Submission Report

Section: Main Menu

Welcome

Welcome to the CDRH Electronic Submissions Software (CeSub)

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

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

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

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

Welcome (Cont.)

Department of Health and Human Services
Food and Drug Administration

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

Section: eRadHealth Menu

Role

What is your role? *	Manufacturer

Submission Information

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

Section: Manufacturer Data

Introduction

Electronic Product Radiation Safety Reporting Form

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

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

submission.

The submission must be addressed to:

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

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

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

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

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

General Information

General Information for Radiological Health Products

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

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

Reports submitted on radiation safety of electronic products must follow the appropriate

form (21 CFR 1002.7). This software application serves the same report responsibility, so long as the submitter or manufacturer prints out the cover letter and sends it in along with the CD containing the report files. The submitter of the report will receive an acknowledgment letter (or email message) with the accession number that CDRH assigns to the report. Please reference this accession number in the future when providing additional information about this model family in either a supplement or the annual report. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database.

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

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

We are providing our new software applications for the old reporting forms upon request during this beta testing period of development in Spring, 2005. Other regulatory information is still available on the Internet under http://www.fda.gov/cdrh/comp/eprc.html. No copyright exists for these forms.

Reproduce these forms as needed. If you would like to comment on the reporting forms, website, or future electronic submissions, you may direct the comments to the address below.

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

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

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

Definitions

Definitions for Rad Health Products

Manufacturers

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

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

Accidental Radiation Occurrences

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

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

Importers

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

United States Agent for Foreign Manufacturers

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

From The Federal Food, Drug, and Cosmetic Act

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

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

Sec. 531 [21 U.S.C. 360hh] (1) the term **''electronic product radiation''**means:

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

Sec. 531 [21 U.S.C. 360hh](2) the term **''electronic product''**means:

(A) any manufactured or assembled product which, when in operation,(i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or

(B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation.

Burden to Industry

Paperwork Reduction Act Statement

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

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

Please DO NOT RETURN this application to this address.

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

Manufacturer Responsible for Product Compliance

Note:	*This is the firm that takes responsibility for certification that the product meets the performance standard. This firm develops and maintains the quality control and testing program that is the basis for the certification of this product. Additionally, this firm usually is the owner of the product design and manufacturing process design.*

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

Fax Number	
Mailing Location:	
Address	

Responsible Individual

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

Copy from contact address book *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Manufacturer's Reporting Official

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

Copy from contact address book *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Electronic Signature

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

Report Submitter

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

Parent Establishment

Is there a parent establishment? *	
Copy from contact address book	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	

Address	

Manufacturer Designated United States Agent

Note:	*Manufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.*
Is there a United States agent that has been designated by the manufacturer? *	

Section: Product Data

Product and Model Identification

Note:	*At this time we are only accepting electronic versions of reporting guides contained within this software. Other reporting guides that are not yet electronic are available for downloading from http://www.fda.gov/cdrh/comp/eprc.html.*

Product Type Reported

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

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

If Other, please identify the specific product type.

Report Information

Is this the first time you've submitted a report on the particular type of product selected in the Product Type Reported section? *	
Since this is not the first time you've reported on this type of product, then is this a report supplement to a previously reported model family?	
Provide the Accession Number of the report for which this is a supplement (Do not enter any Device Premarket Application or Notification document number here, such as PMAs, 510(k)s, IDEs, etc.):	
Are you requesting a new variance, a renewal, extension or amendment to a previous variance? *	
If you are requesting a renewal, extension, or amendment, please provide the variance number that	

was issued by CDRH.	

