Submission Report

eRadHealth Menu

Introduction

Electronic Product Radiation Safety Reporting Form

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

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

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

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

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

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

Note about eSubmitter software:

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

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

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

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

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

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

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

Role

What is your role?	!*	Manufacturer

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

Submission Information

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

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

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

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

Manufacturer Data

Manufacturer Responsible for Product Compliance

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

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

Responsible Individual

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

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

Mailing Location:	
Address	
Telephone Number	
Fax Number	

Manufacturer's Reporting Official

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

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

Report Submitter

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

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

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

Internal Reference Number:	

Parent Establishment

Is there a parent establishment? *	

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

Manufacturer Designated United States Agent

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

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

Importer

Additional Manufacturing Locations

Product Data

Product and Model Identification

Attention - Information about this section

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

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

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

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

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

Product Type Reported

What is the product code? *

To select the three letter product code,

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

Category	
Product Code	
Performance Standard	

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

Report Information

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

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

Special Considerations

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

Noncompliances or Defects

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

Responses to Noncompliances or Defects

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

Exemption Requests

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

Variance Requests

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

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

Responses to Communications from FDA

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

Additional Information

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

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

Private Labeling

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

Medical Devices

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

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

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.

(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 byte 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.

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

(25) "Diagnostic x-ray system" means an x-ray system designedfor irradiationof 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 de by dm, where de is the mean energy imparted by ionizing radiation to matter of mass dm.

(27) "Equipment" means x-ray equipment."Exposure" (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons 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 through a full range of rotations about a common center.

(38) "Kerma" (K) means the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm where dEtr is the sum of the initial kinetic energies offal 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 10millicoulombs (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(Vn -Vi)/Viwhere:Vn = No-load line potential andVi = Load line potential.

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

(46) "Mode of operation" means, forfluoroscopic 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, andphotospot 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 withanimage(s) after termination of the exposure.

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

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

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

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

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

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

(61) "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data 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 ink V, 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 mAsiv. For CT equipment not designed for pulsed operation, peak tube potential ink V, 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 propertiesof 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.

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

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

(76) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray 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 in1020.30, 1020.31 and 1020.32.

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

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

102.0 - Product Identification

Note:	*Give the designation of the system being certified in this report:*

Enter the System Designation: (If you do not use a Model Family or Brand Name, leave the field blank) *			
Item	Model Name	Family Name	Brand Name

Head and/or Body Scanner?	

102.1 Certifiable component

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.*

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 Reference1. Certification Labels 1010.22. Identification Labels 1010.33. Warning Labels 1020.30(j)

Attach PDF file here.

Certification labels are found on PDF page numbers:	
Identification labels are found on PDF page numbers:	
Warning labels are found on PDF page numbers:	

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?	
Attach PDF file here.	

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))
Please provide the compatibility specifications (21 CFR Reference: 1020.30(g))
Please provide the tube reloading instructions (21 CFR Reference: 1020.30(e))

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?	

Attach PDF file here.	
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:	
X-ray controland 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)).
Please provide tube housing assembly information (21CFR Reference: 1020.33(h)(2)).
Please provide x-ray control and generator information (21CFR Reference: 1020.33(h)(3)).
Please provide beam-limiting device information (21CFR Reference: 1020.33(h)(4)).
Please provide reference plane alignment directions (21CFR Reference: 1020.33(g)(2)).
Please provide offset plane alignment directions (21CFR Reference: 1020.33(g)(4)).
Pleaseprovide instructions concerning the use of the method provided for calculation of the CT number mean and standard deviation (21CFR Reference: 1020.33(j)(2)).
Please provide operating instructions (21CFR Reference: 1020.33(h)).

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?	
Attach PDF file here.	
A statement of the CT conditions of operation used to provide the dose information requested below and inappendix 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 phantomposition 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 centerlocation 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 intermediateselection.*	
	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 selectionsare 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))		
Dose Information (21 CFR Reference: 1020.33(c)(2)) and Imaging Performance Information (1020.33(c)(93))		
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	
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 shallbe given forthe 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	
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)	
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.	
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	

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 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?	
Attach PDF file here.	

