Form Approved: OMB No. 0910-0025
Expiration Date: October 31, 2013

FORM FDA 3626 (5/11)

A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

More industry guidance and assistance can be found at the FDA homepage, see: http://www.fda.gov/Radiation-EmittingProducts/ .

Send your completed report to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

Questions about reporting and suggestions for changes to this guide may be sent to the above address or may be discussed by calling (301) 796-5710.

A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components

Published by
Office of Compliance
X-Ray Products Branch

February 1973
Revised January 1982

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Silver Spring, MD 20993

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A GUIDE FOR THE SUBMISSION OF INITIAL REPORTS ON DIAGNOSTIC X-RAY SYSTEMS AND THEIR MAJOR COMPONENTS

INTRODUCTION

This guide outlines for a manufacturer, a format for the presentation of initial and supplemental reports on diagnostic x-ray systems and their major components which are subject to the Performance Standard 21 CFR 1020.30,1020.31, and 1020.32. The diagnostic x-ray equipment subject to the standard includes: tube housing assemblies, x-ray controls, x-ray high voltage generators, tables, cradles, film changers, cassette holders, beam-limiting devices, spot film devices, image intensifiers, cephalometric devices, image receptor support devices for mammographic x-ray systems, and diagnostic x-ray systems incorporating one or more previously listed components.

The subject reporting guide is an attempt to identify the pertinent information needed by the Bureau of Radiological Health (BRH) to fulfill its delegated responsibilities under the Radiation Control for Health and Safety Act of 1968 (PL 90-602). It is also believed that identification of this information will make the manufacturer's reporting task somewhat easier since, after the initial organization of the material, the manufacturer will not be obligated to prepare and submit such voluminous reports as in the past. Manufacturers may elect to continue using a previous version of the Reporting Guide when supplementing old reports. It is required that all new initial reports follow this revision of the Reporting Guide consistent with 21 CFR 1002.7 (b).

This guide asks for information in four parts. PART 100 - IDENTIFICATION, containing two sections, asks for information with regard to identification, labels and instructions pertaining to the manufacturer's equipment. The manufacturer must answer all questions in sections 101.0 and 102.0 of this part. PART 200 - COMPONENT DESCRIPTION, containing eight sections, ask for information pertaining to specific performance characteristics of the equipment. The manufacturer must answer all questions in the section(s) of this part that are identified by the component type(s) reported in PART 100. PART 300 - QUALITY CONTROL TESTING, containing twenty-five sections, ask for presentations of prototype, production and assembler test methods and results. Sections to be answered in this part are identified in sections 201 through 208 of PART 200 and in Table 1. PART 400 - COMMON ASPECTS, containing two sections, asks for test instrument specifications and sampling protocols. The manufacturer must answer all questions in the applicable paragraphs of section 401.0 and, when appropriate, all questions in section 402.0 of this part.

Manufacturers are encouraged to submit a “Common Aspects Report” in order to simplify their reporting obligations. The Common Aspects Report is a separate initial report that incorporates a description of test methods, instrumentation, and sampling plans common to several models. This Common Aspects Report is not intended as a means for certification of any specific model. Currently, separate initial reports from the same manufacturer often provide identical descriptions of the quality control program. Such duplication is costly and entails extra effort for

both the manufacturer and the Bureau. By development of a Common Aspects Report, standardized test methods, instrumentation, and sampling plans may be collected into one report. Initial reports for specific models can now reference applicable sections of the Common Aspects Report. For example, an initial report on an x-ray control must include responses to the appropriate sections of PART 100-IDENTIFICATION and PART 200-COMPONENT DESCRIPTION, however, information with respect to test methods in PART 300-QUALITY CONTROL TESTING and also PART 400-COMMON ASPECTS may be provided by referencing the Common Aspects Report. Sample test data solicited in PART 300 must still be included in the initial report.

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

Table 1 provides a reference to aid the manufacturer in readily identifying which sections of each part he must complete for the particular component(s) that he is reporting. To use the table, the component is found in the left hand column and the sections within each part to be completed for that component are found in the columns to the right.

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

Table 1. - Applicable sections required to be completed for each component type

Component type	Applicable sections			
	PART 100	PART 200	PART 300	PART 400
Tube Housing Assembly	101.0, 102.0	201.0	301.0, 302.0	401.0, (402.0 as applicable)
Beam-Limiting Device All (answer these sections and those below as appropriate)	101.0, 102.0	202.0	301.0, 302.0	401.0, (402.0 as applicable)
Diagnostic source assembly used in capacitor energy storage equpiment			304.0	401.0, (402.0 as applicable)
Positive beam limitation capability			315.0, 316.0 317.0, 318.0	401.0, (402.0 as applicable)
Fixed SID/fixed image Receptor size use			319.0, (315.0, 316.0, 317.0 as applicable)	401.0, (402.0 as applicable)
Spot-film use			320.0	401.0, (402.0 as applicable)
Fluoroscopic use			321.0	401.0, (402.0 as applicable)
Dental use			322.0	401.0, (402.0 as applicable)
Mammographic use			323.0	401.0, (402.0 as applicable)
Other uses			324.0, (315.0, 316.0, 317.0 as applicable)	401.0, (402.0 as applicable)
X-Ray Control All (answer these sections and those below as appropriate)	101.0, 102.0	203.0	307.0	401.0, (402.0 as applicable)

kVp selection capability			309.0	401.0, (402.0 as applicable)
mA selection capability			310.0	401.0, (402.0 as applicable)
mAs selection capability			311.0	401.0, (402.0 as applicable)
Time selection capability			312.0	401.0, (402.0 as applicable)
Automatic exposure control			313.0, 314.0	401.0, (402.0 as applicable)
Fluoroscopy selection capability			305.0	401.0, (402.0 as applicable)
High-Voltage Generator	101.0, 102.0	204.0	308.0	401.0, (402.0 as applicable)
Spot-Film Device	101.0, 102.0	205.0	306.0	401.0, (402.0 as applicable)
Image Intensifier	101.0, 102.0	205.0	306.0, 308.0	401.0, (402.0 as applicable)
Tables, Cassette Holders, Cradles, Film Changers	101.0, 102.0	206.0	303.0	401.0, (402.0 as applicable)
Cephalometric Device Fixed SID	101.0, 102.0	207.0	319.0	401.0, (402.0 as applicable)
Variable SID	101.0, 102.0	207.0	324.0	401.0, (402.0 as applicable)
Mammographic Image Receptor Support Device	101.0, 102.0	208.0	325.0	401.0, (402.0 as applicable)

DEFINITIONS

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

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

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

(3) “Assembler” means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem

(4) “Attenuation block” means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation.

(5) “Automatic exposure control” 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.

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

(7) “Beam-limiting device” means a device which provides a means to restrict the dimensions of the x-ray field.

(8) “Coefficient of variation” means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[\sum_{i=1}^{n} \frac{(X_i - \bar{X})^2}{n - 1} \right]^{1/2}$$

where

s = Estimated standard deviation of the population

$\bar{X}$ = Mean value of observations in sample

X_i = ith observation sampled

n = Number of observations sampled

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

(10) “Cooling curve” means the graphical relationship between heat units stored and cooling time.

(11) “Diagnostic source assembly” means the tube housing assembly with a beam-limiting device attached.

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

(13) “Equipment" means x-ray equpiment.