Noncompliances or Defects

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

Responses to Noncompliances or Defects

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

Exemption Requests

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

Variance Requests

Message:	*Click the "Add" button to select the desired requirement from which you are seeking a variance.*
This submission includes an application for a variance from certain requirements. *	
Item	

Provide an explanation and attach supporting files, if necessary. Click on the Add... button below to attach files.	
Details	
File Attachment	
Error:	*In addition to the electronic copy of this submission, please be sure to submit one hard-copy of the signed variance request document to the following address:* *Division of Dockets Management (HFA-305)* *Food and Drug Administration* *Rm 1061, 5630 Fishers Lane* *Rockville, MD 20852*

Responses to Communications from FDA

Does this document or any of its attachments contain:		
A response to an inspection?	*	
What was the date of the inspection?		
A response to a warning letter from the Food and Drug Administration (FDA)?	*	
What was the date of the Warning Letter?		
A response to a report review inquiry from the Center for Devices and Radiological Health (CDRH) (the inquiry may have been in the form of a letter, email, or phone call)?	*	
What was the date of the inquiry?		
A response to any other communication from FDA?	*	
What was the date of the communication?		
Provide an explanation:		

Use Environment

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

[ ] Elderly
[ ] Employees/Workers
[ ] Engineers or Scientists
[ ] General Public
[ ] Medical Staff
[ ] Patients
[ ] Other

Additional Information

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

Private Labeling

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

Medical Devices

Provide the premarket 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one of these numbers has been assigned by FDA yet.
If it has not been assigned yet, provide an explanation and submit it as soon as you receive such a filing number.

Electromagnetic Compatibility and Interference

Note:	*Electromagnetic Compatability (EMC) and Electromagnetic Interference (EMI) description: This question concerns the evaluation of your product's susceptibility to EMI and/or freedom from causing EMI.For additional information on EMC and EMI please refer to the FDA website at: http://www.fda.gov/cdrh/emc/emc-in-hcf.html*

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

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

Section: Product & Model ID

1.0 X-RAY REPORTING

INTRODUCTION TO DIAGNOSTIC X-RAY REPORTING

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

2.1 REPORTING GUIDE

INTRODUCTION TO THE DIAGNOSTIC X-RAY REPORTING GUIDE

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

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

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

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

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

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

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

2.2 COMMON ASPECTS REPORT

INTRODUCTION TO THE COMMON ASPECTS REPORT

Manufacturers are encouraged to submit a "Common Aspects Report" in order to simplify their reporting obligations. The Common Aspects Report is a separate product report that incorporates a description of test methods, instrumentation, and sampling plans common to several models. This Common Aspects Report is not intended as a means for certification of any specific model. Currently, separate product reports from the same manufacturer often provide identical descriptions of the quality control program. Such duplication is costly and entails extra effort for both the manufacturer and the Center. By development of a Common Aspects Report, standardized test methods, instrumentation, and sampling plansmay be collected into one report. Product reports for specific models can then reference the applicable section and page number of the Common Aspects Report where the required information can be found. For example, a product report on an x-ray control must include responses to the appropriate sections of

PART 1And 2 -MANUFACTURER AND REPORT IDENTIFICATION, PRODUCT AND MODEL IDENTIFICATION and PART 200-COMPONENT DESCRIPTION, however, information with respect to test methods in PART 300-QUALITY CONTROL TESTING and also PART 400 -COMMON ASPECTS may be provided by referencing specific sections and pages to the Common Aspects Report. Sample test data solicited in PART 300 must still be included in the product report.

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

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

2.3 DEFINITIONS

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

(1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

(2) "accessory component" means

a) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this subchapter but which requires an initial determination of compatibility with the system; or

b) A component necessary for compliance of the system with applicable provisions of this subchapter but which may be interchanged with similarcompatible components without affecting the system's compliance, such as one of a set of interchangeable

beam-limiting devices; or

c)A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

(3) "Air kerma" means kerma in air (see kerma).

(4) "Air kerma rate" (AKR) means the air kerma per unit time.

(5) "Aluminum equivalent" means the thickness of aluminum (type 1100alloy) affording the same attenuation, under specified conditions, as the material in question.

(6) "Articulated joint" means a joint between two separate sections of a tabletop which joint provides the capacity for one of the sections to pivot on the line segment along which the sections join.