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 tostore and display such images. PDF page numbers:	

Quality assurance instructions*(21 CFR Reference: 1020.33(d))
Phantom description.
Instructions on phantom use and schedule for use.
Listing of allowable variations for the indicated parameters.
Description of the method to store quality assurance data.
Representative images obtained or a description of the means used to store and display such images.

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.*

Part 200 - System Description

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

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 witha 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	
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 preindicatedtechnique factors. Click on the Add... button below to attach any supporting files.	
Details	

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 indicatingthe appropriate section to review within the PDF, or byanswering 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?	
Attach only one PDF file here.	
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:	

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.
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.
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.
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 toonly those circumstances stated above.
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.
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.

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 thePDF, 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?	
Attach PDF file here.	
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 thespecific means utilized for indication of location on the patient where the tomogram will be obtained. PDF page numbers:	
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:	

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.
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.

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.*
Note:	*Give a complete description of the means provided to satisfy the requirement.*

Is this data located in a PDF file?	
Attach PDF file here.	

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:	
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:	
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.
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 whetherthe shutter is open or closed (1020.33(h)(1)). In addition to a description of this means, provide adrawing or picture to show the visual indicators.

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.
Visual indicators (indicating x ray production andshutter 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.

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.*
Note:	*Give a complete description of the means provided to satisfy the requirement.*
Is this data located in a PDF file?	
Attach PDF file here.	
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:	
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:	

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.
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.

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.*
Note:	*Give a complete description of the means provided to satisfy the requirement.*
Is this data located in a PDF file?	
Attach PDF file here.	

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)).
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)).
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)).
If the place of manufacture as stated on the identification label is coded, please provide that code (1010.3(a)(2)(i)).

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?	

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

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)).

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:

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.

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. 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 withan 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 thicknessat 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.

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 modelwith 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 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.

301.4i Sampling

Do you test 100% of the produced models?	
Are any performance parameters tested other than 100%?	
List each performance parameter test that is sampled.	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.	
Details	
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.	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
Describe the action taken if the sampling plan leads to a rejection decision.	

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:

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.

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.*

Is this data located in aPDF file?

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

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.*

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)).

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.*

a. The test results must includedata 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 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.

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.*

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.

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.*

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:

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 yourdetailed 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.

302.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	
Are any performance parameters tested other than 100%?	
List each performance parameter test that is sampled.	
Describe the sampling plan used for each performance test andprovide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.	
Details	

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.	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
Describe the action taken if the sampling plan leads to a rejection decision.	

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.*
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.

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.*
Is this data located in a PDF file?	

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

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.*
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:	

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)).

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.

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 sufficientlyrestrictive 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 thedose 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 froma direct measurement of theaverage 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.

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.*

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 itis 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 numberof 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 intervalequal 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 itis 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 numberof your detailed instructions for performing the test andindicate 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 intervalequal to the slice thickness at the center of a series of 14 scans that are spaced by the nominal tomographic slice thickness.

303.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	
Are any performance parameters tested other than 100%?	
List each performance parameter test that is sampled.	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lotsize, sample size, rejection criterion). Attach a copy of the plan.	
Details	
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.	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
Describe the action taken if the sampling plan leads to a rejection decision.	

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 inherentinaccuracies 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 instructionsfor performing each	

test) should have already been provided in APPENDIX B and thus may bereferenced 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.

304.0 - Tube Current

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?

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

304.1 Requirement

Note:	*For each applicable test listed below, verify that the testing adequatelyreflects the critical parameters andaddresses 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 deviationof 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)).

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.

304.3 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 froma 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.

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.*
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 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.

304.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	
Are any performance parameters tested other than 100%?	
List each performance parameter test that is sampled.	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.	
Details	
The lot size (N)	
The sample size (n)	
The reject level number (c)	
A single or double sampling plan (S or D)	
Theacceptable 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.	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
Describe the action taken if the sampling plan leads to a rejection decision.	

