical basis for this grouping is clearly stated in the description of prototype testing (see (a) under Prototype Testing).	
Critical Parameters and "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.
B.	Message:	To assure compliance with the centering requirement, the testresults must include data for various combinationsof SIDS and image receptor sizes.
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?		[L]
A.	Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each modelwith respect to this requirement.	
	[HTML Text]	
B.	Identify the instrument(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 compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	Does the testinvolve 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, .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 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	

I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	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, .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 supportsthe use of the test in question (C.)		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
E.	Attach a copy of the detailed instructions for performing each test.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
F.	Identify the instrument(s) used for each test by manufacturer and model number.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
G.	For each test method 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 method listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]		
Details	[HTML Text]		

318.0 Radiographic X-Ray Field Size and Image Receptor Size

Requirement:			
A.	Message:	General purpose stationary x-ray systems: The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted. Indication of field size dimensions and SID's shall be specified in inches and/or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is perpendicular to the plane of the image receptor (see 1020.31(e)(1)(ii) and (iii)).	
Applicability:			
Message:	This requirement is applicable to beam-limiting devices and permanently mounted cassette holders that are used in stationary general purpose systems. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 318.4(a)).		
Critical Parameters and "Worst Case" Conditions:			
A.	Message:	The test results must include data representative of each compatible combination of tube housing assemblies and beam-limiting 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:	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. If this does not apply go to 318.5 for production testing. Does 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.		
	[Multi-Line Plain Text]		
B.	Identify the instrument(s) used for the test by manufacturer and model number.		
	[Multi-Line Plain Text]		

C.	Attach a sample of raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[Multi-Line Plain Text]	
D.	Is the actual compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	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, .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 thetest in question (C.)		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
E.	Attach a copy of the detailed instructions for performing each test.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
F.	Identify the instrument(s) used for each test by manufacturer and model number.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
G.	For each test method 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the 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, .zip)]	
	Details	[Multi-Line Plain Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	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, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
C.	If any test usedto 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 instrument(s) used for each test by manufacturer andmodelnumber.		

	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 method listed in question (B.), please attach sample raw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
I.	Is the actual compliance value calculated from the raw test data?	[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

319.0 X-Ray Field Size Determination for Fixed SID/Image Receptor Size Equipment

Requirement:	
Message:	Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor (see 1020.31(f)(2)).
Applicability:	
Message:	This requirement is applicable to beam-limiting devices. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technicalbasis for this grouping is clearly stated in the description of prototype testing (see 319.4(a)).
Critical Parameters and "Worst Case" Conditions:	
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.
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?		[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]	
B.	Identify the instrument(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 compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	Does the testinvolve 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, .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 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the 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, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	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, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
C.	If any test used to monitor compliance does notactually measure x radiation, explain why it is an accurate indication of compliance with this requirement.		
	[HTML Text]		
D.	Submit the technical 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.	Identifythe 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 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 method listed in question (B.), please attach sample raw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
I.	Is the actual compliance value calculated from the rawtest data?	[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

320.0 Alignment of the X-Ray Field and Spot-Film Cassette

Requirement:		
A.	Message:	The total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image 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)).
B.	Message:	The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID (see 1020.31(h)(3)).
Applicability:		
Message:	This requirement is applicable to beam-limiting devices and spot-film devices. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 320.4(a)).	
Critical 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 the range of SID's and applicable spot-film formats for each image receptor size.

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?			[L]
A.	Describe the direct test method (i.e., onethat actually measures x radiation) employed in testing and measuring each model with respect to this requirement.		
	[HTML Text]		
B.	Identify the instrument(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	[HTML Text]	
D.	Is the actual compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	Does thetest 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 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 monitor compliance does not actuallymeasure 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 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	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 testprotocol 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.	Submitthe 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)]
	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 method listed in question (B.), please attach sample raw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
I.	Is the actual compliance value calculated from the raw test data?	[L]
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]	
Details	[HTML Text]	