(7) "Assembler" means any person engaged in the business of assembling,replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

(8) "Attenuation block" means a block or stack of type 1100 aluminumalloy or aluminum alloy having equivalent attenuation with dimensions 20 centimeters or larger by 20 centimeters or larger by 3.8 centimeters.When used, the attenuation block shall be large enough to intercept the entire x-ray beam.

(9) "Automatic exposure control" (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

(10) "Automatic exposure rate control" (AERC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation per unit time.

(11) "Beam axis" means a line from the source through the centers of the x-ray fields.

(12) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

(13) "C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected orcoordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

(14) "Cantilevered tabletop" means a tabletop designed such that the unsupported portion can be extended at least 100 centimeters beyond the support.

(15) "Cassette holder" means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film cassette during an x-ray exposure.

(16) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

(17) "Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations.

(18) "Computed Tomography" (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission -.

(19) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

(20) "Cooling curve" means the graphical relationship between heat units stored and cooling time.

(21) "Cradle" means:

(a) A removable device which supports and may restrain a patient abovean x-ray table; or

(b) A device; (i) Whose patient support structure is interposed between the patient and the image receptor during normal use; (ii) Which is equipped with means for patient restraint; and(iii) Which is capable of rotation about its long (longitudinal) axis

(22) "CT Gantry" means tube housing assemblies, beam-limiting devices,detectors, and the supporting structures, frames, and covers which hold and/or enclose these components.

(23) "Cumulative air kerma" means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

(24) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

(25) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

(26) "Dose" means the absorbed dose as defined by the International Commission on

Radiation Units and Measurements. The absorbed dose, D, isthe quotient of de by dm, where de is the mean energy imparted by ionizing radiation to matter of mass dm.

(27) "Equipment" means x-ray equipment."Exposure" (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons andpositrons) liberated by photons in a volume element of air having mass dm are completely stopped in air. "Exposure" is also used with a second meaning to refer to the process or condition during which the x-ray tube produces x-ray radiation. Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to action of an electric field.

(28) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(29) "Fluoroscopic radiation-emissions-display device" means a device,subsystem or component that provides the displays of AKR and cumulativeair kerma required by 1020.32(k). It includes radiation detectors, if any, electronic and computer components, associated software, and data displays.

(30) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the imagereceptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

(31) "Fluoroscopy" means a technique for generating x-ray images and presenting them continuously as visible images for the purpose of providing the user a visual display of dynamic processes.

(32) "General purpose radiographic x-ray system" means any radiographicx-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

(33) "Half-value layer, (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the air kerma rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(34) "Image Intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

(35) "Image receptor" means any device, such as a fluorescent screen,radiographic film, x-ray image intensifier tube, solid-state detector,or gaseous detector, which transforms incident x-ray photons either into a visible image or into another form which can be made

into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "imagereceptor" shall mean the preselected portion of thedevice.

(36) "Image receptor support device" means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

(37) "Isocenter" means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range ofrotations about a common center.

(38) "Kerma" (K) means the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm where dEtr is the sum of the initial kineticenergies of all the charged ionizing particles liberated by uncharged ionizing particles in a material of mass dm. When the material is air,the quantity is "air kerma."

(39) "Last image hold (LIH) radiograph" means an image obtained either by retaining one or more fluoroscopic images, which may be temporally integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

(40) "Lateral fluoroscope" means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

(41) "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(i)The useful beam and

(ii) Radiation produced when the exposure switch or timer is not activated.

(42) "Leakage technique factors" means the technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:

(i)For tube housing assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peaktube potential with the quantity of charge per exposure being 10 millicoulombs (or 10 mAs) or the minimum obtainable from the unit, whichever is larger.

(ii) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and(iii) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

(43) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor whose perimeter is the locus of points at which the illumination is one-fourth of the maximumin the intersection.

