25 Pa Code Article V, Radiological Health

Frequently Asked Questions

The purpose of this FAQ is to highlight changes in the regulations. This FAQ should not be used in lieu of reference to the Pa Code itself. The information in this guidance is solely advisory and does not represent a legal interpretation by the Department. Nothing in this summary shall affect any requirements.

Q: Does § 215.24(b) effectively prohibit Physician's Assistants (PA) or Nurse Practitioners from performing any radiographic and/or fluoroscopic procedures?

A: No, § 215.24(b) references 49 PA Code Part I, Subpart A, Chapters 5, 16, 17, 18, 25, 29, and 33, with PA's and Nurse Practitioners being specifically referenced in Chapter 16.

Q: Regarding Subparagraph (ii) in § 219.3's definition of *Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures - (ii) An unintended dose, other than skin dose, in a single procedure exceeding five times the facility's established protocol and 50 rad (0.5 Gy) to any organ.* The word protocol is not defined within the PA Code, therefore how should a registrant interpret and apply this part of the regulation?

A: The word "Protocol" shall refer to CT protocol when using CT and shall refer to the facility's policy and procedure when using other equipment.

Q: Does the definition of "direct supervision" in § 221.2 conflict with the definition in 49 Pa Code Subpart A, Subchapter E, § 18.201 (If, "yes", how should this be addressed?)

A: No. Both definitions detail the immediate availability of the supervisor, who needs to be monitoring the procedure to provide assistance if necessary.

Q: Does the definition of "FGI – Fluoroscope-guided interventional procedures" in § 221.2 effectively make any of the regulations applicable to FGI procedures to be applicable only to those FGI procedures that also meet the definition of "High-risk procedure"?

A: Yes. The definition specifically points to high risk procedures. "An interventional diagnostic or therapeutic high-risk procedure performed by…"

Q: Regarding § 221.11(b)(1) which reads as follows: *"(1) The operator or the individual who supervises the operation of a high-risk procedure shall have additional instruction, which may*

include certification or registration in the applicable specialty by a professional organization recognized by the Department. Continuing education for high-risk procedures shall occur, at a minimum, every 2 years." Part 1 of the question is: What level of supervision is being referred to here? Part 2 of the question is what is meant by "*certification or registration?"*

A: Part 1: The level of supervision should be interpreted as "personal." Part 2: The phrasing with "certification or registration" was meant to be worded such that it indicated that certification or registration by/with a DEP recognized organization would demonstrate compliance. The list of those organizations can be found at this link: http://files.dep.state.pa.us/RadiationProtection/BureauOfRadiationProtection/BRPPortalFiles/National_Accrediting_Organizations_and_Boards.pdf

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Q: In § 221.11 *"Registrant responsibilities."*, specifically section (l) the registrant is responsible for taking corrective action as appropriate regarding CT studies if an artifact is present. Does this refer to patient-related artifacts or to equipment-related artifacts.

A: This refers to equipment-related artifacts.

Q: Which regulation for operator training is primary §§ 221.11 (B)(1) or 221.16(a)(1)? As both of these regulations reference training topics for operation of X-Ray systems and § 221.11 also references Appendix A (which also has training topics).

A: § 221.16(a)(1) is the primary regulation regarding training and competency. § 221.11 references Appendix A which includes the basic radiation safety that each operator needs to be familiar with and the training needs for accelerator operators, as noted from Chapter 228 references. § 221.16 further references modality and facility specific training.

Q: § 221.16(a)(2) reads: "An individual who operates X-ray equipment during potentially high-risk diagnostic or interventional procedures or supervises the operation of X-ray equipment during these procedures is registered or credentialed and privileged in the applicable specialty by a professional organization recognized by the Department." Please explain what is meant by "credentialed and privileged", as professional organizations do not credential or privilege.

A: The intent of this regulation is to require individuals who operate X-ray equipment during potentially high-risk diagnostic or interventional procedures or who supervise the operation of X-ray equipment during these procedures be certified by a professional organization recognized by the DEP as noted on the PA DEP website (accessible by link at the end of this question). The facility can then, themselves, credential or grant privileges within their organization accordingly. http://files.dep.state.pa.us/RadiationProtection/BureauOfRadiationProtection/BRPPortalFiles/National_Accrediting_Organizations_and_Boards.pdf

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Q: Please explain what is meant by “radiologist assistant” as noted in § 221.35a(b)(2). Also, please explain if all the categories in § 221.35a(b)(4) are meant to be “in training” or is it just radiologic technology student?

A: The definition that is meant to be used for the category of radiologist assistant is as defined by the American Society of Radiologic Technologists (ASRT): “Radiologist assistants are experienced, registered radiographers who have obtained additional education and certification that qualifies them to serve as radiologist extenders. They work under the supervision of a radiologist to provide patient care in the diagnostic imaging environment.” Properly qualified radiology assistants would be considered auxiliary personnel to the DEP. All noted categories in § 221.35a(b)(4) are meant to be read as “in training.”

Q: Please explain the CR/DR regulation § 221.50(c): “Facilities other than dental, podiatric and veterinary shall complete phantom image evaluation using a phantom approved by a QMP, system manufacturer or the Department. The evaluation shall be completed on a quarterly basis and include, at a minimum, all of the following:….”

A: The regulation is as stated. However, to clarify some points only one phantom is needed, in most cases with that phantom being used at all registered locations. The DEP recognizes some financial burden; however, some registrants are already in compliance with this regulation with no hardships. The DEP has composed a list of three phantoms that regional inspectors have seen in use already to comply with this regulation. They are listed here. Also, please note that for facilities using CT, as per FDA regulation 21 CFR 1020.33(d)(1) you should have received a phantom with your unit and should contact the manufacturer.

1. **Fuji One Shot phantom**
2. **Nuclear Associates 07-605-7777 EZ CR-DIN**
3. **Ludlum Model L-777, part number 99-9412**

Q: Regarding § 221.202(a): “*Accreditation.* All diagnostic CT X-ray systems must be accredited by an accrediting organization recognized by the Department within 1 year from first patient use.” Would the DEP accept the Joint Commission for this accreditation, as their standards now mirror the American College of Radiology (ACR) standards for CT?

A: Yes, the DEP does recognize the Joint Commission as meeting this regulation. Please use this link to find all current certifying bodies recognized by the DEP. http://files.dep.state.pa.us/RadiationProtection/BureauOfRadiationProtection/BRPPortalFiles/National_Accrediting_Organizations_and_Boards.pdf

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