RHODE ISLAND GOVERNMENT REGISTER

PUBLIC NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

Title of Rule: Medical Diagnostic and Interventional X-Ray and Imaging Systems (216-RICR-40-20-4)

Rule Identifier: 216-RICR-40-20-4

Rulemaking Action: Proposed Amendment

Important Dates:

Date of Public Notice: January 24, 2022

Hearing Date: February 7, 2022

End of Public Comment: February 23, 2022

Rulemaking Authority:

R.I. Gen. Laws § 23-1.3-5

Summary of Rulemaking Action:

This regulation is being amended to reflect the incorporation of additional requirements regarding fluoroscopically guided interventional procedures. All proposed changes implement the most current revisions to Part F of the Suggested State Regulations for the Control of Radiation published by the Conference of Radiation Control Program Directors Inc.

Additional Information and Public Comments:

All interested parties are invited to request additional information or submit written or oral comments concerning the proposed amendment until February 23, 2022 by contacting the appropriate party at the address listed below:

Paula Pullano

Department of Health

3 Capitol Hill

Room 410

Providence, RI 02908-5097

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Public Hearing:

A public hearing, in accordance with R.I. Gen. Laws § 42-35-2.5, to consider the proposed amendment shall be held at which time and place all persons interested therein will be heard. This hearing is subject to R.I. Gen. Laws Chapter 42-46, Open Meetings.

Public Hearing Information:

Date: February 7, 2022

Time: 10:00 A.M.

Location: Zoom Link to Come Providence, RI, 02908

The place of the public hearing is accessible to individuals with disabilities. If communication assistance (readers/interpreters/captioners) is needed, or any other accommodation to ensure equal participation, please call 401-222-3395 or RI Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting. For questions regarding available parking, please contact the agency staffperson listed above.

Regulatory Analysis Summary and Supporting Documentation:

In development of this rule, consideration was given to:
1)Alternative approaches;

2)Overlap or duplication with other statutory and regulatory provisions; and

3)Significant economic impact on small business
No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.

For full regulatory analysis or supporting documentation contact the agency staffperson listed above.

STATE OF RHODE ISLAND
RHODE ISLAND DEPARTMENT OF HEALTH
CONCISE STATEMENT OF PROPOSED NON-TECHNICAL AMENDMENTS
(AMENDMENTS TO AN EXISTING REGULATION)

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-1.7(b)(8), the following is a concise statement of proposed non-technical amendments to Part 1, Part 2, Part 3, Part 4, Part 5, Part 6, Part 7, Part 8, Part 9, Part 10, Part 11, Part 12, Part 13 and Part 15 of 216-RICR-40-20, *Radiation*.

Regulation	**Rationale/Summary of Change**
§ 1.2 (A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 20
§ 2.2 (A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 19
§ 3.10(A)(4)	Revised to require submission of RCA Form 2579 in lieu of an equivalent USFDA form which is being phased out.
§ 3.13(C)(1)(c)	Corrects internal cross reference to another section in Part 3
§ 3.13(D)	Corrects internal cross reference to another section in Part 3
§ 3.14(C)	Corrects internal cross reference to another section in Part 3
§ 3.14(D)(1)	Corrects internal cross reference to another section in Part 3
Part 4 (Title)	Title of this Part has been revised to reflect the incorporation of additional requirements regarding fluoroscopically guided interventional procedures. All changes to Part 4 implement the most current revisions to Part F of the Suggested State Regulations for the Control of Radiation (SSRCR) published by the Conference of Radiation Control Program Directors, Inc. (CRCPD).
§ 4.1(B)	Clarifies that use of X-ray equipment must be under the supervision of an individual authorized by and licensed in accordance with applicable provisions of the R.I. Gen. Laws to engage in the healing arts or veterinary medicine
§ 4.1(C) &(D)	Deleted and consolidated with § 4.1(B).
§ 4.1.1(B) &(C)	Added to incorporate two additional documents by reference
§ 4.2(A)(30)	Corrects a spelling error
§ 4.2(A)(92)	"Protective garment" replaces "protective apron" for consistency with other changes
§ 4.3.1(A) and (B)	Specifies that administrative controls must include an effective radiation safety program.
§ 4.3.1(C) to (G)	Reflects the incorporation of additional administrative controls specified in the most current revision to Part F of the SSRCR.
§ 4.3.2(A)	Language added to allow limited operation of noncompliant X-ray equipment after review by a Qualified Medical Physicist

Regulation	Rationale/Summary of Change
§ 4.3.3(C) to (F)	Clarifies required training that must be completed before an individual is allowed to operate fluoroscopic X-ray equipment.
§ 4.3.3(H)	Clarifies required training that must be completed before an individual is allowed to operate dental X-ray equipment.
§ 4.3.4(A)	Clarifies information that has to be readily available to an operator of an X-ray system.
§ 4.3.6(A)	Clarifies safety precautions for individuals (other than patient) who are in the room where an X-ray is being taken.
§ 4.3.7	Deleted to address changes in "best practices".
§ 4.3.9	Clarifies safety precautions when a patient or image receptor must be provided with auxiliary support while an X-ray is being taken.
§ 4.3.10(D)	Deleted and consolidated with other Quality Control requirements in § 4.10.1
§ 4.3.10(E) and (G)	Language revised to reflect the most current revision to Part F of the SSRCR.
§ 4.3.10(F), (H) and (I)	Deleted to reflect the most current revisions to Part F of the SSRCR.
§ 4.3.10(J) and (K)	Language added to reflect the most current revisions to Part F of the SSRCR.
§ 4.3.13	Clarifies retention period for maintenance records and associated information
§ 4.3.14(A)(4)	Removes text which refers to a deleted section.
§ 4.3.14(D)	Clarifies record retention requirements for veterinary X-ray facilities
§ 4.3.15(C)	Language revised to synchronize wording with equivalent requirements in § 5.3.12(E)(1)(b) and 10 C.F.R. 35.3047
§ 4.4.3	Revised to reflect different labeling requirements for systems manufactured before 10 June 2006
§ 4.4.7	Deletes information on dental X-ray systems which has been moved to § 4.14
§ 4.4.10	Clarifies requirements regarding technique factors and kVp accuracy
§ 4.4.13	Clarifies requirements regarding use of calibrated dosimetry systems
§ 4.4.14(F)	Requires information pertaining to a radiation medical event be maintained as part of a patient's permanent medical record
§ 4.5.2	Language revised for consistency with other sections of this Part
§ 4.5.3	Clarifies training required before an individual can operate fluoroscopy equipment
§ 4.5.6	Language revised for consistency with other sections of this Part
§ 4.5.7	Language revised to reflect the most current revisions to Part F of the SSRCR.
§ 4.5.11	Deleted to reflect the most current revisions to Part F of the SSRCR.

Regulation	Rationale/Summary of Change
§ 4.5.12	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.5.13	Language added to reflect the most current revisions to Part F of the SSRCR regarding fluoroscopically-guided interventional (FGI) procedures.
§ 4.5.14(B)	Language revised to correct internal cross-reference
§ 4.5.16	Language revised for consistency with other sections of this Part
§ 4.6.1	Clarifies applicability of section to various types of X-ray systems
§ 4.6.2(C)(3)	Language revised to correct internal cross-reference
§ 4.6.2(D)	Clarifies operator protection requirements for veterinary X-ray systems
§ 4.6.3(A)	Removes language that is duplicated in another part of the regulations
§ 4.6.3(C)(4)	Language revised to correct internal cross-reference
§ 4.6.4(G)	Requires use of manual collimation standards when PBL is disabled
§ 4.6.5	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.6.6	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.6.9	Removes language that is duplicated in another part of the regulations
§ 4.6.11	Removes requirement that is superseded by MQSA standards in § 4.8
§4.6.12(A)(3)	Language deleted to reflect the most current revisions to Part F of the SSRCR
§ 4.6.14	Language revised to reflect the most current revisions to Part F of the SSRCR
§4.6.15(A)	Removes requirement that is now included in § 4.14
§4.6.15(C)	Removes requirement that is superseded by MQSA standards in § 4.8
§4.7.1(A)	Language added to reflect the most current revisions to Part F of the SSRCR
§4.7.1(F)&(G)	Language deleted to reflect the most current revisions to Part F of the SSRCR
§ 4.7.3	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.7.5	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.6	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.7	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.8	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.9	Language revised to reflect the most current revisions to Part F of the SSRCR

Regulation	Rationale/Summary of Change
§ 4.10	Language revised to consolidate QA/QC requirements in a single section to reflect the most current revisions to Part F of the SSRCR
§ 4.13	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.14	New section added to consolidate all dental X-ray system requirements in a single section to reflect the most current revisions to Part F of the SSRCR
§ 5.3.12(E)(1)(b)	Synchronize wording with equivalent requirements in 10 C.F.R. 35.3045
§ 5.4.2(A)(4)	Language revised to remove obsolete cross-reference to another section of this Subpart
§ 5.4.4	Language added to clarify that "records" refers to "records of surveys"
§§ 5.5.2 & 5.5.3	Synchronize wording with equivalent requirements in 10 C.F.R. 35.3047
§ 5.6.17(F)	Review interval revised to synchronize with equivalent requirements in 10 C.F.R. 35.642
§ 5.6.18(A)	Corrects internal cross-reference to another section of this Part
§ 5.7.1	Corrects internal cross-reference to another section of this Part
§ 5.7.4(B)	Corrects internal cross-reference to another section of this Part
§§ 5.11.11(D) & (H)	Corrects internal cross-references to other sections of this Part
§§ 6.5(D)(1) & (D)(2)	Corrects internal cross-references to other sections of this Part
§ 6.6(A)(1)	Corrects internal cross-reference to another section of this Subchapter
§ 7.2.1(A)	Revises incorporate on by reference date to 2021 to capture updates to 10 C.F.R. § 30.34 published in the Federal Register [83 FR 33046]. This C.F.R. section is already incorporated by reference in § 7.6.3
§ 7.2.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 31
§ 7.2.3(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. § 32.72 published in the Federal Register [83 FR 33046 & 83 FR 57231]. This C.F.R. section is already incorporated by reference in §§ 7.6.3 and 7.6.16(A).
§ 7.2.3(B)	Corrects typo regarding portions of 10 C.F.R Part 32 that are not being incorporated by reference.
§ 7.2.4(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 33
§ 7.2.5(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 40
§ 7.2.5(B)	Corrects typo regarding portions of 10 C.F.R Part 40 that are not being incorporated by reference.
§ 7.2.6(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 70

Regulation	Rationale/Summary of Change
§ 7.2.6(C)	Incorporates the provisions of 10 C.F.R. § 150.11(b) by reference.
§ 7.4.10	Revises wording for consistency with U.S. Nuclear Regulatory Commission usage.
§ 7.6.7(B)	Language added to further clarify when a license amendment is required
§ 7.6.8	Revise language to remove duplicate reference
§ 7.6.13	Revises paragraph numbering for consistency with other sections in this Part
§ 8.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 37 published in the Federal Register [83 FR 57231]. These 10 C.F.R. Part 37 sections are already incorporated by reference in §§ 8.6.4 and 8.6.6.
§ 8.4.4(B)	Updates mailing address
§ 8.5.9	Adds a specific incorporation by reference citation for reporting of certain events
§ 9.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 35 published in the Federal Register [83 FR 33046, 85 FR 33527 and 85 FR 44685]. These 10 C.F.R. Part 35 sections are already incorporated by reference in §§ 9.3, 9.4.7, 9.5.5, 9.5.10, 9.5.11(A), 9.5.12(A), 9.5.13(A), 9.5.18, 9.6.4, 9.7.2, 9.7.4(A), 9.7.5, 9.8.1, 9.8.4, 9.8.5, 9.8.6, 9.8.7, 9.9.1, 9.9.7, 9.9.9, 9.9.10, 9.10.1, 9.10.2, 9.11.1, 9.11.4, 9.11.15, and 9.11.17.
§ 9.2(B)	Identifies 10 C.F.R. Part 35 amendments published in the Federal Register [83 FR 33046] which are not incorporated by reference.
§ 9.4.3(B)(2)	Implements 83 FR 33046 requirements for training & qualifications of Associate Radiation Safety Officer and Ophthalmic Physicist as part of a radioactive materials license application.
§ 9.4.3(B)(4)	Corrects internal cross-reference to another section of this Subchapter
§ 9.4.5(A)(2)	Clarifies utilization of a Visiting Ophthalmic Physicist without requiring a radioactive materials license amendment [related to 83 FR 33046 amendments].
§ 9.4.5(A)(9) and (A)(10)	Implements 83 FR 33046 requirements for obtaining a radioactive materials license amendment prior to performing certain specified activities.
§ 9.4.6(A)(1) (A)(5) & (A)(6)	Implements 83 FR 33046 requirements for certain notifications that must be submitted to the RI Radiation Control Agency.
§ 9.5.1(A)(2)	Implements a requirement for written management approval to utilize a Visiting Ophthalmic Physicist [related to 83 FR 33046 amendments].
§ 9.5.1(B)	Implements 83 FR 33046 requirements for approval of Associate Radiation Safety Officer.
§ 9.5.1(C)	Eliminates unnecessary language [related to 83 FR 33046 amendments].
§ 9.5.1(K)	Implements 83 FR 33046 recordkeeping requirements for approval of Associate Radiation Safety Officer.

Regulation	Rationale/Summary of Change
§ 9.5.4(B)(5)	Implements 83 FR 33046 requirements regarding the contents of a written directive for permanent implant brachytherapy.
§ 9.5.4(B)(6)	Renumbers current § 9.5.4(B)(5) as § 9.5.4(B)(6)
§ 9.5.6 and § 9.5.6(D)	Clarifies utilization of a Visiting Ophthalmic Physicist [related to 83 FR 33046 amendments] and corrects internal cross-reference to other section of this Part
§ 9.5.6(E) & (F)	Renumbers current § 9.5.6(D) and (E) as § 9.5.4(E) and (F) respectively.
§ 9.5.9(A)	Implements 83 FR 33046 requirements regarding the definition of a misadministration.
§ 9.5.9(G)(3)	Implements 85 FR 33527and 85 FR 44685 requirements regarding the use of a social security number to identify an individual in a misadministration report.
§ 9.5.10	Implements 83 FR 33046 requirements regarding training for an Associate Radiation Safety Officer.
§ 9.5.11(B)	Corrects internal cross-reference to another section of this Subchapter
§ 9.5.16(F)(1)	Corrects internal cross-reference to another section of this Part
§ 9.7.4(B), (C) and (D)	Implements 83 FR 33046 recordkeeping requirements regarding elution of radionuclide generators.
§ 9.11.15	Implements 83 FR 33046 requirements regarding full-inspection servicing of teletherapy and gamma stereotactic radiosurgery units.
§ 9.5.19(A)	Clarifies wording to indicate that the dose limits established in § 1.8 are being referenced
§ 9.5.19(B)	Corrects internal cross-reference to another section of this Part
§ 9.6.3(B)	Clarifies rcord maintenance requirement for consistency with § 9.6.2(B)
§ 9.6.8(F)	Clarifies wording regarding detection limit for consistency with other applicable NRC guidance
§ 9.6.8(H)	Corrects internal cross-reference to another section of this Part
§ 9.6.9(E)	Corrects internal cross-reference to another section of this Part
§ 9.7.6(D)	Corrects internal cross-reference to another section of this Subchapter
§ 9.11.6(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.6(A)
§ 9.11.7(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.7(A)
§ 9.11.8(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.8(A)
§ 9.11.9(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.9(A)
§ 9.11.15(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.15(A)
§ 9.12.1	Header is removed and contents of section are collapsed into § 9.12

Regulation	Rationale/Summary of Change
§ 10.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 34 published in the Federal Register [85 FR 15347]. These 10 C.F.R. Part 34 sections are already incorporated by reference in §§ 10.6.6 and 10.7.7.
§ 10.6.3(C) (2)	Corrects internal cross-reference to another section of this Part
§ 10.6.3(C) (4)	Corrects internal cross-reference to another section of this Part
§ 10.6.3(H)	Corrects internal cross-reference to another section of this Part
§ 10.7.1(A) (7), (8) & (9)	Corrects internal cross-references to other sections of this Part
§ 10.7.10(A)	Corrects internal cross-reference to another section of this Part
§ 10.7.2(A)(9)	Corrects internal cross-reference to another section of this Part
§ 10.7.3(A)(2)	Corrects internal cross-reference to another section of this Part
§ 11.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 39 published in the Federal Register [85 FR 15347]. This 10 C.F.R. Part 39 section is already incorporated by reference in § 11.6.3.
§ 11.7.2(A)(9)	Corrects internal cross-reference to another section of this Part
§ 11.7.3(A)(2)	Corrects internal cross-reference to another section of this Part
§ 12.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. § 71.97 published in the Federal Register [83 FR 57231]. This C.F.R. section is already incorporated by reference in § 12.8.9.
§ 12.2(B)	Revises incorporation by reference date to 2021 to capture updates to 39 C.F.R. § 111.1
§ 12.2(C)	Identifies an additional subsection of 71 C.F.R. 101 that is not incorporated by reference
§ 12.8.8	Corrects section title for consistency with 10 C.F.R. 71.95
§ 12.9.1	Clarifies that RCA and not NRC is responsible for certificate approval.
§ 13.4.7(A) & (B)	Corrects internal cross-references to another section of this Subchapter
§ 15.5.7(C) (11)(c)	Language added to clarify that Category 3K also includes all other use of unsealed radioactive material not authorized for commercial distribution.

Diagnostic X-Rays and Associated Imaging Systems in the Healing Arts

216-RICR-40-20-4

Benefit-Cost Analysis

January 2022

The Rhode Island Department of Health (RIDOH) is amending the regulations pertaining to Diagnostic X-Rays and Associated Imaging Systems in the Healing Arts (216-RICR-40-20-4) to adopt the most current revision to Part F of the Suggested State Regulations for the Control of Radiation, *Medical Diagnostic and Interventional X-Ray and Imaging Systems*, published by the Conference of Radiation Control Program Director's, Inc. The proposed changes include renaming 216-RICR-40-20-4 to *Medical Diagnostic and Interventional X-Ray and Imaging Systems* to better reflect the scope of the amended regulation.