(44) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load linepotential; that is,Percent line-voltage regulation = 100(Vn -Vi)/Viwhere:Vn = No-load line potential andVi = Load line potential.

(45) "Maximum line current" means the route mean square current in the supply line of an x-ray machine operating at its maximum rating.

(46) "Mode of operation" means, for fluoroscopic systems, a distinctmethod of fluoroscopy or radiography selected with a set of technique factors or other control settings uniquely associated with the mode.Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog), digital cineradiography, digital subtraction angiography,electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, air kerma rate, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration,number of pulses per exposure series, SID, or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different than the one that has been selected.

(47) "Movable tabletop" means a tabletop which, when assembled for use,is capable of movement with respect to its supporting structure within the plane of the tabletop.

(48) "Nonimage-intensified fluoroscopy" means fluoroscopy using only a fluorescent screen.

(49) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(50) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

(51) "Pulsed mode" means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less

than one-half second.

(52) "Quick change x-ray tube" means an x-ray tube designed for use in its associated tube housing such that:

(i) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of paragraphs (k) and (m) of section 1020.30;

(ii) The focal spot position will not cause noncompliance with the provisions of sections 1020.30 through 1020.33;

(iii) The shielding within the tube housing cannot be displaced; and

(iv) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube housing will not result in noncompliance of the x-ray system with the applicable field limitation and alignment requirements of 1020.31 through 1020.33.

(53) "Radiation therapy simulation system " means a radiographic orfluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field

(54) "Radiography" means a technique for generating and recording anx-ray pattern for the purpose of providing the user withanimage(s) after termination of the exposure.

(55) "Rated line voltage" means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

(56) "Rated output current" means the maximum allowable load current of the x-ray high-voltage generator.

(57) "Rated output voltage" means the allowable peak potential, involts, at the output terminals of the x-ray high-voltage generator.

(58) "Rating" means the operating limits specified by the manufacturer.

(59) "Recording" means producing a permanent form of an image resulting from x-ray photons (e.g., film, videotape).

(60) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

(61) "Scan" means the complete process of collecting x-ray transmission data for the

production of a tomogram. Data maybe collected simultaneously during a single scan for the productionof one or moretomograms.

(62) "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

(63) "Solid state x-ray imaging device" means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

(64) "Source" means the focal spot of the x-ray tube.

(65) "Source-image receptor distance, (SID)" means the distance from the source to the center of the input surface of the image receptor.

(66) "Source-skin distance (SSD)" means the distance from the source tothe center of the entrant x-ray field in the plane tangent to the patient skin surface.

(67) "Spot-film device" means a device intended to transportand/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

(68) "Stationary equipment" means equipment which is installed in a fixed location.

(69) "Stationary tabletop" means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

(70) "Technique factors" means the conditions of operation. They are specified as follows:i. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;ii. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses; andiii. For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds,and the number of x-ray pulses per scan, or the product of the tube current, x-ray pulse width, and the number of x-ray pulses in mAsiv. For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; andv. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

(71) "Tomogram" means the depiction of the x-ray attenuation properties of a section

through a body.

(72) "Tube" means an x-ray tube, unless otherwise specified.

(73) "Tube housing assembly" means the tube housing with tube installed.It includes high-voltage and/or filament transformers and otherappropriate elements when they are contained within the tube housing.

(74) "Tube ratingchart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(75) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

(76) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray fieldsize at a given SID.

(77) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

(78) "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, photo timers, automatic brightness stabilizers, and similar devices, which control the technique factors ofan x-ray exposure.

(79) "X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-raye quipment are as follows:(i) Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;(ii) Portable x-ray equipment means x-ray equipment designed to be hand-carried; and(iii)Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.

(80) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(81) "X-ray high-voltage generator" means a device which transformselectrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filamenttransformers for the x-ray tube(s), high-voltage switches, electricalprotective devices, and other appropriate elements.

(82) "X-ray system" means an assemblage of components for the controlled production of x rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures.

