

Section: eRadHealth Menu

Introduction

Electronic Product Radiation Safety Reporting Form

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

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

Information about the FDA Electronic Submissions Gateway can be found at

www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm. Please contact the Gateway Helpdesk with your questions about that system.

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

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

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

Note about eSubmitter software:

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

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

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

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

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

Definitions

Definitions for Rad Health Products

Manufacturers

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

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

Importers

Importer is any person or 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

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

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

- (A) any ionizing or non-ionizing electromagnetic or particulate radiation, or
- (B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

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

- (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or
- (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effect

Role

What is your role?		[L]
Note:	If you are acting as an agent of the actual manufacturer, please select your role as, for example, perhaps an Importer or Consultant. Later in the report, under Manufacturer Data, you will be prompted to enter both manufacturer and submitter information.	
Information:	The following screen provides several options for you to accurately define what type of eSubmission you intend to create for FDA. Below are explanations of your options. Please feel free to review this screen, advance to the next screen and view the picklists, but if you're confused, come back to read this screen again to be certain you are selecting the correct report or correspondence type you want to create.	

Submission Information

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

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- | |
|--|
| <input type="checkbox"/> Laser Original Equipment/Component Manufacturer Registration (21 CFR 1040.10(a)(3)(ii)) |
| <input type="checkbox"/> Abbreviated Report (21 CFR 1002.12) |

After answering the Submission Type question above, one of the questions below may become active and required (see the blue dot to the right of the question). If there is an active question, select the appropriate product area or document type from the question's pick list. [QUESTION TYPE NOT YET IMPLEMENTED: HEADER STEP]

What Type of Product is this Radiation Safety Report about?

[L]

What Type of Product is this Annual Report about?

[L]

What Laser Light Show Document are you filing?

[L]

What Type of Correspondence is this?

[L]

What Type of Product is this Variance Request about?

[L]

FDA or State Inspector

Abbreviated Report Applicability

OEM Laser Applicability

Section: Manufacturer Data

General Information

General Information for Radiological Health Products

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

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

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

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

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

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

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

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

A complete Product Report is required for each product model or model family. Product Reports are now more generally referred to as Radiation Safety Reports to distinguish the Radiological Health submissions from medical device submissions. CDRH suggests that a complete report on one model of a family be submitted, with a separate Supplemental Report for each of the other models in the family. The Supplemental Report should respond in detail to the parts of the form where there are differences to report, referencing the number of the affected item. Items that are unchanged will still appear in the supplement from the original report. When new models of a product are introduced, if the models satisfy the criteria for an established reporting exemption or if the new models do not involve changes in radiation emission or performance requirements, then the manufacturer need not report the models prior to introduction into commerce. Rather, the manufacturer is only required to identify them in the annual report, or in quarterly updates to the annual report. Quarterly updates to annual reports may be submitted using the Annual Report software included in this application. [See 21 CFR 1002.13(c).]

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

Burden to Industry

Paperwork Reduction Act Statement

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

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

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

Manufacturer and Report Information

Confirmation:	<p>This Manufacturer section of this report requests names, addresses, phone numbers, etc. for your firm, various officials of your firm, consultants who may assist in preparing the report, parent firm (if any), importer and designated agent (for foreign firms). Some of this information is mandatory and its absence will prevent you from completing the report submission. Because some of these entries may be redundant, utilize the 'Contact Address Book' feature so you can save your data and reselect the entries later and in the future. (See the upload/download buttons in upper right corner of the screens).</p> <p>You can check for missing data at any time using the "Missing Data Report" from the "Output" menu across the top of this application. The Missing Data Report lists all missing responses that are required (that have the blue dot).</p>
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Information:	<p>Attention: Variance Applicants</p> <p>If you are acting as an agent or consultant for, or on behalf of, or filing for, a company that will be manufacturing or producing a Class IIIb or IV projector or laser light show or both which require an approved variance, the following explanations may provide further clarification.</p> <p>Manufacturer: This is the firm or company who is requesting the variance, will certify the product or show, and will be the holder and owner of the variance. This is not the agent or consultant who may be filing this report or Variance request for the manufacturer; that agent may be the submitter, identified in a later screen.</p> <p>Responsible Individual: This person works for the Manufacturer and is responsible for compliance of the projector and/or show. In the case of laser light shows, he or she may be the company president, CEO, or the laser light show head operator or a manager who oversees the shows.</p> <p>Reporting Official: This person works for the Manufacturer and is responsible for reports, recordkeeping, and submitting FDA required documents and correspondence.</p>
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Manufacturer Responsible for Product Compliance

Note:	<p>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.</p> <p>Be sure to enter address information for each tab below:</p>
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Select the Manufacturer's address from the Establishment Address book: [QUESTION TYPE NOT YET IMPLEMENTED: ESTABLISHMENT COMPLEX]

Responsible Individual

Note:	<p>The responsible individual is the highest level and most responsible individual affiliated with this establishment.</p>
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Select the Responsible Individual from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

Manufacturer's Reporting Official

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

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

Report Submitter

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

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

Internal Reference Number:

Parent Establishment

Is there a parent establishment? [L]

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

Manufacturer Designated United States Agent

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

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

Written Agreement

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

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

Note: If any of the required responses below do not apply to your designated agent, enter 'NOT APPLICABLE' or 'NA.'

Select the Designated Agent from the Contact Address book:

Contact Name

Occupation Title

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

Importer

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

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

Additional Manufacturing Locations

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

Note: If any of the products certified in this report are manufactured at locations other than listed in the Manufacturer Responsible for Product Compliance section, then the names, addresses, and FDA registration numbers should be provided. In addition any codes used on labels to identify a manufacturing location must be provided. Each factory location must assure all production procedures are followed identically step by step as provided in this report. If the procedures are not the same then separate reports should be filed.

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

Code used on identification labels:

Section: Product Data

Product and Model Identification

Attention - Information about this section

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

- (1) Identify your product's radiation type and the CDRH Product Code.
- (2) Enter an Accession number if this will be a report supplement. If you are preparing a supplement, you'll see that after entering a valid 7-digit Accession number many questions will no longer be required (they will either be disabled or will be optional, meaning they will no longer have the blue dot).
- (3) You will also have several questions that are of high significance for FDA/CDRH - why you might be submitting this report or

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correspondence. Please read these questions carefully, referring to the 21 CFR regulations on the website www.FDA.gov if you are unsure if the question is relevant to your firm's situation.

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

Product Type Reported

Note:	Each product that CDRH regulates is assigned a product code by CDRH.
What is the product code?	
To select the three letter product code,	
<ul style="list-style-type: none"> - Click the plus sign. You will see a product code filter dialog box. - Select the appropriate category name from the pick list. You will be provided a list of product codes from which to choose. - Select the best match to your product. - The remaining fields will be filled in for you when you select your product code. [QUESTION TYPE NOT YET IMPLEMENTED: RH SINGLE PRODUCT CODE] 	
If Other, provide a category name for this specific product.	

Examples of X-Ray Products

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

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

Report Information

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

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

Special Considerations

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

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

Responses to Noncompliances or Defects

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

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Note:	If you are submitting a Corrective Action Plan (CAP) following 21 CFR 1004 and information on design changes for future production, the design change information must be submitted in a Radiation Safety (Product) Report or supplemental report. Both the proposed CAP and the design changes may be submitted in one document if you prepare a product report and choose to include the CAP in it as a file attachment. Alternatively, you may create a separate eSubmission for the CAP using the "Correspondence" type template and selecting "Follow-up correspondence to FDA."
A description of any design changes that correct noncompliances for future production?	
	[L]
Note:	If you are submitting information on product design changes for future production due to a discovery of noncompliances or defects in current production, you must use the Radiation Safety (Product) Report template to create the report. Correspondence templates may be used to submit other information such as a proposed corrective action plan pertaining to a noncompliance or defect.
You may add an explanation and/or attach a document here:	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Exemption Requests

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

Variance Requests

Information:	Please note: in addition to responding to these questions below, a separate General Variance Request or Laser Light Show Variance Request form must be completed and submitted to CDRH, with a hard copy sent to FDA's Division of Dockets Management as instructed below for any variance request. The information requested on this screen does not constitute the full structured content of the variance request. The 2 types of Variance forms can be created in eSubmitter by selecting the appropriate Variance submission type under the eRad Health Menu section of this application.
Message:	Click the plus sign to list the requirements from which you are requesting a variance.
This submission includes an application for a variance from certain requirements.	
Item 1	
Item 2	
Item 3	
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	

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

Responses to Communications from FDA

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

Additional Information

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

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	.zip)]
Details	[HTML Text]

Private Labeling

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

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

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

Enter brand names and/or model designations in the following table by clicking on the Add button. If you prefer to attach a file, please click on the Add button and enter the text "See File Attachment" as the first table entry.