(14) “Exposure” 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.

(15) “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.

(16) “Fluoroscopic imaging assembly” means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

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

(18) “Half-value layer, HVL” means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure 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.

(19) “Image receptor” means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

(20) “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.

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

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

(ii) For tube housing 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.

(iii) For all other tube housing assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

(22) “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.

(23) “Line-voltage regulation” means that difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

Percent line-voltage regulation = 100 $(V_n - V_i)/V_i$

where:

V_n = No-load line potential and

V_i = Load line potential.

(24) “Maximum line current” means the rms current in the supply line of an x-ray machine operating at its maximum rating.

(25) “Peak tube potential” means the maximum value of the potential difference across the x-ray tube during an exposure.

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

(27) “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.

(28) “Rated output current” means the maximum allowable load current of the x-ray high-voltage generator.

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

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

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

(32) “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.

(33) “Source” means the focal spot of the x-ray tube.

(34) “Source-image receptor distance, (SID)” means the distance from the source to the center of the input surface of the image receptor.

(35) “Stationary equipment” means equipment which is installed in a fixed location.

(36) “Technique factors” means the conditions of operation. They are specified as follows:

(i) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(ii) For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses; and

(iii) For 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.

(37) “Tube” means an x-ray tube, unless otherwise specified.

(38) “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.

(39) “Tube rating chart” means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(40) “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.

(41) “Variable-aperture beam-limiting device” means beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

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

(43) “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, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

(44) “X-ray equipment” means an x-ray system, subsystem, or component thereof.

(45) “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.

(46) “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.

(47) “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.

(48) “X-ray subsystem” means any combination of two or more components of an x-ray system for which there are requirements specified in §§ 1020.30, 1020.31 and 1020.32.

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

(50) “Radiation therapy simulation system" means a 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.

(51) “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 an image intensifier for the purpose of making a radiograph.

(52) “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.

(53) “Cephalometric device” means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

(54) “Image receptor support” means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

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PART 100 - IDENTIFICATION

101.0 REPORT IDENTIFICATION

Please confirm that this report is subjected pursuant to paragraph (c)(1) of section 1002.61. State each of following:

Report type (initial or supplement to BRH Accession # _____)

Name of Manufacturer

Name of Submitter

Corresponding Official

102.0 PRODUCT IDENTIFICATION

102.1 Give the model designation for any of the following components that you are certifying in this report (tube housing assemblies, x-ray controls, x-ray high-voltage generators, tables, cradles, film changers, cassette holders, beam-limiting devices, spot-film devices, image intensifiers, cephalometric devices, and image receptor support devices for mammographic x-ray systems).

Certifiable component type	Model designation
_____	_____
_____	_____

102.2 If you combine components under a single certification label pursuant to 21 CFR 1020.30(c), provide the model number for any combination that you are certifying in this report. High voltage generators contained within tube housings, beam-limiting devices contained within tube housing, beam-limiting devices which are integral parts of tube housings, and high voltage generators and x-ray controls which are inseparable and housed jointly are the only combinations that may be combined under a single certification label. Other combinations may be authorized by the Bureau of Radiological Health upon application by their manufacturer. Authorization for single labeling may be granted only for inseparable combinations of components that are contained within a single housing.

Certifiable combination type	Model designation
_____	_____
_____	_____

102.3 If any of the models reported in 102.1 and/or 102.2 are sold under name(s) other than your own, provide the model designation and the name and address of each company under whose name the model is sold.

102.4 For every model listed under 102.1 and 102.2, provide an exact replica of all labels complete with the following:

a. the certification statement;

b. the name and address of the manufacturer (or the individual or company under whose name it is sold);

c. the date and place of manufacture; and

d. the model designation and sample serial number;

e. the manufacturer, model designation and sample serial number of the tube insert if applicable.

f. In addition, the standard requires that the labels be permanently affixed, legible, and accessible to view. Provide a drawing or photograph of each certifiable component and/or combination showing the attached label. Attach all of the requested information under this paragraph (102.4) as APPENDIX A.

102.5 For each complete x-ray system or subsystem that incorporates components being certified in this report, give the system/subsystem designation.

Also, for each system/subsystem, identify each certifiable component by component type, model designation, and manufacturer. Example: If you market an x-ray system and call it “Super 100,” and it consists of Tube Housing Assembly X, High-voltage Generator Y, X-Ray Control Z, and Beam-Limiting Device A; you would list “Super 100” and the component type, model designation, and manufacturer of the four certifiable components that comprise the system.

Use the following or a similar format:

System designation: _____

Component type	Model designation	Manufacturer
_____	_____	_____
_____	_____	_____

102.6 Attach “Information to Assemblers” (1020.30(g)) as APPENDIX B. Include each of the following:

a. assembly and testing instructions necessary for assuring compliance to the Performance Standard.

b. compatibility specifications referenced in 21 CFR 1020.30(g).

102.7 Attach “Information to Users” (1020.30(h)) as APPENDIX C. Include each of the following:

a. operating instructions;

b. picture or drawing of product;

c. product specifications;

d. cautionary statements for 21 CFR 1020.32(a)(1) and (f) if applicable; and

e. maintenance schedule.

PART 200 - COMPONENT DESCRIPTION

201.0 TUBE HOUSING ASSEMBLY

This section should be completed for each tube housing assembly listed in section 102.1 of PART 100 and any combination listed in section 102.2 of PART 100 that contains a tube housing assembly as an integral part thereof.

201.1 State the maximum rated peak tube potential for each model tube housing assembly.

201.2 For each model intended for use on a general purpose x-ray system, cite the specific paragraph(s) in your instructions to assemblers that lists compatible tube stands and/or other equipment necessary for indication (as required under 21 CFR 1020.31(e)(1)(i), (g)(2), and 1020.32(b)(1)(ii), (b)(2)(iii)) of:

a. the perpendicularity of the beam axis to the image receptor, and

b. the SID.

201.3 If you reload tube housing assemblies, describe how you remove, deface, or cover the original labels on the assembly.

201.4 Answer the questions in sections 301.0 and 302.0, PART 300.

202.0 BEAM-LIMITING DEVICES

This section should be completed for each beam-limiting device listed in section 102.1 of PART 100 and any combination listed in section 102.2 of PART 100 that contains a beam-limiting device as an integral part thereof.

202.1 List all use or applications for which each model is intended, such as: general purpose radiographic, general purpose fluoroscopic, combination radiographic and fluoroscopic, tomographic, angiographic, podiatric, urologic, mammographic, chest, head-neck, panoramic, intraoral (general purpose dental), cephalometric, and computerized tomography.

202.2 Dental (excluding cephalometric and panoramic)

a. If the beam-limiting device is used with an intraoral image receptor, specify the minimum source-to-skin distance (SSD) and the dimensions and geometric configuration (e.g., circular, rectangular, or elliptical) of the x-ray field produced by each beam-limiting device at its minimum SSD.

b. If the beam-limiting device is used with an extraoral image receptor, answer the questions in 202.9 of this section.

c. Answer the questions in section 322.0, PART 300.