Additional components which function with the system are considered integral parts of thesystem.

(83) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in1020.30, 1020.31 and 1020.32.

(84) "X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel,fluoroscopic image receptor, or spot-film device beneath the tabletop.

(85) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

2.4 MODEL DESIGNATION

Give the model designation for any components (including combination components) that are being certified in this report. Also provide the model designation for each combination that is being certified in this report. Do not list components which are not being certified by this report. For all components certified by this report and its supplements identify the model exactly as it appears on the identification label.

Item	

2.5 INDIVISIBLE COMBINATION OF COMPONENTS

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:*

Attach a file that contains a replica of labels for every model listed under 2.4, 2.5 and 2.6. Click on the Add... button below to attach any supporting files.

File Attachment	

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?	

2.9 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).*

Are there assembly and testing instructions necessary at the installation site for assuring compliance to the federal standards?	
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:*
Attach for each model, system or subsystem (as appropriate) the above information in a separate file. Click on the Add... button below to attach any supporting files.	
File Attachment	

2.11 ADDITIONAL INFORMATION

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

2.11.1 BEAM LIMITING DEVICE (BLD)

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

2.11.2 HV GENERATOR

Note:	*Answer the following questions if certifying a High Voltage Generator in this submission.*
Is this report intended for the certification of an x-ray high voltage generator (either separately or in combination)?	

2.11.3 X-RAY CONTROL

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

Maximum Deviation from Indicated Value

For each model x-ray control certified in this report, list in an attached table, maximum deviation from the indicated value as given in the user technical specifications (models with identical specifications may be grouped together).	
Note:	*See the three sample tables below for the required format. Three levels of operation are provided in the sample tables for mid level, low level, and high level techniques. The selection of the mid level has been provided. If the unit is not capable of operating at the specified value, then choose a value as close to that listed as possible. For any techniqes that are fixed, use the same level for all three levels. The sample tables are also separated into three kVp ranges. If the control only operates on one range then leave the other ranges blank and state that the maximum deviations shall be listed as +/- values in units of the technique value (e.g., kVp, mAs, mA, mS).If the controls only operate in one of the kVp ranges then only that column should have values listed in it.*Click on the HTML editor box in the supporting details section to create the*

	tables or copy thesample tables into a new document, enter the appropriate values and attach the file below.

	EXAMPLE of Low-level specifications DESIGNED kVp OPERATING RANGE					
	BELOW 51 kVp		**51 TO 70 kVp**		**ABOVE 70 kVp**	
	INDICATED	**MAXIMUM DEVIATION**	**INDICATED**	**MAXIMUM DEVIATION**INDICATED	**MAXIMUM DEVIATION**	
kVp	20	+/-2	56	+/-3	80	+/-4
mAS	10	+/-2	20	+/-3		
Or						
mA			50	+/-2	100	+/-2
TIME mS			400	+/-4	100	+/-3

	EXAMPLE of High-level specifications DESIGNED kVp OPERATING RANGE					
	BELOW 51 kVp		**51 TO 70 kVp**		**ABOVE 70 kVp**	
	INDICATED	**MAXIMUM DEVIATION**	**INDICATED**	**MAXIMUM DEVIATION**	**INDICATED**	**MAXIMUM DEVIATION**
kVp	40	+/-3	68	+/-3	120	+/-6
mAS	80	+/-4	140	+/-3		
Or						
mA			200	+/-4	600	+/-6
TIME mS			700	+/-7	800	+/-6

Click on the Add... button below to attach the appropriate files.
File Attachment

Section: Component Description

201.0 TUBE HOUSING ASSEMBLY

Note:	*This section should be completed for each tube housing assembly listed in section 2.4 and any combination listed in section 2.5 that contains a tube housing assembly as an integral partthereof.*

Is this report intended for the certification of a tube housing assembly or combination containing a tube housing assembly?	

202.0 BEAM-LIMITING DEVICES

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

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?	

202.2 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?	