Item 1	
Item 2	
Item 3	
List of Brand Names and/or Model Designations	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

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

Explain how the brand names and model designations correspond with your own brand names and model designations:

[Multi-Line Plain Text]

Medical Devices

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

[Multi-Line Plain Text]

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

[Multi-Line Plain Text]

Note:	See also http://www.fda.gov/MedicalDevices/default.htm for more information on medical device premarket clearance procedures.
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Section: Part 100 - Identification

101.0 Definitions

As used in this guide and 21 CFR 1020.30, 1020.31, 1020.32 and 1020.33, 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 similar compatible 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 1100 alloy) affording the same attenuation, under specified conditions, as the material in question.
- (6) "Articulated joint" means a joint between two separate sections of a table top 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 aluminum alloy 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.

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

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

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

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

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

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

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

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

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

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

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

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

(21) "Cradle" means:

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

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

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

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

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(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 , is the quotient of d_e by dm , where d_e 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 and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air. "Exposure" is also used with a second meaning to refer to the process or condition during which the x-ray tube produces x-ray radiation. Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to action of an electric field.

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

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

(30) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(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 radiographic-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 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 reselect a portion of the image receptor, the term "imagereceptor" shall mean the preselected portion of the device.

(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

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through a full range of rotations about a common center.

(38) "Kerma" (K) means the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dE_{tr} by dm where dE_{tr} is the sum of the initial kinetic energies of 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 peak tube potential with the quantity of charge per exposure being 10 millicoulombs (or 10 mAs) or the minimum obtainable from the unit, whichever is larger.

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

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

(44) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is, Percent line-voltage regulation = $100(V_n - V_l)/V_l$ where: V_n = No-load line potential and V_l = Load line potential.

(45) "Maximum line current" means the root 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 distinct method 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,

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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 or fluoroscopic 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 an x-ray pattern for the purpose of providing the user with an image(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, in volts, at the output terminals of the x-ray high-voltage generator.

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

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(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 may be collected simultaneously during a single scan for the production of one or more tomograms.

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

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

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

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

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

(67) "Spot-film device" means a device intended to transport and/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 affixed 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; and iii. For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mill amperes (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 mAs; iv. 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; and v. 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 other appropriate elements when they are contained within the tube housing.

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- (74) "Tube rating chart" 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 field size at a given SID.
- (77) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.
- (78) "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, photo timers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.
- (79) "X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment 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 affixed 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 transforms electrical 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, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.
- (82) "X-ray system" means an assemblage of components for the controlled production of x rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.
- (83) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in 1020.30, 1020.31 and 1020.32.
- (84) "X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.
- (85) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

102.0 - Product Identification

Note:	Give the designation of the system being certified in this report:
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Enter the System Designation: (If you do not use a Model Family or Brand Name, leave the field blank)			
Item			
Item 1		Item 2	

Head and/or Body Scanner?	[L]
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102.1 Certifiable component

Item: 1 (could contain up to 500 items with none required)

Certifiable Component Type	[L]
Model Designation:	
Manufacturer	
Certifying in this report	[L]
Product report number where certified	

103.0 - Labeling / Information

Note:	In sections 103.1 - 103.5, please provide the answers to each question listed. This can be done by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. Each attached PDF file may contain multiple pages, but only one attachment per section is allowed.
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103.1 - Appendix A

Note:	Please provide the answers to each question listed by attaching a PDF file and indicating the appropriate section to review within the PDF.
Note:	Provide copies of the following labels along with a photograph or drawing of each certifiable component and/or system showing the location of the attached label. The standard requires that labels be permanently affixed, legible, and accessible to view. In the case of beam limiting devices and tube housing assemblies contained within the gantry, the identification and certification labels shall be mounted on the component even though the component is not visible. The gantry certification shall serve as the certifying label for the entire CT system. In addition, the date of manufacture as indicated on the gantry label shall serve as the manufacturing date for the entire CT system. Content 21 CFR Reference 1. Certification Labels 1010.22. Identification Labels 1010.33. Warning Labels 1020.30(j)
Attach PDF file here.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	
Certification labels are found on PDF page numbers:	
Identification labels are found on PDF page numbers:	
Warning labels are found on PDF page numbers:	

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103.2 - Appendix B

Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.	
Note:	Provide a copy of the assembler information requested below.	
Is this data located in a PDF file?		[L]
Attach PDF file here.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[HTML Text]		
Assembly & test instructions to assure compliance (21 CFR Reference: 1020.30(g)). PDF page numbers:		
Compatibility specifications (21 CFR Reference: 1020.30(g)). PDF page numbers:		
Tube reloading instructions (21 CFR Reference: 1020.30(e)). PDF page numbers:		

Please provide the assembly & test instructions to assure compliance (21 CFR Reference: 1020.30(g))		
[HTML Text]		
Please provide the compatibility specifications (21 CFR Reference: 1020.30(g))		
[HTML Text]		
Please provide the tube reloading instructions (21 CFR Reference: 1020.30(e))		
[HTML Text]		

103.3 - Appendix C

Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.	
Note:	Provide a copy of the Operator's Manual and other user information listed below. All user information listed below shall be identified and provided in a separate section of the user instruction manual or in a separate manual devoted only to this information.	
Is this data located in a PDF file?		[L]
Attach PDF file here.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[HTML Text]		
X-ray safety & maintenance schedule (21 CFR Reference: 1020.33(h)(1)). PDF page numbers:		
Tube housing assembly information (21CFR Reference: 1020.33(h)(2)). PDF page numbers:		

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X-ray control and generator information (21CFR Reference: 1020.33(h)(3)). PDF page numbers:	
Beam-limiting device information (21CFR Reference: 1020.33(h)(4)). PDF page numbers:	
Reference plane alignment directions (21CFR Reference: 1020.33(g)(2)). PDF page numbers:	
Offset plane alignment directions (21CFR Reference: 1020.33(g)(4)). PDF page numbers:	
Instructions concerning the use of the method provided for calculation of the CT number mean and standard deviation (21CFR Reference: 1020.33(j)(2)). PDF page numbers:	
Operating instructions (21CFR Reference: 1020.33(h)). PDF page numbers:	

Please provide x-ray safety & maintenance schedule (21 CFR Reference: 1020.33(h)(1)).
[HTML Text]
Please provide tube housing assembly information (21CFR Reference: 1020.33(h)(2)).
[HTML Text]
Please provide x-ray control and generator information (21CFR Reference: 1020.33(h)(3)).
[HTML Text]
Please provide beam-limiting device information (21CFR Reference: 1020.33(h)(4)).
[HTML Text]
Please provide reference plane alignment directions (21CFR Reference: 1020.33(g)(2)).
[HTML Text]
Please provide offset plane alignment directions (21CFR Reference: 1020.33(g)(4)).
[HTML Text]
Please provide instructions concerning the use of the method provided for calculation of the CT number mean and standard deviation (21CFR Reference: 1020.33(j)(2)).
[HTML Text]
Please provide operating instructions (21CFR Reference: 1020.33(h)).
[HTML Text]

103.4 - Appendix D

Note:	Provide a copy of the Operator's Manual and other user information listed below. Provide below the exact page number of the location of each item. All user information listed below shall be identified and provided in a separate section of the user instruction manual or in a separate manual devoted only to this information.
Is this data located in a PDF file?	[L]
Attach PDF file here.	

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File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[HTML Text]		
A statement of the CT conditions of operation used to provide the dose information requested below and in appendix E, part 5 (21 CFR Reference: 1020.33(c)(1)). PDF page numbers:		
Dose Information (21 CFR Reference: 1020.33(c)(2)) and Imaging Performance Information (1020.33(c)(93)). PDF page numbers:		
a	Note:	CTDI along the axis of rotation of the phantom and along lines parallel to the axis of rotation and 1.0 centimeter interior to the surface of the phantom and 90 0 apart. One of the surface positions shall be the maximum CTDI obtainable at the 1.0 centimeter depth. The CT conditions of operation (e.g., kVp, mAs, slice thickness, scan diameter, etc.) shall be the typical values. The location of the phantom position where the surface (1 cm interior) CTDI is maximum shall be indicated with respect to the CT system.
A statement of the noise. PDF page numbers:		
b	Note:	CTDI in the center location of the phantom for each selectable CT condition of operation that varies either the rate or duration of the exposure. Each condition of operation shall be presented as normalized to the value in (a) above with the other conditions of operation the same as in (a). If more than three selections for a condition of operation are available the normalized values shall be given for the maximum, minimum, and an intermediate selection.
A graphical presentation of the modulation transfer function for the same imaging processing & presentation mode as that used in the statement of the noise. PDF page numbers:		
c	Note:	CTDI at the location of the maximum CTDI at 1.0 centimeter interior to the surface of the phantom for each selectable peak tube potential. If more than three selections are available, the normalized values shall be given for the maximum, minimum, and an intermediate selection.
A statement of the nominal tomographic section thickness(es). PDF page numbers:		
d	Note:	Dose profile in the center location of the dosimetry phantom for each selectable nominal tomographic section thickness. If more than three selections of section thickness are available, the normalized values shall be given for the maximum, minimum, and an intermediate thickness. The dose profile shall be on the same graph and to the same scale as the corresponding sensitivity profile.
A graphical presentation of the sensitivity profile, as measured in the center of the dosimetry phantom for the selectable nominal tomographic section thickness for which the dose profiles are given. This shall be presented on the same graph and to the same scale as the corresponding dose profiles. The nominal section thickness shall be defined as the distance between the 50% sensitivity points on the sensitivity curve. PDF page numbers:		
e	Note:	A statement of the accuracy of the values given in a through d above.
A description of the phantom or device and test protocol or procedure used to determine the specifications and a statement of the maximum deviation from the specifications for items (a-d) above. PDF page numbers:		