202.3 General Purpose Radiographic - mobile and stationary (excluding mammographic attachments, spot-film devices, and dental units)

a. Is the adjustment for the size of the x-ray field stepless?

b. Provide a statement of the minimum x-ray field size at 100 centimeters SID for the tube housings for which the beam-limiting device is designed.

c. If the beam-limiting device is used in mobile or portable x-ray systems, state the minimum SSD.

d. If the beam-limiting device(s) is equipped with a light localizer, answer the questions in section 315.0, PART 300.

e. Answer the questions in section 316.0, PART 300.

202.4 Stationary General Purpose Radiographic (excluding mammographic attachments, spot-film devices, and dental units)

a. Describe the means provided to indicate when the beam axis (both vertical and horizontal) is perpendicular to the plane of the image receptor.

b. Describe the means provided to indicate each design SID.

c. Provide a drawing or picture of the indicator on the beam-limiting device that shows the relationship of the field size dimensions to SID. Attach as APPENDIX D.

d. Answer the questions in section 317.0, PART 300.

e. List the design SID's and/or range of SID's for positive beam limitation (PBL) operation for each permanently mounted cassette holder used with the beam-limiting device.

f. If the PBL cassette tray is designed with discrete cassette size sensing, list the applicable cassette sizes.

g. If the PBL cassette tray is designed with continuous cassette size sensing, give the applicable range of cassette sizes.

h. Provide a copy of the circuit diagram and interlock mechanism that prevents the production of x rays when the PBL system is positioned at SID's at which it is not designed to operate and/or when an improper cassette is inserted. Attach as APPENDIX E.

i. Is the PBL adjustment of the x-ray field automatic or manual?

j. If the PBL adjustment of the x-ray field is accomplished automatically in greater than 5 seconds or is manual, provide a copy of the circuit diagram and interlock mechanism that prevents the production of x rays until such adjustment is completed. Enclose in APPENDIX E.

k. Answer the questions in section 318.0, PART 300.

l. Can the PBL x-ray field be adjusted to dimensions smaller than those of the image receptor?

m. What is the size, in centimeters, of the minimum x-ray field at 100 centimeters SID?

n. When the PBL x-ray field is adjusted to dimensions smaller than the image receptor, state how the beam-limiting device returns to positive beam limitation upon a change in image receptor.

o. Does the PBL system have a bypass mode? If so, specify all conditions under which the bypass mode is activated, and state whether the bypass mode is activated under conditions other than: (1) when radiography is conducted that does not use the cassette tray or permanently mounted vertical cassette holder; (2) when either the beam axis or table angulation is not within 10° of the horizontal or vertical during any part of the exposure; or (3) during stereoscopic radiography.

p. If the PBL system has a bypass mode, specify the conditions under which the system will automatically return to the PBL mode.

q. Describe each service switch and/or capture key override available with the PBL system.

r. Provide a drawing or picture showing the location of each PBL override switch. Enclose in APPENDIX E.

s. Provide circuit diagrams and description of function for each PBL bypass and override circuit. Enclose in APPENDIX E.

202.5 Beam-Limiting Device Used with Spot Film Radiography (excluding therapy simulators)

a. Describe how reduction of the x-ray field is accomplished when the fluoroscopic x-ray field is larger than the selected portion of the film.

b. Describe how the enlargement of the x-ray field is accomplished when the fluoroscopic x-ray field is smaller than the selected portion of the film.

c. Describe the means available to adjust the x-ray field to a size smaller than the selected portion of the film.

d. What spot-film formats (i.e., geometrical size(s) and configuration(s)) are available with this beam-limiting device(s)?

e. Answer the questions in section 320.0, PART 300.

f. What is the minimum x-ray field at the greatest SID for tube housings for which the beam-limiting device is designed?

g. Specify the location of the beam-limiting device with respect to both the patient and the image receptor when it is assembled in a fluoroscopic system. (Does the beam-limiting device restrict the size of the x-ray beam before or after the x-ray beam passes through the patient?)

h. If means are provided for system failure override, describe: (1) each service switch and/or capture key; (2) the label advising need for repair in the event of system failure; and (3) the visual indication of the override condition at the fluoroscopist position.

202.6 Beam-Limiting Device Used with Fluoroscopy

a. Describe the means provided to adjust the x-ray field to dimensions smaller than the entire visible area of the image receptor. If circular collimation of any kind is provided, state the available diameter(s).

b. What is the minimum x-ray field at the greatest SID for tube housings for which the beam-limiting device is designed?

c. If the beam-limiting device(s) is used in nonimage-intensified fluoroscopy, describe the means for limiting the x-ray field within the visible area of the image receptor.

d. If the beam-limiting device(s) is used in image-intensified fluoroscopy, other than radiation therapy simulation, answer the questions in section 321.0, PART 300.

e. For each beam-limiting device used in routine fluoroscopy give its model designation, the applicable system(s) designation(s), a statement of whether it is mobile or stationary, and the minimum SSD.

f. If any beam-limiting device/system combination is designed for special surgical procedures, describe the provisions for maintaining an SSD of greater than 20 centimeters.

g. If means are provided for system failure override, describe (1) each service switch and/or capture key; (2) the label advising need for repair in the event of system failure; and (3) the visual indication of the override condition at the fluoroscopist position.

202.7 X-Ray Systems Designed for One SID and Image Receptor Size Combination (e.g., chest, skull, and cephalometric)

a. For each beam-limiting device state its model designation, the design SID, and the image receptor size.

b. For each beam-limiting device describe the means for limiting and/or centering the x-ray field.

c. If the beam-limiting device has a light field that defines the perimeter of the x-ray field, answer the questions in sections 315.0 and 316.0, PART 300.

d. If the x-ray field extends beyond any edge of the image receptor, answer the questions in 317.0, PART 300.

e. Answer the questions in section 319.0, PART 300.

202.8 X-Ray Systems Designed for or Provided with Special Attachments for Mammography

a. For each removable fixed aperture or multiple fixed aperture beam-limiting device, state the maximum design SID and image receptor size.

b. Provide an exact replica of all labels that show the maximum design SID and image receptor size.

c. Answer the questions in section 323.0, PART 300.

202.9 Other Radiographic X-Ray Systems (e.g., extraoral dental, CT, podiatric, and cephalometric)

a. For each beam-limiting device describe the means for limiting and/or centering the x-ray field.

b. For each removable fixed aperture, provide an exact replica of each label or marking that shows the SID and image receptor size.

c. For each multiple fixed aperture, provide an exact replica of each label or marking that shows the design SID(s) and image receptor sizes.

d. If the beam-limiting device has a light field that defines the perimeter of the x-ray field, answer the questions in sections 315.0 and 316.0, PART 300.

e. If the x-ray field extends beyond any edge of the image receptor, answer the questions in 317.0, PART 300.

f. Answer the questions in section 324.0, PART 300.

202.10 State the maximum kVp at which each model beam-limiting device is designed to operate.

202.11 If any filtration that is part of the beam-limiting device is variable, describe any system of filter identification and the means of assuring the presence of the required minimum filtration in the beam before the tube can be

activated. If an interlock system is used, supply or answer the following:

a. Provide circuit diagrams of the interlock tied to the kilovoltage selector that is part of the beam-limiting device. Attach as APPENDIX F.

b. Describe the electrical and mechanical characteristics of the interlock system.

202.12 Answer the questions in section 301.0, PART 300.

202.13 If any model beam-limiting device contains filters, answer the questions in section 302.0, PART 300.

202.14 If any model beam-limiting device is intended to be used on capacitor storage x-ray systems, answer the questions in section 304.0, PART 300.

