

Radiological Health: Proposed Regulatory Changes

Radiation Protection Advisory Committee
October 28, 2026



Proposed Amendments

- **Chapter 215**

- § 215.24 Human Use: Auxiliary personnel employed by a health care facility regulated by the Commonwealth of Pennsylvania Department of Health and Human Services may only use radiation sources in the healing arts in accordance with written job descriptions and employee qualifications.

- **Chapter 217**

- Clarify condition requirements for general licenses in § 217.203.

- **Chapter 221**

- Change QE (Qualified Expert) to QMP (Qualified Medical Physicist) throughout Chapter 221.

Proposed Amendments

Chapter 221 (continued)

- Clarify language in § 221.64 CBCT (Cone beam computed tomography):
Performance evaluations. A performance evaluation shall be performed by or under the direction of a QMP. The evaluation shall follow nationally recognized standards and tolerances or those recommended by the manufacturer. The evaluation shall be performed within 30 days after any change or replacement of components which could cause a change in the radiation output or image quality. At a minimum, evaluations shall include all of the following:
 - Kilovoltage (kV) accuracy.
 - Beam quality.
 - Output reproducibility.
 - A safety evaluation of audible and visual signals and posting requirements.
 - A review of the results of the routine QC required under subsection (b).

Proposed Amendments

Chapter 221 (continued)

§ 221.64 CBCT (continued)

- *For routine QC*
 - The registrant shall document and implement QC guidelines in accordance with nationally recognized guidelines. In the absence of manufacturer provided QC recommendations, the registrant shall implement and document QC guidelines on a quarterly basis or on a schedule established by a QMP.
 - The registrant shall document and implement a policy addressing deviations from established protocols.

Proposed Amendments

Chapter 221 (continued)

§ 221.64 CBCT (continued)

- *For radiation protection surveys.*
 - CBCT X-ray systems shall have a survey performed at the time of installation by or under the direction of a QMP. In addition, a survey shall be performed after a change in the facility or equipment which might cause a significant increase in radiation hazard.
 - The registrant shall obtain a written report of the survey from the QMP, and a copy of the report shall be made available to the Department upon request and shall be maintained by the registrant for the life of the facility.

Proposed Amendments

Chapter 221 (continued)

§ 221.64 CBCT (continued)

- *For training and competency.*
 - In addition to the requirements of § 221.16 (relating to training, competency and continuing education), the CBCT X-ray system shall only be operated by an individual who has been specifically trained in its operation.
 - The CBCT operator shall have instructions on all of the following:
 - Performing routine QC, including the use of CBCT QC phantom(s).
 - A schedule of routine QC for the system.
 - Allowable variations set by the QMP, if required, for the indicated parameters.
 - The results of at least the most recent routine QC completed on the system.

Proposed Amendments

Chapter 221 (continued)

§ 221.64 CBCT (continued)

- *For records retention.*
 - The facility shall maintain documentation of the performance evaluations, routine QC and established standards and tolerances for 5 years for inspection by the Department.
- *For exemptions.*
 - CBCT systems are otherwise exempt from §§ 221.202-221.205. (relating to CT equipment).
 - CBCT systems that are utilized solely in a panoramic modality and which have 3D imaging capability fully disabled, or otherwise prevented from activation, are exempt from § 221.64.



Proposed Amendments

- **Chapter 223**

- Language for radiation protection surveys of CT X-ray systems added to § 223.31.

- **Chapter 225**

- Equipment requirements added to § 225.89:
 - Radiation-producing devices used in industrial radiographic operations shall conform to the following:
 - The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 100 mR (0.88mGy air kerma) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

Proposed Amendments

Chapter 225 (continued)

Equipment requirements added to § 225.89 (Continued):

- Radiation-producing devices used in industrial radiographic operations shall conform to the following:
 - The radiation-producing device shall be equipped with collimators which are capable of restricting the useful beam to the area of interest. Collimators shall provide the same degree of protection required in paragraph (1).
 - A means shall be provided to terminate the exposure after a preset time, a preset to image receptor or a preset product of exposure time and tube current.
 - The X-ray controls shall indicate the technique factors, such as kilovoltage, tube current and exposure time or the product of tube current and exposure time.
 - The radiation-producing device shall be labeled with a readily discernible sign bearing the radiation symbol and the words “CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED” or words having a similar intent, near any switch that energizes the X-ray tube.

