

**2009
RATIONALE FOR REVISIONS**

**PART F
DIAGNOSTIC X-RAYS AND IMAGING SYSTEMS IN THE HEALING ARTS**

Introduction

This amendment to Part F includes the addition of revised performance standards specified in Title 21, Code of Federal Regulations (CFR), Part 1020, effective June 10, 2006, quality assurance program requirements, and hand-held dental units. In addition, Sections F.13 - Mammography Definitions for States with Certifying Authority. and Sec. F.14 - Mammography Requirements for States with Certifying Authority. have been deleted.

Specific Provisions:

"Part F - Diagnostic X-Rays and Imaging Systems in the Healing Arts"

Throughout Part F, "license, " "licensee, " and "licensed, " have been added alongside "registration, " "registrant, " and "registered," respectively, as an optional term. State radiation control programs differ in the regulation of diagnostic and imaging systems by utilizing registration or licensure of machines and/or facilities.

In addition, "qualified expert" has been replaced by "qualified medical physicist. "

Section F.1 - Purpose and Scope.

Part Z is added to recognize medical credentialing of operators utilizing diagnostic x-ray and imaging systems.

Section F.2 - Definitions.

The following definitions were added, revised, or replaced in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006:

- "Accessory component" - Added
- "Air kerma" -Added
- "Air kerma rate" -Added
- "Articulated joint" -Added
- "Automatic exposure rate control" -Added
- "C-arm x-ray system" –Replaced with "C-arm fluoroscope"
- "Cantilevered tabletop" -Added
- "Cassette holder" –Added w/option for computed radiography (CR)
- "Coefficient of variation (C)" -Amended

"Computed tomography (CT)" -Amended
"Cradle"-Added
"CT gantry" -Added
"Cumulative air kerma" -Added
"Dose" -Added
"Exposure (X) " -Added
"Fluoroscopic air kerma display device" -Added
"Fluoroscopic imaging assembly" -Amended
"Fluoroscopic irradiation time" -Added
"Fluoroscopy" -Added
"Half-value layer (HVL)" -Amended
"Image receptor" -Amended
"Image receptor support device" -Added
"Isocenter" -Added
"Kerma" -Added
"Last image hold (LIH) radiograph" -Added
"Lateral fluoroscope" -Added
"Leakage technique factors" -Amended
"Line-voltage regulation" -Amended
"Mode of operation" -Amended
"Movable tabletop" -Amended
"Non-image-intensified fluoroscopy" -Amended
"Primary protective barrier" –Added with clarification
"Protective barrier" -Deleted
"Pulsed mode" -Added
"Quick change x-ray tube" -Added
"Radiography" -Added
"Rated line voltage" -Added
"Rated output current" -Added
"Rating" -Amended
"Recording" -Amended
"Scan" -Added
"Scan time" -Added
"Secondary protective barrier" -Deleted
"Solid state x-ray imaging device" -Added
"Source-skin distance (SSD)" -Added
"Spot film device" -Amended
"SSD" -Deleted
"Stationary tabletop" -Added
"Technique factors" -Amended
"Useful beam" -Amended
"X-ray control" -Added
"X-ray field" -Added
"X-ray subsystem" -Added
"X-ray table" -Amended
"X-ray tube" -Amended

The following definitions were added or changed for clarification:

- "Diagnostic x-ray system" –Option added for veterinary use
- "Hand-held x-ray equipment" –Added
- "Qualified expert" replaced with "Qualified medical physicist"

Editorial change was made in the following definition:

- "Leakage radiation"

The following definitions were deleted because they are not used in Part F:

- "Added filtration"
- "Cephalometric device"
- "Certified components"
- "Certified system"
- "Changeable filters"
- "Dead-man switch"
- "Diagnostic imaging system"
- "Entrance exposure rate"
- "Inherent filtration"
- "Maximum line current"
- "Radiographic imaging system"
- "Termination of irradiation"

Section F.3 - General and Administrative Requirements.

Changes are as follows:

- F.3a.ii.: Changed to reflect the upcoming Part Z – Medical Credentialing.
- F.3a.iii.(3): Changed to recognize CR systems.
- F.3a.viii.: Changed to recognize CR systems.
- F.3a.viii.(6): Editorial correction.
- F.3a.ix(1): Changed to recognize CR systems.
- F.3a.xi.: Editorial correction.

Section F.4 - General Requirements for All Diagnostic X-Ray Systems.

The entire Section F.4 was amended in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

- F.4a.: Updated.
- F.4b.: Deleted.
- F.4c.: Redesignated F.4b. and updated.
- F.4d.: Redesignated F.4c. and updated.

F.4e.: Redesignated F.4d. and updated.
New F.4e.: Added.
New F.4f.: Added.
New F.4g.: Added.
F.4f.: Redesignated F.4h.
F.4g.: Redesignated F.4i.
F.4h.: Redesignated F.4j.
F.4i.: Redesignated F.4k.
F.4j.: Redesignated F.4l.

Section F.5 - Fluoroscopic X-Ray Systems.