Background

The various parts of the Suggested State Regulations for the Control of Radiation published by the Conference of Radiation Control Program Director's, Inc. are developed by teams which include members from various state radiation control programs, federal agencies, and representatives of various professional organizations with expertise in the subject matter (e.g., ABR, AAPM). The draft of a major revision is prepared on the basis of all available resources, including standards and experts in the field, and is sent out for review and comment to those groups indicated above. The comments are analyzed by the working group for that part and a revised draft is prepared on the basis of the analysis of comments. A Regulations Overview Committee (ROC), composed of representatives of CRCPD and the participating Federal agencies, conducts the final review of each of the revised parts and rationale and the analysis of comments. Each of the participating groups is then asked to concur in the final draft.

216-RICR-40-20-4 establishes requirements, for which a registrant is responsible, for use of diagnostic X-ray equipment and associated imaging systems in the healing arts or veterinary medicine. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of Subchapter 216-RICR-40-20. Although the regulations do establish technical specifications for the use of diagnostic X-ray in the healing arts, the fundamental purpose of these regulations is to ensure that patients do not receive exposure to ionizing radiation beyond what is medically necessary for diagnosis and treatment. The regulations also include requirements which are designed to minimize radiation exposure to medical personnel who are conducting radiographic imaging.

Status Quo

Other than the renumbering required by conversion to the RICR format in 2019, this Part has not been amended since 2013. However, during this period the technology associated with the use of diagnostic X-ray has evolved to include applications which were not anticipated under the current regulations and/or cannot be effectively regulated under the status quo.

Proposed Regulation

The extent of changes to 216-RICR-40-20-4 is described in the *Concise Statement of Proposed Non-Technical Amendments* document for this rulemaking. However, the areas which have the most significant impact are the addition of requirements for training, computed tomography (CT)/cone beam computed tomography (CBCT) units, interventional radiology, digital imaging, quality control programs, and the consolidation of all requirements for use of dental X-ray into a single section.

§ 4.3.3(C) & (D) specify the required training for individuals who will use, or supervise the use of, fluoroscopic equipment. The amended regulations provide more specificity than the current regulations with regard to required training but do not impose any substantial additional burden. Fluoroscopy training is primarily an issue in hospitals (because that is where the majority of the complex fluoroscopic procedures are performed). However, because of JCAHO and other requirements most hospitals already have some type of credentialing program in place for individuals performing fluoroscopy. The amended regulations will standardize all future training and minimize the need for additional cross training as individuals move from facility to facility. The requirement in § 4.3.3(E) that this training be provided by a Qualified Medical Physicist or another individual approved by the Agency should not impose any significant additional burden because the training is typically presented by a medical physicist or a company tech rep. However, the intent of this requirement was to make it clear that this is not the type of instruction to be conducted by a facility's "training officer" or other individuals without adequate qualifications.

§ 4.3.3(H) establishes a more specific requirement for training of individuals who will operate dental X-ray equipment. It replaces a more general requirement to provide training to individuals before allowing them to operate X-ray equipment. However, the extent and type of training varied significantly from facility to facility. This standardizes the content of the required training.

§ 4.3.7, which required the use of gonadal shielding, has been deleted. This change is consistent with the latest research in the field and is endorsed by all of the relevant professional groups (e.g., ABR, AAPM).

§ 4.3.10(E) establishes the requirements for X-ray film processing. However, the use of film (analog) for diagnostic imaging has been replaced by digital imaging for virtually all applications. This section is being amended and retained to cover those few legacy situations where film (analog) imaging is still being used. § 4.3.10(J) establishes comparable requirements for use of digital imaging and does not impose any significant additional burden in terms of "new" requirements.

§ 4.4 establishes general requirements for interventional X-ray systems. Interventional X-ray is an emerging technology that is not specifically addressed in the current regulations. Interventional X-ray is a subset of fluoroscopy and would be regulated as such under the current regulations. However, interventional X-ray is significantly distinct from traditional fluoroscopy and needs its own set of regulations. Therefore, there would be no "new" facilities regulated under these requirements. Most interventional X-ray facilities are hospital-based and are subject to facility credentialling requirements (already mandated by JCAHO and other credentialing organizations) which should not be significantly different from these proposed regulations.

§ 4.5.1(B) specifies that only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy. While this is new regulatory text, it does not impose any additional

regulatory burdens. Early generation fluoroscopes were direct read where all of the X-rays went through the patient to the individual viewing the fluoroscope. This often led to fairly high exposures for those involved in the procedure. All current generation fluoroscopes involve an indirect read via some type of screen or image capture device. This requirement essentially prohibits use of equipment that should only be found in a museum and not in regular clinical use.

§ 4.7.1(A)(1) requires all diagnostic CT X-ray equipment for human use shall be accredited by an accrediting organization recognized by the Agency unless otherwise authorized by the Agency. The Department does not believe this imposes any additional regulatory burden because CT equipment is also subject to CON regulations [216-RICR-40-10-22] and participation in an accreditation process is typically a condition of CON approval. Therefore, it is the Department's understanding that all facilities currently have the required certification. However, there is sufficient "wiggle room" in the requirement to address unusual situations on a case-by-case basis.

§ 4.7.5 requires the establishment of a Radiation Protocol Committee (RPC) for all CT facilities. While this is a new requirement in these regulations, the Department doesn't believe this constitutes an unreasonable additional regulatory burden because most facilities would already have a similar credentialing committee because of JCAHO or other accreditation requirements. Furthermore, §§ 4.7.5(A)(2), (A)(3) and (A)(4) provide options which can reduce duplication of effort with regard to the RPC.

§§ 4.7.4, 4.7.6 and 4.7.7 specify that CT systems used for treatment planning in radiation oncology, PET, and SPECT and veterinary applications are only subject to a limited subset of the requirements applicable to CT systems used in typical clinical applications. These specific exemptions are only available as an interpretation under the current regulations.

§ 4.7.8 establishes general requirements for cone beam computed tomography System (CBCT) X-ray systems. CBCT is an emerging technology that is not specifically addressed in the current regulations. CBCT X-ray is a subset of CT and would be regulated as such under the current regulations. However, CBCT X-ray is significantly distinct from traditional CT and needs its own set of regulations. Therefore, there would be no "new" facilities regulated under these requirements.

§ 4.10 currently establishes general requirements for quality control (QC)/quality assurance (QA) of X-ray systems. These requirements are a more detailed version of what exists under the current regulations. These requirements represent a "best practices" standard for the industry. In theory, most facilities should already have had their medical physicist (consultant or in-house) develop a QA program that incorporates most of these elements. These QA requirements are consistent with what is recommended by AAPM for an effective QA program. The incremental cost for compliance with these requirements would depend on exactly what QA programs have already been put in-place by their medical physicist. Consequently, it would be difficult to come up with a one size fits all answer. However, using some very "broad brush" assumptions, the total cost (not incremental cost due to new regulations) of implementing a QA/QC program can be calculated as follows:

- Recordkeeping and performing daily QA/QC tests: Radiologic Technologist – 0.25-0.5 hour/day @ $35.64/hour[1] [$2,300- $4,600/year].
- Medical physicist quarterly/annual audit: 4 hours/quarter @ $66.74/hour + additional 8 hours for annual report @ $66.74/hour [$1,600/year].

The numbers would be slightly different for dental facilities:

- Recordkeeping and performing daily QA/QC tests: Dental Assistant – 0.25-0.5 hour/day @ $23.24/hour [$1,450-$2,900/year].
- Facility QA/QC activity review by dentist: 2 hours/quarter @ $120.18/hour + additional 8 hours for annual report @ $120.18/hour [$ 1,200/year].

§ 4.14 establishes requirements for dental X-ray facilities. Prior to the 2013 amendments, the regulations contained a specific section for dental X-ray. When the current regulations were adopted in 2013, the requirements for dental X-ray were merged into the more general requirements. However, it was subsequently determined that dental X-ray should have its own section. § 4.14 consolidates all of the dental X-ray requirements. There are no significant changes from what is required under the current regulations. Specifically with regard to QA, the new regulations provide more specific detail compared with what is currently required.

Alternatives

Although there may be slight incremental costs associated with implementation of these proposed amendments, these costs are outweighed by the benefits of protecting patients, medical staff, and the public from the harmful effects of ionizing radiation. In addition, the Department believes that these proposed amendments do not pose an unreasonable regulatory burden on the regulated community. Therefore, the Department does not believe there are any viable alternatives to the proposed amendments to 216-RICR-40-20-4. By adopting the most current revision to Part F of the Suggested State Regulations for the Control of Radiation, *Medical Diagnostic and Interventional X-Ray and Imaging Systems*, published by the Conference of Radiation Control Program Director's, Inc., the Department will be implementing a national consensus "best practices" standard that has already been adopted by many other state radiation control programs. Furthermore, as noted previously, since these regulations were last amended in 2013, the technology associated with the use of diagnostic X-ray has evolved to include applications which were not anticipated under the current regulations and/or cannot be effectively regulated under the status quo.

Determination

Based on the above analysis, the Department has determined that the current proposed amendments to 216-RICR-40-20-4 provide the only viable regulatory solution to carry out its statutory mandate for the protection of the public health and safety by developing policies and programs for evaluation of hazards associated with the use of radiation sources and for their amelioration [RI Gen. Laws § 23-1.3-2(c)].

[1] All salary data based on Bureau of Labor Statistics (BLS) May 2020 Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates for Providence-Warwick, RI-MA, where available, otherwise based on best available BLS regional/national data. [https://www.bls.gov/oes/current/oes_77200.htm]

216-RICR-40-20-4

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 20 – RADIATION

PART 4 – ~~Diagnostic X-Rays and Associated Imaging Systems in the Healing Arts~~ Medical Diagnostic and Interventional X-Ray and Imaging Systems

4.1 Authority

A. This Part is promulgated pursuant to the authority conferred under R.I. Gen. Laws § 23-1.3-5.

B. This Part establishes requirements, for which a registrant is responsible, for use of diagnostic and interventional X-ray equipment and ~~associated~~ imaging systems by, or under the supervision of, an individual authorized by and licensed in accordance with applicable provisions of the R.I. Gen. Laws to engage in the healing arts or veterinary medicine. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of this Subchapter.

~~C. The use of diagnostic X-ray equipment and associated imaging systems for the intentional exposure of individuals for diagnosis shall be by or under the supervision of a licensed practitioner of the healing arts.~~

~~D. The use of diagnostic X-ray equipment and associated imaging systems in the practice of veterinary medicine shall be by or under the supervision of an individual authorized by and licensed in accordance with R.I. Gen. Laws Chapter 5-25 to practice veterinary medicine.~~

~~E~~C. Any notifications, reports or correspondence required by this Part shall be directed to the Agency using contact information specified in § 1.4 of this Subchapter.

4.1.1 Incorporation by Reference

A. Except as provided in this Part, the requirements of 21 C.F.R. Part 900 (2018) are incorporated by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this Part.

B. The requirements of ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (ACR Resolution 44 – 2013) are incorporated by reference, not including any further editions or amendments

thereof and only to the extent that the provisions therein are not inconsistent with this Part.

C. The requirements of NCRP Report 168, Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures (2010) are incorporated by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this Part.

4.2 Definitions

A. Whenever used in this Part, the following terms shall be construed as follows:

1. "Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

2. “Act” means R.I. Gen. Laws Chapter 23-1.3, entitled "Radiation Control."

3. “Agency” means Rhode Island Radiation Control Agency (RCA), Center for Health Facilities Regulation – Radiation Control Program, Rhode Island Department of Health.

4. "Air kerma" means kerma in air (see definition of Kerma).

5. "Air kerma rate” or “AKR" means the air kerma per unit time.

6. "Alert value" means a dose index (e.g., of $CTDI_{vol}$(mGy) or DLP(mGy-cm)) that is set by the registrant to trigger an alert to the CT operator prior to scanning within an ongoing examination. The Alert value represents a universal dose index value well above the registrant's established range for the examination that warrants more stringent review and consideration before proceeding.

7. "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. [The nominal chemical composition of type 1100 aluminum is ninety-nine percent (99.00%) minimum aluminum, twelve one hundredths of one percent (0.12%) copper.]

8. "Articulated joint" means a joint between two (2) separate sections of a tabletop which joint provides the capacity of one (1) of the sections to pivot on the line segment along which the sections join.

9. "Attenuation block" means a block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions twenty (20) centimeters (cm) or larger by twenty (20) cm or larger by three and

eight tenths (3.8) cm, that is large enough to intercept the entire x-ray beam.

10. "Automatic exposure control" or "AEC)" means a device which automatically controls one (1) or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

11. "Automatic exposure rate control" or "AERC)" means a device which automatically controls one (1) or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation per unit time.

12. "Barrier" (See "Protective barrier").

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

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

15. "Bone densitometry" means a noninvasive measurement of certain physical characteristics of bone that reflect bone strength. Test results are typically reported as bone mineral content or density and are used for diagnosing osteoporosis, estimating fracture risk, and monitoring changes in bone mineral content.

16. "Bone densitometer" means a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

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

18. "Cantilevered tabletop" means a tabletop designed such that the unsupported portion can be extended at least one hundred (100) cm beyond the support.

19. "Cassette holder" means a device, other than a spot-film device, that supports and/or fixes the position of the image receptor during a radiographic exposure.

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

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

where: s = Estimated standard deviation of the population | $\bar{x}$ = Mean value of observations in sample | xi = ith observation in sample | and n = Number of observations in sample.

21. "Computed radiography (CR; also see DR)" means a digital x-ray imaging method in which a photo-stimulable phosphor is used to capture and store a latent image. The latent image is read out by stimulating the phosphor with a laser. Computed radiography systems may use cassettes to house the phosphor, or it may be integrated into a digital radiography system.

22. "Computed tomography" or "CT" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

23. "Computed tomography dose index" or "CTDI" means the average absorbed dose, along the z-axis, from a series of contiguous irradiations. It is measured from one (1) axial CT scan (one (1) rotation of the x-ray tube) and is calculated by dividing the integrated absorbed dose by the nominal total beam collimation. The scattering media for CTDI consist of two (2) (sixteen (16) and thirty-two (32) cm in diameter) polymethylmethacrylate (PMMA, e.g., acrylic or Lucite) cylinders of fourteen (14) cm length. The equation is:

$$CTDI = \frac{1}{NT} \int_{-\infty}^{\infty} D(z)dz \ ,$$

where:

D(z) = the radiation dose profile along the z-axis,

N = the number of tomographic sections imaged in a single axial scan. This is equal to the number of data channels used in a particular scan. The value of N may be less than or equal to the maximum number of data channels available on the system, and

T = the width of the tomographic section along the z-axis imaged by one (1) data channel. In multiple-detector-row (multislice) CT scanners, several detector elements may be grouped together to form one (1) data

channel. In single-detector-row (single-slice) CT, the z-axis collimation (T) is the nominal scan width.

24. "$CTDI_{100}$" means the accumulated multiple scan dose at the center of a one hundred (100) mm scan and underestimates the accumulated dose for longer scan lengths. It is thus smaller than the equilibrium dose. The $CTDI_{100}$, requires integration of the radiation dose profile from a single axial scan over specific integration limits. In the case of $CTDI_{100}$, the integration limits are + fifty (50) mm, which corresponds to the one hundred (100) mm length of the commercially available "pencil" ionization chamber. $CTDI_{100}$ is acquired using a one hundred (100) mm long, three (3) cc active volume CT "pencil" ionization chamber and one (1) of the two (2) standard CTDI acrylic phantoms (sixteen (16) and thirty-two (32) cm diameter) and a stationary patient table. The equation is:

$$CTDI_{100} = \frac{1}{NT}\int_{-50mm}^{50mm} D(z)dz$$

25. "Cone Beam Computed Tomography" or "CBCT" is a volumetric imaging modality. Volumetric data are acquired using two-dimensional digital detector arrays, and a cone-shaped x-ray beam (instead of fan-shaped) that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

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

27. "Cradle" means:

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

    b. A device:

        (1) Whose patient support structure is interposed between the patient and the image receptor during normal use;

        (2) Which is equipped with means for patient restraint; and

        (3) Which is capable of rotation about its long (longitudinal) axis.

28. "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors as defined in § 4.2 of this Part.

29. "CT gantry" means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components within a computed tomography system.

30. "CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image:

$$\overline{CTN} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where: k = A constant, a normal value of one thousand (1,000) when the ~~Houndsfield~~ Hounsfield scale of CT number is used;

u_x = Linear attenuation coefficient of the material of interest; and

u_w = Linear attenuation coefficient of water.

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

32. "Detector" (See "Radiation detector")

33. "Diagnostic reference level" or "DRL" means an investigational level used to identify unusually high radiation doses or dose rates for common medical X-ray imaging procedures. DRLs are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses. DRLs should not be applied to an individual patient.

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

35. "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human [or animal] body for the purpose of diagnosis or visualization.

36. "Digital radiography" or "DR" means an x-ray imaging method (or radiography) which produces a digital rather than analog image. DR includes both computed radiography and direct digital radiography.

37. "Direct digital radiography (DDR; also see CR and DR)" means an x-ray imaging method in which a digital sensor, usually incorporating a thin-film transistor, is used to capture an x-ray image. Some DDR systems use a scintillator to convert x-rays to light and a photodiode array to convert light to charge, while others use a photoconductor to convert x-rays directly to charge, which is stored on the thin-film transistor.

38. "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

39. "Direct supervision" means a qualified practitioner must exercise general supervision and be present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the licensed practitioner must be present in the room when the procedure is being performed.

40. "Dose" means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name of the unit of absorbed dose is gray (Gy).

41. "Dose area product" or "DAP," a/k/a kerma-area product" or "KAP," means the product of the air kerma and the area of the irradiated field and is typically expressed in Gy-cm2, so it does not change with distance from the x-ray tube.

42. "Dose length product" or "DLP" means the indicator of the integrated radiation dose from a complete CT examination. It addresses the total scan length by the formula: DLP (mGy-cm) = $CTDI_{vol}$ (mGy) x scan length (cm).

43. "Dose profile" means the dose as a function of position along a line.

44. "Effective dose (E)" means the sum of the tissue-weighted equivalent doses for the radiosensitive tissues and organs of the body. It is given by the expression $E = \Sigma T (w_T H_T)$, in which H_T is the equivalent dose in tissue or organ T and w_T is the tissue weighting factor for tissue or organ T. The unit of E and H_T is joule per kilogram ($J \cdot kg^{-1}$), with the special name sievert (Sv).

45. "Equipment" (See "X-ray equipment") means x-ray equipment.

46. "Exposure (X)" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation.

47. "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.

48. "Filter" means material placed in the useful beam to preferentially absorb selected radiations.

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

50. "Fluoroscopic irradiation time" means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

51. "Fluoroscopically-Guided Interventional (FGI) Procedures" means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

52. "Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term “radioscopy” in the standards of the International Electrotechnical Commission.