321.0 Alignment of Edges of the X-Ray Field with Edges of Fluoroscopic Receptor

Requirement:		
Message:	For nonimage intensified fluoroscopy, the x-ray field shall not extend beyond the visible area of the image receptor.	
Message:	For image intensified fluoroscopy:	
A.	Message:	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.
B.	Message:	For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor (see 1020.32(b)(2)(ii)).
Applicability:		
Message:	This requirement is applicable to beam-limiting devices and image intensifiers. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see	

	321.4(a)).	
Critical Parameters and "Worst Case" Conditions:		
A.	Message:	The test results must include data representative of each compatible combination of beam-limiting devices and image intensifiers.
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 fluoroscopic x-ray field limitation requirement, the test results must include data for the range of SID's and available magnification modes that result in different visual areas on the input phosphor of the image intensifier.
Prototype Testing:		
This section is for start up prior to full production phase and thus the testing and quality controlprocedures may not be the sameas production testing. Does prototype testing apply?		[L]
A.	Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring eachmodel with respect to this requirement.	
	[HTML Text]	
B.	Identify the instrument(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	[HTML Text]
D.	Is the actual compliance 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	[HTML Text]
Explain how compliance is established.		
[Multi-Line Plain Text]		
Production Testing:		
A.	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, .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 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 forperforming 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	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, .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 instrument(s) used foreach test by manufacturer and model number.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
G.	For each test method listed in question(B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
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 value calculated from the raw test data?		[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

322.0 X-Ray Field Size Determination for Dental Equipment

Requirement:	
Message:	Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beamsuch that if the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; or if the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters (see 1020.31(f)(1)(i) and (ii)).

Applicability:		
Message:	This requirement is applicable to beam-limiting devices. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basisfor this grouping is clearly stated inthe description of prototype testing (see (a) under Prototype testing below).	
Critical Parameters and "Worst Case" Conditions:		
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.	
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 asproduction testing. Does 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]	
B.	Identify the instrument(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	[HTML Text]
D.	Is the actual compliance 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	[HTML Text]
Explain how compliance is established.		
[Multi-Line Plain Text]		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	[L]
B.	Describe all methods employed intesting 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, .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 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 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 theactual compliance 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, .zip)]
	Details	[HTML Text]
Explain how compliance is established.		
[Multi-Line Plain Text]		
J.	Is this performance parameter tested on 100 percent of the produced models?	[L]
Assembler Testing:		
Does assembler testing apply?		[L]
A.	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, .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 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 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 method listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

323.0 X-Ray Field Size Determination for Mammographic Equipment

Requirement:		
A.	Message:	Mammographic equipment manufactured prior to September 30,1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor doesnot extend beyond any edge of the image receptor at any designated SID except theedge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID.
B.	Message:	Mammographic equipment manufactured after September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane ofthe image receptor does not extend beyond anyedge of the image receptor at any designated SID by more than 2

		percent of the SID.
Message:	Permanent, clearly legible markings shall indicatethe image receptor size and maximum SID for which each aperture is designed (see 1020.31(f)(3)).	
Applicability:		
Message:	This requirement is applicable to beam-limiting devices. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 323.4(a)).	
Critical Parameters and "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.
B.	Message:	The test results must include data for each aperture sizeat the maximum designated SID.
C.	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?			[L]
A.	Describe the direct test method (i.e., one that actuallymeasures x radiation) employed in testing and measuring each model with respect to this requirement.		
	[HTML Text]		
B.	Identify the instrument(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	[HTML Text]	
D.	Is the actual compliance value calculated from the raw test data?		[L]
E.	Attach a sample 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]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
Production Testing:			
A.	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 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 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 thedetailed 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			

Does assembler testing apply?			[L]
A.	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, .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 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 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 method listed 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 compliance value calculated from the raw test data?		[L]

Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

324.0 X-Ray Field Size Determination for Radiographic Equipment not in 318 - 323

3626 Diagnostic X-Ray Product Rpt (OMB 0910-0025)

Requirement:			
Message:	Radiographic x-ray systems otherthan: (a) stationary general purpose systems; (b) systems designed for one image receptor size and SID; (c) spot-film devices; (d) mobile equipment; and (e) equipment designed for use with intraoral image receptors shall be provided with means to limit the x-ray beam such that when the axis of the x-ray beam is perpendicular to the plane of the image receptor, the dimensions of the x-ray field shall not exceed the corresponding dimensions of the image receptor by more than 2 percent of the SID, or shall be provided with means to bothsize and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor (see 1020.31(f)(4)).		
Applicability:			
Message:	This requirement is applicable to beam-limiting devices. Similar models of a single component type may be grouped for presentaiton of test results applicable to this requirement when the technical basis for this grou ing is clearly stated in the description of prototype testing (see 324.4(a)).		
Critical Parameters and "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.	
B.	Message:	The test results must include data for each aperture size.	
C.	Message:	Sincethe 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 startup prior to full production phase and thus the testing and quality controlprocedures may not be the same as production testing. Does 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]		
B.	Identify the instrument(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	[HTML Text]	
D.	Is the actual compliance 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	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			

Production Testing:			
A.	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, .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 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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from theraw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	

Explain how compliance is established.			
[Multi-Line Plain Text]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	Doesthe 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 ismade to a test protocol document, provide a copy as an attachment for documentation.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
C.	If any test used to monitor compliance does not actually measure x radiation, explain why itis an accurate indication of compliance with this requirement.		
	[HTML Text]		
D.	Submit the technicaldata that supports the use of the test in question (C.)		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
E.	Attach a copy of the detailed instructions for performing each test.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
F.	Identify the instrument(s) used for each test by manufacturer and model number.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
G.	For each test method 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 method listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]
Details	[HTML Text]

325.0 Transmission Limit for Image Receptor Support Devices for Mammographic Syst

Requirement:		
Message:	The transmission of the primary beam throughany image receptor support provided with the mammographicx-ray system shall be limited suchthat the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 micrograys (or 0.1 milliroentgen) for each activation ofthe tube (see 1020.31(m)(3)).	
Applicability:		
Message:	This requirement is applicable to mammographic image receptor supporting devices. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see325.4(a)).	
Critical Parameters and "Worst Case" Conditions:		
Message:	Asa result ofinherent inaccuracies of the test method and instrumentation, rejection limits for any testmust be sufficiently restrictive to assure compliance with the standard.	
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?		[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]	
B.	Identify the instrument(s) used forthe 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 compliance 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	[HTML Text]
Explain how compliance is established.		
[Multi-Line Plain Text]		
ProductionTesting:		

A.	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.		
	Details	[Multi-Line Plain Text]	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
C.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.		
	[HTML Text]		
D.	Submit the technical 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)]	
	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 listed in question (B.), please attach sample raw test data.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
–	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
	Details	[HTML Text]	
Explain how compliance is established.			
[Multi-Line Plain Text]			

J.	Is this performance parameter tested on 100 percent of the produced models?	[L]
Assembler Testing:		
Does assembler testing apply?		[L]
A.	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, .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 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 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 method listed in question (B.), please attach sample raw test data.	
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
	Details	[HTML Text]
I.	Is the actual compliance value calculated from the raw test data?	[L]
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]	
Details	[HTML Text]	

3626 Diagnostic X-Ray Product Rpt (OMB 0910-0025)

326.0 Radiographic PBL Field Size and Image Receptor Size Differences

Note:	Answer the following questions if certifying a beam-limiting device that is designed for PBL.	
Requirement:		
Message:	Systems with positive beam limitation: The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than 3 percent of the SID and that the sum of the length and width differences without regard to sign be no greater than 4 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor (see 1020.31(g)(1)(i) and (ii)).	
Applicability:		
Message:	This requirement is applicable to beam-limiting devices and permanently mounted cassette holders that are used in stationary general purpose systems with PBL collimators. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 326.4(a)).	
Critical Parameters and "Worst Case" Conditions:		
A.	Message:	The test results must include data representative of each compatible combination of tube housing assemblies and beam-limiting 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 positive beam limitation requirements, the test results must include data for (1) the horizontal and vertical ranges of SID's and image receptor sizes and (2) the ± 3° range of angulation relative to a line 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?		[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.	
	[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)]
D.	Is the actual compliance 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.	