A statement of the CT conditions of operation used to provide the dose information requested below and in appendix E, part 5 (21 CFR Reference: 1020.33(c)(1))	
[HTML Text]	

3627 DX CT Blank Product rpt (OMB 0910-0025)

Dose Information (21 CFR Reference: 1020.33(c)(2)) and Imaging Performance Information (1020.33(c)(93))		
[HTML Text]		
a	Note:	CTDI along the axis of rotation of the phantom and along lines parallel to the axis of rotation and 1.0 centimeter interior to the surface of the phantom and 90 0 apart. One of the surface positions shall be the maximum CTDI obtainable at the 1.0 centimeter depth. The CT conditions of operation (e.g., kVp, mAs, slice thickness, scan diameter, etc.) shall be the typical values. The location of the phantom position where the surface (1 cm interior) CTDI is maximum shall be indicated with respect to the CT system.
		A statement of the noise
		[HTML Text]
b	Note:	CTDI in the center location of the phantom for each selectable CT condition of operation that varies either the rate or duration of the exposure. Each condition of operation shall be presented as normalized to the value in (a) above with the other conditions of operation the same as in (a). If more than three selections for a condition of operation are available the normalized values shall be given for the maximum, minimum, and an intermediate selection.
		A graphical presentation of the modulation transfer function for the same imaging processing & presentation mode as that used in the statement of the noise
		[HTML Text]
c	Note:	CTDI at the location of the maximum CTDI at 1.0 centimeter interior to the surface of the phantom for each selectable peak tube potential. If more than three selections are available, the normalized values shall be given for the maximum, minimum, and an intermediate selection.
		A statement of the nominal tomographic section thickness(es)
		[HTML Text]
d	Note:	Dose profile in the center location of the dosimetry phantom for each selectable nominal tomographic section thickness. If more than three selections of section thickness are available, the normalized values shall be given for the maximum, minimum, and an intermediate thickness. The dose profile shall be on the same graph and to the same scale as the corresponding sensitivity profile.
		A graphical presentation of the sensitivity profile, as measured in the center of the dosimetry phantom for the selectable nominal tomographic section thickness for which the dose profiles are given. This shall be presented on the same graph and to the same scale as the corresponding dose profiles. The nominal section thickness shall be defined as the distance between the 50% sensitivity points on the sensitivity curve.
		[HTML Text]
e	Note:	A statement of the accuracy of the values given in a through d above.
		A description of the phantom or device and test protocol or procedure used to determine the specifications and a statement of the maximum deviation from the specifications for items (a-d) above
		[HTML Text]

103.5 - Appendix E

Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section
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3627 DX CT Blank Product rpt (OMB 0910-0025)

	within the PDF where the answer to each question can be found.	
Note:	Provide a copy of the Operator's Manual and other user information listed below. All user information listed below shall be identified and provided in a separate section of the user instruction manual or in a separate manual devoted only to this information.	
Is this data located in a PDF file?		[L]
Attach PDF file here.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[HTML Text]		
Quality assurance instructions*(21 CFR Reference: 1020.33(d))		
1.	Phantom description. PDF page numbers:	
2.	Instructions on phantom use and schedule for use. PDF page numbers:	
3.	Listing of allowable variations for the indicated parameters. PDF page numbers:	
4.	Description of the method to store quality assurance data. PDF page numbers:	
5.	Representative images obtained or a description of the means used to store and display such images. PDF page numbers:	
Quality assurance instructions*(21 CFR Reference: 1020.33(d))		
Phantom description.		
[HTML Text]		
Instructions on phantom use and schedule for use.		
[HTML Text]		
Listing of allowable variations for the indicated parameters.		
[HTML Text]		
Description of the method to store quality assurance data.		
[HTML Text]		
Representative images obtained or a description of the means used to store and display such images.		
[HTML Text]		
Note:	*QA tests for noise, contrast scale, nominal tomographic section thickness, and mean CT number should be done through the data acquisition stage. Resolution tests of either high or low contrast objects should be done from measurements through the data acquisition and display stages. The QA tests on resolution could be performed as two independent tests, i.e., one test operating on the digital data and one test operating on the display device. The test for contrast scale should include materials with CT numbers close to water so that they are representative of the CT number scale of interest to the user. At least two materials different from water should be used, one with a CT number approximately plus 100-300 and the other with a CT number of minus 100-300.	

Section: Part 200 - System Description

201.0 - Control/Indication CT Conditions of Operation - Visual Indication

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Note:	Give a complete description of the means provided to satisfy the requirement.
All CT conditions of operation must be displayed prior to the initiation of each scan or scan sequence (1020.33(f)(1)). Along with a description of the means provided, you should include a drawing or picture of the preindicators of technique factors to the operator. Click on the Add... button below to attach any supporting files.	
Details	[HTML Text]
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
The displayed conditions of operation must be visible from any position from which scan initiation is possible (1020.33(f)(1)). Provide a drawing or picture that illustrates the proximity of any exposure switch to the preindicated technique factors. Click on the Add... button below to attach any supporting files.	
Details	[HTML Text]
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

202.0 - Control/Indication of the CT Conditions of Operations - Timers

Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.	
Note:	Give a complete description of the means provided to satisfy the requirement.	
Is this data located in a PDF file?		[L]
Attach only one PDF file here.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[HTML Text]		
In the event of equipment failure, means must be provided to automatically limit the total scan time to no more than 110% of its preset value (1020.33(f)(2)(i)). Give a complete description of the backup safety device which is provided for this requirement. PDF page numbers:		
Visual indication must be provided to identify scans terminated through these means (1020.33(f)(2)(i)). In addition to a description of the means provided, you should include a picture or drawing of the visible signal that indicates when an exposure has been terminated by the backup safety device. PDF page numbers:		
Means must be provided for the manual resetting of the conditions of operation, in the event of equipment failure, prior to the initiation of another scan (1020.33(f)(2)(i)). Describe the manual resetting procedures. PDF page numbers:		
Means must be provided such that the exposure from the system does not exceed the radiation levels specified in paragraph 1020.30(k) except when x ray transmission data are being collected for use in image production or technique factor selection (1020.33(f)(2)(ii)). Give a description of your design which will limit the dose to the patient to only those circumstances stated above. PDF page numbers:		
Means must be provided for the operator to terminate the x ray exposure at any time during a scan, or series of scans of greater than 0.5 seconds duration (1020.33(f)(2)(iii)). Describe this method. PDF page numbers:		

3627 DX CT Blank Product rpt (OMB 0910-0025)

Termination of the x ray exposure, by the operator, must require manual resetting of the conditions of operation prior to initiation of another scan (1020.33(f)(2)(iii)). Describe the manual resetting procedure. PDF page numbers:	
In the event of equipment failure, means must be provided to automatically limit the totalscan time to no more than 110% of its preset value (1020.33(f)(2)(i)). Give a complete description of the backup safety device which is provided for this requirement.	
[HTML Text]	
Visual indication must be provided to identify scans terminated through these means (1020.33(f)(2)(i)). In addition to a description of the means provided, you should include a picture or drawing of the visible signal that indicates when an exposure has been terminated by the backup safety device.	
[HTML Text]	
Means must be provided for the manual resetting of the conditions of operation, in the event of equipment failure, prior to the initiation of another scan (1020.33(f)(2)(i)). Describe the manual resetting procedures.	
[HTML Text]	
Means must be provided such that the exposure from the system does not exceed the radiation levels specified in paragraph 1020 30(k) except when x ray transmission data are being collected for use in image production or technique factor selection (1020.33(f)(2)(ii)). Give a description of your design which will limit the dose to the patient to only those circumstances stated above.	
[HTML Text]	
Means must be provided for the operator to terminate the x ray exposure at any time during a scan, or series of scans of greater than 0.5 seconds duration (1020.33(f)(2)(iii)). Describe this method.	
[HTML Text]	
Termination of the x ray exposure, by the operator, must require manual resetting of the conditions of operation prior to initiation of another scan (1020.33(f)(2)(iii)). Describe the manual resetting procedure.	
[HTML Text]	