53. "Focal spot (actual)" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

54. "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.

55. "General supervision" means the procedure is performed under the overall direction and control of the qualified practitioner but who is not required to be physically present during the performance of the procedure.

56. "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced by one-half (1/2) 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.

57. "Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner

of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

58. "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

59. "Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

60. "Image receptor" means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term “image receptor” shall mean the preselected portion of the device.

61. "Irradiation" means the exposure of matter to ionizing radiation.

62. "Isocenter" means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

63. "Kerma" means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus K=dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

64. "Kerma-area product” or “KAP" (See "dose area product").

65. "Kilovolts peak" (See "Peak tube potential").

66. "kV" means kilovolts.

67. "kWs" means kilowatt second.

68. "Last-image hold (LIH) radiograph" means an image obtained either by retaining one (1) or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

69. "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

70. "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

    a. The useful beam; and

    b. Radiation produced when the exposure switch or timer is not activated.

71. "Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

    a. For diagnostic source 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 ten (10) millicoulombs (or ten (10) mAs) or the minimum obtainable from the unit, whichever is larger;

    b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and

    c. For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

72. "Light field" means that area of the intersection of the light beam from the beam-limiting device and one (1) 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 (1/4) of the maximum in the intersection.

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

74. "mA" means milliampere.

75. "mAs" means milliampere second.

76. "Mode of operation" means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control.

Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

77. "Multiple tomogram system" means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

78. “Noise” means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \mu_x \cdot s}{\mu_w}$$

where μ_x = Linear attenuation coefficient of the material of interest, μ_w = Linear attenuation coefficient of water, and s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

79. "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

80. "Notification value" means a protocol-specific dose index (e.g., $CTDI_{vol}$(mGy) or of DLP(mGy-cm)) that is set by the registrant to trigger a notification to the CT operator prior to scanning when the dose index exceeds the established range for the examination.

81. "Patient" means an individual or animal subjected to healing arts examination, diagnosis or treatment.

82. "Picture element" means an elemental area of a tomogram.

83. "PBL (" See "Positive beam limitation.").

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

85. "Personal supervision" means a qualified practitioner must exercise General Supervision and be present in the room or adjacent control area during the performance of the procedure.

86. "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

87. "Photostimulable storage phosphor" or "PSP" means a material used to capture and store radiographic images in computed radiography systems.

88. "Pitch" means the table incrementation, in CT, per x-ray tube rotation, divided by the nominal x-ray beam width at isocenter.

89. "Position indicating device" or "PID" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

90. "Positive beam limitation" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

91. "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure (beyond the patient and cassette holder) for protection purposes.

92. "Protective ~~apron~~ garment" means ~~an apron~~ a garment made of radiation absorbing materials used to reduce radiation exposure.

93. "Protocol" means a collection of settings and parameters that fully describe an examination.

94. "Pulsed mode" means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half (1/2) second.

95. "Quality Assurance" means a program providing for verification by written procedures such as testing, auditing, and inspection to ensure that deficiencies, deviations, defective equipment, or unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation devices are identified, promptly corrected, and reported to the appropriate regulatory authorities as required.

96. "Qualified Medical Physicist" or "QMP" (for activities authorized pursuant to this Part) means an individual registered to provide Radiation Physics

Services (Diagnostic X-ray Physics Services) in accordance with § 3.6 of this Subchapter.

97. "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one (1) or more quantities of incident radiation.

98. “Radiation medical event” means an event that meets the criteria in § 4.4.14(A) of this Part.

99. "Radiation Protocol Committee” or “RPC" means the representative group of qualified individuals in a CT or FGI facility responsible for the ongoing review and management of CT or FGI protocols to ensure that exams being performed achieve the desired diagnostic image quality at the lowest radiation dose possible while properly exploiting the capabilities of the equipment being used.

100. "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

101. "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

102. "Radiography" means a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

103. "Recording" means producing a retrievable form of an image resulting from x-ray photons.

104. "Reference plane" means a plane which is parallel to and which can be offset (as specified in manufacturer information provided to users) from the location of the tomographic plane(s).

105. “Registrant” means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to this Subchapter and the Act.

106. “Registration” means registration with the Agency pursuant to this Subchapter and the Act.

107. "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one (1) or more tomograms.

108. "Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

109. "Scan sequence" means a pre-selected set of two (2) or more scans performed consecutively under pre-selected CT conditions of operation.

110. "Scan time" means the time elapsed during the accumulation of x-ray transmission data for a single scan.

111. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

112. "Sensitivity profile" means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

113. "Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

114. "Shutter" means a device attached to the tube housing assembly which can intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

115. "Size-specific dose estimate" or “SSDE” means a patient dose estimate which takes into consideration corrections based on the size of the patient, using linear dimensions measured on the patient or patient images.

116. "Source" means the focal spot of the x-ray tube.

117. "Source-image receptor distance" or “SID” means the distance from the source to the center of the input surface of the image receptor.

118. "Source-skin distance" or “SSD” means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

119. "Spot-film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure. Digital image receptors used in place of film with spot-film devices should be considered "spot-film."

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

121. "Stray radiation" means the sum of leakage and scattered radiation.

122. "Substantial radiation dose level" or "SRDL" means an appropriately-selected dose used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically-relevant injury in an average patient.

123. "Technique factors" means the following conditions of operation:

    a. For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);

    b. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray pulses;

    c. For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, X-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, X-ray pulse width, and the number of X-ray pulses in mAs;

    d. For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

    e. 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.

124. "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

125. "Tomographic plane" means that geometric plane which the manufacturer identified as corresponding to the output tomogram.

126. "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

127. "Tube" means an x-ray tube, unless otherwise specified.

128. "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

129. "Unintended" radiation dose in diagnostic or interventional x-ray means a patient radiation dose resulting from a human error or equipment malfunction during the procedure.

130. "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.

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

132. "Volume Computed Tomography Dose Index ($CTDI_{vol}$)" means a radiation dose parameter derived from the $CTDI_w$ (weighted or average CTDI given across the field of view). The formula is: $CTDI_{vol} = (N)(T)(CTDI_w)/I$, where N = number of simultaneous axial scans per x-ray source rotation, T = thickness of one axial scan (mm), and I = table increment per axial scan (mm). Thus, $CTDI_{vol} = CTDI_w$ / pitch.

133. "Weighted Computed Tomography Dose Index ($CTDI_w$)" means the estimated average $CTDI_{100}$ across the field of view (FOV). The equation is: $CTDI_w = 1/3\ CTDI_{100,center} + 2/3\ CTDI_{100,edge}$

Where one third (1/3) and two third (2/3) approximate the relative areas represented by the center and edge values derived using the sixteen (16) or thirty-two (32) cm acrylic phantom. $CTDI_w$ uses $CTDI_{100}$ and an f-factor for air (0.87 rad/R or 1.0 mGy/mGy).

134. "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.

135. "X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

136. "X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

a. "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

b. "Portable x-ray equipment" means x-ray equipment designed to be hand-carried; and

c. "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

d. "Hand-held x-ray equipment" means x-ray equipment that is designed to be hand-held during operation.

137. "X-ray field" means that area of the intersection of the useful beam and any one of a set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is one fourth (1/4) of the maximum in the intersection.

138. "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.

139. "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.

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

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

4.3 General and Administrative Requirements

4.3.1 Administrative Controls

A. The registrant shall be responsible for directing the operation of the X-ray system(s) under their administrative control. The registrant or the registrant's agent shall assure that the requirements of this Subchapter are met in the operation of the X-ray system(s).

B. The registrant shall have a radiation safety program. The radiation safety program shall include but not be limited to the following:

1. The use of ionizing radiation within its purview is performed in accordance with the Act and Agency Regulations.

2. All persons are protected as required by Part 1 of this Subchapter.

C. The registrant shall have a mechanism in place for the referring physician to access information on selecting the most appropriate diagnostic procedure to answer the clinical question.

D. The registrant shall utilize nationally recognized diagnostic reference levels (DRLs) when applicable.

E. The registrant shall select the appropriate technique and employ available dose reduction methods and technologies across all patient sizes and clinical indications.

F. Each registrant shall have a documented procedure in place for verification of patient identity and exam to be performed, including identification of the appropriate body part.

G. All x-ray equipment shall be installed and used in accordance with the equipment manufacturer's specifications.

4.3.2 Operation Prohibited

A. An X-ray system which does not meet the provisions of this Part shall not be operated for diagnostic purposes unless the Agency or a Qualified Medical Physicist determines that the non-compliance will not pose a significant radiation risk or significantly affect image quality, and arrangements have been made to correct the non-compliance within thirty (30) days.

4.3.3 Individuals Operating X-ray Systems for Healing Arts Use

A. Individuals who will be operating the X-ray systems for healing arts use shall possess a current license in accordance with Subchapter 05 Part 34 of this Chapter, Licensure of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants, unless the individual is specifically exempted from licensure by said Regulations. Individuals who will be operating the X-ray systems and who are not subject to licensure under Subchapter 05 Part 34 of this Chapter shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. As a minimum, such instruction shall consist of subjects outlined in § 4.12 of this Part.

B. The names and qualifications of all personnel operating X-ray equipment for healing arts use must be kept on file for Agency inspection at each facility location.

C. All individuals operating, or supervising the operation of, fluoroscopic X-ray systems shall have completed a minimum of four (4) hours training, prior to performing fluoroscopy procedures that includes but is not limited to the following: ~~at least the following training before using fluoroscopy independently:~~

1. Biological effects of X-ray;

2. ~~Principles of radiation protection~~ Radiation protection methods for patients and staff;

3. Factors affecting fluoroscopic outputs;

4. Dose management including dose reduction techniques, monitoring, and recording ~~for fluoroscopic X-ray systems~~;

5. Principles and operation of the specific fluoroscopic X-ray system(s) to be used;

6. Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically; ~~and~~

7. Basic properties of radiation;

8. Units of measurement and dose, including DAP (dose-area product) values and air kerma;

9. High level control options; and

10. Applicable requirements of this Subchapter.

D. All persons operating, or supervising the operation of, fluoroscopy systems during fluoroscopically-guided interventional (FGI) procedures shall have completed a minimum of eight (8) hours of training approved by the Agency. The training shall include, but not be limited to:

1. The topics provided in § 4.3.3(C) of this Part;

2. Methods to reduce patient dose using advanced imaging and recording features;

3. Procedures for recording pertinent data specified in § 4.5.13 of this Part; and

4. A minimum of one (1) hour of hands-on fluoroscopic machine training demonstrating application of topics required in § 4.3.3(D) of this Part.

E. The training required §§ 4.3.3(C) and (D) of this Part shall be provided by a Qualified Medical Physicist or another individual approved by the Agency.

~~D~~ F. The registrant shall either provide a minimum of two (2) hours in-service training for all ~~operators of~~ individuals operating or supervising the operation of fluoroscopy systems used ~~for high dose, high risk procedures, as defined in § 4.5.13 of this Part~~, at intervals not to exceed twenty-four (24) months or require evidence of continuing medical education, in fluoroscopic radiation safety and patient dose management at intervals not to exceed twenty-four (24) months.

~~E~~G. Documentation pertaining to the requirements of §§ 4.3.3(B), (C) and (D) of this Part shall be maintained for review for three (3) years.

H. A dental facility registrant shall provide initial training and annual evaluations of X-ray operators to include but not limited to: positioning of the X-ray tube, image processing, operator location during X-ray exposure, source to skin distance, radiation protection, appropriate radiographic protocol, and applicable regulatory requirements. Records of training and annual evaluations shall be maintained for inspection by the Agency for three (3) years.

4.3.4 ~~Written~~ Technique Protocols ~~Information~~

A. ~~Written technique information shall be provided in the vicinity of the diagnostic X-ray system's control panel, which specifies, for all examinations performed with that system,~~ For general radiographic systems not equipped with an operational anatomic programming option, protocols shall be documented and readily available to the operator. At a minimum, these protocols shall include the following information:

1. Patient's (adult or pediatric, as applicable) body part and anatomical size;~~, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;~~

2. Technique factors ~~Equivalent manual technique information if AEC is not available;~~

3. Type ~~and size~~ of the image receptor ~~combination~~ to be used~~, if any;~~

4. Source to image receptor distance to be used (except for dental intraoral radiography, which shall list cone length to be used); and

5. Type of grid, if any.~~and location of placement of patient shielding (e.g., gonad, thyroid, lap apron, etc.); and~~

~~6. For mammography, indication of kVp/target/filter combination and, if phototimed setting is used, the density setting.~~

4.3.5 Written Safety Procedures

The registrant of a facility shall create and make available to X-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

4.3.6 Room Occupancy During Radiographic Exposure

A. ~~Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined~~ The registrant shall restrict the presence of individuals in the

immediate area of the patient being examined, while the X-ray tube is energized, to those required and, as applicable, those in training for the medical procedure, or the parent or guardian of a patient. The following applies to all individuals, other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than one half (0.5) millimeter lead equivalent material.

2. ~~The X-ray operator, other staff, ancillary personnel and other persons required for the medical procedure~~ All individuals shall be protected from the ~~direct scatter~~ secondary radiation by protective ~~aprons~~ garments or whole-body protective barriers of not less than twenty-five one hundredths of one (0.25) millimeter lead equivalent material.

3. ~~Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two (2) meters from both the tube head and the nearest edge of the image receptor~~ Instances may warrant having human patients other than the one being examined in the room during the exam. If the procedure results in scatter radiation in excess of two one hundredths (0.02) mSv (2 mR) in any one (1) hour at the position of these patients, such patients shall be protected from the direct scatter radiation by whole body protective barriers of not less than twenty-five one hundredths of one (0.25) millimeter lead equivalent material or shall be positioned so that the two one hundredths (0.02) mSv (2 mR) in any one (1) hour limit is met.

4. Written safety procedures, as required by § 4.3.5 of this Part, shall describe how the requirements of this section will be met when using mobile or portable X-ray systems.

4.3.7 [Reserved] ~~Gonadal Shielding~~

~~Gonadal shielding of not less than 0.5 millimeter lead equivalent material shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.~~

4.3.8 Non-Healing Arts Exposure Prohibited

Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes, and exposure of an individual for the purpose of healing arts screening except as authorized by § 4.3.12 of this Part.

4.3.9 When a Patient or Image Receptor Must be Provided with Auxiliary Support During a Radiation Exposure

A. In cases where a patient or image receptor must be provided with auxiliary support, mechanical support devices shall be used whenever possible. ~~Mechanical holding devices shall be used when the technique permits.~~ The written safety procedures, required by § 4.3.5 of this Part, shall list individual projections where holding devices cannot be utilized;

B. Written safety procedures, as required by § 4.3.5 of this Part, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

C. The human holder shall be instructed in personal radiation safety and protected as required by § 4.3.6 of this Part;

D. No individual shall be used routinely to hold image receptor or patients during a radiation exposure;

E. In those cases where the patient must hold the image receptor, except during ~~dental~~ intraoral examinations covered by this Part, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than five tenths of one (0.5) millimeter lead equivalent material; and

F. Each facility shall have protective garments (e.g., aprons, ~~and~~ gloves, collars) and shields available in sufficient numbers to provide protection for all patients and personnel who are involved with X-ray operations and who are otherwise not shielded.

1. All protective apparel and auxiliary shields shall be evaluated annually for integrity and clearly labeled with their lead equivalence.

G. A record shall be made of the examination and shall include the name of the human holder, date of the examination, number of exposures and technique factors utilized for the exposure(s).

4.3.10 Procedures and Auxiliary Equipment Designed to Minimize Patient and Personnel Exposure Commensurate with The Needed Diagnostic Information Shall Be Utilized

A. The fastest imaging system consistent with the diagnostic objective of the examinations shall be used. Film cassettes without intensifying screens shall not be used for any diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intraoral use in dental radiography.

B. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality. The registrant shall use auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information.

C. Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.

~~D. Facilities shall establish and implement a quality assurance program for X-ray film processing, whether processing is manual or automatic.~~

~~E~~D~~.~~. X-ray Film Processing Facilities ~~and Practices. Each installation using a radiographic X-ray system and~~ A registrant using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions.

1. ~~Manual Processing of~~ Manually Developed Film

a. ~~Processing of film:~~ The temperature of solutions in the tanks shall be maintained within the range of sixty degrees Fahrenheit (60º F) to eighty degrees Fahrenheit (80º F) degrees (sixteen degrees Celsius (16º C) to twenty-seven degrees Celsius (27º C)). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

Manuel Film Developing Technique Chart				
Developer Temperature °C/°F	Developing Time (Minutes)		Developer Temperature °C/°F	Developing Time (Minutes)
26.7/80	2.0		20.6 / 69	4.5
26.1 / 79	2.0		20.0 / 68	5.0
25.6 / 78	2.5		19.4 / 67	5.5
25.0 / 77	2.5		18.9 / 66	5.5
24.4 / 76	3.0		18.3 / 65	6.0
23.9 / 75	3.0		17.8 / 64	6.5
23.3 / 74	3.5		17.2 / 63	7.0
22.8 / 73	3.5		16.7 / 62	8.0

22.2 / 72	4.0		16.1 / 61	8.5
21.7 / 71	4.0		15.6 / 60	9.5
21.1 / 70	4.5			

b. Devices shall be utilized which will:

(1) Indicate the actual temperature of the developer; and

(2) Give an audible or visible signal indicating the termination of a preset time.

c. ~~Processing~~ Developing tanks shall be constructed of mechanically rigid, corrosion resistant material.

d. Developing solutions shall be prepared, replenished, and replaced following manufacturer recommendations.

2. Automatic ~~Processors~~ Developers and Other Closed ~~Processing~~ Developing Systems

a. Films shall be ~~processed~~ developed in accordance with the time temperature relationships recommended by the film manufacturer or, in the absence of such recommendations, with the following time-temperature chart:; and

Developer Temperature		Minimum Immersion Time[a/]
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24

32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30
[a/] Immersion time only, no crossover time included.		

b. ~~Processing~~ Developing deviations from the requirements of § 4.3.10(~~E~~D)(2)(a) of this Part shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

c. Automatic developers shall be operated and maintained following manufacturer specifications.

~~F. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:~~

~~1. Be positioned properly (i.e., tube side facing the proper direction) and grid centered to the central ray.~~

~~2. If of the focused type, be of the proper focal distance for the SID being used.~~

~~G~~F. ~~Other~~ Additional Requirements for Facilities Using Analog Image Receptors

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. ~~The darkroom shall be light-tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.05 when exposed in the darkroom for two (2) minutes with all safelights on. If used, daylight film handling systems shall preclude fogging of the film.~~ Facilities shall maintain a light-tight darkroom,

use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six (6) months and after any change that may impact film fog.