203.0 X-RAY CONTROLS

This section should be completed for each x-ray control listed in section 102.1 of PART 100 and any combination listed in section 102.2 of PART 100 that contains an x-ray control as an integral part thereof.

203.1 List all uses or applications for which each model is intended, such as: general purpose radiographic, general purpose fluoroscopic, combination radiographic and fluoroscopic, tomographic, angiographic, podiatric, urologic, mammographic, chest, head-neck, panoramic, intraoral (general purpose dental), cephalometric, and computerized tomography.

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

203.3 If the x-ray control is used with a battery powered generator, describe the visual means provided to indicate whether or not the battery is in a state of charge adequate for proper operation.

203.4 Radiography (x-ray controls used for radiography, i.e., recording of images except from image intensifiers)

a. For each x-ray control panel, provide the following: (1) the type and range of the markings on the technique factor indicators and the applicable accuracy limits; (2) a drawing or picture of the preindicators of technique factors to the operator; (3) a drawing or picture that illustrates the proximity of any exposure switch to the preindicated technique factors; (4) a drawing or picture of the indicator of x-ray production; and (5) a description of the audible signal used to indicate exposure termination. Enclose in APPENDIX G.

   NOTE: “Satellite” or “remote stations” are certifiable components and must comply with all applicable requirements pertaining to x-ray controls.

b. For each accuracy specification referenced in 203.4(a), state the applicable criteria that defines the technique factors, e.g., the begin and end points of exposure time could be defined with respect to a certain percentage of the voltage waveform.

c. Answer the questions in sections 307.0, PART 300 and as applicable, sections 309.0, 310.0, 311.0, and 312.0, PART 300.

d. If two or more tubes are controlled by the same exposure switch, describe the pre-exposure tube selection indicator on the control panel and the provisions for indication on the diagnostic source assemblies.

e. Describe the control device(s) for initiating and terminating x-ray production. Include each method by which x-ray exposure is terminated (e.g., preset time, mAs, pulses, limit switches, or exposure to the image receptor).

f. Describe the method by which the operator can terminate an exposure or series of exposures that last longer than one-half second.

g. Describe the method by which termination of the exposure causes automatic resetting of the timer to its initial setting or to zero.

h. If a “zero” or “off” position is provided, is x-ray production prevented when the timer is set to either position?

i. If the x-ray control incorporates an automatic exposure control, provide a drawing or picture of (1) the indicator for automatic exposure control selection and (2) the visible signal that indicates when an exposure has been terminated by the backup safety device. Enclose in APPENDIX G.

j. If the exposure has been terminated by the backup safety device during automatic exposure control operation, describe the manual resetting procedures.

k. If the x-ray control incorporates an automatic exposure control, answer the questions in sections 313.0 and 314.0, PART 300.

203.5 Fluoroscopy (x-ray controls used for fluoroscopy and for the recording of images through an image intensifier)

a. For each fluoroscopic exposure switch, describe the method employed to prevent the production of x rays when the primary protective barrier is not in position to intercept the entire useful beam.

NOTE: Therapy simulator systems with remote control are exempt from this requirement

b. Describe each control device (e.g., normal fluoroscopy, cine, and test mode) for initiating and maintaining fluoroscopic x-ray production.

c. Describe the means provided to preset the cumulative on-time of the fluoroscopic tube, and state the maximum available cumulative time.

d. For each fluoroscopic control device, describe the method of providing a continuing audible signal that indicates to the fluoroscopist x-ray production beyond the completion of any preset cumulative on-time.

e. For each x-ray and remote control panel, provide a drawing or picture of the indicators that allow continuous monitoring of kVp and mA during fluoroscopy. Enclose in APPENDIX G.

f. For each manual and/or automatic exposure rate control mode that initiates exposure without the permanent recording of fluoroscopic images, state the respective maximum values of fluoroscopic entrance exposure rates.

g. For each manual and/or automatic exposure rate control mode, describe any provisions for optional high-level control and the special means provided for activation of this option.

h. For each high-level control, describe the continuous audible signal that indicates to the fluoroscopist that the high-level control is being employed.

i. Describe the method by which the fluoroscopist can terminate the recording of serial fluoroscopic images.

j. Answer the questions in sections 305.0, 306.0, 309.0, and 310.0, PART 300.

204.0 HIGH-VOLTAGE GENERATORS

This item should be completed for each high-voltage generator listed in section 102.1 of PART 100 and any combination listed in section 102.2 of PART 100 that contains a high-voltage generator as an integral part thereof.

204.1 List all uses or applications for which each model is intended, such as: general purpose radiographic, general purpose fluoroscopic, combination radiographic and fluoroscopic, tomographic, angiographic, podiatric, urologic, mammographic, chest, head-neck, panoramic, intraoral (general purpose dental), cephalometric and computerized tomography.

204.2 State the generator type (e.g., single-phase half-wave, three-phase full-wave, capacitor discharge, or field emission).

204.3 If any model high-voltage generator contains a thermionic diode valve, answer the questions in section 308.0, PART 300.

205.0 SPOT-FILM DEVICES AND IMAGE INTENSIFIERS

This section should be completed for each spot-film device and image intensifier listed in section 102.1 of PART 100 and any combination listed in section 102.2 of PART 100 that contains such components as an integral part thereof.

205.1 If the reported system is a mobile fluoroscope, is it image intensified?

205.2 For each model spot-film device and image intensifier, describe the means to prevent the fluoroscopic tube from producing x radiation whenever the primary protective barrier is not in position to intercept the entire useful beam. If there is an interlock, describe its electrical and mechanical characteristics and provide circuit diagrams. Attach as APPENDIX H.

205.3 If the spot-film device or image intensifier permits technique factor adjustment, answer the questions in section 203.0, PART 200 - COMPONENT DESCRIPTION.

205.4 For each spot-film device answer the questions in sections 306.0, PART 300.

205.5 For each image intensifier answer the questions in sections 306.0 and 308.0, PART 300.

206.0 TABLE, CASSETTE HOLDERS*, FILM CHANGERS AND CRADLES

This section should be completed for each table, cassette holder, film changer and/or cradle listed in section 102.1 of PART 100 and any combination listed in section 102.2 of PART 100 that contains such components as an integral part thereof.

206.1 If any of the subject components (1) allows for operator adjustment of technique factors or (2) provides limit switches that automatically preempt the preset exposure time of the master control panel, answer the questions in section 203.0, PART 200 - COMPONENT DESCRIPTION.

206.2 If any film changer is built into a stationary radiographic table, explain how positive beam limitation is accomplished for serial radiography.

206.3 For each model film changer, explain the provision(s) enabling the operator to terminate an exposure or series of exposures that last longer than one-half second.

206.4 For each model table x-ray table, identify its appropriate characteristics from the following: stationary table, movable table, stationary tabletop, movable tabletop, table designed for therapy simulation, table designed for computed tomography, cantilevered table, weight-bearing radiolucent attachment for surgical tables, other (describe).

206.5 For each table intended for use on a general purpose x-ray system, cite the specific paragraph(s) in your instructions to assemblers that lists compatible tube stands and/or other equipment necessary for indication (as required under 21 CFR 1020.31(e)(1)(i), (g)(2), and 1020.32(b)(1)(ii), (b)(2)(iii)) of:

a. the perpendicularity of the beam axis to the image receptor, and

b. the SID.