203.0 - Tomographic Plane Indication & Alignment

Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
Note:	Give a complete description of the means provided to satisfy the requirement.
Is this data located in a PDF file?	[L]
Attach PDF file here.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	
For any single tomogram, system, means shall be provided to permit visual determination of the tomographic plane or an offset reference plane (1020.33(g)(1)). Describe these specific means utilized for indication of location on the patient where the tomogram will be obtained. PDF page numbers:	

3627 DX CT Blank Product rpt (OMB 0910-0025)

For any multiple tomogram system, means must be provided to permit visual determination of the location of a reference plane (1020.33(g)(2)). For multiple tomogram systems, describe the relationship of the reference plane alignment to the actual position of the tomograms. PDF page numbers:	
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For any single tomogram, system, means shall be provided to permit visual determination of the tomographic plane or an offset reference plane (1020.33(g)(1)). Describe the specific means utilized for indication of location on the patient where the tomogram will be obtained.
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[HTML Text]

For any multiple tomogram system, means must be provided to permit visual determination of the location of a reference plane (1020.33(g)(2)). For multiple tomogram systems, describe the relationship of the reference plane alignment to the actual position of the tomograms.
--

[HTML Text]

204.0 - Beam On and Shutter Status Indicators

Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
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Note:	Give a complete description of the means provided to satisfy the requirement.
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Is this data located in a PDF file?	[L]
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Attach PDF file here.

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

Means shall be provided on the x ray control and on or near the housing of the scanning mechanism to provide visual indication when and only when X rays are produced (1020.33(h)(1)). In addition to a description of this means, provide a drawing or picture to show visual indicators. PDF page numbers:	
--	--

If applicable, means shall be provided on the x ray control and on or near the housing of the scanning mechanism to provide visual indication of whether the shutter is open or closed (1020.33(h)(1)). In addition to a description of this means, provide a drawing or picture to show the visual indicators. PDF page numbers:	
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The minimum period for x ray on indication must be 0.5 seconds or greater (1020.33(h)(1)). Describe the means provided to meet this requirement. PDF page numbers:	
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Visual indicators (indicating x ray production and shutter status) on or near the housing of the scanning mechanism shall be discernible from any point external to the patient opening, where insertion of any part of the human body into the primary beam is possible (1020.33(h)(1)). In addition to the description of this means, provide a drawing or picture that illustrates the location of all indicators at or near the housing of the scanning mechanism, in relation to the patient opening. PDF page numbers:	
--	--

Means shall be provided on the x ray control and on or near the housing of the scanning mechanism to provide visual indication when and only when X rays are produced (1020.33(h)(1)). In addition to a description of this means, provide a drawing or picture to show visual indicators.
--

[HTML Text]

3627 DX CT Blank Product rpt (OMB 0910-0025)

If applicable, means shall be provided on the x ray control and on or near the housing of the scanning mechanism to provide visual indication of whether the shutter is open or closed (1020.33(h)(1)). In addition to a description of this means, provide a drawing or picture to show the visual indicators.

[HTML Text]

The minimum period for x ray on indication must be 0.5 seconds or greater (1020.33(h)(1)). Describe the means provided to meet this requirement.

[HTML Text]

Visual indicators (indicating x ray production and shutter status) on or near the housing of the scanning mechanism shall be discernible from any point external to the patient opening, where insertion of any part of the human body into the primary beam is possible (1020.33(h)(1)). In addition to the description of this means, provide a drawing or picture that illustrates the location of all indicators at or near the housing of the scanning mechanism, in relation to the patient opening.

[HTML Text]

205.0 - CT Number Mean and Standard Deviation

Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
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Note:	Give a complete description of the means provided to satisfy the requirement.
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Attach PDF file here.

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

Means must be provided for the user to calculate the mean and standard deviation of CT numbers for an array of picture elements about any location in the image (1020.33(j)(1)). Describe this means. PDF page numbers:	
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The number of elements in this array must be under user control (1020.33(j)(1)). Describe the means provided to the user for varying the number of elements in the array. PDF page numbers:	
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Means must be provided for the user to calculate the mean and standard deviation of CT numbers for an array of picture elements about any location in the image (1020.33(j)(1)). Describe this means.

[HTML Text]

The number of elements in this array must be under user control (1020.33(j)(1)). Describe the means provided to the user for varying the number of elements in the array.

[HTML Text]

206.0 - Labeling

Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
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3627 DX CT Blank Product rpt (OMB 0910-0025)

Note:	Give a complete description of the means provided to satisfy the requirement.	
Is this data located in a PDF file?		[L]
Attach PDF file here.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
[HTML Text]		
The warning label must be legible and clearly visible on the control panel containing the main power switch (1020.30(j)). PDF page numbers:		
The identification label must contain the name & address of the manufacturer (or the individual or company under whose name it was sold), the place of manufacture, & the model designation and serial number (1010.3(a)(1)(2)). PDF page numbers:		
The month and year of manufacture must be provided clearly & legibly without abbreviation, and with the year shown as a four digit number follows: manufactured: (insert month and year of manufacture) (1010.3(a)(2)(ii)). PDF page numbers:		
If the place of manufacture as stated on the identification label is coded, please provide that code (1010.3(a)(2)(i)). PDF page numbers:		

The warning label must be legible and clearly visible on the control panel containing the main power switch (1020.30(j)).		
[HTML Text]		
The identification label must contain the name & address of the manufacturer (or the individual or company under whose name it was sold), the place of manufacture, & the model designation and serial number (1010.3(a)(1)(2)).		
[HTML Text]		
The month and year of manufacture must be provided clearly & legibly without abbreviation, and with the year shown as a four digit number follows: manufactured: (insert month and year of manufacture) (1010.3(a)(2)(ii)).		
[HTML Text]		
If the place of manufacture as stated on the identification label is coded, please provide that code (1010.3(a)(2)(i)).		
[HTML Text]		

Section: Part 300 - Quality Control

301.0 - Leakage Radiation From the Diagnostic Source Assembly

Note:	Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.	
Is this data located in a PDF file?		[L]
Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.		
[HTML Text]		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	

3627 DX CT Blank Product rpt (OMB 0910-0025)

301.1 Requirement

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
The leakage radiation from the diagnostic source assembly measured at distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens in 1hour 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)). PDF page numbers:	

The leakage radiation from the diagnostic source assembly measured at distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens 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)).	
[HTML Text]	

301.2 Critical Parameters and "Worst Case" Conditions

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. The test results must include data representative of each compatible combination of tube housing assembly, beam limiting device, and gantry. b. 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.c. For any test using a scan of the diagnostic source assembly, the rate of scan specified in the test method(s) must account for the response time of the radiation instrumentation.d.Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method. PDF page numbers:	
[HTML Text]	

a. The test results must include data representative of each compatible combination of tube housing assembly, beam limiting device, and gantry.b. 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.c. For any test using a scan of the diagnostic source assembly, the rate of scan specified in the test method(s) must account for the response time of the radiation instrumentation.d. Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method.	
[HTML Text]	

301.3 Prototype Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c.	

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Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

[HTML Text]

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

301.4 Production Testing

Note:

For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

[HTML Text]

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

3627 DX CT Blank Product rpt (OMB 0910-0025)

301.4i Sampling

Do you test 100% of the produced models?		[L]
Are any performance parameters tested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
The lot size (N)		
The sample size (n)		
The reject level number (c)		
A single or double sampling plan (S or D)		
The acceptable quality level (AQL)		
The lot tolerance percent defective (LTPD)		
The producer's risk (alpha)		
The consumer's risk (beta)		
The operating characteristic (OC) curve (page no)		
The average outgoing quality level (AOQL)		
The procedures for segregation of the lot until sampling allows the lot to be released.		
[HTML Text]		
Describe the procedures used for selecting the sample and indicate how randomness is assured.		
[HTML Text]		
Describe the action taken if the sampling plan leads to a rejection decision.		
[HTML Text]		

301.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a-i. If test instructions are provided to the assembler, answer the questions in 301.4 with respect to assembler testing. Note: The information requested in 301.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:	

3627 DX CT Blank Product rpt (OMB 0910-0025)

a-i. If test instructions are provided to the assembler, answer the questions in 301.4 with respect to assembler testing. Note: The information requested in 301.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.

[HTML Text]

302.0 - Beam Quality

Note:	Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
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Is this data located in aPDF file?

[L]

Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.

[HTML Text]

File Attachment

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

302.1 Requirement

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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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)). PDF page numbers:

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)).