Proposed Amendments

Chapter 225 (continued)

- Equipment requirements added to § 225.89 (Continued):
 - Radiation-producing devices used in industrial radiographic operations shall conform to the following:
 - For radiation-producing devices, an easily visible warning light shall be located adjacent to the X-ray tube and labeled with the words “X-RAY ON” or words having a similar intent. The warning light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.

Proposed Amendments

Chapter 225 (continued)

- Equipment requirements added to § 225.89 (Continued):
 - Radiation-producing devices used in industrial radiographic operations shall conform to the following:
 - The registrant shall perform radiation surveys to demonstrate compliance with 10 CFR 20.1301 (relating to dose limits for individual members of the public) and maintain records of these surveys for inspection by the Department for 5 years:
 - (i) upon acceptance of the equipment;
 - (ii) following maintenance requiring the disassembly or removal of any shielding component; and
 - (iii) when a visual inspection reveals an abnormal condition.
 - The registrant shall test on-off switches, interlocks and safety devices at intervals not exceeding 12 months and make repairs as necessary to maintain all safety features including warning labels. Records of these tests shall be maintained for inspection by the Department for 5 years.

Proposed Amendments

Chapter 225 (continued)

- Permanent industrial radiography and Shielded room industrial radiography are being taken from Chapter 227a and moved to Chapter 225.

Chapter 227a

- A new section is being added for cabinet and baggage x-ray systems in Chapter 227a:
 - Cabinet and baggage X-ray systems that are certified under 21 CFR Chapter I, Subchapter J (relating to radiological health) shall also meet the requirement of 21 CFR 1020.40 (relating to cabinet X-ray systems).
 - A cabinet X-ray system may not be energized unless all openings are securely closed and exposure to radiation from the system does not exceed the limits in § 219.51 (relating to dose limits for individual members of the public). Each access door to the cabinet shall have an interlock that terminates the exposure whenever the door is opened. The enclosure shall be shielded so that every location on the exterior meets the conditions for an unrestricted area.

Proposed Amendments

Chapter 227a (continued)

- New section for cabinet and baggage x-ray systems (continued):
 - A registrant may not permit an individual to operate a cabinet X-ray system or baggage X-ray system until the individual has received a copy of, and instruction in, the operating procedures for the X-ray system and has demonstrated competency in the use of the X-ray system and an understanding of the operating procedures.
 - The registrant shall perform radiation surveys to demonstrate compliance with § 219.51 (relating to radiation dose limits for individual members of the public) and maintain records of the surveys for inspection by the Department for 5 years. At a minimum, surveys shall be performed in the following instances:
 - (1) Upon installation of the equipment.
 - (2) Following a change in the initial arrangement, relocation of the unit, or following any maintenance requiring the disassembly or removal of any shielding component.
 - (3) When a visual inspection reveals an abnormal condition.

Proposed Amendments

Chapter 227a (continued)

- New section for cabinet and baggage x-ray systems (continued):
 - The registrant shall test on-off switches, interlocks, and safety devices at intervals not to exceed 12 months, and make repairs as necessary to maintain all safety features including warning labels. Records of these tests shall be maintained for inspection by the Department for 5 years.
 - Baggage X-ray systems must have a mechanism to ensure operator presence at the control area in a location that enables surveillance of the openings and doors of the control area during generation of radiation. The following apply:
 - During an exposure or preset succession of exposures of 0.5 second or greater duration, the closed-beam radiation-producing machine must have a mechanism to enable the operator to terminate the exposure or preset succession of exposures at any time.
 - During an exposure or preset succession of exposures of less than 0.5 second duration, the closed beam radiation-producing machine must have a mechanism to allow completion of the exposure in progress but must enable the operator to prevent additional exposures.
 - Cabinet X-ray systems and baggage X-ray systems are exempt from other provisions of this chapter except for § 227a.10, 227a.11, and 227a.12.

Proposed Amendments

Chapter 228

- QE is being changed to QMP throughout Chapter 228.
- New language and clarification is being added to the minimum radiation safety survey requirements in Chapter 228.38.

Chapter 240

- Requirements for certifications were combined into one section instead of being broken out by tester, mitigator, and laboratory.
- Outdated protocols and standards are being deleted and being replaced by references to national protocols and standards.



Get in Touch

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