Section F.5, including title, was amended in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

New F.5a.: Added.
F.5a.: Redesignated F.5b.
F.5a.i thru iii: Deleted.
F.5a.iv.: Amended.
F.5b.: Redesignated F.5c. and amended.
New F.5d.: Added.
New F.5e.: Added.
New F.5f.: Added.
New F.5g.: Added.
New F.5h.: Added.
New F.5i.: Added.
New F.5j.: Added.
New F.5k.: Added.
F.5c.: Deleted.
F.5d.: Deleted.
F.5e.: Deleted.
F.5f.: Deleted.
F.5g.: Deleted.
F.5h.: Redesignated F.5l and amended.
F.5i.: Deleted.
F.5j.: Deleted.
F.5k.: Redesignated F.5m.
F.5l.: Redesignated F.5n.

The following were amended to reflect recommendations from the Task Force on Fluoroscopic Use:

F.5m.
F.5n.

Section F.6 - Radiographic Systems Other than Fluoroscopic, Dental Intraoral, Bone Densitometry or Computed Tomography X-Ray Systems.

Section F.6, including title, was amended in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

- New F.6a.: Added.
- New F.6b.: Added.
- New F.6c.: Added.
- New F.6d.: Added.
- New F.6e.: Added.
- New F.6f.: Added.
- New F.6g.: Added.
- New F.6h.: Added.
- New F.6i.: Added.
- New F.6j.: Added.
- New F.6k.: Added.
- New F.6l.: Added.
- New F.6m.: Added.
- F.6a.: Redesignated F.6o. and amended.
- F.6a.i. thru iv.: Deleted.
- F.6b.: redesignated F.6p.
- F.6b.iii. thru v.: Deleted.
- F.6b.vi.: Redesignated F.6.p.iii.
- F.6b.vii.: Redesignated F.6.p.iv.; added reference to hand-held radiographic devices.
- F.6c.: Deleted.
- F.6d.: Deleted.
- F.6e.: Deleted.
- F.6f.: Deleted.
- F.6g.: Deleted.
- F.6h.: Deleted.
- F.6i.: Redesignated F.6q.

Section F.7 - Intraoral Dental Radiographic Systems.

Title was changed to reflect categorical change from “x-ray systems” in Sections F.5 and F.6 to “equipment.”

Performance standards for intraoral equipment are now specified in Section F.6. This will facilitate future revisions of 21 CFR Part 1020. Therefore, Section F.7 only includes requirements not specifically identified as performance standards.

- F.7a.: Deleted.
- F.7b.: Deleted.
- F.7c.i.(2): Deleted.

- F.7c.ii. thru iv.: Deleted.
- F.7c.v.: Redesignated F.7b.
- F.7d.: Deleted.
- F.7e.: Deleted.
- F.7f.: Deleted.
- F.7g.: Redesignated F.7c.
- F.7h.: Redesignated F.7d.
- F.7h.ii.: Redesignated as F.7d.ii.; specifies Appendix B for hand-held dental radiographic units.
- F.7h.iii.: Deleted since beam limitation requirements are in Section F.6.
- F.7h.iv.: Redesignated F.7d.iii.

Section F.11 - Computed Tomography X-Ray Systems.

Section F.11, including title, was modified in accordance with the changes specified in 21 CFR Part 1020, effective June 10, 2006.

F.11d.ii.(2): Amended to clarify the necessity for appropriate and timely calibration.

Section F.13 – Mammography Definitions for States with Certifying Authority.

This section was deleted in conjunction with the deletion of text in Section F.14.

Section F.14 – Mammography Requirements for States with Certifying Authority.

The text in this section was deleted and replaced by a statement incorporating 21 CFR Part 900 in F.14. Incorporation can include the “current” version or a “dated” version. The inclusion of the full text in Part F in 2001 resulted in the adoption of a version which was outdated when adopted. This was due to periodic changes to 21 CFR Part 900 which could not be included during the adoption process. States desiring to have certifying authority should develop rules or regulations directly from 21 CFR Part 900.

Section F.15 - Bone Densitometry.

Changes are as follows:

- F.15c.iii.: Amended to recognize certification.
- F.15e.: Editorial correction.
- F.15g.: Editorial correction.

Section F.16 - Quality Assurance Program.

This section was added to address the necessity for quality assurance programs in facilities with diagnostic x-ray and imaging systems. General requirements are specified in accordance with type of x-ray equipment, mode of imaging processing, and radiation protection practices. The text was developed generically to assure current and future

application for all types of facilities, programs, and use. This precludes the use of overly prescriptive requirements which may be outdated upon adoption.

Appendix A - Determination of Competence

This appendix was deleted in deference to the anticipated Part Z Medical Credentialing.

Appendix B - Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening

This appendix was redesignated Appendix A. In addition, changes were made to clarify paragraphs c., d., f., k., l., m., and n. Paragraphs e. and g. were designated optional. Paragraph o. was added to specify program duration.

Appendix B (New)- Hand-Held Intraoral Dental Radiographic Unit Requirements for Use

This appendix was added to provide guidance to states on the use of hand-held dental radiographic units.

Appendix C - Exemptions from Shielding for Certain Fluoroscopic Procedures

This appendix is now inappropriate, and therefore, deleted in its entirety.

Appendix D - Focal Spot Tolerance Limit

This appendix is now inappropriate, and therefore, deleted in its entirety.

Appendix E - X-Ray Tube Voltage (Kilovolt Peak) and Minimum HVL

This appendix is now inappropriate, and therefore, deleted in its entirety.