[HTML Text]

302.2 Critical Parameters and "Worst Case" Conditions

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a. The test results must include data representative of each compatible combination of tube housing assembly and beam limiting device. b. 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. c. To minimize the effect of scatter radiation, the x ray field specified in the test method(s) must be just large enough to cover the sensitive volume of the detector. d. Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method. PDF page numbers:

a. The test results must include data representative of each compatible combination of tube housing assembly

3627 DX CT Blank Product rpt (OMB 0910-0025)

andbeam limiting device.b. 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.c. To minimize the effect of scatter radiation, the x ray field specified in the test method(s) mustbe just largeenough to cover the sensitive volume of the detector.d. Please note and describe any critical parameters and "worst case" conditionswhich are unique to your system or test method.

[HTML Text]

302.3 Prototype Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions.As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identifythe instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If theactual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

302.4 Production Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions.As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 foreach instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether themaximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

3627 DX CT Blank Product rpt (OMB 0910-0025)

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a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement. b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement. c. Submit the technical data that supports the use of the test in part b. d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F. e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s). f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified. g. For each of the above test methods, provide sample raw test data. h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

302.4i Sampling

Is this sampling plan the same as any previous sampling plan?		[L]
Please Attach/Select the appropriate file		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Please indicate the PDF page numbers where the sampling plan is located:		
Do you test 100% of the produced models?		[L]
Are any performance parameters tested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
The lot size (N)		
The sample size (n)		
The reject level number (c)		
A single or double sampling plan (S or D)		
The acceptable quality level (AQL)		
The lot tolerance percent defective (LTPD)		
The producer's risk (alpha)		
The consumer's risk (beta)		
The operating characteristic (OC) curve (page no)		
The average outgoing quality level (AOQL)		

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The procedures for segregation of the lot until sampling allows the lot to be released.

[HTML Text]

Describe the procedures used for selecting the sample and indicate how randomness is assured.

[HTML Text]

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

[HTML Text]

302.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a-i. If test instructions are provided to the assembler, answer the questions in 302.4 with respect to assembler testing. Note: The information requested in 302.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:

a-i. If test instructions are provided to the assembler, answer the questions in 302.4 with respect to assembler testing. Note: The information requested in 302.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.

[HTML Text]

303.0 - Peak Tube Potential

Note:	Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
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Is this data located in a PDF file?

[L]

Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.

[HTML Text]

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

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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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 pe4 tube potential shall not exceed the limits given (see 1020.30(h)(3)(vi)). PDF page numbers:

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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 pe4 tube potential shall not exceed the limits given (see 1020.30(h)(3)(vi)).

[HTML Text]

303.2 Critical Parameters and "Worst Case" Conditions

Note: For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

a. 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, minimum, and maximum allowable line voltage regulation).b. Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method. PDF page numbers:

a. 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, minimum, and maximum allowable line voltage regulation).b. Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method.

[HTML Text]

303.3 Prototype Testing

Note: For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

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[HTML Text]

303.4 Production Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
<p>a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement. b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement. c. Submit the technical data that supports the use of the test in part b. d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F. e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s). f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified. g. For each of the above test methods, provide sample raw test data. h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:</p>	

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement. b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement. c. Submit the technical data that supports the use of the test in part b. d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F. e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s). f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified. g. For each of the above test methods, provide sample raw test data. h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

303.4i Sampling

Is this sampling plan the same as any previous sampling plan?		[L]
Please Attach/Select the appropriate file		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Please indicate the PDF page numbers where the sampling plan is located:		
Do you test 100% of the produced models?		[L]
Are any performance parameters tested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		

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Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lotsize, sample size, rejection criterion). Attach a copy of the plan.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
The lot size (N)	
The sample size (n)	
The reject level number (c)	
A single or double samplingplan (S or D)	
The acceptable quality level (AQL)	
The lot tolerance percent defective (LTPD)	
The producer's risk (alpha)	
The consumer's risk (beta)	
The operating characteristic (OC) curve (page no)	
The average outgoing quality level (AOQL)	
The procedures for segregation of the lot until sampling allows the lot to be released.	
[HTML Text]	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
[HTML Text]	
Describe the action taken if the sampling plan leads to a rejection decision.	
[HTML Text]	

303.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a-i. If test instructions are provided to the assembler, answer the questions in 303.4 with respect to assembler testing. Note: The information requested in 303.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:	

a-i. If test instructions are provided to the assembler, answer the questions in 303.4 with respect to assembler testing. Note: The information requested in 303.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.	
[HTML Text]	

304.0 - Tube Current

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Note:	Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
Is this data located in a PDF file?	[L]
Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.	
[HTML Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

304.1 Requirement

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
The manufacturer shall state the maximum deviation of the 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 1020.30(h)(3)(vi)). PDF page numbers:	

The manufacturer shall state the maximum deviation of the 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 1020.30(h)(3)(vi)).	
[HTML Text]	

304.2 Critical Parameters and "Worst Case" Condition

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. 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, minimum, and maximum allowable line voltage regulation). b. Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method. PDF page numbers:	

a. 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, minimum, and maximum allowable line voltage regulation). b. Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method.	
[HTML Text]	

304.3 Prototype Testing

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Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value iscalculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

304.4 Production Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 foreach instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each testby manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual

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compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

304.4i Sampling

Is this sampling plan the same as any previous sampling plan?		[L]
Please Attach/Select the appropriate file		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Please indicate the PDF page numbers where the sampling plan is located:		
Do you test 100% of the produced models?		[L]
Are any performance parameters tested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
The lot size (N)		
The sample size (n)		
The reject level number (c)		
A single or double sampling plan (S or D)		
The acceptable quality level (AQL)		
The lot tolerance percent defective (LTPD)		
The producer's risk (alpha)		
The consumer's risk (beta)		
The operating characteristic (OC) curve (page no)		
The average outgoing quality level (AOQL)		
The procedures for segregation of the lot until sampling allows the lot to be released.		
[HTML Text]		
Describe the procedures used for selecting the sample and indicate how randomness is assured.		
[HTML Text]		
Describe the action taken if the sampling plan leads to a rejection decision.		
[HTML Text]		

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303.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a-i. If test instructions are provided to the assembler, answer the questions in 304.4 with respect to assembler testing. Note: The information requested in 304.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:	

a-i. If test instructions are provided to the assembler, answer the questions in 304.4 with respect to assembler testing. Note: The information requested in 304.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.	
[HTML Text]	

305.0 - Scan Time

Note:	Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
Is this data located in a PDF file?	[L]
Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	

305.1 Requirement

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
The manufacturer shall state the maximum deviation of the scan time 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 scan time shall not exceed the limits given (see 1020.30(h)(3)(vi)). PDF page numbers:	

The manufacturer shall state the maximum deviation of the scan time 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 scan time shall not exceed the limits given (see 1020.30(h)(3)(vi)).	
[HTML Text]	

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305.2 Critical Parameters and "Worst Case" Conditions

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. 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, minimum and maximum allowable line voltage regulation).b. Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method. PDF page numbers:	

a. 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, minimum and maximum allowable line voltage regulation).b. Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method.	
[HTML Text]	

305.3 Prototype Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:	

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.	
[HTML Text]	

305.4 Production Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these
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	inaccuracies.
<p>a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:</p>	

<p>a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.</p>	
[HTML Text]	

305.4i Sampling

Is this sampling plan the same as any previous sampling plan?		[L]
Please Attach/Select the appropriate file		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Please indicate the PDF page numbers where the sampling plan is located:		
Do you test 100% of the produced models?		[L]
Are any performance parameters tested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
The lot size (N)		

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The sample size (n)	
The reject level number (c)	
A single or double sampling plan (S or D)	
The acceptable quality level (AQL)	
The lot tolerance percent defective (LTPD)	
The producer's risk (alpha)	
The consumer's risk (beta)	
The operating characteristic (OC) curve (page no)	
The average outgoing quality level (AOQL)	
The procedures for segregation of the lot until sampling allows the lot to be released.	
[HTML Text]	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
[HTML Text]	
Describe the action taken if the sampling plan leads to a rejection decision.	
[HTML Text]	

305.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a-i. If test instructions are provided to the assembler, answer the questions in 305.4 with respect to assembler testing. Note: The information requested in 305.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:	

a-i. If test instructions are provided to the assembler, answer the questions in 305.4 with respect to assembler testing. Note: The information requested in 305.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.	
[HTML Text]	

306.0 - Tube Current - Exposure Time Product

Note:	Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
Is this data located in a PDF file?	[L]

3627 DX CT Blank Product rpt (OMB 0910-0025)

Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.

[HTML Text]

File Attachment

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

306.1 Requirement

Note:

For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

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 (see 1020.30(h)(3)(vi)). PDF page numbers:

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 (see 1020.30(h)(3)(vi)).

[HTML Text]

306.2 Critical Parameters and "Worst Case" Conditions

Note:

For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

a. 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, minimum and maximum allowable line voltage regulation). b. Please note and describe any critical parameters and "worst case", conditions which are unique to your system or test method. PDF page numbers:

a. 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, minimum and maximum allowable line voltage regulation). b. Please note and describe any critical parameters and "worst case", conditions which are unique to your system or test method.