206.6 If the vertical cassette holder is equipped with cassette size sensors, state the intended image receptor sizes.

206.7 Answer the questions in section 303.0, PART 300.

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*Applicable only to cassette holders that are intended for permanent vertical mounting and/or contain a front panel.

207.0 CEPHALOMETRIC DEVICES

This section should be completed for each cephalometric device listed in section 102.1 of PART 100.

207.1 For each model cephalometric device that includes a beam-limiting device as an integral design feature, answer the applicable questions in section 202.0, PART 200 - COMPONENT DESCRIPTION.

207.2 For each model cephalometric device that includes a cassette holder with a front panel as an integral design feature, answer the questions in section 303.0, PART 300.

208.0 IMAGE RECEPTOR SUPPORT DEVICES FOR MAMMOGRAPHIC X-RAY SYSTEMS

This section should be completed for each image receptor support device listed in section 102.1 of PART 100.

208.1 For each model image receptor support device that includes a cassette holder with a front panel as an integral part, answer the questions in section 303.0, PART 300.

208.2 Answer the questions in section 325.0, PART 300.

PART 300 - QUALITY CONTROL TESTING

301.0 LEAKAGE RADIATION FROM THE DIAGNOSTIC SOURCE ASSEMBLY

301.1 Requirement

The leakage radiation from the diagnostic source assembly measured at a 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 Applicability

This requirement is applicable to the diagnostic source assembly (tube housing assembly combined with a beam-limiting device). Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 301.4(a)).

301.3 Critical Parameters and “Worst Case” Conditions

a. The test results must include date representative of each compatible combination of tube housing assembly and beam-limiting device.

b. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

c. To assure the use of maximum rated peak tube potential and continuous tube current, the test method(s) must provide the procedure for periodic calibration of technique factors.

d. 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.

301.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

301.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with the requirement.

c. Submit the technical data that supports the use of the test in b.

d. Provide a copy of the detailed instructions for performing each test. Attach as APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 301.5, give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 301.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

301.6 Assembler Testing

a.-i. If test instructions are provided to the assembler, answer the questions in 301.5 with respect to assembler testing. Note: The information requested in 301.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

302.0 BEAM QUALITY

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)).

302.2 Applicability

This requirement is applicable to the tube housing assembly or the diagnostic source assembly if the beam-limiting device contains filtration. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 302.4(a)).

302.3 Critical Parameters and "Worst Case" Conditions

a. The test results must include data representative of each compatible combination of tube housing assembly and beam-limiting device.

b. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

c. Since the peak tube potential has a critical effect on determining the half-value layer, the test method(s) must provide the procedure for periodic calibration of tube potential.

d. To minimize the sources 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.

302.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

302.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.

c. Submit the technical data that supports the use of the test in b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 302.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 302.5(a) provide sample raw test data.

h. If the actual compliance value is calculated from the raw test data, provided a sample of calculated compliance values complete with an explanation of any correction factors employed.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

302.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 302.5 with respect to assembler testing. Note: The information requested in 302.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

303.0 ALUMINUM EQUIVALENCE

303.1 Requirement

The aluminum equivalent of the front panels of cassette holders and film changers, tabletops, and cradles that are used between the patient and image receptor shall not exceed the limits indicated in Table II of the diagnostic x-ray standard (see 1020.30(n)).

303.2 Applicability

The requirement is applicable to cassette holders, film changers, tables and cradles. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 303.4(a)).

303.3 Critical Parameters and "Worst Case" Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. Since the peak tube potential has a critical effect on determining the aluminum equivalent, the test method(s) must provide the procedure for periodic calibration of tube potential.

c. Since compliance will be measured at 100 kVp and 2.7 millimeters of aluminum half-value layer, test data resulting from other conditions must be extrapolated to the value at the specified conditions.

303.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

303.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.

c. Submit the technical data that supports the use of the test in b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 303.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 303.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

303.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 303.5 with respect to assembler testing. Note: The information requested in 303.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

304.0 STANDBY RADIATION FROM CAPACITOR ENERGY STORAGE EQUIPMENT

304.1 Requirement

Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open (see 1020.31(k)).

304.2 Applicability

The requirement is applicable to the diagnostic source assembly of capacitor energy storage equipment. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 304.4(a)).

304.3 Critical Parameters and "Worst Case" Conditions

a. The test results must include data representative of each compatible combination of tube housing assembly and beam-limiting device.

b. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

c. To test for the maximum standby radiation, the beam-limiting device must be fully open and the highest available peak tube potential must be used. These conditions must be specified in the test method(s).

d. For any test using a scan of the diagnostic source assembly, the rate of scan specified in the test method(s) must take into account the response time of the radiation instrument.

304.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

304.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.

c. Submit the technical data that supports the use of the test in b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 304.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 304.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

304.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 304.5 with respect to assembler testing. Note: The information requested in 304.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

305.0 FLUOROSCOPIC ENTRANCE EXPOSURE RATE

305.1 Requirement

a. Fluoroscopic equipment that is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 roentgens per minute at the point where the center of the useful beam enters the patient, except:

(1) during recording of fluoroscopic images, or

(2) when an optional high-level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high-level control is activated.

b. Fluoroscopic equipment that is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient, except:

(1) during recording of fluoroscopic images, or

(2) when an optional high-level control is activated (see 1020.32(d)).

305.2 Applicability

The requirement is applicable to fluoroscopic and automatic exposure rate x-ray control. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 305.4(a)).

305.3 Critical Parameters and “Worst Case” Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. To test for the maximum entrance exposure rate, the beam-limiting device must be fully open. This condition must be specified in the test method(s).

c. For equipment without automatic exposure rate control, the test results must include data for “worst case” combinations of peak tube potentials and tube currents (e.g., maximum kVp and mA).

d. For equipment with automatic exposure rate control, the technique factors specified in the test method(s) must be driven to the maximum design limits for this test.

e. For automatic exposure rate control equipment using direct viewing optics, the test must be performed with suppressed ambient light conditions.

305.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

305.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.

c. Submit the technical data that supports the use of the test in b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 305.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 305.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

304.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 305.5 with respect to assembler testing. Note: The information requested in 305.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

306.0 PRIMARY PROTECTIVE BARRIER TRANSMISSION

306.1 Requirement

The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate (see 1020.32(a)(i)).

306.2 Applicability

The requirement is applicable to fluoroscopic imaging assemblies or the following component parts thereof: spot-film device; image intensifier; and fluoroscopic screen assembly. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 306.4(a)).

306.3 Critical Parameters and "Worst Case" Conditions

a. The test results must include data representative of each compatible combination of components that comprise the fluoroscopic imaging assembly.

b. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

c. For any test using a scan of the fluoroscopic imaging assembly, the rate of scan specified in the test method(s) must take into account the response time of the radiation instrument.

d. To test for the transmission of radiation through the primary protective barrier, the beam-limiting device must be fully open and the highest available peak tube potential must be used. These conditions must be specified in the test method(s).

e. If an oblique fluoroscopic capability is provided, the radiation transmitted through the primary protective barrier must be measured at the maximum oblique fluoroscopic angles.

f. If the fluoroscopic beam-limiting device is equipped with an override capability, the radiation transmitted through the primary protective barrier must be measured at the largest x-ray field setting.

