Submission Report

eRadHealth Menu

Introduction

Electronic Product Radiation Safety Reporting Form

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

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

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

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

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

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

Note about eSubmitter software:

Instructions provided in this software briefly summarize the requirements of the regulations under the Federal Food, Drug and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product

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

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

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

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

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

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0025 (expires January 31, 2017).

Role

What is your role?	!*	Manufacturer

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

Submission Information

Step 1	**Use the radio buttons to identify the type of submission you are preparing. (Supplements should be prepared using the same document type as the original submission.)**

What Type of Submission is this? (Supplements should be submitted selecting the same document type as the original report.)	!*	(•) Radiation Safety Report (Product) Report (21 CFR 1002.10) ( ) Annual Report (21 CFR 1002.13) ( ) Laser Light Show Documents (all relevant documents) (21 CFR 1040.11(c)) ( ) Correspondence

	( ) Variance Request (General, not Laser Light Show) (21 CFR 1010.4) ( ) Laser Original Equipment/Component Manufacturer Registration (21 CFR 1040.10(a)(3)(ii)) ( ) Abbreviated Report (21 CFR 1002.12)

Step 2	**After answering the Submission Type question above, one of the questions below may become active and required (see the blue dot to the right of the question). If there is an active question, select the appropriate product area or document type from the question's pick list.**
What Type of Product is this Radiation Safety Report about?	**!***
Diagnostic X-Ray Systems and Major Components	
What Type of Product is this Annual Report about?	
What Laser Light Show Document are you filing?	
What Type of Correspondence is this?	
What Type of Product is this Variance Request about?	

Manufacturer Data

Manufacturer Responsible for Product Compliance

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

Select the Manufacturer's address from the Establishment Address book: *	
Establishment Information:	
Establishment Name	
Division Name	
Home Page	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

Responsible Individual

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

Select the Responsible Individual from the Contact Address book: *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	

Mailing Location:	
Address	
Telephone Number	
Fax Number	

Manufacturer's Reporting Official

Note:	*This is the person at the manufacturing facility that is knowledgeable and responsible for addressing all aspects of the testing and quality control procedures for certification as reported to FDA in the product report. Documentation of changes intesting and quality control procedures submitted to FDA must be signed by this individual.*

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

Report Submitter

Note:	*The submitter may be a consulting individual or firm providing assistance in report preparation and maintenance. Documents or submissions such as this one that are prepared by the submitter must have an accompanying authorization letter from the manufacturer's reporting official for authenticity.*

Select the Submitter from the Contact Address book: *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	

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

Internal Reference Number:	

Parent Establishment

Is there a parent establishment? *	

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

Manufacturer Designated United States Agent

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

Is there a United States agent that has been designated by the manufacturer? *	

Importer

Additional Manufacturing Locations

Product Data

Product and Model Identification

Attention - Information about this section

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

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

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

(3) You will also have several questions that are of high significance for FDA/CDRH - why you might be submitting this report or correspondence. Please read these questions carefully, referring to the 21 CFR regulations on the website www.FDA.gov if you are unsure if the question is relevant to your firm's situation.

(4) If you find that you have more information that you want the FDA/CDRH to read but it doesn't seem to fit under other questions, we have a final "***Additional Information***" question in this section which invites you to add comments and/or attach a file that provides further information from your firm about this submission. This is the place to add that extra information.

Product Type Reported

What is the product code? *

To select the three letter product code,

- Click the plus sign. You will see a product code filter dialog box.
- Select the appropriate category name from the pick list. You will be provided a list of product codes from which to choose.
- Select the best match to your product.
- The remaining fields will be filled in for you when you select your product code.