[HTML Text]

306.3 Prototype Testing

Note:

For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

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a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement. b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s). c. Provide sample raw test data. d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement. b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s). c. Provide sample raw test data. d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

306.4 Production Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement. b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement. c. Submit the technical data that supports the use of the test in part b. d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F. e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s). f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified. g. For each of the above test methods, provide sample raw test data. h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement. b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement. c. Submit the technical data that supports the use of the test in part b. d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F. e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s). f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified. g. For each of the above test methods, provide sample raw test data. h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

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[HTML Text]

306.4i Sampling

Is this sampling plan the same as any previous sampling plan?		[L]
Please Attach/Select the appropriate file		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Please indicate the PDF page numbers where the sampling plan is located:		
Do you test 100% of the produced models?		[L]
Are any performance parameterstested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
The lot size (N)		
The sample size (n)		
The reject level number (c)		
A single or double sampling plan (S or D)		
The acceptable quality level (AQL)		
The lot tolerance percent defective (LTPD)		
The producer's risk (alpha)		
The consumer's risk (beta)		
The operating characteristic (OC) curve (page no)		
The average outgoing quality level (AOQL)		
The procedures for segregation of the lot untilsampling allows the lot to be released.		
[HTML Text]		
Describe the procedures used for selecting the sample and indicate how randomness is assured.		
[HTML Text]		
Describe the action taken if the sampling plan leads to a rejection decision.		
[HTML Text]		

306.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods
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3627 DX CT Blank Product rpt (OMB 0910-0025)

	and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a-i. If test instructions are provided to the assembler, answer the questions in 306.4 with respect to assembler testing. Note: The information requested in 306.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:

a-i. If test instructions are provided to the assembler, answer the questions in 306.4 with respect to assembler testing. Note: The information requested in 306.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.

[HTML Text]

307.0 - CTDI/Dose Profile Information

Note:	Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
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Is this data located in a PDF file?	[L]
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Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.

[HTML Text]

File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
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Indicate for each modality, e.g., head, body, or spine procedure:

- A statement of the typical scan technique factors (e.g., kVp, mAs, pulse width, time, etc.)
- A statement of the scan diameter.
- A statement of the system slice thicknesses.
- A statement of the accuracy of the parameters indicated above.
- A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.
- A statement of accuracy of the exposure measurement.

Pages:

Indicate for each modality, e.g., head, body, or spine procedure:

- A statement of the typical scan technique factors (e.g., kVp, mAs, pulse width, time, etc.)
- A statement of the scan diameter.
- A statement of the system slice thicknesses.
- A statement of the accuracy of the parameters indicated above.
- A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.
- A statement of accuracy of the exposure measurement.

[HTML Text]

307.1 Requirement

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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The manufacturer shall state the maximum deviation of the dose values given to the user in accordance with sections 1020.33(c)(2)(i), (ii), (iii), and (iv). The deviation from these values shall not exceed the limits given (1020.33(c)(2)(v)). PDF page numbers:

The manufacturer shall state the maximum deviation of the dose values given to the user in accordance with sections 1020.33(c)(2)(i), (ii), (iii), and (iv). The deviation from these values shall not exceed the limits given (1020.33(c)(2)(v)).

[HTML Text]

307.2 Critical Parameters and "Worst Case" Conditions

Note: For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

a. All dose measurements must be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuating materials present.
b. The CT conditions of operation for obtaining the CTDI at the five specified locations shall correspond to typical values (e.g., kVp, mAs, scan diameter slice thickness) suggested by the manufacturer for CT of the head, body, or spine as may be appropriate.
c. The normalized CTDI values must be at least the minimum, maximum mid range values for the condition of operation or the values available with the other conditions of operation set at the typical values.
d. Please note any assumptions made in or limitations of your test methods in determining the dose values for your system. PDF page numbers:

a. All dose measurements must be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuating materials present.
b. The CT conditions of operation for obtaining the CTDI at the five specified locations shall correspond to typical values (e.g., kVp, mAs, scan diameter slice thickness) suggested by the manufacturer for CT of the head, body, or spine as may be appropriate.
c. The normalized CTDI values must be at least the minimum, maximum mid range values for the condition of operation or the values available with the other conditions of operation set at the typical values.
d. Please note any assumptions made in or limitations of your test methods in determining the dose values for your system.

[HTML Text]

307.3 Prototype Testing

Note: For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.
b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).
c. Provide sample raw test data.
d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.
e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

3627 DX CT Blank Product rpt (OMB 0910-0025)

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement. b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s). c. Provide sample raw test data. d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

307.4 Production Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement. b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement. c. Submit the technical data that supports the use of the test in part b. d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F. e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s). f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified. g. For each of the above test methods, provide sample raw test data. h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement. b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement. c. Submit the technical data that supports the use of the test in part b. d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F. e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s). f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified. g. For each of the above test methods, provide sample raw test data. h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

307.4i Sampling

Is this sampling plan the same as any previous sampling plan?	[L]
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Please Attach/Select the appropriate file

File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
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3627 DX CT Blank Product rpt (OMB 0910-0025)

Please indicate the PDF page numbers where the sampling plan is located:		
Do you test 100% of the produced models?		[L]
Are any performance parameters tested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
The lot size (N)		
The sample size (n)		
The reject level number (c)		
A single or double sampling plan (S or D)		
The acceptable quality level (AQL)		
The lot tolerance percent defective (LTPD)		
The producer's risk (alpha)		
The consumer's risk (beta)		
The operating characteristic (OC) curve (page no)		
The average outgoing quality level (AOQL)		
The procedures for segregation of the lot until sampling allows the lot to be released.		
[HTML Text]		
Describe the procedures used for selecting the sample and indicate how randomness is assured.		
[HTML Text]		
Describe the action taken if the sampling plan leads to a rejection decision.		
[HTML Text]		

307.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a-i. If test instructions are provided to the assembler, answer the questions in 307.4 with respect to assembler testing. Note: The information requested in 307.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:	
[HTML Text]	

3627 DX CT Blank Product rpt (OMB 0910-0025)

a-i. If test instructions are provided to the assembler, answer the questions in 307.4 with respect to assembler testing. Note: The information requested in 307.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.

[HTML Text]

308.0 - Imaging Performance

Note: Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.

Is this data located in a PDF file?

[L]

Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.

[HTML Text]

File Attachment

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

308.1 Requirement

Note: For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

The manufacturer shall state the maximum deviation from the specifications regarding imaging performance provided in accordance with section 1020.33(c)(3)(i), (ii), (iii), and (iv). The deviation from these values shall not exceed the limits given (1020.33(c)(3)(v)). Questions in this section should be answered as they relate to each of the items listed in the specified paragraphs of 1020.33(c)(3). PDF page numbers:

The manufacturer shall state the maximum deviation from the specifications regarding imaging performance provided in accordance with section 1020.33(c)(3)(i), (ii), (iii), and (iv). The deviation from these values shall not exceed the limits given (1020.33(c)(3)(v)). Questions in this section should be answered as they relate to each of the items listed in the specified paragraphs of 1020.33(c)(3).

[HTML Text]

308.2 Critical Parameters and "Worst Case" Conditions

Note: For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

a. The CT conditions of operation shall correspond to those of (1020.33(c)(2)(i)), the typical conditions of operation suggest the manufacturer or CT of the head, body, or spine as may be appropriate. b. All aspects of data collection including the x ray attenuation properties of the material in the tomographic section shall be similar to those used to provide the dose information required section 1020.33(c)(2)(i). c. Please note any assumptions made in, or limitations of, the methods in determining the imaging parameters. PDF page numbers:

3627 DX CT Blank Product rpt (OMB 0910-0025)

a. The CT conditions of operation shall correspond to those us(1020.33(c)(2)(i), the typical conditions of operation suggest the manufacturer or CT of the head, body, or spine as may be appropriate.b. All aspects of data collection including the x ray attenuat properties of the material in the tomographic section shall similar to those used to provide the dose information required section 1020.33(c)(2)(i).c. Please note any assumptions made in, or limitations of, the methods in determining the imaging parameters.

