Submission Report

Section: Main Menu

Welcome

Welcome to the CDRH Electronic Submissions Software (CeSub)

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

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

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

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

Welcome (Cont.)

Department of Health and Human Services
Food and Drug Administration

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

Section: eRadHealth Menu

Role

What is your role? *	Manufacturer

Submission Information

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

Section: Manufacturer Data

Introduction

Electronic Product Radiation Safety Reporting Form

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

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

submission.

The submission must be addressed to:

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

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

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

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

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

General Information

General Information for Radiological Health Products

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

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

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

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

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

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

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

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

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

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

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

Definitions

Definitions for Rad Health Products

Manufacturers

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

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

Accidental Radiation Occurrences

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

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

Importers

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

United States Agent for Foreign Manufacturers

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

From The Federal Food, Drug, and Cosmetic Act

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

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

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

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

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

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

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

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

Burden to Industry

Paperwork Reduction Act Statement

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

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

Please DO NOT RETURN this application to this address.

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

Manufacturer Responsible for Product Compliance

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

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

Fax Number	
Mailing Location:	
Address	

Responsible Individual

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

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

Manufacturer's Reporting Official

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

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

Electronic Signature

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

Report Submitter

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

Parent Establishment

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

Address	

Manufacturer Designated United States Agent

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

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

Section: Product Data

Product and Model Identification

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

Product Type Reported

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

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

If Other, please identify the specific product type.

Report Information

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

was issued by CDRH.	

Noncompliances or Defects

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

Responses to Noncompliances or Defects

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

Exemption Requests

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

Variance Requests

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

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

Responses to Communications from FDA

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

Use Environment

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

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

Additional Information

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

Private Labeling

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

Medical Devices

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

Electromagnetic Compatibility and Interference

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

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

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

Section: 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

System Designation	

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.	
File Attachment	
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.	
File Attachment	
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.	
File Attachment	

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.

File Attachment	

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:	
	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:	
	A statement of the nominal tomographic section thickness(es). PDF page numbers:	
	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:	
	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 statement of the noise
	A graphical presentation of the modulation transfer function for the same imaging processing & presentation mode as that used in the statement of the noise
	A statement of the nominal tomographic section thickness(es)
	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.
	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.	
File Attachment	

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:	

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.*

Section: Part 200 - System Description

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

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	
File Attachment	

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	
File Attachment	

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.*
Is this data located in a PDF file?	
Attach only one PDF file here.	
File Attachment	
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:	

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.*
Is this data located in a PDF file?	
Attach PDF file here.	
File Attachment	
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:	

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.*

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

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.
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.*

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

File Attachment	

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:	

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.*

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

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:	

Section: Part 300 - Quality Control

301.0 - Leakage Radiation From the Diagnostic Source Assembly

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

Is this data located in a PDF file?	
Please attach any relevant documents in PDF format that provide answers and explanation for the questions asked in this section.	
File Attachment	

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

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

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

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.	
File Attachment	
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

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:

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.	
File Attachment	

302.1 Requirement

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:

302.2 Critical Parameters and "Worst Case" Conditions

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:

302.3 Prototype Testing

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:

302.4 Production Testing

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	
File Attachment	
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.	
File Attachment	
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

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:

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.	
File Attachment	

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:	

303.2 Critical Parameters and "Worst Case" Conditions

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:

303.3 Prototype Testing

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	
File Attachment	
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.	
File Attachment	
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

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:

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.	
File Attachment	

304.1 Requirement

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:

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

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:

304.4 Production Testing

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	
File Attachment	
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.	
File Attachment	
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

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:

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.	
File Attachment	

305.1 Requirement

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:

305.2 Critical Parameters and "Worst Case" Conditions

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:

305.3 Prototype Testing

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:

305.4 Production Testing

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	
File Attachment	
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.	
File Attachment	
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

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:

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.	
File Attachment	

306.1 Requirement

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:

306.2 Critical Parameters and "Worst Case" Conditions

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:

306.3 Prototype Testing

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:

306.4 Production Testing

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	
File Attachment	
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.	
File Attachment	
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

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:

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.	
File Attachment	

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

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:

307.2 Critical Parameters and "Worst Case" Conditions

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:

307.3 Prototype Testing

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:

307.4 Production Testing

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	
File Attachment	
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.	
File Attachment	
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

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:

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.	
File Attachment	

308.1 Requirement

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:

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

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:

308.4 Production Testing

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	
File Attachment	
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.

File Attachment	
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

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:

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.	
File Attachment	

309.1 Requirement

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:

309.2 Critical Parameters and "Worst Case" Conditions

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

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:

309.4 Production Testing

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:

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309.4i Sampling

Is this sampling plan the same as any previous sampling plan?	
Please Attach/Select the appropriate file	
File Attachment	
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.	
File Attachment	
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

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:

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.	
File Attachment	

310.1 Requirement

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:

310.2 Critical Parameters and "Worst Case" Conditions

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

310.3 Prototype Testing

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:

310.4 Production Testing

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	
File Attachment	
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.	
File Attachment	
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

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:

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.	
File Attachment	

311.1 Requirement

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

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

311.3 Prototype Testing

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:

311.4 Production Testing

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	
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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.	
File Attachment	
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

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:

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.	
File Attachment	

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

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

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:

312.4 Production Testing

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	
File Attachment	

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.	
File Attachment	
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

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:

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.	

File Attachment	

313.1 Requirement

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

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

313.3 Prototype Testing

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:

313.4 Production Testing

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	
File Attachment	
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.	
File Attachment	
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

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:

Section: Part 400 - Common Aspects

401.0 - Instrumentation

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