	[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]			
Production Testing:			
A.	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.		
	[Multi-Line Plain Text]		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
C.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.		
	[HTML Text]		
D.	Submit the technical 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 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)]	
F.	Identify the instrument(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 listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.		
	[Multi-Line Plain Text]		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
H.	For each test method listed inquestion (B.), please attach sample raw test data.		
	[Multi-Line Plain Text]		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
I.	Is the actual compliance 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.		
	[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]			
J.	Is this performance parameter tested on 100 percent of the produced models?		[L]
Assembler Testing:			
Does assembler testing apply?			[L]
A.	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.		
	[Multi-Line Plain Text]		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
C.	If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.		
	[HTML Text]		
D.	Submit the technical 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 instrument(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 listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.		
	[Multi-Line Plain Text]		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
H.	For each test method listed in question (B.), please attach sample raw test data.		

	[Multi-Line Plain Text]		
	File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
I.	Is the actual compliance value calculated from the raw test data?		[L]
Provide a copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate 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)]		
Details	[HTML Text]		

Section: Common Aspects

401.0 Instrumentation

Radiation Measurement:		
Do any of the test protocols use Radiation Measuring instruments?		[L]
Describe each radiation measurement instrument that you refer to in Part 300, giving the following: manufacturer and model number if the instrument is commercially available; type of instrument; precision; accuracy; response time; energy dependence; angularresponse; exposure rate dependence; ranges; and effective measurement area.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.		
[HTML Text]		
How do you assure proper day-to-day operation of each instrument?		
[HTML Text]		
Illuminance and Contrast Measurement:		
Do any of the test protocols measure Illuminance and/or Contrast?		[L]
Describe each illuminance and/or contrast measurement instrument that you refer toin Part 300, giving the following: manufacturer and model number if theinstrument is commercially available; type of measuring instrument; precision; accuracy; and ranges.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.		
[HTML Text]		
How do you assure proper day-to-day operation of each instrument?		
[HTML Text]		
Electrical Measurement:		
Describe each electrical measurement instrument that you referred to in Part 300, giving the following:type of instrument; manufacturer and model number if the instrument is commercially available; rated accuracy; precision; ranges; and response time. If anynumber of commercially available instruments withcertain basic characteristics may		

be used, it is sufficient to state the minimum accuracy, precision, ranges, response time, and so forth, of the class of instruments that will be used. If any instrument is unique or of special manufacture then the manufacturer and model number should be stated.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
[HTML Text]	
Show where each instrument listed in the above question under Electrical Measurement is connected during testing with the use of a schematicdiagram.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Other Measurement:	
Describe each measurement instrument (other than radiation, illuminance and contrast, or electrical)that you refer to in Part 300, giving thefollowing: type of instrument; manufacturer and model number if the instrument is commercially available; rated accuracy; precision; and ranges. If any number of commercially available instruments with certain basic characteristics may be used, it is sufficient to state the minimum accuracy, precision ranges, and so forth, of the class of instruments that will be used.If any instrument is unique or of special manufacture, however, then the manufacturer and model number should be stated. Please attachanymanuals for the testing instruments.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
[HTML Text]	

402.0 Sampling

Are any performance parameters tested other than 100 percent?	[L]
List each performance parameter test that is sampled.	
[HTML Text]	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Click on the Add... button below to attach files.	
[HTML Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Provide the following parameters in an attachment above.

(1) The lot size (N)
(2) The sample size (n)
(3) The reject level number (c)
(4) A single or double sampling plan (S or D)
(5) The acceptable quality level (AQL)
(6) The lottolerance percent defective (LTPD)
(7)Theproducer's risk
(8) Theconsumer's risk

(9) The operating characteristic (OC) curve
(10) The average outgoing quality level (AOQL)
(11) Theprocedures for segregation of the lot until sampling allow the lot to be released.

Describe the procedure used for selecting the sample and indicate how randomness is assured.
[HTML Text]
Describe the action taken if the sampling plan leads to a rejection decision.
[HTML Text]

Stop:	You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.
Message:	Form FDA 3626 A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components (10/31/2013)