[HTML Text]

308.3 Prototype Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

308.4 Production Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained

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from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement. b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement. c. Submit the technical data that supports the use of the test in part b. d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F. e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s). f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified. g. For each of the above test methods, provide sample raw test data. h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

308.4i Sampling

Is this sampling plan the same as any previous sampling plan?		[L]
Please Attach/Select the appropriate file		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Please indicate the PDF page numbers where the sampling plan is located:		
Do you test 100% of the produced models?		[L]
Are any performance parameters tested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
The lot size (N)		
The sample size (n)		
The reject level number (c)		
A single or double sampling plan (S or D)		
The acceptable quality level (AQL)		
The lot tolerance percent defective (LTPD)		
The producer's risk (alpha)		

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The consumer's risk (beta)	
The operating characteristic (OC) curve (page no)	
The average outgoing quality level (AOQL)	
The procedures for segregation of the lot until sampling allows the lot to be released.	
[HTML Text]	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
[HTML Text]	
Describe the action taken if the sampling plan leads to a rejection decision.	
[HTML Text]	

308.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a-i. If test instructions are provided to the assembler, answer the questions in 308.4 with respect to assembler testing. Note: The information requested in 308.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:	

a-i. If test instructions are provided to the assembler, answer the questions in 308.4 with respect to assembler testing. Note: The information requested in 308.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.	
[HTML Text]	

309.0 - Equipment Failure Exposure Termination

Note:	Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
Is this data located in a PDF file?	[L]
Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
[HTML Text]	

309.1 Requirement

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods
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	and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
Means shall be provided to terminate the x ray exposure automatically by either deenergizing the x ray source or shuttering the x ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function (1020.33(f)(2)(i)). PDF page numbers:	

Means shall be provided to terminate the x ray exposure automatically by either deenergizing the x ray source or shuttering the x ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function (1020.33(f)(2)(i)).	
[HTML Text]	

309.2 Critical Parameters and "Worst Case" Conditions

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method. PDF page numbers:	

Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method.	
[HTML Text]	

309.3 Prototype Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement. b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s). c. Provide sample raw test data. d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:	

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement. b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s). c. Provide sample raw test data. d. If the actual compliance value is calculated from the raw test data, provide a sample of	
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calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

309.4 Production Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

309.4i Sampling

Is this sampling plan the same as any previous sampling plan?	[L]
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Please Attach/Select the appropriate file

File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
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Please indicate the PDF page numbers where the sampling plan is located:

Do you test 100% of the produced models?	[L]
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Are any performance parameters tested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
The lot size (N)		
The sample size (n)		
The reject level number (c)		
A single or double sampling plan (S or D)		
The acceptable quality level (AQL)		
The lot tolerance percent defective (LTPD)		
The producer's risk (alpha)		
The consumer's risk (beta)		
The operating characteristic (OC) curve (page no)		
The average outgoing quality level (AOQL)		
The procedures for segregation of the lot until sampling allows the lot to be released.		
[HTML Text]		
Describe the procedures used for selecting the sample and indicate how randomness is assured.		
[HTML Text]		
Describe the action taken if the sampling plan leads to a rejection decision.		
[HTML Text]		

309.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a-i. If test instructions are provided to the assembler, answer the questions in 309.4 with respect to assembler testing. Note: The information requested in 309.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:	

a-i. If test instructions are provided to the assembler, answer the questions in 309.4 with respect to assembler testing. Note: The information requested in 309.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.	
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[HTML Text]

310.0 - Tomographic Plane Location

Note:	Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
Is this data located in a PDF file?	[L]
Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.	
[HTML Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

310.1 Requirement

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
The distance between the indicated location of the tomographic plane or reference plane and its actual location shall not exceed 5 millimeters(1020.33(g)(3)). PDF page numbers:	

The distance between the indicated location of the tomographic plane or reference plane and its actual location shall not exceed 5 millimeters (1020.33(g)(3)).	
[HTML Text]	

310.2 Critical Parameters and "Worst Case" Conditions

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method. PDF page numbers:	

Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method.	
[HTML Text]	

310.3 Prototype Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worstcase" conditions. As a result of inherent inaccuracies of the test methods
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	and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample ofcalculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slicethickness. PDF page numbers:	

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample ofcalculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced bythe nominal tomographic slice thickness.	
[HTML Text]	

310.4 Production Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test.Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 foreach instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:	

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an inaccurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods givethe page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained	
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from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

310.4i Sampling

Is this sampling plan the same as any previous sampling plan?		[L]
Please Attach/Select the appropriate file		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Please indicate the PDF page numbers where the sampling plan is located:		
Do you test 100% of the produced models?		[L]
Are any performance parameters tested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
The lot size (N)		
The sample size (n)		
The reject level number (c)		
A single or double sampling plan (S or D)		
The acceptable quality level (AQL)		
The lot tolerance percent defective (LTPD)		
The producer's risk (alpha)		
The consumer's risk (beta)		
The operating characteristic (OC) curve (page no)		
The average outgoing quality level (AOQL)		
The procedures for segregation of the lot until sampling allows the lot to be released.		
[HTML Text]		
Describe the procedures used for selecting the sample and indicate how randomness is assured.		
[HTML Text]		
Describe the action taken if the sampling plan leadsto a rejection decision.		
[HTML Text]		

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310.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a-i. If test instructions are provided to the assembler, answer the questions in 310.4 with respect to assembler testing. Note: The information requested in 310.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:	

a-i. If test instructions are provided to the assembler, answer the questions in 310.4 with respect to assembler testing. Note: The information requested in 310.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.	
[HTML Text]	

311.0 - Illumination Levels of the Light Source...

Note:	Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
Is this data located in a PDF file?	[L]
Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.	
[HTML Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

311.1 Requirement

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
If a device using a light source is used to satisfy the requirements of paragraph 1020.33(g)(1) &(2), the light source shall permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux (1020.33(g)(5)). PDF page numbers:	

If a device using a light source is used to satisfy the requirements of paragraph 1020.33(g)(1) &(2), the light source shall permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux (1020.33(g)(5)).	
[HTML Text]	

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311.2 Critical Parameters and "Worst Case" Conditions

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method. PDF page numbers:	

Please note and describe any critical parameters and "worstcase" conditions which are unique to your system or test method.	
[HTML Text]	

311.3 Prototype Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement. b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s). c. Provide sample raw test data. d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:	

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement. b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s). c. Provide sample raw test data. d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.	
[HTML Text]	

311.4 Production Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement. b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement. c. Submit the technical data that supports the use of the test in part b. d. Provide a copy of the detailed	

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instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

311.4i Sampling

Is this sampling plan the same as any previous sampling plan?		[L]
Please Attach/Select the appropriate file		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Please indicate the PDF page numbers where the sampling plan is located:		
Do you test 100% of the produced models?		[L]
Are any performance parameters tested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
The lot size (N)		
The sample size (n)		
The reject level number (c)		
A single or double sampling plan (S or D)		

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The acceptable quality level (AQL)	
The lot tolerance percent defective (LTPD)	
The producer's risk (alpha)	
The consumer's risk (beta)	
The operating characteristic (OC) curve (page no)	
The average outgoing quality level(AOQL)	
The procedures for segregation of the lot until sampling allows the lot to be released.	
[HTML Text]	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
[HTML Text]	
Describe the action taken if the sampling plan leads to a rejection decision.	
[HTML Text]	

311.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a-i. If test instructions are provided to the assembler, answer the questions in 311.4 with respect to assembler testing. Note: The information requested in 311.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:	

a-i. If test instructions are provided to the assembler, answer the questions in 311.4 with respect to assembler testing. Note: The information requested in 311.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.	
[HTML Text]	

312.0 - Shutter Leakage Radiation

Note:	Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
Is this data located in a PDF file?	[L]
Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.	
[HTML Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

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312.1 Requirement

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
For systems that allow high voltage to be applied to the x ray tube continuously and that control the emission of x rays with a shutter, the radiation emitted shall not exceed 100 milliroentgens (2.58 x 10 ⁵ coulomb/kilogram) in 1 hour at any point 5 centimeters outside the external surface of the housing of the scanning mechanism when the shutter is closed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters (1020.33(h)(2)). PDF page numbers:	

For systems that allow high voltage to be applied to the x ray tube continuously and that control the emission of x rays with a shutter, the radiation emitted shall not exceed 100 milliroentgens (2.58 x 10 ⁵ coulomb/kilogram) in 1 hour at any point 5 centimeters outside the external surface of the housing of the scanning mechanism when the shutter is closed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters (1020.33(h)(2)).	
[HTML Text]	

312.2 Critical Parameters and "Worst Case" Conditions

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. For any test using a scan of the diagnostic source assembly, the rate of scan specified in the test method(s) must account for the response time of the radiation instrumentation.b. Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method. PDF page numbers:	

a. For any test using a scan of the diagnostic source assembly, the rate of scan specified in the test method(s) must account for the response time of the radiation instrumentation.b. Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method.	
[HTML Text]	

312.3 Prototype Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are	

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spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

312.4 Production Testing

Note:

For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.c. Submit the technical data that supports the use of the test in part b.d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.g. For each of the above test methods, provide sample raw test data.h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

312.4i Sampling

Is this sampling plan the same as any previous sampling plan?