Category	
Product Code	
Performance Standard	

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

Report Information

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

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

Special Considerations

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

Noncompliances or Defects

Does this document or any of its attachments contain:	
A notification of noncompliance or defect? *	
You may provide an explanation and/or attach a document here:	
Details	

Responses to Noncompliances or Defects

Does this document or any of its attachments contain any of these responses concerning noncompliances or defects?	
A refutation of noncompliances or defects identified to your firm? *	
A request for an exemption from notification to purchasers (see 21 CFR 1003.21 and 1003.30)? *	
Corrective action plans you intend to implement to correct noncompliances or defects discovered in past or current production? *	
Note:	*If you are submitting a Corrective Action Plan (CAP) following 21 CFR 1004 and information on design changes for future production, the design change information must be submitted in a Radiation Safety (Product) Report or supplemental report. Both the proposed CAP and the design changes may be submitted in one document if you prepare a product report and choose to include the CAP in it as a file attachment. Alternatively, you may create a separate eSubmission for the CAP using the "Correspondence" type template and selecting "Follow-up correspondence to FDA."*
A description of any design changes that correct noncompliances for future production? *	
Note:	*If you are submitting information on product design changes for future production due to a discovery of noncompliances or defects in current production, you must use the Radiation Safety (Product) Report template to create the report . Correspondence templates may be used to submit other information such as a proposed corrective action plan pertaining to a noncompliance or defect.*
You may add an explanation and/or attach a document here:	
Details	

Exemption Requests

Does this document or any of its attachments contain:	
Exemption of a product for government use from a standard (21 CFR 1010.5)? *	
Exemption for products for government use from reporting and recordkeeping (21 CFR 1002.51)? *	
Special exemption of products from reporting and/or recordkeeping (21 CFR 1002.50)? *	
Request for approval of alternate labeling? *	
Application for alternate test procedures (21 CFR 1010.13)? *	
You may provide an explanation and/or attach any relevant documents here:	

Variance Requests

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

Message:	*Click the plus sign to list the requirements from which you are requesting a variance.*
This submission includes an application for a variance from certain requirements.	
Item	No Information Provided.
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	
Details	
Stop:	*For all Variance requests, two submissions must be made to the FDA.* *The electronic version should be submitted following the Packaging Files for Submission instructions located under Output in the Menu bar, and explained in subsection 4.3 of the User Manual. If sending a CD & submittal letter, please mail to:* *U.S. Food and Drug Administration* *Center for Devices and Radiological Health* *Attn: eSubmitter Team* *Document Mail Center - WO66-0609* *10903 New Hampshire Avenue* *Silver Spring, MD 20993-0002* *Additionally, a paper version (hard-copy) of the signed Variance request document should be submitted to:* *Food and Drug Administration* *Division of Dockets Management (HFA-305)* *5630 Fishers Lane, Room 1061* *Rockville, MD 20857*

Responses to Communications from FDA

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

Additional Information

Here's your opportunity to add anything else to this submission that you want to tell the FDA!

Is there any other relevant information or additional comments that would help expedite the review of this submission? Click the plus sign below to attach any supporting files.	
Details	

Private Labeling

Is the product sold by other companies under different brand names? *	

Medical Devices

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

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

Product & Model ID

2.4 MODEL DESIGNATION

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

Item	Model Name	Family Name	Brand Name

2.4.1 MODEL TYPE DESIGNATION

2.5 INDIVISIBLE COMBINATION OF COMPONENTS

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

2.5.1 COMBINATION OF COMPONENTS

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?	

2.6.1 Names or Labels

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.

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?	

2.8 PART 2: COMPLETE SYSTEMS AND SUBSYSTEMS

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.

Details	

Are there assembly and testing instructions necessary at the installation site for assuring compliance to the federal standards?	

Attach Assembly and Testing Instructions necessary for assuring compliance to the Performance Standard as a separate file.

Details	

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.

2.11 ADDITIONAL INFORMATION

2.11.1 BEAM LIMITING DEVICE (BLD)

Is this report intended for the certification of a beam limiting device (either seperately or in combination)?	

Use and Type of Collimation

2.11.2 HV GENERATOR

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

Use and Type

2.11.3 X-RAY CONTROL

Is this report intended for the certification of an x-ray control (either separately or in combination)?	