3. Darkrooms typically used by more than one (1) individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light-tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to assure radiographs of good diagnostic quality.

6. Outdated x-ray film shall not be used for diagnostic radiographs~~, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.~~

7. ~~Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.~~ The film and intensifying screen shall be spectrally compatible.

8. Facilities other than dental, podiatry, and veterinary facilities shall:

   a. Have a continuous and documented sensitometric quality control program, including quality control tests for speed, contrast and fog. These tests shall be performed according to specifications of the manufacturer, a Qualified Medical Physicist, or a nationally recognized organization.

   b. Maintain a light-tight darkroom and use proper safelighting such that any film type in use exposed in a cassette to X-ray radiation sufficient to produce an optical density from one (1) to two (2) when developed shall not suffer an increase in density greater than one tenth (0.1) when exposed in the darkroom for two (2) minutes with all safelights on. If used, daylight film handling systems shall preclude fogging of the film.

   c. Limit the base plus fog of unexposed film to an optical density less than twenty-five one hundredths (0.25) when developed by the routine procedure used by the facility.

~~H. The tube housing and the position indicating device (PID) for a permanently mounted intraoral dental system shall not be hand-held during an exposure. § 4.13 of this Part specifies requirements for the use of intraoral dental radiographic units designed to be hand-held during patient examination.~~

~~I. Dental fluoroscopy without image intensification shall not be used.~~

G. Facilities Using Computed Radiography (CR) or Direct Digital Radiography (DDR).

1. When exposure indicators are available, the facility shall establish and document an acceptable range for the exposure values for examinations routinely performed at the facility. The indicated exposure values for each image shall be compared to the established range. Consistent deviations from established ranges shall be investigated, corrective actions taken as necessary, and results documented.

2. CR facilities shall perform at least weekly erasure of all CR cassettes.

H. Dental Facilities

1. If using film, the facility shall maintain a light-tight darkroom, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six (6) months and after any change that may impact film fog.

2. If using a filmless system, the facility shall maintain and operate photostimulable storage phosphor (PSP) and DDR systems according to manufacturer specifications.

4.3.11 Additional Compliance Required

All individuals who are associated with the operation of an X-ray system are subject to the applicable requirements of Parts 1 and 2 of this Subchapter.

4.3.12 Healing Arts Screening

Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in § 4.11 of this Part. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

4.3.13 Information and Maintenance Record and Associated Information

A. The registrant shall maintain the following information. The information shall be maintained in a separate file or package in chronological order for each X-ray

system, ~~for inspection by the Agency~~ for a minimum of five (5) years or as noted below:

1. Maximum rating of technique factors;

2. Model and serial numbers of all major components, and user's manuals for those components, including software, shall be maintained for the life of the system;

3. Aluminum equivalent filtration in the useful beam, including any routine variation;

4. Tube rating charts and cooling curves;

5. Records of surveys, calibrations, maintenance, and modifications (e.g., major software and hardware upgrades) performed on the X-ray system(s), with the names of the persons who performed such services;

6. A scale drawing of the room in which a stationary X-ray system is located with such drawing indicating the current use of areas adjacent to the room and an estimate of the extent of occupancy by an individual in such areas. In addition, the drawing shall include the results of a survey for radiation levels present at the operator's position, and at pertinent points outside the room at specified test conditions; or the type and thickness of materials, or lead equivalency, of each protective barrier.

7. A copy of all correspondence with this Agency regarding that X-ray system.

4.3.14 X-Ray Utilization Log

A. Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed. The record shall also include the following information:

1. Name of the licensed practitioner of the healing arts ordering the examination.

2. Name(s) of individuals who performed the examination.

3. Any deviation from the standard procedure as specified on the technique chart, including all repeat exposures.

~~4. When applicable, the fluoro recordkeeping requirements of § 4.5.3(E) of this Part~~.

~~5~~4. When applicable, the X-ray system used.

~~6~~5. When the patient or image receptor must be provided with human auxiliary support, the name of the human holder.

B. X-ray utilization logs shall be maintained for a minimum of five (5) years following the examination or treatment of adult patients. Records of examination or treatment of minors shall be maintained for a minimum of five (5) years beyond the age of majority.

C. If X-ray utilization logs are stored electronically, records shall be maintained in a manner that will allow retrieval of records for any specified time period.

D. Each veterinary facility shall maintain a record containing the type of examinations and the dates the examinations were performed. The record shall also include the following information:

1. Name(s) of individuals who performed the examination;

2. Any deviation from the standard procedure as specified on the technique chart, including all repeat exposures;

3. When applicable, the X-ray system used; and

4. When the patient or image receptor must be provided with human auxiliary support, the name of the human holder.

4.3.15 Report and Notification of a Dose to an Embryo/Fetus

A. ~~1.~~ A registrant shall report any dose to an embryo/fetus that is greater than fifty (50) mSv (5 rem) dose equivalent that is a result of an administration of radiation to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the referring prescribing physician.

1. A registrant shall report any dose to a nursing child that is a result of an administration of radiation to a breast-feeding individual that is greater than fifty (50) mSv (5 rem) total effective dose equivalent or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

B. The registrant shall notify the Agency by telephone no later than the next business day after discovery of a dose to the embryo/fetus or nursing child that requires a report in §§ 4.3.15(A) or (A)(1) of this Part.

C. The registrant shall submit a written report, prepared by a Qualified Medical Physicist, to the Agency within fifteen (15) business days after discovery of a dose to the embryo/fetus that requires a report in §§ 4.3.15(A) or (1) of this Part.

1. The written report ~~shall~~ must include:

a. The registrant's name and registration number;

b. The name of the ~~referring~~ prescribing physician;

c. A brief description of the event;

d. Why the event occurred;

e. The effect, if any, on the embryo/fetus or the nursing child;

f. What actions, if any, have been taken or are planned to prevent recurrence; and

g. Certification that the registrant notified the mother (or the ~~pregnant individual's~~ mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

D. The registrant shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than twenty-four (24) hours after discovery of an event that would require reporting under §§ 4.3.15(A) or (A)(1) of this Part, unless the referring physician personally informs the registrant either that he or she will inform the ~~pregnant individual~~ mother or that, based on medical judgment, telling the ~~pregnant individual~~ mother would be harmful. The registrant is not required to notify the ~~pregnant individual~~ mother without first consulting with the referring physician. If the referring physician or ~~pregnant individual~~ mother cannot be reached within twenty-four (24) hours, the registrant shall make the appropriate notifications as soon as possible thereafter. The registrant may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the ~~pregnant individual's~~ mother's or child's responsible relative or guardian instead of the pregnant individual. If a verbal notification is made, the registrant shall inform the ~~pregnant individual~~ mother, or the ~~pregnant individual's~~ mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

E. A registrant shall:

1. Annotate a copy of the report provided to the Agency with the:

a. Name of the pregnant individual or the nursing child who is the subject of the event; and

b. Identification number or if no other identification number is available, the social security number ~~or other identification number, if one has been assigned,~~ of the pregnant individual or the nursing child who is the subject of the event; and

2. Provide a copy of the annotated report to the referring physician, if other than the registrant, no later than fifteen (15) days after the discovery of the event.

4.4 General Requirements for All Diagnostic and Interventional X-Ray Systems

4.4.1 Applicability

In addition to other requirements of this Part, all diagnostic and interventional X-ray systems shall meet the requirements of § 4.4 of this Part. Requirements specific to dental intra-oral, panoramic, cephalometric, volumetric dental imaging equipment are included in § 4.14 of this Part.

4.4.2 Maintaining Compliance

Diagnostic and interventional X-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 C.F.R. Part 1020) shall be maintained in compliance with applicable requirements of that standard.

4.4.3 Warning Label

A. On systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear the following warning statement, or the warning statement in § 4.4.3(B) of this Part, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

B. On systems manufactured after June 10, 2006, the control panel containing the main power switch shall bear the following warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors, ~~and~~ operating instructions and maintenance schedules are observed."

4.4.4 Battery Charge Indicator

On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

4.4.5 Leakage Radiation from the Diagnostic Source Assembly

The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed eighty-eight one hundredths (0.88) milligray (mGy) air kerma [one hundred (100) milliroentgen (mR) exposure] in one (1) hour when the X-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum X-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters (100 cm^2) with no linear dimension greater than twenty (20) centimeters.

4.4.6 Radiation from Components Other Than the Diagnostic Source Assembly

The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of eighteen (18) µgray [two (2) milliroentgens exposure] in one (1) hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters (100 cm^2) with no linear dimension greater than twenty centimeters (20 cm).

4.4.7 Beam Quality

A. Half-Value Layer (HVL)

1. The HVL of the useful beam for a given X-ray tube potential shall not be less than the values shown in § 4.4.7(B) of this Part [Table 1], ~~under the heading "Specified Dental Systems," for any dental X-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; under the heading," Other X-Ray Systems2" for any dental X-ray system designed for use with intraoral image receptors and manufactured before or on December 1,1980, and all other X-ray systems subject to this section and manufactured before June 10, 2006; and under the heading, "Other X-Ray Systems" for all X-ray systems, except dental X-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.~~ If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in § 4.4.7(B) of this Part [Table 1], linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one (1) thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent X-ray emissions if the minimum required filtration is not in place.

2. Optional Filtration on Fluoroscopic Systems. Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an X-ray tube(s) with a continuous output of one (1) kilowatt or more and an anode heat storage capacity of one million (1,000,000) heat units or more shall provide the option of adding X-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions of § 4.4.7(A)(1) of this Part. The selection of this additional X-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the X-ray beam shall be provided.

B. Table 1 – X-Ray Tube Voltage (kilovolt peak)

Design Operating Range	**Measured Operating Potential**	**Minimum HVL (mm in Aluminum)**		
		~~**Specified Dental Systems (Dental X-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980)**~~	~~**Other X-Ray Systems (Dental X-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other X-ray systems** **subject to § 4.4.7) of this Part ~~this section~~ and manufactured before June 10, 2006)**	~~**Other** **X-Ray Systems (All X-ray systems, except dental X-ray systems designed for use with intraoral image receptors,** **subject to § 4.4.7 of this Part and manufactured on or after June 10, 2006)**
Below 51	30	~~1.5~~	0.3	0.3
	40	~~1.5~~	0.4	0.4
	50	~~1.5~~	0.5	0.5

51 to 70	51	~~1.5~~	1.2	1.3
	60	~~1.5~~	1.3	1.5
	70	~~1.5~~	1.5	1.8
Above 70	71	~~2.1~~	2.1	2.5
	80	~~2.3~~	2.3	2.9
	90	~~2.5~~	2.5	3.2
	100	~~2.7~~	2.7	3.6
	110	~~3.0~~	3.0	3.9
	120	~~3.2~~	3.2	4.3
	130	~~3.5~~	3.5	4.7
	140	~~3.8~~	3.8	5.0
	150	~~4.1~~	4.1	5.4

~~C. Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.~~

~~D~~C. Measuring Compliance. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

~~E~~D. Aluminum Equivalent of Material Between Patient and Image Receptor. ~~-~~Except when used in a CT X-ray system, the aluminum equivalent of each of the items listed in § ~~4.3.7(F)~~ 4.4.7(E) of this Part [Table 2], which are used between the patient and the image receptor, ~~shall~~ may not exceed the indicated limits. Compliance shall be determined by X-ray measurements made at a potential of one hundred (100) kilovolts peak and with an X-ray beam that has an HVL specified in § ~~4.3.7(B)~~ 4.4.7(B) of this Part [Table 1] for the potential. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids.

~~F~~E. Table 2 – Maximum Aluminum Equivalent (millimeters)

ITEM	Maximum Aluminum Equivalent (millimeters)
1. Front panel(s) of cassette holders (total of all)	1.2
2. Film panel(s) of film changer (total of all)	1.2
3. Cradle	2.3
4. Tabletop, stationary, without articulated joints	1.2
5. Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.7
6. Tabletop, with radiolucent panel having one articulated joint	1.7
7. Tabletop, with radiolucent panel having two or more articulated joints	2.3
8. Tabletop, cantilevered	2.3
9. Tabletop, radiation therapy simulator	5.0

~~G~~F. Modification of Certified Diagnostic X-ray Components and Systems

1. Diagnostic X-ray components and systems certified in accordance with 21 C.F.R. Part 1020 shall not be modified such that the component or system fails to comply with any applicable provision of this Part ~~unless a variance in accordance with 21 C.F.R. 1010.4 or an exemption under § 534(a)(5) or § 538(b) of the Federal Food, Drug, and Cosmetic Act has been granted.~~

2. The owner of a diagnostic X-ray system who uses the system in a professional or commercial capacity may modify the system provided the modification does not result in the failure of the system or component to comply with the applicable requirements of his Part. The owner who causes such modification need not submit the reports required by this Subchapter, provided the owner records the date and the details of the modification in the system records and maintains this information, and

provided the modification of the X-ray system does not result in a failure to comply with this Subchapter.

~~H. kVp Limitations. Dental X-ray machines with a nominal fixed kVp of less than fifty (50) kVp shall not be used to make diagnostic dental radiographs of humans.~~

4.4.8 Multiple Tubes

Where two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

4.4.9 Mechanical Support of Tube Head

The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

4.4.10 Technique Indicators

A. For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

B. The requirement of § 4.4.10(A) of this Part may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

C. The accuracy of the indicated kilovoltage peak (kVp) shall meet manufacturer specifications. In the absence of a manufacturer specification, kVp accuracy shall be within ± ten percent (10%).

4.4.11 Structural Shielding

Structural shielding shall be provided whenever necessary to meet the requirements of §§ 1.7.1 and 1.8.1 of this Subchapter, in addition to specific requirements contained in other parts of this Subchapter.

4.4.12 Locks

All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

4.4.13 Use of Calibrated Dosimetry System

~~The~~ Measurements ~~of the radiation output of an X-ray system~~ required in §§ 4.10.1(A)(3), (4) and (5) of this Part shall be performed with a calibrated dosimetry system per manufacturer recommendations. The calibration of such a system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two (2) years and records of calibration maintained for five (5) years for inspection by the Agency.

4.4.14 Reports and Notifications of Radiation Medical Events

A. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of ionizing radiation from a diagnostic radiation machine meets one (1) or more of the following criteria:

1. A patient or human research subject receives an unintended skin dose to the same area in a single procedure greater than two (2) Gy [two hundred (200) rads].

2. A patient or human research subject receives an unintended dose other than skin dose in a single procedure greater than:

   a. Five (5) times the facility's established protocol, and five hundred (> 500) mGy [fifty (50) rads] to any organ; or

   b. Five (5) times the facility's established protocol, and fifty (> 50) mSv [five (5) rem] total effective dose.

3. Wrong patient or wrong site for the entire procedure when the resultant dose:

   a. Exceeds five hundred (500) mGy [fifty (50) rads] to any organ; or

   b. Total Effective dose is greater than or equal to (≥) fifty (50) mSv [five (5) rem].

4. Equipment failure, personnel error, accident, mishap or other unusual occurrence with the administration of ionizing radiation that exceeds fifty (50) mGy [five (5) rads] ~~total~~ effective dose.

B. Any wrong patient or wrong site imaged regardless of dose received ~~should~~ shall be reported, documented and addressed internally within the facility.

C. The registrant shall notify the Agency by telephone no later than the next business day after discovery of the radiation medical event.

1. All required notifications shall use Agency contact information specified in § 1.4 of this Subchapter.

D. The registrant shall submit a written report to the Agency, prepared by a Qualified Medical Physicist, to the Agency within fifteen (15) business days after discovery of the radiation medical event. The written report shall include:

1. The registrant's name;

2. Date of event and date discovered;

3. The ~~total~~ estimated dose received;

4. The imaging procedure(s) performed;

5. The type of equipment in use (e.g., CT, fluoroscopy, radiographic, other);

6. The manufacturer and model of the unit used:

7. Why the event occurred;

8. How the event was discovered;

9. The effect, if any, on the individuals(s) who is the subject of the radiation medical event;

10. Actions, if any, that have been taken, or are planned, to prevent recurrence;

11. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

12. If there was notification, what information was provided to the individual.

E. The registrant shall provide a clinical summary of the radiation medical event to the prescribing physician and patient within fifteen (15) business days.

4.4.15 Records of Radiation Medical Events

~~A~~ The registrant shall retain a record of a radiation medical event reported in accordance with § 4.4.14 of this Part as part of the patient's permanent medical record.

4.5 Fluoroscopic Equipment

4.5.1 Applicability

A. The provisions of § 4.5 of this Part apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor. X-ray systems subject to § 4.5 of this Part shall also meet the requirements of § 4.4 of this Part.

B. Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy.

4.5.2 Primary Protective Barrier

A. Limitation of Useful Beam. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam. The air kerma ~~(exposure)~~ rate [AKR] due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor shall not exceed 3.34×10^{-3} percent of the entrance ~~air kerma (exposure) rate~~ AKR, at a distance of ten (10) cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor.

B. Measuring Compliance. The ~~air kerma (exposure) rate~~ AKR shall be measured in accordance with § ~~4.6~~ 4.5.6 of this Part. The ~~air kerma (exposure) rate~~ AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of one hundred square centimeters (100 cm^2) with no linear dimension greater than twenty (20) cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty (30) cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than thirty (30) cm. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam ten (10) cm from the point of measurement of entrance AKR ~~air kerma (exposure) rate~~ and between this point and the input surface of the fluoroscopic imaging assembly.

4.5.3 Equipment Operation

A. All ~~imaging formed by the use of~~ fluoroscopic ~~x-ray systems~~ images shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.

B. The operation of mobile or portable fluoroscopic X-ray systems, by radiologic technologists, for positioning purposes only, shall be performed under the direct supervision of a licensed practitioner of the healing arts who meets the requirements of § 4.3.3(C) of this Part.

C. A medical resident or radiologic technology student in training shall not be allowed to operate fluoroscopic x-ray systems unless in the physical presence of

a licensed practitioner of the healing arts and a radiologic technologist, as specified in § 4.3.3(C) of this Part.

D. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

E. ~~Each registrant that uses fluoroscopic x-ray systems shall maintain a record of the cumulative fluoroscopic exposure time used and the number of images recorded from the fluoroscopic image receptor for each examination. This record shall include patient identification, type and date of examination, the fluoroscopic system used, and operator's name. The record shall be maintained for five (5) years.~~ Operators shall be competent in the standard operating procedures of the unit in use, including the use of available dose-saving features, and the relative radiation output rates of the various modes of operation.