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 thequestions in 304.4 with respect to assembler testing. Note: The information requested in 304.5 (d) (i.e., a copy of detailed instructions for performingeach 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.

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

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 anexposure, 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)).

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.

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 testmust be sufficiently restrictive to account for these inaccuracies.*

a. Provide adescription 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.

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 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 itis 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 inPart 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 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 spacedby the nominal tomographic slice thickness.

305.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate thePDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	
Are any performance parameters tested other than 100%?	

List each performance parameter test that is sampled.

Describe the sampling plan usedfor 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.	
Details	
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.

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

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

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 inaccuraciesof 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 copyof 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.

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

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

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. Asa 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, minimumand 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 resultsmust 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.

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.*

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 modelwith respect to this requirement.b. Identify the instrument(s) used for the test by manufacturerand 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 14scans 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 seriesof 14 scans that are spaced by the nominal tomographic slice thickness.

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.*

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 partb.d.Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX F.e. Identify theinstrument(s) used for each test by manufacturer and model number. Answer the appropriatesection 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. Foreach 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.

306.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	
Are any performance parameterstested other than 100%?	
List each performance parameter test that is sampled.	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.	
Details	
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.	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
Describe the action taken if the sampling plan leads to a rejection decision.	

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 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 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.

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.*

Is this data located in a PDF file?

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

Indicate for each modality, e.g., head, body, or spine procedure:a. A statement of the typical scan technique factors (e.g., kVp, mAs, pulse width, time, etc.)b. A statement of the scan diameter.c. A statement of the system slice thicknesses.d. A statement of the accuracy of the parameters indicated above.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.f. A statement of accuracy of the exposure measurement.Pages:

Indicate for each modality, e.g., head, body, or spine procedure:a. A statement of the typical scan technique factors (e.g., kVp, mAs, pulse width, time, etc.)b. A statement of the scan diameter.c. A statement of the system slice thicknesses.d. A statement of the accuracy of the parameters indicated above.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.f. A statement of accuracy of the exposure measurement.

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 resultof 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 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)).

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 aresult 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 leastthe minimum, maximum mid range values for the condition of operation or the values available with the other conditions of operation set atthe typical values.d. Please note any assumptions made in or limitations of your testmethods 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 atthe typical values.d. Please note any assumptions made in or limitations of your test methods in determining the dose values for your system.

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 actualcompliance 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 testby 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 dosein 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.

307.4 Production Testing

Note:	*For eachapplicable 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 directand 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 APPENDIXF.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 thatsupports 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.

307.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the producedmodels?	
Are any performance parameters tested other than 100%?	
List each performance parameter test that is sampled.	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.	
Details	
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.	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
Describe the action taken if the sampling plan leads to a rejection decision.	

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:	

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.

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

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 shallstate 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 inthe specified paragraphs of 1020.33(c)(3).

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 us(1020.33(c)(2)(i), the typical conditions of operation suggel 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 imagingparameters. PDF page numbers:	

a. The CT conditions of operation shall correspond to those us(1020.33(c)(2)(i), the typical conditions of operation suggel 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.

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.*
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 fromthe 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 intervalequal 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 asample 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 aninterval equal to the slice thickness at the center of a series of 14 scans that are spaced bythe nominal tomographic slice thickness.

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.*
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) usedfor 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 theaverage 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.

308.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	
Are any performance parameters tested other than 100%?	
List each performance parameter test that is sampled.	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size,sample size, rejection criterion). Attach a copy of the plan.	
Details	
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 tolerancepercent 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.
Describe the procedures used for selecting the sample and indicate how randomness is assured.
Describe the action taken if the sampling plan leads to a rejection decision.

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 havealready been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.

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

309.1 Requirement

Note:	*For each applicable test listed below, verify thatthe 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.*
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)).

309.2 Critical Parameters and "Worst Case" Conditions

Note:	*For each applicable test listed below, verify thatthe testing adequately reflects the critical parametersand addresses the "worst case" conditions. As a result of inherentinaccuracies 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.