Use, Maximum kVp, and Fluoroscopic Control

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).
Click on the plus sign below to attach the appropriate files.

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?	

201.1 Tube Housing Assembly Information

202.0 BEAM-LIMITING DEVICES

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

Is the beam limiting device designed for intraoral dental?	

202.1 Dental BLD (intraoral)

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?	

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

202.2 Part 2: General Purpose Radiographic BLD

202.3 Part 1: Stationary General Purpose Radiographic

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

202.3 Part 2: Stationary General Purpose Radiographic BLD

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?	

202.4 Part 2: Beam Limiting Device used with Spot Film

202.5 Part 1: Beam Limiting Device used for Fluoroscopy

Is the BLD designed for fluoroscopy use?	

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

202.5 Part 2: Beam Limiting Device used for Fluoroscopy

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?	

Do any of the beam-limiting devices have a light field that defines the perimeter of the x-ray field?	
Are any of the beam-limiting devices designed for fixed SID/image receptor size?	

202.6 Part 2: X-Ray Systems Designed for One SID

202.7 Part 1: Beam Limiting Devices Designed for Mammography

Is the BLD designed for mammography?	

Does the beam-limiting device have a light field that defines the perimeter of the x-ray field?	

202.7 Part 2: Beam Limiting Devices Designed for Mammography

202.8 Part 1: Other Radiographic X-Ray Systems

Is the BLD designed for other radiographic systems?	

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

202.8 Part 2: Other Radiographic X-Ray Systems

202.9 Part 1: Variable Filtration

Does the beam-limiting device have variable filtration selection?	

202.9 Part 2: Variable Filtration

202.10 Capacitor Storage X-Ray Systems

Is any model beam-limiting device intended to be used on capacitor storage x-ray systems?	

List each model that is designed for capacitor storage units.

Item	No Information Provided.

203.0 X-RAY CONTROLS

Is this report intended for the certification of an x-ray control or combination containing an x-ray control?	

203.1 Warning Label

Provide a replica of the warning label affixed to the control panel and specify where the label is located with respect to the main power switch.

203.2 Part 1: Battery Powered Generator

Is the x-ray control used with a battery powered generator?	

203.2 Part 2: Battery Powered Generator

203.3 Part 1: Radiography

Radiography (x-ray controls used for radiography, i.e., recording of static images viewed after termination of exposure)

Is the x-ray control designed to operate in the radiographic mode?	

203.3 Part 2: Radiography

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?	

203.4 Part 2: Fluoroscopy

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?	
Do any model high-voltage generators contain a thermionic diode valve?	

List each model that has a thermionic diode.

Item	No Information Provided.

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?	

205.1 Spot Film Device

205.2 Technique Factor Adjustment

205.3 Part 1: Image Intensifier

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

205.3 Part 2: Image Intensifier

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?	

206.1 Subject Component Capabilities

Do any of thesubject components allow for operator adjustment of technique factors?	
Do any of the subject components provide limit switches that automatically preempt the preset exposure time of the master control panel?	

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?	

206.2 Part 2: Model Film Changer

206.3 X-Ray Tables

Is this report for the certification of an x-ray table?	

206.4 Model X-Ray Table Characteristics

206.5 Verticle Cassette Holder

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

206.6 Image Receptor Sizes

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?	

207.1 Cephalometric Device Including a Beam-Limiting Device

207.2 Cephalometric Device Including a Cassette Holder

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?	

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?	

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliancevalue calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		

Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliancevalues complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as anattachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
C.	Attach a sample of raw test data.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	

	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	

E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	Foreach test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed 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.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	

	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?		
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.	

B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percentof the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.		

	Describe all methods employed in testing of each model with respect to this requirement. If reference is madeto a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailedinstructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?		
A.	Describe the directtest method (i.e., one that actually measures x radiation) employedin testing and measuring each model with respect to this requirement.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, providea copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), pleaseattach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of anycorrection factors employed.	
	Details	

Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach acopy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated fromthe raw test data?	
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.		
Details		

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?	
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.
B.	Identify the instrument(s) used for the test by manufacturer and model number.