202.3 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)?	

202.4 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?	

202.5 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?	

202.6 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?	

202.7 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?	

202.8 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?	

202.9 Part 1: Variable Filtration

Does the beam-limiting device have variable filtration selection?	

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	

203.0 X-RAY CONTROLS

Note:	*This section shouldbe completed for each x-ray control listed in section 2.4 and any combination listed in section 2.5 that containsan x-ray control as an integral part thereof. If this report is not certifying an x-ray control then go to section 204.0*
Is this report intended for the certification of an x-ray control or combination containing an x-ray control?	

203.1 Warning Label

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

203.2 Part 1: Battery Powered Generator

Is the x-ray control used with a 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?	

203.4 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?	

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	

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?	

205.3 Part 1: Image Intensifier

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

206.3 X-Ray Tables

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

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?	

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?	

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?	

Section: Quality Control Testing

301.0 Leakage Radiation from the Diagnostic Source

Note:	*Answer the following questions if certifying a beam-limiting device or tube housing assembly in this submission (i.e., if yes was selected for question 2.4 (a),(b), 2.5 (a), (b), (c) or (d)).*
Requirement:	
Message:	*The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgens (mR) exposure) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters (1020.30(k)).*
Applicability:	
Message:	*This requirement is applicable to the diagnostic source assembly (tube housing assembly combined with a beam-limiting device). Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see Prototype Testing (a)).*
Critical Parameters and "Worst Case" Conditions:	

A.	*Message:*	*The test results must include data representative of each compatible combination of tube housing assembly and beam-limiting device.*
B.	*Message:*	*As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.*
C.	*Message:*	*To assure the use of maximum rated peak tube potential and continuous tube current, the test method(s) must provide the procedure for periodic calibration of technique factors.*
D.	*Message:*	*For any test using a scan of the diagnostic source assembly, the rate of scan specified in the test methods) must account for the response time of the radiation instrumentation.*

Prototype Testing:		
This section is for start up prior to full production phase and thus the testing and quality control procedures may not be the same as production testing. Does prototype testing apply?		
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.	
	File Attachment	
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.	
	File Attachment	
F.	Explain howcompliance 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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	

G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
C.	Attach a sample of raw test data.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailedinstructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	

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. *	
File Attachment	

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	Foreach test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
I.	Is the actual compliance value calculated from the raw test data?	

Provide a copy of the pages in the user manualthat specifies no assembly or installation instructions are necessary and all that is needed to operate the system is to plug the power cord into the wall socket. *	
File Attachment	

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailedinstructions for performing each test.	
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F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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 toplug the power cord into the wall socket. *	
File Attachment	

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	

	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), pleaseattach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	Explain how compliance is established. *	
J.	Is this performance parameter tested on 100 percent of the produced models?	
Assembler Testing:		
Does assemblertestingapply?		
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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach acopy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	

	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *	
File Attachment	

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	

F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
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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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	

H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *		
File Attachment		

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.	
	File Attachment	
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.	
	File Attachment	

F.	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.	
	File Attachment	
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.)	
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E.	Attach a copy of the detailed instructions for performing each test.	
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F.	Identify the instrument(s) used for each test by manufacturer and model number.	
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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.	
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-	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.	

	File Attachment	
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.)	
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Providea copy of the pages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate the system is to plug the power cord into the wall socket. *	
File Attachment	

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.	
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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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
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F.	Identify the instrument(s) used for each test by manufacturer and model number.	
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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.	
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H.	For each test method listed in question (B.), please attach sample raw test data.	

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I.	Is the actual compliance value calculated from the raw test data?	
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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.	
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D.	Submit the technical data that supports the use of the test in question (C.)	
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G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
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	File Attachment	
I.	Is the actual compliance value calculated from the raw test data?	
Provide a copy of the pages in the user manualthat specifies no assembly or installation instructions are necessary and all that is needed to operate the system is to plug the power cord into the wall socket. *		
File Attachment		

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	

	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), pleaseattach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing eachtest.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	

	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *		
File Attachment		

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.	
	File Attachment	
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.	