306.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

306.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.

c. Submit the technical data that supports the use of the test in b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 306.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 306.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

306.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 306.5 with respect to assembler testing. Note: The information requested in 306.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

307.0 REPRODUCIBILITY AND LINEARITY

307.1 Requirement

When the x-ray unit is operated on an adequate power supply as specified by the manufacturer; (1) the estimated coefficient of variation of radiation exposure shall not be greater than 0.05 for any specific combination of technique factors, and (2) the average ratios of exposure to the indicated tube current exposure time product (mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum, or

$$\frac{\left| \bar{X}_1 - \bar{X}_2 \right|}{\bar{X}_1 + \bar{X}_2} \leq 0.10$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of two consecutive tube current settings.
(see 1020.31(b) and (c)).

307.2 Applicability

The requirement is applicable to radiographic x-ray controls and high-voltage generators. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 307.4(a)).

307.3 Critical Parameters and “Worst Case” Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. To assure compliance with the reproducibility and linearity requirements, the test results must include data for “worst case” combinations of technique factors and supply line conditions (e.g., low kVp, high mA, low-line voltage, and highest allowed line-voltage regulation).

c. To determine compliance, variable controls for technique factors shall be adjusted to alternate settings and rest to the test setting between measurements.

307.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

307.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.

c. Submit the technical data that supports the use of the test in b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 407.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 407.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

307.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 307.5 with respect to assembler testing. Note: The information requested in 307.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

308.0 RADIATION FROM COMPONENTS OTHER THAN THE DIAGNOSTIC SOURCE ASSEMBLY

308.1 Requirement

The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under an conditions for which it was designed (see 1020.30(1)).

308.2 Applicability

The requirement is applicable to x-ray controls, high-voltage generators that contain thermionic diode valves (valve tubes), and image intensifiers. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 308.4(a)).

308.3 Critical Parameters and “Worst Case” Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. For any test using a scan of the subject components, the rate of scan specified in the test method(s) must take into account the response time of the radiation instrument.

c. To test for the maximum leakage radiation from the subject component, the highest available peak tube potential must be used. This condition must be specified in test method(s).

308.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

308.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.

c. Submit the technical data that supports the use of the test in b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 308.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 308.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

308.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 308.5 with respect to assembler testing. Note: The information requested in 308.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

309.0 PEAK TUBE POTENTIAL

309.1 Requirement

The manufacturer shall state the maximum deviation of the peak tube potential from its preindicated value during an exposure, when the equipment if connected to an adequate power supply as specified by the manufacturer. The deviation of the peak tube potential shall not exceed the limits given (see 1020.31(a)(4) and 1020.32(e)).

309.2 Applicability

The requirement is applicable to fluoroscopic and radiographic x-ray controls and high-voltage generators. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 309.4(a)).

309.3 Critical Parameters and "Worst Case" Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. To assure compliance with the maximum deviation statements provided to the user, the test results must include data for "worst case" combinations of technique factors and supply line conditions (e.g., highest kW, low line voltage, and highest allowed line-voltage regulation).

309.4 Prototype Testing

a. Describe the direct test method (i.e., a direct electrical measurement such as a voltage divider, oscilloscope or voltmeter) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

309.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance is not a direct electrical measurement such as a voltage divider, oscilloscope or voltmeter, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 309.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 309.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

309.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 309.5 with respect to assembler testing. Note: The information requested in 309.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

310.0 TUBE CURRENT

310.1 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 1020.31(a)(4) and 1020.32(e)).

310.2 Applicability

The requirement is applicable to fluoroscopic and radiographic x-ray controls and high-voltage generators. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 310.4(a)).

310.3 Critical Parameters and “Worst Case” Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. To assure compliance with the maximum deviation statements provided to the user, the test results must include data for “worst case” combinations of technique factors and supply line conditions (e.g., highest kW, low line voltage, and highest allowed line-voltage regulation).

310.4 Prototype Testing

a. Describe the direct test method (i.e., a direct electrical measurement such as a voltage divider, oscilloscope or voltmeter) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

310.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance is not a direct electrical measurement such as a voltage divider, oscilloscope or voltmeter, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 310.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 310.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

310.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 310.5 with respect to assembler testing. Note: The information requested in 310.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

311.0 TUBE CURRENT-EXPOSURE TIME PRODUCT

311.1 Requirement

The manufacturer shall state the maximum deviation of the tube current exposure time product (mAs) from its preindicated value during and 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 1020.31(a)(4)).

311.2 Applicability

The requirement is applicable to radiographic x-ray controls and high-voltage generators that have mAs settings. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 311.4(a)).

311.3 Critical Parameters and “Worst Case” Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. To assure compliance with the maximum deviation statements provided to the user, the test results must include data for “worst case” combinations of technique factors and supply line conditions (e.g., highest kW, low line voltage, and highest allowed line-voltage regulation).

311.4 Prototype Testing

a. Describe the direct test method (i.e., a direct electrical measurement such as a milliampere - second meter) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

311.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance is not a direct electrical measurement such as a milliampere - second meter, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 311.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 311.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

311.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 311.5 with respect to assembler testing. Note: The information requested in 311.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

312.0 EXPOSURE TIME

312.1 Requirement

The manufacturer shall state the maximum deviation of the exposure time from its preindicated value during an exposure, when the equipment is connected to an adequate power supply as specified by the manufacturer. The deviation of exposure time shall not exceed the limits given (see 1020.31(a)(4)).

312.2 Applicability

The requirement is applicable to radiographic x-ray controls and high-voltage generators. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 312.4(a)).

312.3 Critical Parameters and "Worst Case" Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. To assure compliance with the maximum deviation statements provided to the user, the test results must include data for "worst case" combinations of technique factors and supply line conditions (e.g., highest kW, low-line voltage, and highest allowed line-voltage regulation).

312.4 Prototype Testing

a. Describe the direct test method (i.e., a direct radiation or electrical measurement such as a voltage divider, oscilloscope) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

312.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance is not a direct radiation or electrical measurement such as a voltage divider or oscilloscope, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 312.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 312.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

312.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 312.5 with respect to assembler testing. Note: The information requested in 312.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

313.0 AUTOMATIC EXPOSURE CONTROL LIMITS

313.1 Requirement

Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure (see 1020.31(a)(3)(iii)).

313.2 Applicability

The requirement is applicable to radiographic x-ray controls and high-voltage generators used in systems with automatic exposure controls. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 313.4(a)).

313.3 Critical Parameters and "Worst Case" Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. To assure compliance with 60 kWs, 600 mAs, or 2000 mAs limits applicable to this system, the test results must include data for various combinations of technique factors.

313.4 Prototype Testing

a. Describe the direct test method (i.e., a direct electrical measurement such as a voltage divider, oscilloscope or voltmeter or millampere-second meter) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

313.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance is not a direct electrical measurement such as a voltage divider, oscilloscope, voltmeter or milliampere - second meter, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 313.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 313.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

313.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 313.5 with respect to assembler testing. Note: The information requested in 313.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

314.0 AUTOMATIC EXPOSURE CONTROL MINIMMUM EXPOSURE TIME

314.1 Requirement

When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time of field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses, and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater (see 1020.31(a)(3)(ii)).

314.2 Applicability

The requirement is applicable to radiographic x-ray controls and high-voltage generators used in systems with automatic exposure controls. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 314.4(a)).

