25 Pa Code Article V, Chapters 215—221, 223—228, 230, 232 and 240 Revisions

Frequently Asked Questions

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 therefore 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: 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: 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

---

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: In § 221.11(c) which reads as follows: *"Protocol information, which specifies…shall be provided in the vicinity of each diagnostic X-ray system's control panel."* Part 1 of the question is: Would a document posted on an intranet accessible via PC or smartphone be acceptable? Part 2 of the question is: Does § 221.11(c) apply to fluoroscopy or only radiography? Part 3 of the question is: Is there a model QA program available?

A: Part 1: Electronic document availability is acceptable for documentation that needs to be available; however, if the documentation needs to be ***posted***, electronic document availability is not acceptable. Also, please note that this information, if requested, should be *immediately* available to any inspector and must be *current*. Part 2: As noted in §221.35a(a), § 221.11(c) also applies to fluoroscopy. Part 3: Model QA programs can be found at this link: https://www.dep.pa.gov/Business/RadiationProtection/RadiationControl/X-rayMachineProgram/Pages/Quality.aspx.

Q: In § 221.11(l), regarding the required quality assurance (QA) program, it states *"For CT, each study shall be checked."* Would a policy be adequate to document this? How else could a facility document that every study is checked for artifacts?

A: A policy or some other inspectable method of noting the files have been reviewed would be acceptable.

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

---

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."

CLARIFICATION OF § 221.35a(b)

(1) The licensed practitioner should be in compliance with §221.16.

(2) The Department in this case is the facility not the Bureau of Radiation Protection. It is the facility who decides the staff that are working as radiologist assistants, physician assistants or a radiology resident.

(3) No explanation needed.

(4) A radiology resident and physician assistant once properly trained as under §221.16 shall be able to perform procedures under direct supervision of a Radiologist. A medical resident that has met the criteria of §216.16 and has completed the appropriate training may also perform procedures under direct supervision of a licensed practitioner working within his scope of practice. Training documents must be assessable during inspections. A radiologist assistant in training or a radiologic technologist student in training shall be under the personal supervision of a licensed practitioner working within his scope of practice.

Q: § 221.50(a) reads: "When exposure indicators are available, the facility shall establish, document and post an acceptable range for the exposure values…" Can the posting be on a website accessible via smartphone? This can be especially important for portable X-ray units.

A: No, if the information is required to be posted this is not acceptable. The information must be posted and visible.

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: § 221.64(a)(1) *Beam alignment* reads: "*The X-ray field in the plane of the image receptor may not exceed beyond the edge of the image receptor by more than 2% of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the X-ray field must be aligned with the center of the image receptor to within 2% of the SID*." On dental CBCT systems, it is often impossible to perform such a beam alignment test because projection images are not produced only 3D reconstructions. The X-ray field can be measured with various tools, but the dimensions of the image receptor field are difficult or impossible to ascertain.

A: DEP is aware of the vast differences in manufacturer designs and the lack of standardized testing protocols, therefore this regulation will be enforced if the manufacture design allows this alignment to be completed.

Q: § 221.64(a)(4) reads: "*The registrant shall document and implement a policy addressing deviations from established protocols*." Is the word "protocol" intended to mean "clinical protocol?"

A: Yes.

Q: § 221.64(b)(1) reads: "*The CBCT operator shall have instructions on all of the following: (1) Performing routine QC, including the use of the CBCT phantom*." Do 3D c-arms and o-arms fall under the CBCT regulations, or only dental CBCT systems? Dental CBCT systems are often shipped with a quality phantom, but C-Arms and O-Arms are not

A: Both the ACR and FDA classify O-Arms as fluoroscopic. Therefore, this regulation would not apply to them. For C-Arms that have an FDA certification that calls for a phantom and instructions to be issued with them (this includes all dental units), DEP would expect the registrant to have these instructions. DEP also recognizes that phantoms may not yet be currently available for some 3D units and, therefore, would not enforce the regulation until the equipment becomes available.

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

---

Q: Regarding § 221.204(a)(4)(x) reads: "*For dosimetry, a review of the protocols deemed appropriate by the QMP which could result in significant doses. This review must include acquisition and reconstruction parameters, and radiation dose*. *At a minimum, the QMP shall review the following clinical protocols, if performed, at intervals not to exceed 14 months:*" It is not clear if these protocols should be reviewed or the dose from these protocols should be measured. Please clarify. It may not be possible to measure brain perfusion dose if the system operates in shuttle mode. A review of the clinical protocol is appropriate.

A: The QMP-deemed protocols should be reviewed; however, this review shall include radiation dose. If the dose cannot be measured using a phantom, then other sources shall be used to estimate the radiation dose.

Q: Regarding § 221.204(a)(5) reads: *"A performance evaluation shall be made within 30 days after any change or replacement of components which, in the opinion of the QMP, could cause a change in the radiation output or image quality*." Does this regulation mean that ALL factors contained in § 221.204(a)(4) shall be included after each change or replacement of parts, or only the factors the QMP thinks are affected by the change or replacement?

A: DEP recognizes that certain changes or replacement of components in these machines would not necessarily affect all factors noted in § 221.204(a)(4). The QMP should evaluate the machine and document his recommendation on which performance evaluation standards are necessary to be completed based on the change or replacement of parts that has occurred.