	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy ofthe detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *	
File Attachment	

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	

	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question(B.), please attach sample raw test data.	
	File Attachment	
I.	Is the actual compliance value calculated from the raw test data?	
Provide a copy ofthe pages inthe user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate the system is to plug the power cord into the wall socket. *		
File Attachment		

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	

	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each testmethod listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	

	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *		
File Attachment		

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.	
	File Attachment	
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.	

	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
I.	Is the actual compliance valuecalculated from the raw test data?	
-	Please attach a sample of calculated compliance values complete with an explanation of any correction factors employed.	
	File Attachment	
-	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.	

	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions forperforming the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *	
File Attachment	

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 forstart 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 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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	

-	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.	
	File Attachment	

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.)	
	File Attachment	

E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	

F.	Identify the instrument(s) used for each test by manufacturerand model number.	
	File Attachment	

G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	

H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	

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. *	
File Attachment	

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attacha copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	

F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.)under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *		
File Attachment		

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.	
	File Attachment	

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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *		
File Attachment		

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	

	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer andmodelnumber.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	

	File Attachment	
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 orinstallation instructions are necessary and all that is neededto operate the system is to plug the power cord into the wall socket.	*
File Attachment	

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	

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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	Explain howcompliance 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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	

	File Attachment	
F.	Identifythe instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *	
File Attachment	

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	

-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *		
File Attachment		

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	

	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions forperforming the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used foreach test by manufacturer and model number.	

	File Attachment	
G.	For each test method listed in question(B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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 toplug thepower cord into the wall socket. *		
File Attachment		

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.
	File Attachment
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.

	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	

	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s)used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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 isneeded to operate the system is to plug the power cord into the wall socket. *	
File Attachment	

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of thedetailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test	

	where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attachsample raw testdata.	
	File Attachment	

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

Provide a copy of thepages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate the system is to plug the power cord into the wall socket. *	
File Attachment	

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	

	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
I.	Is the actual compliance value calculated from the raw test data?	
Provide a copy of thepages in the user manual that specifies no assembly or installation instructions are necessary and all that is needed to operate the system is to plug the power cord into the wall socket. *		
File Attachment		

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.	

	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.)under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *		
File Attachment		

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.	
	File Attachment	
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.	
	File Attachment	
F.	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performing each test.	

	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Production Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	
	File Attachment	
H.	For each test method listed inquestion (B.), please attach sample raw test data.	
	File Attachment	
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.	
	File Attachment	
-	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.	
	File Attachment	
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.)	
	File Attachment	
E.	Attach a copy of the detailed instructions for performingeach test.	
	File Attachment	
F.	Identify the instrument(s) used for each test by manufacturer and model number.	
	File Attachment	
G.	For each test method listed in question (B.) under Assembler Testing, attach the detailed instructions for performing the test where the rejection limits are specified.	

	File Attachment	
H.	For each test method listed in question (B.), please attach sample raw test data.	
	File Attachment	
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. *	
File Attachment	

Section: 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.	
File Attachment	
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.	
File Attachment	
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.	
File Attachment	
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.
File Attachment
Other Measurement:
Describe each measurement instrument (other than radiation, illuminance and contrast, or electrical)that you refer to in Part 300, giving thefollowing: type of instrument; manufacturer and model number if the instrument is commercially available; rated accuracy; precision; and ranges. If any number of commercially available instruments with certain basic characteristics may be used, it is sufficient to state the minimum accuracy, precision ranges, and so forth, of the class of instruments that will be used.If any instrument is unique or of special manufacture, however, then the manufacturer and model number should be stated. Please attachanymanuals for the testing instruments.
File Attachment
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.	
File Attachment	

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.

Error:	*You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.*
Message:	*Form FDA 3626 A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components (03/06)*