314.3 Critical Parameters and “Worst Case” Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

314.4 Prototype Testing

a. Describe the direct test method (i.e., a direct radiation or electrical measurement) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

314.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance is not a direct radiation or electrical measurement, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 314.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 314.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

314.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 314.5 with respect to assembler testing. Note: The information requested in 314.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

315.0 ILLIMINANCE OF LIGHT LOCALIZERS

315.1 Requirement

When a light localizer is used to define the perimeter of the x-ray field, it shall provide an average illumination of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field (see 1020.31(d)(2)(ii) and (f)(4)(i)).

315.2 Applicability

The requirement is applicable to any beam-limiting devices in a general purpose or other radiographic system that uses a light localizer to define the perimeter of the x-ray field. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 315.4(a)).

315.3 Critical Parameters and "Worst Case" Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

315.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually measures illumination) employed in testing each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

315.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure illumination, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 315.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 315.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

315.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 315.5 with respect to assembler testing. Note: The information requested in 315.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

316.0 ALIGNMENT OF VISUALLY DEFINED X-RAY FIELDS AND CONTRAST OF LIGHT DEFINED X-RAY FIELDS

316.1 Requirement

a. Visual fields (including light fields): Means shall be provided for visually defining the perimeter of the x-ray field for all general purpose x-ray systems. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam (see 1020.31(d)(2)(i)).

b. Light fields: The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary general purpose equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile general purpose and other radiographic equipment (see 1020.31(d)(2)(iii) and (f)(4)(i).

316.2 Applicability

The requirement is applicable to any beam-limiting device in a general purpose or other radiographic system that uses a light localizer to define the perimeter of the x-ray field. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 316.4(a)).

316.3 Critical Parameters and “Worst Case” Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. To assure compliance with the requirement for visually defining the perimeter of the x-ray field, the test results must include data for the range of SID's and image receptor sizes.

316.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually measures alignment and the contrast ratio) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

316.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure the alignment and contrast ratio, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 316.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 316.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

316.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 316.5 with respect to assembler testing. Note: The information requested in 316.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

317.0 ALIGNMENT OF THE CENTER OF THE RADIPGRAPHIC X-RAY FIELD WITH THE CENTER OF THE IMAGE RECEPTOR

317.1 Requirement

a. For stationary general purpose x-ray systems, the center of the x-ray field shall align with the center of the image receptor to within 2 percent of the SID (see 1020.31(e)(1)(i)).

b. For other x-ray systems, the center of the x-ray field shall align with the center of the image receptor to within 2 percent of the SID unless means are provided to size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor (see 1020.31(f)(2) and (4)).

317.2 Applicability

This requirement is applicable to beam-limiting device used in radiographic x-ray systems other than (a) mobile x-ray systems; (b) systems for spot filming; (c) systems intended solely for intraoral image receptors; and (d) systems used solely for mammography. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 317.4(a)).

317.3 Critical Parameters and “Worst Case” Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. To assure compliance with the centering requirement, the test results must include data for various combinations of SIDs and image receptor sizes.

317.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually compares the alignment of the parameters in the requirement) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

317.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually compare the alignment of the parameters in the requirement, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 317.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 317.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

317.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 317.5 with respect to assembler testing. Note: The information requested in 317.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

318.0 RADIOGRAPHIC X-RAY FIELD SIZE AND IMAGE RECEPTOR SIZE

318.1 Requirement

a. General purpose stationary x-ray systems: The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted. Indication of field size dimensions and SID's shall be specified in inches and/or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is perpendicular to the plane of the image receptor (see 1020.31(e)(1)(ii) and (iii)).

b. Systems with positive beam limitation: The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than 3 percent of the SID and that the sum of the length and width differences without regard to sign be no greater than 4 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor (see 1020.31(e)(2)(ii)).

318.2 Applicability

This requirement is applicable to beam-limiting device and permanently mounted cassette holders that are used in stationary general purpose systems. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 318.4(a)).

318.3 Critical Parameters and “Worst Case” Conditions

a. The test results must include data representative of each compatible combination of tube housing assemblies and beam-limiting devices.

b. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

c. To assure compliance with the positive beam limitation requirements, the test results must include date for (1) the horizontal and vertical ranges of SID's and image receptor sizes and (2) the $\pm$10° range of angulation relative to a line perpendicular to the plane of the image receptor.

d. Since the SID is used for calculating the compliance values of this requirement, the accuracy of the SID measurement must be verified.

318.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually compares the alignment of the parameters in the requirement) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

318.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually compare the alignment of the parameters in the requirement, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 318.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 318.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

318.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 318.5 with respect to assembler testing. Note: The information requested in 318.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

319.0 X-RAY FIELD SIZE DETERMINATION FOR FIXED SID/IMAGE RECEPTOR SIZE RADIOGRAPHIC EQUIPMENT

319.1 Requirement

Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor (see 1020.31(f)(2)).

319.2 Applicability

The requirement is applicable to beam-limiting devices. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 319.4(a)).

319.3 Critical Parameters and "Worst Case" Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

319.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually compares the alignment of the parameters in the requirement) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

319.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually compare the alignment of the parameters in the requirement, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 319.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 319.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

318.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 319.5 with respect to assembler testing. Note: The information requested in 319.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

320.0 ALIGNMENT OF X-RAY FIELD AND SPOT-FILM CASSETTE

320.1 Requirement

a. The total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, shall not exceed 3 percent of the SID. The sum without regard to sign of the misalignment along any two orthogonal dimensions shall not exceed 4 percent of the SID (see 1020.31(g)(2)).

b. The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID (see 1020.31(g)(4)).

320.2 Applicability

This requirement is applicable to any beam-limiting devices and spot-film devices. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 320.4(a)).

320.3 Critical Parameters and “Worst Case” Conditions

a. The test results must include data representative of each compatible combination of beam-limiting devices and spot-film devices.

b. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

c. To assure compliance with the spot-film x-ray field limitation requirement, the test results must include data for the range of SID's and applicable spot-film formats for each image receptor size.

320.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually compares the alignment of the parameters in the requirement) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturers and model number. Answer the questions in section 401.0, 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.

320.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually compare the alignment of the parameters in the requirement, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturers and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 320.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 320.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

320.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 320.5 with respect to assembler testing. Note: The information requested in 320.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

321.0 ALIGNMENT OF EDGES OF THE X-RAY FIELD WITH THE EDGES OF THE FLUOROSCOPIC IMAGE RECEPTOR

321.1 Requirement

For nonimage intensified fluoroscopy, the x-ray field shall not extend beyond the visible are of the image receptor. For image intensified fluoroscopy:

a. The total misalignment of the edges of the x-ray field with the respective edges of the visible area of the image receptor along any dimension of the visually defined field in the plane of the image receptor shall not exceed 3 percent of the SID. The sum, without regard to sign, of the misalignment along any two orthogonal dimensions intersecting at the center of the visible area of the image receptor shall not exceed 4 percent of the SID.

b. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor (see 1020.32(b)(2)).

321.2 Applicability

This requirement is applicable to any beam-limiting devices and image intensifiers. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 321.4(a)).

321.3 Critical Parameters and “Worst Case” Conditions

a. The test results must include data representative of each compatible combination of beam-limiting devices and image intensifiers.

b. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

c. To assure compliance with the fluoroscopic x-ray field limitation requirement, the test results must include data for the range of SID's and available magnification modes that result in different visual areas on the input phosphor of the image intensifier.

