

**Authority on Radiation Protection
Regulatory Notice to Practice Community
June 1, 2019**

4465 Delaware Administrative Code, Radiation Control Regulations

Summary of Changes Effective November 13, 2018

On November 1, 2018, several parts of the Radiation Control Regulations were amended to modify definitions, and two parts were repealed and replaced (Parts F & H), adopting with modification the Suggested State Regulations published by the Conference of Radiation Control Program Directors, Inc. (CRCPD). CRCPD is a non-profit organization funded substantially by grants from several federal agencies with an interest in radiation protection (FDA, NRC, EPA, DOE), and healthcare practice organizations (ACR, AAPM, ASTRO), to promote radiological health in all aspects and phases, and foster uniformity of radiation control laws and regulations throughout the states, commonwealths and territories of the United States.

Parts A, B, D, G, H, J, K and X were published on November 1, 2018 and became effective as final regulations on November 13, 2018. However, certain new provisions in Part F – Medical Diagnostic and Interventional X-Ray and Imaging Systems will be afforded a grace period to enable healthcare facilities to come into compliance with new requirements. The grace period began with the effective date of the regulations, November 13, 2018 and will end one year from the date of this Regulatory Notice, June 1, 2020. Immediately after publication of the regulations, the Agency received a request for temporary exemption for the definition of “licensed practitioner” from the Delaware Association of Nurse Anesthetists due to concern about scope of practice. The temporary exemption was granted, and a more permanent solution is in progress as of the date of this notice.

Part F elements subject to the grace period that ends June 1, 2020 are highlighted below, see the published regulations text for additional details:

- **3.0 General and Administrative Requirements:**
 - Mandatory reporting of diagnostic medical events,
 - Quality Assurance Program managed by an appropriately trained individual, documenting minimum qualifications for licensed practitioners, medical physicists and x-ray equipment operators, preventive maintenance of x-ray devices with limited exemptions for dental, podiatry, and veterinary facilities.

- **5.0 Fluoroscopic X-Ray Systems:**
 - In addition to applicable provisions in Section 3.0, requirements for protection from scatter radiation (individuals in room, apart from patient),
 - Minimum operator qualifications for use of fluoroscopy for clinical purposes,
 - Requirement for Qualified Medical Physicist (QMP) to evaluate fluoroscopy unit performance at least annually for units used for clinical purposes,
 - Additional requirements for facilities performing Fluoroscopically-Guided Interventional (FGI) procedures include establishing a Radiation Protocol Committee to establish protocols, monitor patient dose during FGI, establish dose notification levels and ensure reporting and recordkeeping requirements are met for the facility or organization.
 - The Radiation Protocol Committee shall include annual report to facility or organization Radiation Safety Committee (if existing). Minimum qualifications specified for members of Radiation Protocol Committee.

**Authority on Radiation Protection
Regulatory Notice to Practice Community
June 1, 2019**

- **6.0 Radiographic Equipment:**
 - In addition to applicable provisions in Section 3.0, digital radiographic systems must be evaluated by a Qualified Medical Physicist (QMP), or Qualified Expert (QE), depending on modality, prior to clinical use and annually,
 - Hand-held dental intraoral x-ray units used in veterinary practice shall meet the requirements in Section 7.0 Dental Facilities, Section 7.7.

- **7.0 Dental Facilities:**
 - In addition to applicable provisions in Section 3.0, requirements specified for use of intraoral, panoramic, and cephalometric x-ray equipment are cited with reference to federal FDA regulation,
 - Section 7.7 specifies requirements for hand-held devices as a condition of registration, replacing variance approved by Authority on Radiation Protection with a waiver approved by the Office of Radiation Control,

- **11.0 Computed Tomography (CT)**
 - In addition to applicable provisions in Section 3.0, establishing a Radiation Protocol Committee to establish and review CT protocols used frequently, and/or which could result in significant doses (e.g. brain perfusion, pediatric head & abdomen, adult head, chest & abdomen, etc.).
 - Radiation Protocol Committee to establish and implement written or electronic protocol system meeting specified criteria, with actions to be taken for cases exceeding dose trigger values, process to determine who has access and authority to change protocols,
 - Radiation Protocol Committee shall include annual report to facility or organization Radiation Safety Committee (if existing). Minimum qualifications provided for Radiation Protocol Committee members,
 - Radiation protection surveys completed by or under direct supervision of a Qualified Medical Physicist (QMP). Existing systems not previously surveyed shall have a survey within 12 months of effective date of regulation,
 - Initial and Annual testing shall be performed by or under the personal supervision of a QMP who assumes responsibility and signs the final performance evaluation report,
 - Evaluation standards and tolerances shall be established by the QMP, and maintained by the facility, and must meet nationally recognized standards and tolerances for the CT x-ray system.
 - CT systems used solely for treatment planning in radiation oncology shall meet the requirements in Part X, Section 10.0 of these regulations.
 - Veterinary CT Systems used solely in non-human imaging shall meet requirement Part F.11.3.1 (radiation protection surveys), and are otherwise exempt from Part F.11.0.
 - New section on Cone Beam CT systems requirements added in Section 11.8.

- **15.0 Computed Tomography (CT) Dual-Energy X-Ray Absorptiometry (DXA) Bone Densitometry**
 - New Section on DXA systems added in Section 15.0.