C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete withan explanation of any correctionfactors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement.If reference is made to a test protocol document, provide a copy as an attachment for documentation.	

	Details	
C.	If any test used to monitor compliance doesnot actually measure xradiation, explain why it is an accurate indication of compliance with this requirement.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

306.0 Primary Protective Barrier Transmission

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		

Production Testing:

A.	Does the test involve a direct test of the performance parameter?	
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.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
	-	

	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	

Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copyas an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturerand model number.	
	Details	
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.	
	Details	
H.	For each test method listed inquestion (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		*
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.		
Details		

308.0 Radiation from Components other than the Diagnostic Source Assembly

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?	
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.
B.	Identify theinstrument(s) used for the test by manufacturer and model number.
C.	Attach a sample of raw test data.
	Details
D.	Is the actual compliance value calculated from the raw test data?
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.
	Details
Explain how compliance is established.	
Production Testing:	
A.	Does the test involve a direct test of the performance parameter?
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.
	Details
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.
D.	Submit the technical data that supports the use ofthe test in question (C.)
	Details
E.	Attach a copy of the detailed instructions for performing each test.
	Details
F.	Identify the instrument(s) used for each test by manufacturer and model number.

	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does thetest involve a direct test of the performance parameter?	
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.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		

Production Testing:

A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test inquestion (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	

	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), pleaseattach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve adirect test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing eachtest.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made toa test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test inquestion (C.)	

	Details	
E.	Attach a copy ofthe detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete withan explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submitthe technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		

Details	

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer andmodel number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		

Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	

D.	Submit the technical data that supports the use of the test in question (C.)
	Details
E.	Attach a copy of the detailed instructions for performing each test.
	Details
F.	Identify the instrument(s) used for each test by manufacturer and model number.
	Details
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.
	Details
H.	For each test method listed in question (B.), please attach sample raw test data.
	Details
I.	Is the actual compliance value calculated from the raw test data?
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.
	Details
Explain how compliance is established.	
J.	Is this performance parameter tested on 100 percent of the produced models?
Assembler Testing:	
Does assembler testing apply?	
A.	Does the test involve a direct test of the performance parameter?
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.
	Details
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.
D.	Submit the technical data that supports the use of the test in question (C.)
	Details
E.	Attach a copy of the detailed instructions for performing each test.
	Details
F.	Identify the instrument(s) used for each test by manufacturer and model number.
	Details
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.
	Details
H.	For each test method listed in question(B.), please attach sample raw test data.
	Details
I.	Is the actual compliance value calculated from the raw test data?

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.

Details	

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
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.	
	Details	

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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each testmethod listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does thetest involve a direct test of the performance parameter?	
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.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	

	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		

Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made toa test protocol document, provide a copy as an attachment for documentation.	

	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment fordocumentation.	
	Details	
C.	If any test used to monitor compliance does not actuallymeasure x radiation, explain why it is an accurate indication of compliancewith this requirement.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	

H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	

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.
Details

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?		
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.	
B.	Identify the instrument(s) used for thetest by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
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.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturerand model number.	
	Details	
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.	

	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?		
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.	
B.	Identify the instrument(s) usedfor the test by manufacturer and model number.	
C.	Attach asample of raw test data.	
	Details	

D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation ofany correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
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.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attacha copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from theraw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Isthis performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	

D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	

C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the testinvolve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	

	Details	
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.	
D.	Submit the technical data that supportsthe use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of thetest in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the rawtest data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		

J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer andmodelnumber.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the testinvolve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the rawtest data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	

Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document,provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identifythe instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the rawtest data?	
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.		
Details		

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	

Explain how compliance is established.

