

**2015
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 requirements specific to fluoroscopically guided interventional (FGI) procedures, medical events in diagnostic and interventional x-ray, expanded QA/QC for CR/DR systems, and updated suggested standards for computed tomography. During the revision process, the working group reviewed recent publications and drafts, including Federal Guidance Report No. 14 (the draft provided for public peer review), NCRP Report No. 168 and No. 172, and numerous AAPM and ACR reports.

Specific Provisions:

X-ray is used for guidance during fluoroscopically guided interventional procedures rather than diagnostic purposes. Therefore, the name of Part F has been changed to: “Part F - Medical Diagnostic and Interventional X-ray and Imaging Systems.”

Section F.1 - Purpose and Scope.

Interventional procedures are added to better describe these important procedures that do not technically use the radiation for diagnostic purposes.

Section F.2 - Definitions.

There are significant additions to the definitions as well as a decision to combine the definitions specific to computed tomography (CT) which originally were standalone in the CT section with the main set of definitions.

Our FDA partners expressed throughout the revision process that they continue to have difficulty revising their own standards. The FDA is in the process of referencing International Electrotechnical Commission (IEC); believing this is the best way to assure new radiation producing equipment being manufactured and marketed in the U.S. will meet the latest recognized minimum standard. They advised the SR-F working group (WG) against using existing FDA definitions and standards and recommended we use IEC safety standards. As of the date of this SR-F revision, the FDA has not completed the process of formalizing the referencing of IEC safety standards.

The WG understands why FDA is pursuing the referencing of IEC standards. The IEC can revise their standards very quickly compared to the time it takes FDA to update their regulations. Unfortunately, even with the assistance of our FDA representatives, the WG

has not received open access to IEC safety standards and definitions so that we could complete a comparison and determine if following FDA's path to referencing them was appropriate. State radiation control programs (SRCP) must regulate not only new radiation producing machines, but equipment manufactured 20+ years ago. It is the understanding of the WG that the SRCPs would need access to the IEC safety standard in effect at the time of manufacturer, if it exists. The IEC safety standards are copyrighted and available for purchase. Since the FDA's efforts to reference IEC safety standards is not final and the WG believes it is important to provide updated suggested standards SRCPs can readily implement, the decision was made to continue using relevant FDA regulations and suggested standards developed by the SR-F committee.

The new definitions for DLP and the different types of CTDI were extracted from the AAPM Report 96. A further explanation of these indices is found in the AAPM report. Any definition directly from current FDA standards is now followed with “*”.

Section F.3 - General and Administrative Requirements.

Section F.3 has been significantly revised. In subsection F.3.a., a registrant [licensee] is required to have a radiation safety program. New to this section are standards addressing medical events in diagnostic and interventional x-ray. A suggested standard that facilities use Diagnostic Reference Levels (DRLs) is added. A new suggested standard, F.3.a.iii, was created to hopefully clarify when a Qualified Medical Physicist (QMP) is required to verify compliance with a standard pertaining to something unlikely to change without an incident (e.g., tube leakage).

Most of the Quality Assurance (QA) requirements for facilities using film are retained. QA for facilities using computed radiography (CR) or direct digital radiography (DDR) is expanded. F.3.b.i.6. is a new suggested standard requiring the facility to have a preventative maintenance evaluation completed on all x-ray machines at least every 12 months.

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

The title of the section was updated by adding “and Interventional”.

In line with noting the definitions in Section F directly out of 21 CFR, this revision of Section F provides the reference to 21 CFR if a standard's origin is the current federal code. The suggested standard on the warning label, F.4.a., has been amended to reflect the change in 21 CFR in 2006.

Section F.5 - Fluoroscopic X-Ray Systems.

The suggested standard was amended to prohibit the use of non-image intensified fluoroscopes. That is, only image-intensified or direct-digital receptor fluoroscopic equipment shall be used. It is suggested that all fluoroscopic machines equipped with

high-level control be limited to a maximum AKR of 176 mGy per minute (20 R/min). Minimum operator qualifications, F.5.l., for those using or supervising the use of fluoroscopy equipment has been significantly amended. Subsection F.5.n. now requires the facility to evaluate all modes clinically used on each fluoroscopic unit at intervals not to exceed 12 months.