321.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually compares the alignment of the parameters in the requirement) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

321.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure and compare the alignment of the parameters in the requirement, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 321.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 321.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

321.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 321.5 with respect to assembler testing. Note: The information requested in 321.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

322.0 X-RAY FIELD SIZE DETERMINATION FOR DENTAL EQUIPMENT USING INTRAORAL IMAGE RECEPTORS

322.1 Requirement

Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

a. If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; or

b. If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters (see 1020.31(f)(1)(i) and (ii)).

322.2 Applicability

This requirement is applicable to any beam-limiting devices. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 322.4(a)).

322.3 Critical Parameters and “Worst Case” Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

322.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually compares the alignment of the parameters in the requirement) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

321.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually compare the alignment of the parameters in the requirement, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 322.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 322.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

322.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 322.5 with respect to assembler testing. Note: The information requested in 322.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

323.0 X-RAY FIELD SIZE DETERMINATION FOR MAMMOGRAPHIC EQUIPMENT

323.1 Requirement

Mammographic equipment shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. Permanent, clearly legible markings shall indicate the image receptor size and maximum SID for which each aperture is designed (see 1020.31(f)(3)).

323.2 Applicability

This requirement is applicable to beam-limiting devices. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 323.4(a)).

323.3 Critical Parameters and "Worst Case" Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. The test results must include data for each aperture size at the maximum designated SID.

c. Since the SID is used for calculating the compliance values of this requirement, the accuracy of the SID measurement must be verfied.

323.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually compares the alignment of the parameters in the requirement) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

323.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually compare the alignment of the parameters in the requirement, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 323.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 323.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

322.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 323.5 with respect to assembler testing. Note: The information requested in 323.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

324.0 X-RAY FIELD SIZE DETERMINATION FOR RADIOGRAPHIC EQUIPMENT NOT LISTED IN 318.0, 319.0, 320.0, 321.0, OR 323.0

324.1 Requirement

Radiographic x-ray systems other than: (a) stationary general purpose systems; (b) systems designed for one image receptor size and SID; (c) spot-film devices; (d) mobile equipment; and (e) equipment designed for use with intraoral image receptors shall be provided with means to limit the x-ray beam such that when the axis of the x-ray beam is perpendicular to the plane of the image receptor, the dimensions of the x-ray field shall not exceed the corresponding dimensions of the image receptor by more than 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor (see 1020.31(f)(4)).

324.2 Applicability

This requirement is applicable to any beam-limiting devices. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 324.4a).

324.3 Critical Parameters and “Worst Case” Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

b. The test results must include data for each aperture size.

c. Since the SID is used for calculating the compliance values of this requirement, the accuracy of the SID measurement must be verfied.

324.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually compares the alignment of the parameters in the requirement) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

324.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually compare the alignment of the parameters in the requirement, 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 b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 324.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 324.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

324.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 324.5 with respect to assembler testing. Note: The information requested in 324.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

325.0 TRANSMISSION LIMIT FOR IMAGE RECEPTOR SUPPORT DEVICES FOR MAMMOGRAPHIC X-RAY SYSTEMS

325.1 Requirement

The transmission of the primary beam through any image receptor support provided with the mammographic x-ray system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen for each activation of the tube (see 1020.31(l)).

325.2 Applicability

This requirement is applicable to mammographic image receptor supporting devices. Similar models of a single component type may be grouped for presentation of test results applicable to this requirement when the technical basis for this grouping is clearly stated in the description of prototype testing (see 325.4(a)).

325.3 Critical Parameters and "Worst Case" Conditions

a. As a result of inherent inaccuracies of the test method and instrumentation, rejection limits for any test must be sufficiently restrictive to assure compliance with the standard.

325.4 Prototype Testing

a. Describe the direct test method (i.e., one that actually measures x radiation) employed in testing and measuring each model with respect to this requirement.

b. Identify the instrument(s) used for the test by manufacturer and model number. Answer the questions in section 401.0, 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.

325.5 Production Testing

a. Describe all methods employed in direct and indirect testing of each model with respect to this requirement.

b. If any test used to monitor compliance does not actually measure x radiation, explain why it is an accurate indication of compliance with this requirement.

c. Submit the technical data that supports the use of the test in b.

d. Provide a copy of the detailed instructions for performing each test. Enclose in APPENDIX I.

e. Identify the instrument(s) used for each test by manufacturer and model number. Answer the questions in section 401.0, PART 400 for this instrument(s).

f. For each test method in 325.5(a), give the page number of your detailed instructions for performing the test where the rejection limits are specified.

g. For each test method in 325.5(a), 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.

i. If you do not test 100 percent of the produced models, answer the questions in section 402.0, PART 400.

325.6 Assembler Testing

a-i. If test instructions are provided to the assembler, answer the questions in 325.5 with respect to assembler testing. Note: The information requested in 325.6(d) (i.e., copy of detailed instructions for performing each test) should have already been provided in APPENDIX B.

PART 400 - COMMON ASPECTS

401.0 INSTRUMENTATION

401.1 Radiation Measurement

a. Describe each radiation measurement instrument that you reefer to in PART 300, giving the following: manufacturer and model number if the instrument is commercially available; type of instrument; precision; accuracy; response time, energy dependence; angular response; exposure rate dependence; ranges; and effective measurement area.

b. Describe the procedures used for calibration of each instrument including the interval of time between calibrations.

c. How do you assure proper day-to-day operation of each instrument?

401.2 Illuminance and Contrast Measurement

a. Describe each illuminance and/or contrast measurement instrument that you refer to in PART 300, giving the following: manufacturer and model number if the instrument is commercially available; type of measuring instrument; precision; accuracy; and ranges.

b. Describe the procedures used for calibration of each instrument including the interval of time between calibrations.

c. How do you assure proper day-to-day operation of each instrument?

401.3 Electrical Measurement

a. Describe each electrical measurement instrument that you referred to in PART 300, giving the following: type of instrument; manufacturer and model number if the instrument is commercially available; rated accuracy; precision; ranges; and response time. If any number of commercially available instruments with certain basic characteristics may be used, it is sufficient to state the minimum accuracy, precision, ranges, response time, and so forth, of the class of instruments that will be used. If any instrument is unique or of special manufacture then the manufacturer and model number should be stated.

b. Describe the procedures used for calibration of each instrument including the interval of time between calibrations.

c. Show where each instrument listed in 401.3(a) is connected during testing with the use of a schematic diagram.

401.4 Other Measurement

a. Describe each measurement instrument (other than radiation, illuminance and contrast, or electrical) that you refer to in PART 300, giving the following: type of instrument; manufacturer and model number if the instrument is commercially available; rated accuracy; precision; and ranges. If any number of commercially available instruments with certain basic characteristics may be used, it is sufficient to state the minimum accuracy, precision ranges, and so forth, of the class of instruments that will be used. If any instrument is unique or of

special manufacture, however, then the manufacturer and model number number should be stated.

b. Describe the procedures used for calibration of each instrument including the interval of time between calibrations.)

402.0 SAMPLING

a. Describe the sampling plan used and provide the parameters of the plan (e.g., lot size, sample size, rejection criterion).

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

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