309.3 Prototype Testing

Note:	*For each applicable test listed below, verify thatthe 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 testingand/or measuring the parameter for eachmodel 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 singlescan 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 testingand/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.

309.4 Production Testing

Note:	*For each applicable test listed below, verify thatthe 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 400foreach 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 compliancewith this requirement.c. Submit the technical data that supports the use of thetest 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.

309.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	
Are any performance parameters tested other than 100%?	
List each performance parameter test that is sampled.	

Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.	
Details	
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.
Describe the procedures used for selecting the sample and indicate how randomness is assured.
Describe the action taken if the sampling plan leads to a rejection decision.

309.5 Assembler Testing

Note:	*For each applicable test listed below, verify thatthe testing adequately reflects the critical parametersand 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 instructionsare 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.

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

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 ofinherent 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)).

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.

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 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.

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 anaccurate 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 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.

310.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	
Are any performance parameters tested other than 100%?	
List each performance parameter test that is sampled.	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.	
Details	
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.	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
Describe the action taken if the sampling plan leadsto a rejection decision.	

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.

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

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 theseinaccuracies.*
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:	

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.

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 adirect 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., onethat 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 appropriatesection in Part 400 for this instrument(s).c. Provide sample raw test data.d. If the actual compliance value is calculated from the rawtest 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 fromintegration of the dose profile for a single scan or from adirect 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.

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 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 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 arespecified.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.

311.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	
Are any performance parameters tested other than 100%?	
List each performance parameter test that is sampled.	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.	
Details	
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 characetristic (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.	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
Describe the action taken if the sampling plan leads to a rejection decision.	

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 thequestions in 311.4 with respect to assembler testing. Note: The information requested in 311.5 (d) (i.e., a copy ofdetailed 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 toassembler testing. Note: The information requested in 311.5 (d) (i.e., a copy ofdetailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referenced by indicating the appropriate page numbers.

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?

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

312.1 Requirement

Note:	*For each applicable test listed below, verify that the testing adequately reflectsthe 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)).

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.

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 thatdirectlymeasures 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 valuescomplete 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 ofcalculated compliance valuescomplete with an explanation of anycorrection 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 measurementof 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.

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 methodsemployed 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 asAPPENDIX 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.

312.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	
Are any performance parameters tested other than 100%?	
List each performance parameter test that is sampled.	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.	
Details	
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.	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
Describe the action taken if the sampling plan leads to a rejection decision.	

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, answerthe questions in 312.4 with respect to assembler testing. Note: The information requested in 312.5(d) (i.e., acopy of detailed instructions for performing each test) should have already been provided in APPENDIX B and thus may be referencedby indicating the appropriate page numbers. PDF page numbers:	

a-i. If test instructions are provided to the assembler, answer the questionsin 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.

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

313.1 Requirement

Note:	*For each applicabletest 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 indicatedscan increment may be taken anywhere along this travel (1020.33(i)).

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.*

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 toyour system or test method.

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.*

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 seriesof 14 scans that are spaced by the nominal tomographic slice thickness. PDF page numbers:

a. Provide a description ofthe direct test method (i.e., one that directly measuresthe 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 forthis 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.

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 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 theuse 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. Answerthe appropriate section in Part 400 for each instrument(s).f. For each of the abovetest 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.

313.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
Please indicate the PDF page numbers where the sampling plan is located:	
Do you test 100% of the produced models?	
Are any performance parameters tested other than 100%?	
List each performance parameter test that is sampled.	
Describe the sampling plan used for each performance test and provide the parameters of the plan listed below (e.g., lot size, sample size, rejection criterion). Attach a copy of the plan.	
Details	
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.	
Describe the procedures used for selecting the sample and indicate how randomness is assured.	
Describe the action takenif the sampling plan leads to a rejection decision.	

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.

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.*

401.1 - Radiation Measurement

401.2 - Illuminance

401.3 - Electrical Measurement

401.4 - Other Measurements