Subsection F.5.n.i.4 requires an evaluation of the operation of the 5-minute timer, warning lights, interlocks, and collision sensors by the QMP [QE]. The use of the term “interlock” does not imply that the SR-F committee believes interlocks should be installed on fluoroscopy room entry doors. Entrances to fluoroscopy rooms should not be equipped with interlocks designed to terminate x-ray production when triggered.

Subsection F.5.o. provides additional requirements for facilities performing FGI. These facilities are required to have a Radiation Protocol Committee (RPC) with the responsibility of adopting a method to monitor patient dose, setting dose notification levels, and establishing actions to be taken for cases when a substantial radiation dose level (SRDL) is exceeded.

Section F.6 - Radiographic Systems.

The title of Section F.6. was shortened from *Radiographic Systems Other than Fluoroscopic, Dental Intraoral, Bone Densitometry or Computed Tomography X-ray Systems*.

Subsection F.6.a. is a new suggested standard requiring facilities using digital radiography to have an evaluation completed by or under the direction of a QMP within 30-days of clinical use and at intervals not exceeding 12-months unless otherwise determined by the Agency. Dental, podiatric, and veterinary facilities, with exceptions, are exempt.

Section F.7 - Dental Facilities.

The title of the Section was changed from *Intraoral Dental Radiographic Systems* and it was written to serve as a standalone chapter for dental facilities using traditional intraoral, panoramic, or cephalometric dental x-ray equipment. Due to the decision to make this a standalone chapter for these facilities, there are redundancies in some of the operational and equipment standards found elsewhere in this Part.

The appendix providing suggested standards for hand-held dental equipment was eliminated and these standards, with amendments, were included in this Section.

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

As noted in Section F.2., the definitions originally in this Section were moved to F.2.

Subsection F.11.a. requires all diagnostic CT x-ray systems for human use be accredited by an accrediting organization recognized by the Agency unless otherwise authorized by the Agency, and that all technical and safety information relating to the CT system be maintained.

The title of Subsection F.11.c. is amended for clarity. For example, a system performance evaluation rather than a calibration better describes what a QMP performs on a CT system. The role of the QMP is substantially amended. Subsection F.11.d. requires the facility to have an RPC responsible for reviewing CT policies, procedures, and protocols, establishing DRLs, notification & alert levels for the commonly used projections, and managing the access and authority to change a CT protocol. The facility is required to maintain a method to estimate dose to a given patient from a CT study.

The section provides further details on minimum requirements and exemptions for CT systems used solely for treatment planning, calculating attenuation coefficients in PET/CT & SPECT/CT, and non-human (veterinary) use.

Subsection F.11.h. provides minimum suggested standards for CBCT. Included is a requirement that CBCT systems be evaluated annually by a QMP. It was determined by the WG that an annual performance evaluation may not be necessary for the less-powerful systems commonly used in dental practices, etc., so an exemption was written for CBCT systems with a maximum operating potential of 100 kV or 20 mA requiring an evaluation every 24 months or at an interval approved by the Agency.

Fluoroscopy systems capable of CBCT are required to meet a minimum source to skin distance (SSD) requirement of 30 cm in Subsection F.6.i. During federal concurrence, the FDA raised the concern with fluoroscopy systems intended for specific applications (typically extremities) where they allow exceptions to the 30 cm minimum SSD in their regulations. To date, there are no examples of fluoroscopy systems capable of CBCT with a minimum SSD less than 30 cm. The SR-F committee elected to leave the SSR unchanged, and will address certified systems specifically designed to operate at a SSD less than 30 cm if they become available.

Section F.15 - Dual-Energy X-ray Absorptiometry (DXA) (Bone Densitometry).

The title of the Section was amended to provide a more general description of this type of x-ray system.

The operator requirements were amended with reference to Part Z.

Section F.16 - Quality Assurance Program.

This Section was deleted and the QA as added to Section F.3, with modality-specific QA also added to the appropriate sections.

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

Only minor editorial changes were made to this appendix.

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

As noted above, this appendix was deleted and standard for hand-held dental were inserted in Section 7.