Production Testing:

A.	Does thetest involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment fordocumentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	

I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a testprotocol document, provide a copy as anattachment for documentation.	
	Details	
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.	
D.	Submitthe technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?	
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.
B.	Identify the instrument(s) used for the test by manufacturer and model number.
C.	Attach a sample of raw test data.
	Details
D.	Is the actual compliance value calculated from the raw test data?
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.
	Details

Explain how compliance is established.

Production Testing:

A.	Does the test involve a direct test of the performance parameter?
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.
	Details
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.
D.	Submit the technical data that supports the use of the test in question (C.)

	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used foreach test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		

Details	

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?	
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.
B.	Identify the instrument(s) used for the test by manufacturer and model number.
C.	Attach a sample of raw test data.
	Details
D.	Is the actual compliance value calculated from the raw test data?
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.
	Details
Explain how compliance is established.	
Production Testing:	
A.	Does the test involve a direct test of the performance parameter?
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.
	Details
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.

D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is theactual compliance value calculated from the raw test data?	
	- Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document,provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s)used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	

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.
Details

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliancevalues complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		

Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachmentfor documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of thedetailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	

F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attachsample raw testdata.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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

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?		
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.	
B.	Identify the instrument(s) used for the test by manufacturer and model number.	
C.	Attach a sample of raw test data.	

	Details	
D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
Production Testing:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from theraw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Doesthe test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference ismade to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	

D.	Submit the technicaldata that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?	

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.	
B.	Identify the instrument(s) used forthe test by manufacturer and model number.	
C.	Attach a sample of raw test data.	
	Details	

D.	Is the actual compliance value calculated from the raw test data?	
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
ProductionTesting:		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	Details	
Explain how compliance is established.		
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
	Details	
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.	

D.	Submit the technical data that supports the use of the test in question (C.)	
	Details	
E.	Attach a copy of the detailed instructions for performing each test.	
	Details	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	Details	
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.	
	Details	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	Details	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

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?	
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.
B.	Identify the instrument(s) used forthe test by manufacturer and model number.
C.	Attach a sample of raw test data.
D.	Is the actual compliance value calculated from the raw test data?
E.	Attach a sample of calculated compliance values complete with an explanation of any correction factors employed.
Explain how compliance is established.	
Production Testing:	
A.	Does the test involve a direct test of the performance parameter?
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.
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.
D.	Submit the technical data that supports the use of the test in question (C.)
E.	Attach a copy of the detailed instructions for performing each test.
F.	Identify the instrument(s) used for each test by manufacturer and model number.
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.
H.	For each test method listed inquestion (B.), please attach sample raw test data.
I.	Is the actual compliance value calculated from the raw test data?
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.
Explain how compliance is established.	
J.	Is this performance parameter tested on 100 percent of the produced models?

Assembler Testing:		
Does assembler testing apply?		
A.	Does the test involve a direct test of the performance parameter?	
B.	Describe all methods employed in testing of each model with respect to this requirement. If reference is made to a test protocol document, provide a copy as an attachment for documentation.	
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.	
D.	Submit the technical data that supports the use of the test in question (C.)	
E.	Attach a copy of the detailed instructions for performingeach test.	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
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.	
H.	For each test method listed in question (B.), please attach sample raw test data.	
I.	Is the actual compliance value calculated from the raw test data?	
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.		
Details		

Common Aspects

401.0 Instrumentation

Radiation Measurement:	
Do any of the test protocols use Radiation Measuring instruments?	
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.	
Details	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
How do you assure proper day-to-day operation of each instrument?	
Illuminance and Contrast Measurement:	
Do any of the test protocols measure Illuminance and/or Contrast?	
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.	
Details	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
How do you assure proper day-to-day operation of each instrument?	
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.	
Details	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
Show where each instrument listed in the above question under Electrical Measurement is connected during testing with the use of a schematicdiagram.	
Details	
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.	
Details	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	

402.0 Sampling

Are any performance parameters tested other than 100 percent?	
List each performance parameter test that is sampled.	
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.	

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.	
Describe the action taken if the sampling plan leads to a rejection decision.	
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.*