F. Procedure planning for fluoroscopic procedures on pregnant patients shall include feasible modifications to minimize the dose to the conceptus.

G. Procedure planning for fluoroscopic procedures on pediatric patients shall include feasible modifications to minimize dose.

H. The registrant shall use all methods available on the fluoroscopy system to monitor dose during a fluoroscopic procedure.

I. The facility shall establish a written policy regarding patient dose management in fluoroscopically guided procedures in conformance with the ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (ACR Resolution 44 - 2013) incorporated above at § 4.1.1(B) of this Part or NCRP Report 168 Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures incorporated above at § 4.1.1(C) of this Part.

4.5.4 Field Limitation

A. Angulation. For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the X-ray beam is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor. Compliance with §§ 4.5.4(~~D~~C) and (~~E~~D) of this Part shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

B. Further Means for Limitation. Means shall be provided to permit further limitation of the X-ray field to sizes smaller than the limits of §§ 4.5.4(~~D~~C) and (~~E~~D) of this Part. Beam-limiting devices manufactured after May 22,1979 and incorporated in equipment with a variable SID and/or capability of a visible area of greater than three hundred square cm (300 cm^2), shall be provided with means for stepless adjustment of the X-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than three hundred square cm (300 cm^2) shall be

provided with either stepless adjustment of the X-ray field or with a means to further limit the X-ray field size at the plane of the image receptor to one hundred twenty-five square cm (125 cm^2) or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of five (5) cm by five (5) cm. ~~This paragraph does not apply to non-image-intensified fluoroscopy.~~

~~C. Non-Image-Intensified Fluoroscopy. The X-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of five (5) cm by five (5) cm.~~

~~D~~C. Fluoroscopy and Radiography Using the Fluoroscopic Imaging Assembly with Inherently Circular Image Receptors

1. For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

   a. Neither the length nor width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) 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 which pass through the center of the visible area of the image receptor.

2. For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation therapy simulation systems, the maximum area of the X-ray field in the plane of the image receptor shall conform with one (1) of the following requirements:

   a. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to thirty-four (34) cm in any direction, at least eighty percent (80%) of the area of the X-ray field overlaps the visible area of the image receptor, or

   b. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than thirty-four (34) cm in any direction, the X-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two (2) cm.

~~E~~D. Fluoroscopy and Radiography Using Fluoroscopic Imaging Assembly w~~W~~ith Inherently Rectangular Image Receptors. For X-ray systems manufactured on or after June 10, 2006, the following applies:

1. Neither the length nor width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID.

2. The error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

~~F~~E. Override Capability. If the fluoroscopic X-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the operator's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows: FOR X-RAY FIELD LIMITATION SYSTEM FAILURE.

4.5.5 Activation of the Tube

X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images from the fluoroscopic image receptor, the operator shall be able to terminate the X-ray exposure(s) at any time but means may be provided to permit completion of any single exposure of the series in process.

4.5.6 Air Kerma ~~(Exposure)~~ Rates (AKR)

A. For fluoroscopic equipment, the following requirements apply:

1. Fluoroscopic equipment manufactured before May 19, 1995.

   a. Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an AKR ~~air kerma (exposure) rate~~ in excess of eighty-eight (88) mGy per minute (ten (10) R/min) exposure rate at the measurement point specified in 21 C.F.R. § 1020.32(d)(3), except as specified in § 4.5.6(A)(1)(e) of this Part.

   b. Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR ~~air kerma (exposure) rate~~ in excess of forty-four (44) mGy per minute (five (5) R/min exposure rate) at the measurement point

specified in 21 C.F.R. § 1020.32(d)(3), except as specified in § 4.5.6(A)(1)(e) of this Part.

c. Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR ~~air kerma (exposure) rate~~ in excess of eighty-eight (88) mGy per minute (ten (10) R/min exposure rate) in either mode at the measurement point specified in 21 C.F.R. § 1020.32(d)(3), except as specified in § 4.5.6(A)(1)(e) of this Part.

d. Equipment may be modified in accordance with § 4.4.7(~~E~~D)(1) of this Part to comply with § 4.5.6(A)(2) of this Part. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement: MODIFIED TO COMPLY WITH 21 C.F.R. § 1020.32(H)(2).

e. Exceptions:

(1) During recording of fluoroscopic images. ~~or~~

~~(2) When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an air kerma (exposure) rate in excess of the rates specified in §§ 4.5.6(A)(1)(a) through (c) of this Part at the measurement point specified in 21 C.F.R. 1020.32(d)(3), unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the operator shall indicate that the high-level control is being employed.~~

2. Fluoroscopic equipment manufactured on or after May 19, 1995

a. Shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR ~~air kerma (exposure) rate~~ greater than forty-four (44) mGy per minute (five (5) R/min exposure rate) at the measurement point specified in 21 C.F.R. § 1020.32(d)(3). Provision for manual selection of technique factors may be provided.

b. Shall not be operable at any combination of tube potential and current that will result in an AKR ~~air kerma (exposure) rate~~ in excess of eighty-eight (88) mGy per minute (ten (10) R/min exposure rate) at the measurement point specified in 21 C.F.R. § 1020.32(d)(3), except as specified in § 4.5.6(A)(2)(c) of this Part.

c. Exceptions

(1) For equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the X-ray source is operated in a pulsed mode.

(2) For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

(3) Fluoroscopy equipment with optional high-level control. When ~~a mode of operation has an optional~~ high-level control is selected and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR ~~air kerma (exposure) rate~~ in excess of one hundred seventy-six (176) mGy per minute (twenty (20) R/min exposure rate) at the measurement point specified in 21 C.F.R. § 1020.32(d)(3). Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the operator shall indicate that the high-level control is employed.

4.5.7 Measurement of Entrance AKR ~~Air Kerma (Exposure) Rate~~

~~A. Measurement of entrance AKR air kerma (exposure) rate shall be performed for both maximum and typical values and shall be made at intervals not to exceed twelve (12) months or after any maintenance of the system which might affect the air kerma (exposure) rate. Results of these measurements shall be posted where any fluoroscopist may have ready access to such results during the fluoroscopic procedure and in the record required in § 4.3.13(E) of this Part. Results of the measurements shall include the mGy per minute (R/min exposure rate), as well as the technique factors used to determine such results. The name of the Qualified Medical Physicist performing the measurements and the date the measurements were performed shall be included in the results.~~

~~B. Conditions of measurement of maximum entrance air kerma (exposure) rate are as follows:~~

~~1. The measurements shall be made under conditions that satisfy the requirements of § 4.5.6(A) of this Part;~~

~~2. The kVp, mA, and/or other selectable parameters shall be adjusted to those settings which give the maximum air kerma (exposure) rate; and~~

~~3. An X-ray system that incorporates automatic exposure rate control (AERC) shall have sufficient material placed in the useful beam to produce the maximum output of that system.~~

~~C. Conditions of measurement of typical air kerma (exposure) rate are as follows:~~

~~1. The measurements shall be made under conditions that satisfy the requirements of § 4.5.7(D) of this Part and are typical of clinical use of the X-ray system;~~

~~2. The kVp shall be that typical of clinical use of the X-ray system;~~

~~3. An X-ray system(s) that incorporates AERC shall have sufficient material placed in the useful beam to produce operating parameters typical of the use of the X-ray system; and~~

~~4. An X-ray system(s) that does not incorporate an AERC shall utilize a milliamperage typical of the clinical use of the X-ray system.~~

~~a. Material should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.~~

~~D~~A. ~~Measuring Compliance.~~ Compliance with § 4.5.6 of this Part shall be determined as follows:

1. If the source is below the X-ray table, the AKR ~~air kerma (exposure) rate~~ shall be measured at one (1) cm above the tabletop or cradle.

2. If the source is above the X-ray table, the AKR ~~air kerma (exposure) rate~~ shall be measured at thirty (30) cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

3. In a C-arm type of fluoroscope, the AKR ~~air kerma (exposure) rate~~ shall be measured at thirty (30) cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than thirty (30) cm from the input surface of the fluoroscopic imaging assembly.

4. In a C-arm type of fluoroscope having a SID less than forty-five (45) cm, the AKR ~~air kerma (exposure) rate~~ shall be measured at the minimum SSD.

5. In a lateral type of fluoroscope, the AKR ~~air kerma (exposure) rate~~ shall be measured at a point fifteen (15) cm from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than fifteen (15) cm to the centerline of the X-ray table.

4.5.8 Indication of Potential and Current

During fluoroscopy and cinefluorography, the X-ray tube potential and current shall be continuously indicated. Deviation of X-ray tube potential and current from the indicated value shall not exceed the maximum deviation as stated by the manufacturer.

4.5.9 Source-Skin Distance

A. Means shall be provided to limit the source-skin distance to not less than thirty-eight (38) cm on stationary fluoroscopes and to not less than thirty (30) cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operating at shorter source-skin distances but in no case less than twenty (20) cm.

B. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than forty-five (45) cm, means shall be provided to limit the source-skin distance to not less than nineteen (19) cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than ten (10) cm.

4.5.10 Fluoroscopic Irradiation Time, Display and Signal

A. Fluoroscopic equipment manufactured before June 10, 2006:

1. Shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting. A signal audible to the ~~operator~~ fluoroscopist shall indicate the completion of any preset cumulative irradiation time. Such signal shall continue to sound while X-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 C.F.R. § 1020.30(q) to comply with the requirements of § 4.5.10 of this Part. When the equipment is modified, it shall bear a label indicating the statement: MODIFIED TO COMPLY WITH 21 C.F.R. § 1020.32(h)(2)

B. For X-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

1. A display of the fluoroscopic irradiation time at the fluoroscopist's ~~operator's~~ working position. This display shall function independently of the audible signal described § 4.5.10(B)(2) of this Part. The following requirements apply:

   a. When the X-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six (6) seconds.

   b. The fluoroscopic irradiation time shall also be displayed within six (6) seconds of termination of an exposure and remain displayed until reset.

   c. Means shall be provided to reset the display to zero (0) prior to the beginning of a new examination or procedure.

2. A signal audible to the fluoroscopist ~~operator~~ shall sound for each passage of five (5) minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two (2) seconds.

4.5.11 [RESERVED] ~~Mobile and Portable Fluoroscopes.~~

~~In addition to the other requirements of § 4.5 of this Part, mobile and portable fluoroscopes shall provide an image receptor incorporating more than a simple fluorescent screen.~~

4.5.12 ~~Control of~~ Protection From Scattered Radiation

A. ~~Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.~~ For stationary fluoroscopic systems, ancillary shielding, such as drapes, self-supporting curtains, or viewing shields, shall be available and used as supplemental protection for all individuals other than the patient in the room during a fluoroscopy procedure.

B. ~~Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:~~ Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met:

1. ~~Is at least one-hundred twenty (120) centimeters from the center of the useful beam, or~~ Shielding required under § 4.5.12(A) of this Part shall be maintained to the degree possible under the clinical conditions;

2. ~~The radiation has passed through not less than 0.25 millimeter lead equivalent material (e.g., drapes, Bucky-slot cover-sliding or folding panel, or self supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in § 4.3.6 of this Part.~~ All persons, except the patient, in the room where fluoroscopy is performed shall wear protective garments that provide a lead equivalent shielding of at least twenty-five one hundredths of one (0.25) mm;

3. The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest); and

4. Operating and safety procedures shall reflect the above conditions, and fluoroscopy personnel shall exhibit awareness of situations requiring the use and/or non-use of the protective drapes.

~~C. The Agency may grant exemptions to § 4.5.12(B) of this Part where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exception.~~

4.5.13 ~~Patient Dose Evaluation~~ Additional Requirements for Facilities Performing Fluoroscopically-Guided Interventional (FGI) Procedures

A. ~~Each~~ A registrant ~~performing~~ utilizing fluoroscopically-guided interventional (FGI) procedures shall ~~develop written policies and procedures to~~ establish a Radiation Protocol Committee (RPC) in accordance with the following:

1. ~~Identify those procedures which have a potential to result in patient doses exceeding the threshold for injury~~ The registrant may establish a system-wide committee if the registrant has more than one (1) site;

2. ~~Reduce the probability of such exposures~~ Two (2) or more registrants may form a cooperative RPC as long as each facility has a representative on the committee; and

3. ~~Ensure that appropriate action occurs for patients receiving doses that warrant follow-up~~ . If the registrant has already established a radiation safety committee, the requirements of § 4.5.13(A) of this Part may be delegated to that committee if the members meet the requirements of § 4.5.13(E) of this Part.

B. ~~The registrant shall have a patient dose monitoring procedures in place and shall document (in the patient's medical record) an estimate of the absorbed dose to the skin. When the fluoroscopy unit is equipped with an air kerma dose readout,~~

~~the recording of this value shall suffice as a patient dose record.~~ A quorum of the RPC shall meet as often as necessary, but at intervals not to exceed twelve (12) months.

C. ~~The registrant shall conduct patient dose evaluation for any procedure that has a reasonable probability of resulting in a deterministic injury (i.e., a cumulative absorbed dose to the skin equal to or greater than 1 Gy (100 rads)). This evaluation shall be noted in the patient's medical record and reviewed by the Radiation Safety Committee. If the registrant does not have a Radiation Safety Committee, the review shall be conducted by the Radiation Safety Officer and the registrant's medical physicist.~~ A record of each RPC meeting shall include the date, names of individuals in attendance, minutes of the meeting, and any actions taken. The registrant shall maintain the record for inspection by the Agency for three (3) years.

D. The RPC shall provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee.

E. Members of the RPC shall include but not be limited to the following individuals:

1. A supervising physician of the healing arts who meets the requirements in § 4.3.3(C) of this Part;

2. A Qualified Medical Physicist;

3. The lead technologist; and

4. Other individuals as deemed necessary by the registrant.

F. The RPC shall establish and implement written FGI procedure protocols, or protocols documented in an electronic report system, that include but are not limited to the following:

1. Identification of individuals who are authorized to use fluoroscopic systems for interventional purposes;

2. A method to be used to monitor patient radiation dose during FGI;

3. Dose notification levels, as appropriate, at which the physician is notified, and appropriate actions are taken for patient safety;

4. Substantial radiation dose level (SRDL) values following nationally recognized standards;

5. Actions to be taken for cases when a SRDL is exceeded which may include patient follow-up; and

6. A review of the established protocols at an interval not to exceed twelve (12) months.

G. A record of each RPC protocol shall be maintained for inspection by the Agency. If the RPC revises a protocol, documentation shall be maintained that includes the justification for the revision and the previous protocol for inspection by the Agency.

H. A record of radiation output information shall be maintained, for three (3) years for inspection by the Agency so the radiation dose to the skin may be estimated in accordance with established protocols. The record shall include, but not be limited to, the following:

1. Patient identification;

2. Type and date of examination;

3. Identification of the fluoroscopic system used; and

4. Peak skin dose, cumulative air kerma or dose area product used if the information is available on the fluoroscopic system. If the peak skin dose, cumulative air kerma or dose area product are not displayed on the fluoroscopic system, records shall include other information necessary to estimate the radiation dose to the skin in accordance with established protocol or the following as necessary:

a. Fluoroscopic mode, such as, high-level or pulsed mode of operation;

b. Cumulative fluoroscopic exposure time; and

c. Number of films or recorded exposures.

4.5.14 Radiation Therapy Simulation Systems

A. Radiation therapy simulation systems shall be exempt from the requirements of § 4.5.2(A), provided such systems are intended only for remote control operation.

B. Radiation therapy simulation systems shall be exempt from all the requirements of §§ 4.5.4(~~D~~C), 4.5.6, and ~~4.6.12(B)(2)~~ 4.6.12(A)(2) of this Part when used for therapy simulation purposes.

C. As an alternative to the requirements of § 4.5.10 of this Part, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which X-rays were produced, and which is capable of being reset between X-ray examinations.

4.5.15 Display of Last-Image-Hold (LIH)

A. Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure.

B. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

C. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

D. Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

4.5.16 Displays of Values of Air Kerma ~~(Exposure)~~ Rate (AKR) and Cumulative Air Kerma.

A. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the ~~operator's~~ fluoroscopist's working position the AKR ~~air kerma (exposure) rate~~ and cumulative air kerma. The following requirements apply for each X-ray tube used during an examination or procedure:

~~B.~~ 1. When the X-ray tube is activated and the number of images produced per unit time is greater than six (6) images per second, the AKR ~~air kerma (exposure) rate~~ in mGy/min shall be continuously displayed and updated at least once every second.

~~C.~~ 2. The cumulative air kerma in units of mGy shall be displayed either within five (5) seconds of termination of an exposure or displayed continuously and updated at least once every five (5) seconds.

~~D.~~ 3. The display of the AKR ~~air kerma (exposure) rate~~ shall be clearly distinguishable from the display of the cumulative air kerma.

~~E.~~ 4. The AKR ~~air kerma (exposure) rate~~ and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

~~1.~~ a. For fluoroscopes with X-ray source below the X-ray table, X-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in §§ 4.5.7(~~D~~A)(1), (2) or (5) of this Part.

~~2.~~ b. For C-arm fluoroscopes, the reference location shall be fifteen (15) cm from the isocenter toward the X-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the X-ray beam with the patient's skin.

~~F.~~ 5. Means shall be provided to reset to zero (0) the display of cumulative air kerma prior to the commencement of a new examination or procedure.

~~G.~~ 6. The displayed AKR ~~air kerma (exposure) rate~~ and cumulative air kerma shall not deviate from the actual values by more than ± thirty-five percent (± 35%) over the range of six (6) mGy/min and one hundred (100) mGy to the maximum indication of AKR ~~air kerma (exposure) rate~~ and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three (3) seconds.

4.6 Radiographic Equipment

4.6.1 ~~Beam Limitation, Except Mammographic Systems~~ Applicability

A. The provisions of § 4.6 of this Part apply to all non-dental registrants using diagnostic x-ray equipment. X-ray systems subject to § 4.6 of this Part shall also meet the requirements of § 4.4 of this Part. Requirements specific to using dental intra-oral, hand held, panoramic, and cephalometric equipment are in §§ 4.13 and 4.14 of this Part. The useful beam shall be limited to the area of clinical interest. ~~This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of § 4.4.2 of this Part has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).~~

4.6.2 Radiation Exposure Control

A. Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

B. Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

C. Operator Protection, Except Veterinary Systems

1. Stationary Radiographic Systems. Stationary radiographic ~~X-ray~~ systems shall be required to have the X-ray control, including the exposure switch, permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

2. Mobile and Portable Systems. Mobile and portable X-ray systems which are:

   a. Used continuously for greater than one (1) week in the same location (i.e., a room or suite) shall meet the requirements of § 4.6.2(C)(1) of this Part;

   b. Used for less than one (1) week at the same location shall be provided with either a protective barrier at least two (2) meters (six and one half feet (6.5')) high for operator protection during exposures or means shall be provided to allow the operator to be at least two and seven tenths (2.7) meters (nine feet (9')) from the tube housing assembly during the exposure.