[L]

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Please Attach/Select the appropriate file	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	[L]
Are any performance parameters tested other than 100%?	[L]
List each performance parameter test that is sampled.	
[HTML Text]	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
The lot size (N)	
The sample size (n)	
The reject level number (c)	
A single or double sampling plan (S or D)	
The acceptable quality level (AQL)	
The lot tolerance percent defective (LTPD)	
The producer's risk (alpha)	
The consumer's risk (beta)	
The operating characteristic (OC) curve (page no)	
The average outgoing quality level (AOQL)	
The procedures for segregation of the lot until sampling allows the lot to be released.	
[HTML Text]	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
[HTML Text]	
Describe the action taken if the sampling plan leads to a rejection decision.	
[HTML Text]	

312.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a-i. If test instructions are provided to the assembler, answer the questions in 312.4 with respect to assembler testing. Note: The information requested in 312.5(d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:	

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a-i. If test instructions are provided to the assembler, answer the questions in 312.4 with respect to assembler testing. Note: The information requested in 312.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.

[HTML Text]

313.0 - Scan Increment Accuracy

Note: Please provide the answers to each question listed by either attaching a PDF file and in subsequent questions identify the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.

Is this data located in a PDF file?

[L]

Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.

[HTML Text]

File Attachment

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

313.1 Requirement

Note: For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

The deviation of indicated scan increment from actual scan increment shall not exceed 1 mm. Compliance shall be measured as follows: The determination of the deviation of indicated versus actual scan increment shall be based on measurements taken with a mass, less than or equal to 100 kilograms, on the patient support device. The patient support device shall be incremented from a typical starting position to the maximum incrementation distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel (1020.33(i)). PDF page numbers:

The deviation of indicated scan increment from actual scan increment shall not exceed 1 mm. Compliance shall be measured as follows: The determination of the deviation of indicated versus actual scan increment shall be based on measurements taken with a mass, less than or equal to 100 kilograms, on the patient support device. The patient support device shall be incremented from a typical starting position to the maximum incrementation distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel (1020.33(i)).

[HTML Text]

313.2 Critical Parameters and "Worst Case" Conditions

Note: For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.

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Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method. PDF page numbers:

Please note and describe any critical parameters and "worst case" conditions which are unique to your system or test method.

[HTML Text]

313.3 Prototype Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
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a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.
b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).
c. Provide sample raw test data.
d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.
e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Provide a description of the direct test method (i.e., one that directly measures the parameter in question) employed in testing and/or measuring the parameter for each model with respect to this requirement.
b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the appropriate section in Part 400 for this instrument(s).
c. Provide sample raw test data.
d. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.
e. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

313.4 Production Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
-------	---

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.
b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement.
c. Submit the technical data that supports the use of the test in part b.
d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.
e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s).
f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified.
g. For each of the above test methods, provide sample raw test data.
h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed.
j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval

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equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement. b. If an indirect test is used to measure compliance, explain why it is an accurate indication of compliance with this requirement. c. Submit the technical data that supports the use of the test in part b. d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F. e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the appropriate section in Part 400 for each instrument(s). f. For each of the above test methods give the page number of your detailed instructions for performing the test and indicate where the rejection limits are specified. g. For each of the above test methods, provide sample raw test data. h. If the actual compliance value is calculated from the raw test data, provide a sample of calculated compliance values complete with an explanation of any correction factors employed. j. A statement indicating whether the maximum CTDI is obtained from integration of the dose profile for a single scan or from a direct measurement of the average dose in an interval equal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

[HTML Text]

313.4i Sampling

Is this sampling plan the same as any previous sampling plan?		[L]
Please Attach/Select the appropriate file		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Please indicate the PDF page numbers where the sampling plan is located:		
Do you test 100% of the produced models?		[L]
Are any performance parameters tested other than 100%?		[L]
List each performance parameter test that is sampled.		
[HTML Text]		
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
The lot size (N)		
The sample size (n)		
The reject level number (c)		
A single or double sampling plan (S or D)		
The acceptable quality level (AQL)		
The lot tolerance percent defective (LTPD)		
The producer's risk (alpha)		
The consumer's risk (beta)		

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The operating characteristic (OC) curve (page no)	
The average outgoing quality level (AOQL)	
The procedures for segregation of the lot until sampling allows the lot to be released.	
[HTML Text]	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
[HTML Text]	
Describe the action taken if the sampling plan leads to a rejection decision.	
[HTML Text]	

313.5 Assembler Testing

Note:	For each applicable test listed below, verify that the testing adequately reflects the critical parameters and addresses the "worst case" conditions. As a result of inherent inaccuracies of the test methods and instrumentation, rejection limits for any test must be sufficiently restrictive to account for these inaccuracies.
a-i. If test instructions are provided to the assembler, answer the questions in 313.4 with respect to assembler testing. Note: The information requested in 313.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers. PDF page numbers:	

a-i. If test instructions are provided to the assembler, answer the questions in 313.4 with respect to assembler testing. Note: The information requested in 313.5 (d) (i.e., a copy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.	
[HTML Text]	

Section: Part 400 - Common Aspects

401.0 - Instrumentation

Note:	Please provide the answers to each question listed on the following screens in this section (401.1-401.4) by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template in screens 401.1 through 401.4. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
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401.1 - Radiation Measurement

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

Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
Is this data located in a PDF file?	[L]

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Attach only one PDF file here.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Manufacturer and Model Number if Commercially Available, PDF page numbers:	
Type of Instrument, PDF page numbers:	
Precision, PDF page numbers:	
Accuracy, PDF page numbers:	
Response Time, PDF page numbers:	
Energy Dependence, PDF page numbers:	
Angular Response, PDF page numbers:	
Exposure Rate Dependence, PDF page numbers:	
Ranges, PDF page numbers:	
Effective Measurement Area, PDF page numbers:	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations. PDF page numbers:	
How do you assure proper day to day operation of each instrument? PDF page numbers:	

Manufacturer and Model Number if Commercially Available	
Type of Instrument	
Precision	
Accuracy	
Response Time	
Energy Dependence	
Angular Response	
Exposure Rate Dependence	
Ranges	
Effective Measurement Area	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
[HTML Text]	
How do you assure proper day to day operation of each instrument?	
[HTML Text]	

401.2 - Illuminance

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

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Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.	
Is this data located in a PDF file?		[L]
Attach only one PDF file here.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	
Manufacturer and Model Number if the Instrument is Commercially Available, PDF page numbers:		
Type of Instrument, PDF page numbers:		
Precision, PDF page numbers:		
Accuracy, PDF page numbers:		
Ranges, PDF page numbers:		
Describe the procedures used for calibration of each instrument including the interval of time between calibrations. PDF page numbers:		
How do you assure proper day to day operation of each instrument? PDF page numbers:		

Manufacturer and Model Number if the Instrument is Commercially Available	
Type of Instrument	
Precision	
Accuracy	
Ranges	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
[HTML Text]	
How do you assure proper day to day operation of each instrument?	
[HTML Text]	

401.3 - Electrical Measurement

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

Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.	
Is this data located in a PDF file?		[L]
Attach only one PDF file here.		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	

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Details	[HTML Text]
Type of Instrument, PDF page numbers:	
Manufacturer and Model Number if the Instrument is Commercially Available, PDF page numbers:	
Rated Accuracy, PDF page numbers:	
Precision, PDF page numbers:	
Ranges, PDF page numbers:	
Response Time, PDF page numbers:	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations. PDF page numbers:	
Show where each instrument listed is connected during testing with the use of schematic diagrams. PDF page numbers:	

Type of Instrument	
Manufacturer and Model Number if the Instrument is Commercially Available	
Rated Accuracy	
Precision	
Ranges	
Response Time	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
[HTML Text]	
Show where each instrument listed is connected during testing with the use of schematic diagrams. Pages:	
[HTML Text]	

401.4 - Other Measurements

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

Note:	Please provide the answers to each question listed by either attaching a PDF file and indicating the appropriate section to review within the PDF, or by answering each of the listed questions directly in the text boxes provided within the template. If attaching a PDF file, please indicate the page or section within the PDF where the answer to each question can be found.
Is this data located in a PDF file?	[L]
Attach only one PDF file here.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]
Type of Instrument, PDF page numbers:	[L]
Manufacturer and Model Number if the Instrument is Commercially Available, PDF page numbers:	

3627 DX CT Blank Product rpt (OMB 0910-0025)

Rated Accuracy, PDF page numbers:	
Precision, PDF page numbers:	
Ranges, PDF page numbers:	
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. PDF page numbers:	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations. PDF page numbers:	

Type of Instrument	
Manufacturer and Model Number if the Instrument is Commercially Available	
Rated Accuracy	
Precision	
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.	
[HTML Text]	
Describe the procedures used for calibration of each instrument including the interval of time between calibrations.	
[HTML Text]	
Stop:	You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.
Message:	Form FDA 3627 Diagnostic X-Ray CT Products Radiation Safety Report (10/31/2013)