3. Podiatry Systems. Podiatry facilities shall meet the protection requirements in ~~§ 4.6.2(B)(2)(b)~~ § 4.6.2(C)(2)(b) of this Part.

D. Operator and Ancillary Personnel Protection for Veterinary Systems

1. All stationary, mobile or portable X-ray systems used for veterinary work shall be provided with either a two (2) meter (six and one half feet (6.5')) high protective barrier for operator protection during exposures or shall be provided with means to allow the operator to be at least two and seven tenths (2.7) meters (nine feet (9')) from the tube housing assembly during exposures. Otherwise, in cases where animals are held, the operator and ancillary personnel shall be protected by a minimum of twenty-five one hundredths (0.25) mm lead equivalent from scatter radiation and one half (0.5) mm from the useful beam. Refer to § 4.13 of this Part for hand-held intraoral dental radiographic units used in veterinary practice.

~~2. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If necessary, general anesthesia, sedation or tranquilization should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of their body will be struck by the useful beam. No individual shall be used routinely to hold animals or film during radiation exposures. The exposure of any individual used for this purpose shall be monitored, and a record shall be made of the examination, including the name of the human holder, date of the examination, number of exposures and technique factors utilized for the exposure(s).~~

4.6.3 Control and Indication of Technique Factors

~~A. Visual Indication. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the operator.~~

~~B~~A. Timers. Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

1. Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one half (0.5) second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero (0). It shall not be possible to make an exposure when the timer is set to a zero (0) or off position if either position is provided.

2. During serial radiography, the operator shall be able to terminate the X-ray exposure(s) at any time but means may be provided to permit completion of any single exposure of the series in process.

~~C~~B. Automatic Exposure Controls. When an automatic exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;

2. When the X-ray tube potential is equal to or greater than fifty-one (51) kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse 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 one sixtieth of one (1/60) second or a time interval required to deliver five (5) milliampere-seconds (mAs), whichever is greater;

3. Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than sixty (60) kilowatt-seconds (kWs) per exposure or the product of X-ray tube current and exposure time shall be limited to not more than six hundred (600) mAs per exposure, except when the X-ray tube potential is less than fifty-one (51) kVp, in which case the product of X-ray tube current and exposure time shall be limited to not more than two thousand (2,000) mAs per exposure; and

4. A visible signal shall indicate when an exposure has been terminated at the limits described in ~~§ 4.6.3(A)(3)~~ § 4.6.3(B)(3) of this Part, and manual resetting shall be required before further automatically timed exposures can be made.

~~D~~C. Accuracy. Deviation of technique factors under § 4.6.3 of this Part from indicated values shall not exceed the limits given by the manufacturer.

4.6.4 Positive Beam Limitation (PBL)

A. The requirements of § 4.6.4 of this Part shall apply to radiographic systems which contain PBL.

B. Field Size. When a PBL system is provided, it shall prevent X-ray production when:

1. Either the length or width of the X-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than three percent (3%) of the SID; or

2. The sum of the length and width differences stated in § 4.6.4(B)(1) of this Part without regard to sign exceeds four percent (4%) of the SID.

3. The beam-limiting device is at a SID for which PBL is not designed for sizing.

C. Conditions For PBL. When provided, the PBL system shall function as described in § 4.6.4(B) of this Part whenever all the following conditions are met:

1. The image receptor is inserted into a permanently mounted cassette holder;

2. The image receptor length and width are less than fifty (50) cm;

3. The X-ray beam axis is within ± three degrees (± 3°) of vertical and the SID is ninety (90) cm to one hundred thirty (130) cm inclusive; or the X-ray beam axis is within ± three degrees (± 3°) of horizontal and the SID is ninety (90) cm to two hundred five (205) cm inclusive;

4. The X-ray beam axis is perpendicular to the plane of the image receptor to within ± three degrees (± 3°); and

5. Neither tomographic nor stereoscopic radiography is being performed.

D. Measuring Compliance. Compliance with the requirements of § 4.6.4(B) of this Part shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of § 4.6.4(B) of this Part are met. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor.

E. Operator Initiated Undersizing. The PBL system shall be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the

field size. Each dimension of the minimum field size at a SID of one hundred (100) cm shall be equal to or less than five (5) cm. Return to PBL function as described in § 4.6.4(B) of this Part shall occur automatically upon any change of image receptor size or SID.

F. Override of PBL. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows: FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

1. The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

G. Disabling of PBL. A facility has the option to permanently functionally disable a PBL system. When this option is chosen, the standards for manual collimation apply.

4.6.5 Source-to-Skin Distance

A. The minimum source-skin distance shall not be less than thirty (30) cm, except intraoral dental equipment covered under § 4.14 of this Part and veterinary equipment. ~~X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:~~

~~1. Eighteen (18) cm if operable above fifty (50) kVp; or~~

~~2. Ten (10) cm if not operable above fifty (50) kVp.~~

~~B. Mobile and portable X-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than thirty (30) cm.~~

4.6.6 Air Kerma ~~(Exposure)~~ Reproducibility.

A. ~~The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer:~~ Coefficient of variation. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than five one hundredths (0.05).

1. ~~For any specific combination of selected technique factors, the coefficient of variation of the air kerma (exposure) shall be no greater than 0.05.~~ Measuring compliance. Determination of compliance shall be based on ten (10) consecutive measurements taken within a time period of one (1) hour. Equipment manufactured after September 5, 1978, shall be subject

to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be within one (± 1) of the mean value for all measurements. ~~not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}); i.e., $E > 5 (E_{max} - E_{min})$.~~

2. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of twelve (12) pulses on field emission equipment rated for pulsed operation or no less than one tenth (0.1) second per exposure on all other equipment.

4.6.7 Radiation from Capacitor Energy Storage Equipment

A. Radiation emitted from the X-ray tube shall not exceed:

1. An air kerma of twenty-six one hundredths (0.26) µGy (three one hundredths (0.03) mR exposure) in one (1) minute at five (5) cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of one hundred square cm (100 cm^2), with no linear dimensions greater than twenty (20) cm; and

2. An air kerma of eighty-eight one hundredths (0.88) mGy (one hundred (100) mR exposure) in one (1) hour at one hundred (100) cm from the X-ray source, with beam-limiting device fully open, when the system is discharged through the X-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total projected number of discharges in one (1) hour (duty cycle). The measurements shall be averaged over an area of one hundred square cm (100 cm^2) with no linear dimension greater than twenty (20) cm.

4.6.8 ~~Tube Stands for~~ Hand-Holding Restrictions for Portable X-Ray Systems

A. Except during veterinary field operations where it is impractical to do so, a tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be hand-held during exposures.

B. Neither the X-ray tube housing nor the collimating device shall be held during an exposure. Exceptions are allowed for Agency-approved devices specifically designed to be hand-held.

4.6.9 [RESERVED] ~~Measurement of Radiation Output.~~

~~A. Measurement of the radiation output shall be performed at a specified distance and over a range of clinical kVp values and shall be made at intervals not to exceed twelve (12) months or after any maintenance of the system which might affect the radiation output. These measurements shall be performed in-air with minimum scatter conditions. Results of the measurements shall include the µGy/mAs (mR/mAs), as well as the technique factors used to determine such results.~~

~~B. The name and signature of the Qualified Medical Physicist performing the measurements, and the date the measurements were performed, shall be included in the results.~~

~~C. These measurements may be used to estimate entrance skin exposure (ESE) for the average adult patient for selected routine radiographic procedures. These values should be compared with available national reference values.~~

4.6.10 Beam-on Indicators

The X-ray control shall provide visual indication whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

4.6.11 [RESERVED] ~~Primary Protective Barrier for Mammography X-ray Systems~~

~~A. For X-ray systems manufactured after September 5,1978, and before September 30,1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma five (5) cm from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 µGy (0.1 mR exposure) for each activation of the tube.~~

~~B. For mammographic X-ray systems manufactured on or after September 30, 1999:~~

~~1. At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.~~

~~2. The X-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in § 4.6.11(B)(1) of this Part.~~

3. ~~The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma five (5) cm from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 µGy (0.1 mR exposure) for each activation of the tube.~~

C. ~~Compliance with the requirements of §§ 4.6.11(A) and (B)(3) of this Part for transmission shall be determined with the X-ray system operated at the minimum SID for which it is designed, at maximum rated peak tube potential, at the maximum rated product of X-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of one-hundred square cm (100 cm2) with no linear dimension greater than twenty (20) cm. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.~~

4.6.12 Field Limitation and Alignment for Mobile, Portable and Stationary General Purpose X-ray Systems

A. Except when spot-film devices are in service, mobile, portable and stationary general purpose radiographic X-ray systems shall meet the following requirements:

1. Variable X-ray Field Limitation. A means for stepless adjustment of the size of the X-ray field shall be provided. Each dimension of the minimum field size at a SID of one hundred (100) cm shall be equal to or less than five (5) cm.

2. Visual Definition

a. Means for visually defining the perimeter of the X-ray field shall be provided. 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 two percent (2%) 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.

b. When a light localizer is used to define the X-ray field, it shall provide an average illuminance of not less than one hundred sixty (160) lux (fifteen (15) footcandles) at one hundred (100) cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field.

c. The edge of the light field at one hundred (100) cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four (4) in the case of beam-limiting devices designed for use on stationary equipment,

and a contrast ratio of not less than three (3) in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance three (3) mm from the edge of the light field toward the center of the field; and I_2 is the illuminance three (3) mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of one (1) mm.

~~3. Portable X-Ray Systems~~

~~a. Portable X-ray systems shall have an evaluation of light field vs. X-ray field alignment performed at least every six (6) months to determine compliance with both § 4.6.12(A)(2)(c) and § 4.6.13(A)(3) of this Part.~~

~~b. Portable X-ray systems shall have an evaluation of centering alignment performed at least every six (6) months to determine compliance with § 4.6.13(A) of this Part.~~

4.6.13 Field Indication and Alignment on Stationary General Purpose X-ray Equipment

A. Except when spot-film devices are in service, stationary general purpose X-ray systems shall meet the following requirements in addition to those prescribed in § 4.6.12 of this Part:

1. Means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within two percent (2%) of the SID, and to indicate the SID to within two percent (2%);

2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

3. Indication of field size dimensions and SIDs shall be specified in centimeters and/or inches and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent (2%) of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

4. Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of one hundred (100), one hundred fifty (150), and two hundred (200) cm and/or thirty-six (36), forty (40), forty-eight (48), seventy-two (72) inches and nominal image receptor dimensions of thirteen (13), eighteen (18), twenty-four (24), thirty (30), thirty-five (35), forty (40), and forty-three (43) cm and/or

five (5), seven (7), eight (8), nine (9), ten (10), eleven (11), twelve (12), fourteen (14), and seventeen (17) inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic X-ray system is uniquely designed to operate.

4.6.14 Linearity

A. The following requirements apply ~~when the equipment is operated on a power supply as specified by the manufacturer in accordance with 21 CFR Part 1020~~ for any fixed X-ray tube potential within the range of forty percent (40%) to one hundred percent (100%) of the maximum rated:

1. Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios ~~(Xi)~~ of air kerma ~~(exposure)~~ to the indicated milliampere-seconds product (mGy/mAs ~~or mR/mAs~~) obtained at any two (2) consecutive tube current settings shall not differ by more than one tenth (0.10) times their sum: $X1-X2 \leq 0.10 (X1+X2)$, where X1 and X2 are the average mGy/mAs ~~(mR/mAs)~~ values obtained at each of two (2) consecutive tube current settings, or at two (2) settings differing by no more than a factor of two (2) where the mA selector provides continuous selection.

2. Equipment Having Selection of X-Ray Tube Current-Exposure Time Product (mAs). For equipment manufactured after May 3, 1994, the average ratios of air kerma ~~(exposure)~~ to the indicated milliampere-seconds product (mGy/mAs ~~or mR/mAs~~) obtained at any two (2) consecutive mAs selector settings shall not differ by more than one tenth (0.10) times their sum: $X1-X2 \leq 0.10 (X1 +X2)$, where X1 and X2 are the average mGy/mAs values obtained at any two (2) consecutive mAs selector settings, or at two (2) settings differing by no more than a factor of two (2) where the mAs selector provides continuous selection.

3. Measuring Compliance. Determination of compliance will be based on ~~consecutive~~ ten (10) exposures, made within one (1) hour. These two (2) settings may include any two (2) focal spot sizes except where one (1) is equal to or less than forty-five one hundredths of one (0.45) mm and the other is greater than forty-five one hundredths of one (0.45) mm. For purposes of this requirement, focal spot size is the focal spot size specified by the X-ray tube manufacturer. All values for percent line-voltage regulation at any one (1) combination of technique factors shall be within one (± 1) of the mean value for all measurements at these technique factors.

4.6.15 Field Limitation on Radiographic X-ray Equipment Other Than General Purpose Radiographic Systems

~~A. Equipment for Use With Intraoral Image Receptors. Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:~~

~~1. If the minimum source-to-skin distance (SSD) is eighteen (18) cm or more, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven (7) cm; and~~

~~2. If the minimum SSD is less than eighteen (18) cm, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six (6) cm.~~

~~B~~A. X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one (1) 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, and to align the center of the X-ray field with the center of image receptor to within two percent (2%) 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 the edge of the image receptor.

~~C. Systems Designed for Mammography.~~

~~1. Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after November 1, 1977, and before September 30, 1999, shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor 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 two percent (2%) of the SID. This requirement can be met with a system that performs as prescribed in §§ 4.6.15(D)(1), (2), and (3) of this Part. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in §§ 4.6.15(D)(2) and (3) of this Part shall be the maximum SID for which the beam-limiting device or aperture is designed.~~

~~2. Mammographic beam-limiting devices manufactured on or after September 30,1999, shall be provided with a 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 by more than two percent (2%) of the SID. This requirement can be met with a system that performs as prescribed in §§ 4.6.15(D)(1), (2), and (3) of this Part. For systems that allow changes in SID, the SID indication specified in §§ 4.6.15(D)(2) and (3) of this Part shall be the maximum SID for which the beam-limiting device or aperture is designed.~~

~~3. Each image receptor support device manufactured on or after November 1, 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.~~

~~D~~B. Other X-ray Systems. Radiographic systems not specifically covered in §§ 4.6.12, 4.6.13, or 4.6.15(~~B~~A), ~~4.6.15(C)~~ of this Part~~, and systems covered in § 4.6.15(A) of this Part,~~ which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and alignment 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. These requirements may be met with:

1. A system which performs in accordance with §§ 4.6.12 and 4.6.13 of this Part; or when alignment means are also provided, may be met with either;

2. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

3. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

4.6.16 Field Limitation and Alignment for Spot-Film Devices

A. The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

1. Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the X-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the X-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

2. Neither the length nor width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent (3%) of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent (4%) of the SID. On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

3. The center of the X-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two percent (2%) of the SID.

4. Means shall be provided to reduce the X-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

   a. For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the X-ray field, the minimum field size, at the greatest SID, does not exceed one hundred twenty-five square cm (125 cm^2); or

   b. For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of five (5) cm by five (5) cm.

5. A capability may be provided for overriding the automatic X-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the operator's position shall indicate whenever the automatic X-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows: FOR X-RAY FIELD LIMITATION SYSTEM FAILURE.

4.7 Computed Tomography Equipment ~~Systems~~

4.7.1 Requirements for CT Equipment

A. Applicability. X-ray systems subject to § 4.7 of this Part shall also meet the applicable requirements of § 4.4 of this Part. Unless otherwise specified, the requirements for equipment contained in § 4.7.1 of this Part are applicable to CT X-ray systems manufactured or remanufactured on or after September 3, 1985.

1. Accreditation. All diagnostic CT X-ray equipment for human use shall be accredited by an accrediting organization recognized by the Agency unless otherwise authorized by the Agency.

2. Technical and Safety Information. The technical and safety information relating to the conditions of operation, dose information and imaging performance provided by the CT manufacturer shall be maintained by the facility.

B. Termination of Exposure

1. Means shall be provided to terminate the X-ray exposure automatically by either de-energizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than one hundred ten percent (110%) of its preset value through the use of either a backup timer or devices which monitor equipment function.

2. A visible signal shall indicate when the X-ray exposure has been terminated through the means required by § 4.7.1(B) of this Part.

3. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT system control, of greater than one half (0.5) second duration.

C. Tomographic Plane Indication and Alignment

1. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

2. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

3. If a ~~device~~ mechanism using a light source is used to satisfy §§ 4.7.1(C)(1) or (2) of this Part, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to five hundred (500) lux.

D. Beam-On and Shutter Status Indicators and Control Switches

1. The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

2. Each emergency button or switch shall be clearly labeled as to its function.

E. Indication of CT Conditions of Operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

~~F. Extraneous Radiation. When data are being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by § 4.4.5 of this Part.~~

~~G. Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.~~

~~H~~F. Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry

1. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five (5) millimeters.

2. If the X-ray production period is less than one half (0.5) second, the indication of X-ray production shall be actuated for at least one half (0.5) second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

3. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus (± 1) millimeter with any mass from zero (0) to one hundred (100) kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or thirty (30) centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

4. Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

4.7.2 CT Facility Design Requirements

A. Aural Communication. Provision shall be made for two (2) way aural communication between the patient and the operator at the control panel.

B. Viewing Systems

1. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation

and shall be so located that the operator can observe the patient from the control panel.

2. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

4.7.3 Radiation ~~Output Measurements~~ Protection Survey, ~~Spot Checks~~ Routine Quality Control, and Operating Procedures

A. ~~Output Measurements.~~ Radiation Protection Survey

1. All CT X-ray systems shall have a radiation protection survey completed by, or under the direct supervision of, a Qualified Medical Physicist within thirty (30) days of installation. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard. ~~The measurement of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a Qualified Medical Physicist.~~

2. The registrant shall obtain a written report of the survey from the Qualified Medical Physicist, and a copy of the report shall be made available to the Agency upon request. ~~The measurement of the radiation output of a CT X-ray system shall be performed:~~

~~a. Before the first medical use following installation or reinstallation of the CT X-ray system; and~~

~~b. At intervals not to exceed twelve (12) months; and~~

~~c. After any change or replacement of components which, in the opinion of the Qualified Medical Physicist, could cause a change in the radiation output.~~

~~3. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use:~~

~~a. CT dosimetry phantoms shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter (g/cm^3). The phantoms shall be at least fourteen (14) centimeters in length and shall have diameters of thirty-two (32.0) centimeters for testing CT X-ray systems designed to image any section of the body and sixteen (16.0) centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.~~

~~b. CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.~~

~~c. Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.~~

~~d. All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.~~

~~4. These radiation output measurements shall be required for a representative type of head and body scans performed at the facility.~~

~~5. The CTDI along the two (2) axes specified in § 4.7.3(B)(4)(b) of this Part shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.~~

~~a. For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.~~

~~6. Procedures for measurement of radiation output shall be in writing. Records of radiation measurements performed shall be maintained for inspection by the Agency.~~

~~7. The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be readily available.~~

B. ~~Spot-checks~~ Routine Quality Control. A routine QC program on the CT system shall:

1. ~~The spot-check procedures shall be in writing and shall have been~~ Be developed by a Qualified Medical Physicist and include acceptable tolerances for points evaluated.

2. ~~The spot-check procedures shall~~ Incorporate the use of a water equivalent phantom. At a minimum, noise, CT number, and artifacts shall be evaluated. ~~CT imaging phantom which has the capability of providing an~~

~~indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.~~

3. Be completed at time intervals and under system conditions specified by the Qualified Medical Physicist. The interval shall not exceed one (1) week. ~~Spot-checks shall be evaluated for compliance with tolerance limits specified pursuant to § 4.7.3(C)(1) of this Part at the time the radiation measurements required by § 4.7.3(B) of this Part are performed.~~

~~4. Spot-checks shall include acquisition of images obtained with the CT imaging phantoms. The images shall be retained, until a new set of radiation measurements is performed as follows:~~

~~a. If applicable, photographic copies of the images obtained from the image display device;~~

~~b. Images stored in digital form on a storage medium compatible with the CT X-ray system; and~~

~~c. Acceptance criteria for image validation shall be documented.~~

~~4~~5. The registrant shall maintain a record of each ~~spot~~ routine QC check required by § 4.7.3(~~C~~B) of this Part for three (3) years.

C. Operating Procedures

1. The CT X-ray system shall not be operated except by an individual who has been specifically trained ~~in its operation~~ on the operational features of the unit by a manufacturer's applications specialist, Qualified Medical Physicist, or someone deemed qualified by the Agency.

2. The following information shall be readily available to the CT operator: ~~to the CT operator: regarding the operation of the system. Such information shall include the following:~~

   a. The results of at least the most recent routine QC completed on the system: ~~latest set of radiation measurements and spot-checks;~~

   b. Instructions on performing routine QC, including the use of the CT phantom(s), a schedule of routine QC appropriate for the system, and allowable variations set by the Qualified Medical Physicist for the indicated parameters; and ~~the use of the CT imaging phantom, including a schedule of spot-checks appropriate for the system, and allowable variations for the indicated parameters;~~

   c. Scanning protocols established by the RPC, including instructions on reporting deviations.

~~d. Current imaging protocols shall be available at the control panel which specify the CT conditions of operation and the number of scans for each routine examination.~~

3. If the ~~measurement of radiation output or spot-check~~ Qualified Medical Physicist evaluation or routine QC of the CT X-ray system identifies that a system operating parameter has exceeded a tolerance established by a Qualified Medical Physicist, use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the Qualified Medical Physicist. ~~report the problem to the service engineer and notify the Qualified Medical Physicist. The registrant shall maintain a record of all such notifications for three (3) years.~~

4.7.4 CT X-ray System Used for ~~Radiation Therapy Simulation~~ Treatment Planning in Radiation Oncology

A. A CT X-ray system used solely for ~~radiation therapy simulation~~ treatment planning in radiation oncology is exempt from the specific requirements of §§ 4.7.1, 4.7.2, and 4.7.3 of this Part, and is only subject to the requirements of § 5.10 of this Subchapter.

B. A CT X-ray system used for both diagnostic X-ray and radiation therapy simulation is subject to the requirements of both § 4.7 of this Part and § 5.10 of this Subchapter.

4.7.5 CT Radiation Protocol Committee (RPC)

A. The registrant shall develop and maintain an RPC in accordance with the following:

1. Members of the RPC shall include but not be limited to the:

a. Lead CT radiologist;

b. Lead CT technologist;

c. Qualified Medical Physicist; and

d. Other individuals as deemed necessary by the registrant (e.g., Radiation Safety Officer, Chief Medical or Administrative Officer, Radiology Department Administrator/Manager).

2. If the registrant has more than one (1) site with CT, the registrant may establish a system-wide RPC.

3. Two (2) or more registrants may form a cooperative RPC as long as each facility has a representative on the committee.

4. If the registrant has already established a radiation safety committee, the requirements of § 4.7.5 of this Part may be delegated to that committee if the members meet the requirements of § 4.7.5(A)(1) of this Part.

B. Responsibilities of the RPC. The RPC shall:

1. Review existing CT protocols along with the evaluation and implementation of new and innovative technologies that can improve image quality and/or lower patient dose in comparison with the older protocol.

2. Review the capabilities of the individual CT scanner to ensure maximum performance is achieved

3. Determine and review the protocols that are used frequently or could result in significant doses. This review shall include acquisition and reconstruction parameters, image quality, and radiation dose. At a minimum, the facility shall review the following clinical protocols, if performed, at intervals not to exceed twelve (12) months:

   a. Pediatric Head;

   b. Pediatric Abdomen;

   c. Adult Head;

   d. Adult Abdomen;

   e. Adult Chest; and

   f. Brain Perfusion.

4. Establish and implement written protocols, or protocols documented in an electronic reporting system, that include but are not limited to the following:

   a. A method to be used to monitor the CT radiation output.

   b. A standardized protocol naming policy.

   c. A DRL, notification value, and alert value for CT procedures reviewed in § 4.7.5(B)(3) of this Part. Notification and alert values may be applied by using trigger values in conformance with NEMA XR-29 or facility-established values and procedures as defined by the Qualified Medical Physicist.

   d. Actions to be taken for cases when the dose alert value was exceeded which may include patient follow-up.

e. A process determining who has access and authority to make changes to the protocol management systems, including a method to prevent inadvertent or unauthorized modifications to a CT protocol.

5. If CT fluoroscopy is performed, the RPC shall establish and implement operating procedures and training designed to minimize patient and occupational radiation exposure.

6. Provide an annual report to the radiation safety committee or radiation safety officer, in the absence of a radiation safety committee,

7. At a minimum the RPC members in §§ 4.7.5(A)(1)(a) through (c) of this Part shall meet as often as necessary to conduct business but at intervals not to exceed twelve (12) months.

C. Records

1. A record of each RPC meeting shall be maintained. The record shall include the date, names of individuals in attendance, minutes of the meeting, and any action taken.

2. The registrant shall maintain a record of RPC policies and procedures.

3. The registrant shall maintain a record of radiation output information so the radiation dose may be estimated in accordance with established protocols (e.g., SSDE). The record shall include:

a. Patient identification;

b. Type and date of examination;

c. Identification of the CT system used; and

d. The dose values the CT system provides (e.g., $CTDI_{vol}$, DLP, SSDE).

4.7.6 PET CT and SPECT CT System

A. A CT X-ray system used solely to calculate attenuation coefficients in nuclear medicine studies shall meet the applicable requirements in §§ 4.7.1, 4.7.2, 4.7.3, 4.7.5 and 4.10.1 of this Part unless otherwise exempted below:

1. § 4.7.1(A)(1) of this Part – Accreditation

2. In lieu of § 4.10.1(A)(5) of this Part, a Qualified Medical Physicist shall complete a performance evaluation on the CT system following nationally

recognized guidelines or those approved by the Agency at intervals not to exceed twelve (12) months.

3. In lieu of § 4.7.1(B) of this Part, routine QC checks shall be completed at intervals not to exceed one (1) week. These checks shall be established and documented by a Qualified Medical Physicist following nationally recognized guidelines or those approved by the Agency.

4. § 4.7.3(C)(2)(c) of this Part – Scanning protocols established by the RPC.

4.7.7 Veterinary CT System

A CT X-ray system, including a cone beam computed tomography system (CBCT), used solely in non-human imaging shall meet the requirements of § 4.7.3(A) of this Part [radiation protection surveys] and is otherwise exempt from the standards of § 4.7 of this Part.

4.7.8 Cone Beam Computed Tomography System (CBCT)

A. A CBCT facility shall meet §§ 4.4, 4.6.2, 4.6.5, 4.7.1(A)(2), and 4.7.1(B), (C), (D), (E) and (H) of this Part, as applicable.

1. Exemption. A registrant using fluoroscopy systems capable of CBCT shall meet § 4.7.8 of this Part except §§ 4.7.1(A)(2), and 4.7.1(B), (C), (D), (E) and (H) of this Part.

B. Beam Alignment. The X-ray field in the plane of the image receptor shall not exceed beyond the edge of the image receptor by more than two percent (2%) of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the x-ray field shall be aligned with the center of the image receptor to within two percent (2%) of the SID.

C. The registrant or Radiation Protocol Committee (RPC), if established, shall implement and document a policy addressing deviations from established protocols.

D. A CBCT x-ray system shall only be operated by an individual who has been specifically trained in its operation.

E. The following information shall be readily available to the CBCT operator:

1. Instructions on performing routine QC, including the use of the CBCT phantom(s);

2. A schedule of routine QC appropriate for the system;

3. Allowable variations set by the Qualified Medical Physicist, if required, for the indicated parameters; and

4. The results of at least the most recent routine QC completed on the system.

4.8 Mammography

4.8.1 Applicability

The provisions of this section are in addition to, and not in substitution for, other applicable provisions of this Subchapter.

4.8.2 Certification Requirements

A. Only X-ray systems in compliance with the requirements of the Mammography Quality Standards Reauthorization Act of 1998, Pub. Law 105-248, and 21 C.F.R. Part 900 shall be used for screening and diagnostic mammography.

B. A facility performing mammography shall have a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Pub. Law 105-248, and 21 C.F.R. Part 900.

C. A facility performing mammography shall ensure that the additional mammography activities of processing the X-ray film, interpreting the image, and maintaining viewing conditions, wherever performed, meet all quality standards pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Pub. Law 105-248, and 21 C.F.R. Part 900.

4.8.3 Retention of Mammography X-rays

Pursuant to R.I. Gen. Laws § 23-4.9-1, each mammographic imaging facility that takes a mammography X-ray of any individual within Rhode Island shall keep and maintain that mammography X-ray for the life of the individual. However, any mammography X-ray may be destroyed if the individual has had no contact with the mammographic imaging facility for a period exceeding fifteen (15) years.

4.9 Dual-Energy X-Ray Absorptiometry (DXA) (Bone Densitometry)

4.9.1 ~~Bone Densitometry~~ DXA Systems

A. ~~Bone densitometry~~ DXA systems shall be:

1. Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C – Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act;

2. Registered in accordance with Part 3 of this Subchapter; and

3. At a minimum, maintained and operated in accordance with the manufacturer's specification and recommendations.

4.9.2 [RESERVED] ~~Equipment Requirements~~

~~Systems with stepless collimators 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 two percent (2%) of the SID.~~

4.9.3 ~~Bone Densitometry~~ DXA System Operators

A. Operators of ~~bone densitometry~~ DXA systems shall be:

1. Licensed as a practitioner of the healing arts; or

2. Individuals who possess a current license in accordance with Subchapter 05 Part 34 of this Chapter, Licensure of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants, unless the individual is specifically exempted from licensure by said Regulations; or

3. Individuals who are not subject to licensure under Subchapter 05 Part 34 of this Chapter and have been instructed in the proper use of the ~~bone densitometry~~ DXA system. As a minimum, such instruction shall include:

a. Basic radiation protection;

b. Operating procedures for ~~bone densitometry~~ DXA systems, to include use of various system functions, safety, and maintenance; and

c. Patient positioning for the types of examinations performed.

4.9.4 ~~Bone Densitometry~~ DXA System Operation

A. During the operation of any ~~bone densitometry~~ DXA system:

1. In the absence of a survey performed by or under the supervision of a Qualified Medical Physicist determining the minimum distance the operator may be from the patient and radiation source, the operator, ancillary personnel, and members of the general public shall be positioned at least ~~one~~ two (2) meters from the patient and ~~bone densitometry~~ DXA system during the examination.

2. The operator shall advise the patient that the ~~bone densitometry~~ DXA examination is a type of X-ray procedure.

4.9.5 Maintenance of Records

The registrant shall keep maintenance and QC test records for ~~bone densitometry~~ DXA systems as prescribed by §§ 4.9.1(A)(3) and 4.10.1(A)(6) of this Part. These records shall be maintained for inspection by the Agency for ~~five (5)~~ a minimum of three (3) years from the date the maintenance action was completed.

4.9.6 ~~Bone Densitometry~~ DXA Examination Requirements

A. ~~Bone densitometry~~ DXA on human patients shall be conducted only:

1. Under a prescription of a licensed practitioner of the healing arts; or

2. Under a screening program approved by the Agency.

4.9.7 Submission of Information

Any person proposing to conduct a ~~bone densitometry~~ DXA screening program shall submit the information outlined in § 4.11 of this Part and include the name and address of the licensed practitioner of the healing arts who will interpret the screening results.

4.10 Quality Assurance Program

4.10.1 Quality Assurance

A. Except where otherwise specified by the provisions of § 4.10.1(A)(7) of this Part, all registrants of diagnostic X-ray imaging equipment shall establish and maintain a quality assurance program consisting of quality control assessments addressing at least the following items:

1. Administration

   a. Written standard operating procedures on radiation protection are reviewed and updated by management at intervals not to exceed twelve (12) months;

   b. Employee review and written acknowledgement of standard operating procedures and policies on radiation protection at intervals not to exceed twelve (12) months;

   c. ~~Credentialing of~~ Maintenance of documentation of minimum qualifications for practitioners, medical physicists, and X-ray equipment operators; and

   d. Record retention in accordance with applicable Rhode Island statutes and Regulations, but in no case less than three (3) years.

2. Image Processing~~: Equipment: Compliance with § 4.3.10 of this Part.~~

a. Facilities Using Analog Image Receptors

(1) Facilities shall establish and implement a quality assurance program for X-ray film developing, whether developing is manual or automatic, in accord with the recommendations of a Qualified Medical Physicist, the system manufacturer, or a nationally recognized organization.

(2) Facilities other than dental, podiatry, and veterinary shall have a continuous and documented sensitometric quality control program, including quality control tests for speed, contrast and fog. These tests shall be performed according to specifications of a Qualified Medical Physicist, the manufacturer, or a nationally recognized organization.

b. Facilities Using Computed Radiography (CR) or Direct Digital Radiography (DDR).

(1) Facilities shall establish and follow an image quality control program in accordance with the recommendations of a Qualified Medical Physicist, the system manufacturer, or a nationally recognized organization;

(2) Facilities other than dental, podiatric and veterinary, shall quarterly complete phantom image evaluation using a phantom approved by a Qualified Medical Physicist, system manufacturer, or the Agency. At a minimum the analysis shall include: artifacts, spatial resolution, contrast/noise, workstation monitors, and exposure indicator constancy.

c. Dental Facilities

(1) Facilities using analog image receptors shall maintain a light-tight darkroom, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six (6) months and after a change that may impact film fog.

(2) Facilities using a filmless system shall maintain and operate PSP and DDR systems according to manufacturer specifications.

3. Radiographic Equipment

a. Facilities other than dental, podiatry, and veterinary shall have their digital radiographic systems evaluated by a Qualified Medical Physicist prior to initial clinical use after installation or relocation and by or under the direction of a Qualified Medical Physicist at

intervals not to exceed twelve (12) months unless otherwise determined by the Agency. The evaluation shall follow nationally recognized procedures or those recognized by the Agency and shall include a review of any required QC tests. ~~Compliance with performance standards in §§ 4.4 and 4.6 of this Part, as specified by a Qualified Medical Physicist;~~

b. Dental, podiatry, and veterinary facilities shall have their digital radiographic systems evaluated by a Qualified Medical Physicist prior to initial clinical use after installation or relocation. The evaluation shall follow nationally recognized procedures or those recognized by the Agency. ~~Estimated entrance skin exposures for selected patient examinations;~~

c. Measurement of the radiation output shall be performed at a specified distance and over a range of clinical kVp values and shall be made at intervals not to exceed twelve (12) months or after any maintenance of the system which might affect the radiation output. These measurements shall be performed in-air with minimum scatter conditions. Results of the measurements shall include the µGy/mAs (mR/mAs), as well as the technique factors used to determine such results.~~Image printing and viewing equipment;~~

(1) These measurements may be used to estimate entrance skin exposure (ESE) for the average adult patient for selected routine radiographic procedures. These values should be compared with available national reference values.

(2) The name and signature of the Qualified Medical Physicist performing the measurements, and the date the measurements were performed, shall be included in the results.

~~d. Evaluation of image quality; and~~

~~e. Radiation protection.~~

4. Fluoroscopic Equipment

a. ~~Compliance with performance standards in §§ 4.4 and 4.5 of this Part, as specified by a Qualified Medical Physicist;~~ Fluoroscopic equipment shall be evaluated by a Qualified Medical Physicist within thirty (30) days of installation and of any maintenance of the system that may affect the exposure rate. Thereafter, the measurements shall be made annually or at intervals not to exceed twelve (12) months from the date of the prior measurement by or under the direction of a Qualified Medical Physicist. The evaluation

shall include a review of any required QC tests. At a minimum these evaluations shall include:

(1) A measurement of entrance exposure rates that covers the full range of patient thicknesses, including those that are expected to drive the system to maximum output in all modes clinically used, including fluoroscopy, high-level control, acquisition, digital subtraction and CINE, when available. For systems without automatic exposure control, these measurements shall be made utilizing a milliamperage and kVp typical of the clinical use of the fluoroscopic system. For systems with automatic exposure control, these measurements shall be made utilizing sufficient attenuating material in the useful beam to produce a milliamperage and kVp typical of the clinical use of the fluoroscopic system.

(2) A measurement and verification of compliance of maximum AKR for fluoroscopy and high-level control, if available. Measurements shall be made in accordance with § 4.5.7(A) of this Part.

(3) An evaluation of high contrast resolution and low contrast resolution in both fluoroscopic and spot-film modes.

(4) An evaluation of the operation of the five (5) minute timer, warning lights, interlocks, and collision sensors.

(5) An evaluation of the beam quality and collimation in the fluoroscopy and spot-film modes.

(6) An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays.

(7) An evaluation of any changes that may impact patient and personnel protection devices.

b. Results of these measurements shall be posted where any fluoroscopist may have ready access to such results during the fluoroscopic procedure and in the record required in § 4.3.13(E) of this Part. Results of the measurements shall include the mGy per minute (R/min exposure rate), as well as the technique factors used to determine such results. The name of the Qualified Medical Physicist performing the measurements and the date the measurements were performed shall be included in the results. ~~Low and high contrast resolution; and~~

~~c. Radiation protection.~~

5. Computerized Tomography Equipment

a. The evaluation of a CT X-ray system shall be performed after initial installation and before use on human patients, and at intervals not to exceed twelve (12) months. In addition, the Qualified Medical Physicist shall complete an evaluation of the CT system within thirty (30) days or after any change or replacement of components which, in the opinion of the Qualified Medical Physicist, could cause a change in the radiation output or image quality; ~~Compliance with performance standards in § 4.7 of this Part, as specified by a Qualified Medical Physicist;~~

b. The annual testing of the CT X-ray system shall be performed by, or under the personal supervision of, a Qualified Medical Physicist who assumes the responsibility and signs the final performance evaluation report; ~~CT number;~~

c. Evaluation standards and tolerances shall be established by the Qualified Medical Physicist and maintained by the facility. These standards and tolerances shall meet nationally recognized standards and tolerances for the CT X-ray system; ~~Low and high contrast resolution;~~

d. The evaluation shall include but not be limited to: ~~Dosimetry of selected patient examinations to include pediatric patients if applicable;~~

(1) Geometric factors and alignment including alignment light accuracy and table increment accuracy;

(2) Image localization from scanned projection radiograph (localization image);

(3) Radiation beam width;

(4) Image quality including high-contrast (spatial) resolution and low-contrast resolution

(5) Image uniformity;

(6) Noise;

(7) Artifact evaluation;

(8) CT number accuracy;

(9) Image quality for acquisition workstation display devices;

(10) A review of the results of the routine QC required under § 4.7.3(B) of this Part;

(11) A safety evaluation of audible and visual signals, posting requirements;

(12) Dosimetry.

e. Cone Beam CT (CBCT) Systems

(1) Facilities other than dental shall have an evaluation performed by, or under the direct supervision of, a Qualified Medical Physicist. The evaluation shall follow nationally recognized standards and tolerances or those recognized by the Agency. The evaluation shall be performed within thirty (30) days of initial installation, at intervals not to exceed twelve (12) months, and within thirty (30) days after any change or replacement of components which, in the opinion of the Qualified Medical Physicist, could cause a change in the radiation output or image quality. The facility shall maintain documentation of the established standards and tolerances and testing results. Exemption. A Qualified Medical Physicist performance evaluation on CBCT systems capable of operating at no greater than one hundred (100) kV or twenty (20) mA shall be performed at intervals not to exceed twenty-four (24) months, or an interval approved by the Agency.

(2) Facilities other than dental shall follow the QC recommendations provided by the CBCT manufacturer. In the absence of manufacturer provided QC recommendations, the registrant shall implement and document QC guidelines established by a Qualified Medical Physicist in accordance with nationally recognized guidelines or those recognized by the Agency. ~~Image printing and viewing equipment; and~~

(3) Dental facilities shall have an evaluation performed by, or under the direct supervision of, a Qualified Medical Physicist. The evaluation shall be performed within thirty (30) days of initial installation, at intervals not to exceed twelve (12) months, and within thirty (30) days after any change or replacement of components which, in the opinion of the Qualified Medical Physicist, could cause a change in the radiation output or image quality. The evaluation shall include, at a minimum, the following elements:

Test	Standard
Scan Increment Accuracy	±1 mm
Scan Localization Light Accuracy	±5 mm
Patient Dose (Multiple Scan Average Dose – MSAD or Computed Tomography Dose Index- CTDI)	CBCT equipment manufacturer's specifications and scan protocol or phantom manufacturer's specifications
Pre-Patient Collimation Accuracy	Manufacturer's specifications
Contrast Scale	CBCT equipment or phantom manufacturer's specifications
CT Number for Water	CBCT equipment or phantom manufacturer's specifications
Slice Thickness	CBCT equipment or phantom manufacturer's specifications
Field Uniformity	CBCT equipment or phantom manufacturer's specifications
Low Contrast Resolution	CBCT equipment or phantom manufacturer's specifications
High Contrast Resolution	CBCT equipment or phantom manufacturer's specifications
Noise	CBCT equipment or phantom manufacturer's specifications
Scan Protocol Review	As required by § 4.3.4 of this Part

Test	Standard
Review of facility and technologist's QC test	Review QC tests for proper procedure and corrective action
Medical physicist report and recommendations	Communicate results and recommendations to registrant

~~f. Radiation protection.~~

6. ~~Bone Densitometry Equipment~~ DXA Systems

   a. Conform to the DXA system manufacturer recommendations and recommendations of recognized professional societies such as the International Society for Clinical Densitometry or the American College of Radiology. ~~Compliance with requirements in § 4.9 of this Part.~~

7. Clarification of required quality assurance program elements for certain mammography ~~and dental~~ X-ray facilities.

   a. The requirements in § 4.10 of this Part do not pertain to diagnostic X-ray imaging equipment subject to the Mammography Quality Standards Reauthorization Act of 1998, Pub. Law 105-248, and 21 C.F.R. Part 900.

   ~~b. Registrants performing diagnostic radiography limited to intra-oral dental procedures and/or panoramic procedures and cephalometric procedures which do not utilize an open beam configuration are only required to comply with §§ 4.10.1(A)(1)(a), (b), (d), and 4.10.1(A)(2) of this Part.~~

4.10.2 Availability of Quality Assurance Program

The registrant shall establish and maintain written quality assurance (QA) and quality control (QC) procedures, including evaluation frequencies and tolerances. The QA/QC procedures shall be available for review by the Agency.

4.10.3 Implementation of Quality Assurance Program

A. The registrant shall ~~assign qualified personnel to fully implement~~ designate an appropriately trained individual to manage the quality assurance program. Quality control assessments for §§ 4.10.1(A)(2), (3), (4) and (5) of this Part shall be conducted by, or under the direction of, a Qualified Medical Physicist.

B. A Qualified Medical Physicist shall determine the frequency and nature of ~~quality control tests~~ QA/QC procedures, except when the frequency for a specific ~~quality control test~~ QA/QC procedure is defined by this Subchapter.

C. A Qualified Medical Physicist shall perform a review of the Quality Assurance Program at an interval not to exceed twelve (12) months and shall provide a written report which documents the results of this review.

D. The registrant shall maintain documentation showing the testing instruments used in determining compliance with the provisions of this Part are properly calibrated in accordance with § 4.4.13 of this Part and maintained in accordance with the Agency minimum standard or accepted professional standards when no Agency minimum is defined.

E. The registrant shall perform repeat/reject analysis of radiographic images at least quarterly following specifications of a nationally recognized organization.

F. The registrant shall complete preventative maintenance on the X-ray systems in accordance with manufacturer specifications at intervals not to exceed twelve (12) months.

G. The registrant shall check each study for artifacts. If an artifact is present, the source shall be identified, and appropriate action taken.

H. The registrant shall retain QA/QC records of evaluations and reviews in accordance with applicable provisions of the Rhode Island General Laws and this Subchapter, but in no case less than three (3) years.

I. Exemptions

1. Dental facilities. Dental facilities performing only intra-oral, panoramic, cephalometric or volumetric dental imaging are exempt from the following provisions of §§ 4.3 and 4.10.3 of this Part:

   (a) § 4.3.1(C) – information available to referring physician;

   (b) § 4.10.3(E) – repeat analysis

2. Podiatry facilities. Podiatry facilities are exempt from the following provisions of §§ 4.3 and 4.10. of this Part:

   a. § 4.3.1(C) – information available to referring physician;

   (b) § 4.10.3(E) – repeat analysis

3. Veterinary facilities. Veterinary facilities are exempt from the following provisions of §§ 4.3 and 4.10 of this Part:

(a) § 4.3.1(C) – information available to referring physician;

(b) § 4.3.1(D) – use of reference levels;

(c) § 4.3.1(E) – use of dose reduction techniques;

(d) § 4.3.1(F) – patient identification;

(e) § 4.3.6(A)(3) (routine holding of patient);

(f) §§ 4.3.10(F)(8)(a) through (c) – use of sensitometric equipment;

(g) § 4.3.12 – healing arts screening); and

(h) § 4.10.3(E) – repeat analysis.

4.11 Information to Be Submitted By Persons Proposing to Conduct Healing Arts Screening

A. Persons requesting that the Agency approve a healing arts screening program shall submit the following information ~~and~~ for evaluation and approval:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within Rhode Island.

2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.

3. A description of the X-ray examinations proposed in the screening program (i.e., type and number of views).

4. Description of the population to be examined in the screening program, (i.e., age range, gender, physical condition, and other appropriate information).

5. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used in preference to the X-ray examinations.

6. An evaluation ~~conducted~~ by a Qualified Medical Physicist of the X-ray system(s) to be used in the screening program. The evaluation shall include the following:

   a. Documentation that such system(s) satisfy all requirements of this Subchapter; and

   b. ~~Estimation of patient entrance skin~~ Measurement of appropriate patient exposures from the X-ray examinations to be performed.

7. A description of the ~~diagnostic~~ X-ray quality control program.

8. ~~Documentation of the techniques~~ A copy of the protocol information for the X-ray examination procedures to be used.

9. The name and Rhode Island license number of each radiologic technologist who will be operating the X-ray system(s).

10. The name and Rhode Island license number of each health care provider who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the Rhode Island-licensed practitioner of the healing arts who will interpret the images.

12. Procedures to be used in advising the individuals screened and their health care provider(s) of the results of the screening procedure and any further medical needs indicated.

13. Procedures for the retention or disposition of the images and other records pertaining to the X-ray examinations.

14. Frequency of screening of individuals.

15. The duration of the screening program.

4.12 Instruction of Users of X-Ray Equipment In the Healing Arts

A. Fundamentals of Radiation Safety

1. Characteristics of x-radiation.

2. Units of radiation dose.

3. Hazards of excessive exposure to radiation.

4. Levels of radiation from sources of radiation.

5. Methods of controlling radiation dose:

   a. Working time

   b. Working distances

   c. Shielding

B. Radiation Detection Instrumentation to be Used:

1. Radiation survey instruments:

    a. Operation

    b. Calibration

    c. Limitations

2. Survey, monitoring and spot-check techniques.

3. Personnel monitoring devices.

4. Interpretation of personnel monitoring reports.

C. Operation and Control of X-ray Equipment:

1. Collimation and filtration

2. Exposure techniques for the equipment used

3. Image processing techniques

D. Anatomy and positioning:

1. Relevant human anatomy

2. Relevant human physiology

3. Radiographic positioning

E. The requirements of pertinent Federal and State Regulations.

F. The licensee's or registrant's written operating and emergency procedures.

4.13 Requirements for Use of Hand-Held Intraoral Dental Radiographic Unit

A. In addition to the standards in this Part, the following requirements are specifically applicable to intraoral dental radiographic units designed to be operated as a hand-held ~~unit~~ device:

1. For All Uses:

    a. The facility shall maintain documentation that each operator of hand-held X-ray ~~intraoral~~ equipment has completed training as specified by the manufacturer and approved by the Agency. ~~dental radiographic units shall be specifically trained to operate such equipment.~~

b. When operating a hand-held intraoral dental radiographic unit, operators shall wear a one quarter of one (0.25) mm lead equivalent ~~protective~~ apron ~~and thyroid collar~~, unless otherwise authorized by the Agency or recommended by a health physicist or Qualified Medical Physicist.

c. A hand-held intraoral dental radiographic unit shall be held with minimal motion during a patient examination. If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device. ~~A tube stand may be utilized to immobilize a hand-held intraoral dental radiographic unit during patient examination.~~

d. A hand-held X-ray system shall be equipped with a backscatter shield of not less than one quarter of one (0.25) mm lead equivalent and fifteen and two tenths (15.2) cm (six inches (6")) in diameter that is positioned as close as practicable to the distal end of the position indication device. ~~Unless otherwise authorized by the Agency, a hand-held intraoral dental radiographic unit shall be used with a secondary radiation block to shield the operator.~~

e. The operator shall ensure there are no bystanders within a radius of six feet (6') from the patient being examined with a hand-held intraoral radiographic unit.

f. Hand-held intraoral dental radiographic units shall not routinely be used for patient examinations in hallways and waiting rooms.

g. The registrant shall comply with any facility-specific requirements established by the Agency.

h. The facility shall adopt and follow protocols provided by the manufacturer, and approved by the agency, regarding the safe operation of the device.

i. The registrant shall secure the hand-held device from unauthorized removal or use.

2. Additional Requirements for Operatories in Permanent Facilities:

a. When hand-held intraoral dental radiographic units are used for patient examinations in dental operatories, that facility shall meet the structural shielding requirements specified by the Agency or by a health physicist or Qualified Medical Physicist.

4.14 Requirements for Dental Facilities

4.14.1 Applicability

In addition to the applicable requirements of §§ 4.3 and 4.4 of this Part, the requirements of § 4.14 of this Part apply to dental facilities using intraoral, panoramic, and cephalometric X-ray equipment. Dental facilities using cone beam computed tomography (CBCT) technology shall follow applicable provisions of § 4.7.8 of this Part.

4.14.2 Warning Label

A. On systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear the following warning statement or the warning statement in § 4.14.2(B) of this Part, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

B. On systems manufactured after June 10, 2006, the control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."

4.14.3 Radiation Exposure Control

Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

4.14.4 Exposure Control Location and Operator Protection

A. Except for units designed to be hand-held, the exposure control shall allow the operator to be:

1. Behind a protective barrier at least two (2) meters (six and one half feet (6.5')) tall or

2. At least two (2) meters (six and one half feet (6.5')) from the tube housing assembly, outside the path of the useful X-ray beam, while making exposures.

4.14.5 Administrative Controls

A. Patient and image receptor holding devices shall be used when the techniques permit.

B. Except for units designed to be hand-held, the tube housing and position indicating device (PID) shall not be hand-held during an exposure.

C. Dental fluoroscopy without image intensification shall not be used.

4.14.6 Beam-on Indicators

The X-ray control shall provide visual indication whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

4.14.7 Multiple Tubes

Where two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube which has been selected shall be clearly indicated prior to initiation of the exposure. Only the selected tube can be energized. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

4.14.8 Mechanical Support of Tube Head

The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

4.14.9 Battery Charge Indicator

On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

4.14.10 Locks

All position locking, holding, and centering devices on X-ray system components and systems shall function as intended.

4.14.11 Technique Indicators

A. For X-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

B. The requirement of § 4.14.11(A) of this Part may be met by permanent markings on equipment having fixed technique factors.

4.14.12 Exposure Reproducibility

For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than five one hundredths (0.05).

4.14.13 Timers

Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

4.14.14 Kilovolt Peak

Deviation of technique factors from indicated values shall not exceed the limits provided by the manufacturer. (variation of 21 C.F.R. § 1020.31(a)(4)). At a minimum, the kVp on variable kVp units shall be accurate to within ten percent (10%) and within twenty percent (20%) on fixed kVp units.

4.14.15 X-ray Beam Alignment

A. The useful X-ray beam shall be limited to the area of clinical interest.

B Intraoral Dental Units

1. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance (SSD) to not less than eighteen (18) cm

2. The X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven (7) cm.

C. Extraoral, Panoramic and Cephalometric Units

1. X-ray systems designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and alignment of 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. These requirements may be met with:

   (a) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

   (b) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which

each aperture is designed and shall indicate which aperture is in position for use.

4.14.16 Beam Quality

A. The Half Value Layer (HVL) of the useful beam for a given X-ray tube potential shall not be less than the values shown in § 4.14.16(B) of this Part [Table 1]. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in § 4.14.16(B) of this Part, linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one (1) thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent X-ray emissions if the minimum required filtration is not in place.

B. Table 1 - X-Ray Tube Voltage (kilovolt peak)

		Minimum HVL (mm in Aluminum)		
Design Operating Range	Measured Operating Potential	Dental X-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980	Dental X-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980	All X-ray systems, except dental X-ray systems designed for use with intraoral image receptors, subject to § 4.4.16 of this Part and manufactured on or after June 10, 2006
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5

		Minimum HVL (mm in Aluminum)		
Design Operating Range	Measured Operating Potential	Dental X-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980	Dental X-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980	All X-ray systems, except dental X-ray systems designed for use with intraoral image receptors, subject to § 4.4.16 of this Part and manufactured on or after June 10, 2006
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

4.14.17 kVp Limitations

Intraoral dental X-ray machines with a measured kVp of less than fifty-one (51) kVp shall not be used to make diagnostic dental radiographs of humans.

4.4.18 Modification of Certified Diagnostic X-ray Components and Equipment

A. Diagnostic X-ray components and equipment certified in accordance with 21 C.F.R. Part 1020 shall not be modified such that the component or equipment fails to comply with any applicable provision of 21 C.F.R. Part 1020.

B. The owner of a diagnostic X-ray equipment who uses the equipment in a professional or commercial capacity may modify the equipment provided the modification does not result in the failure of the equipment or component to comply with the applicable requirements of 21 C.F.R. Part 1020. The owner who causes such modification need not submit the reports required by 21 C.F.R. Part 1020, provided the owner records the date and the details of the modification in the equipment records and maintains this information, and provided the modification of the X-ray system does not result in a failure to comply with 21 C.F.R. Part 1020.

4.14.19 Leakage Radiation from the Diagnostic Source Assembly

The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed eighty-eight one hundredths (0.88) milligray (mGy) air kerma (vice one hundred (100) milliroentgen (mR) exposure) in one (1) hour when the X-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum X-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of one hundred (100) square centimeters with no linear dimension greater than twenty (20) centimeters.

4.14.20 Radiation from Components Other Than the Diagnostic Source Assembly

The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of eighteen (18) microgray (two (2) milliroentgens exposure) in one (1) hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of one hundred (100) square centimeters with no linear dimension greater than twenty (20) centimeters.

4.14.21 Maintaining Compliance

Diagnostic X-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 C.F.R. Part 1020) shall be maintained in compliance with applicable requirements of that standard.