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TO: PA DEP Bureau of Radiation Protection

FROM: Department of Radiation Physics/Radiation Safety (individual names at end of document)
Allegheny Health Network
Pittsburgh, PA

RE: Comments to Proposed Rulemaking for 25 PA Code Chapters 215-221, 223, 225, 227, 228, 230 and 240

Chapters 215-218 – No comments

Chapter 219 – Standards for Protecting Against Radiation

219.3. Definitions

- *Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures* - It is not clear what the intent of this definition/reporting requirement benefit is; to identify patient harm or potential harm? NCRP Report 168, Radiation Dose Management for Fluoroscopically Guided Interventional Medical Procedures (NCRP 168) states the reportable event level of a peak skin dose (PSD) of 3 Gy equals the substantial radiation dose level (SRDL) defined to be "low enough so that major tissue reactions are unlikely below this level." It is therefore highly likely that many of the reported events at 3 Gy PSD will in fact have no major tissue reactions. A table of specific *Tissue Reactions from Single-Delivery Radiation Dose to Skin of the Neck, Torso, Pelvis, Buttocks, or Arms*, in an article published in the professional journal, Radiology, entitled: Fluoroscopically-Guided Interventional Procedures: A Review of Radiation Effects on Patients' Skin and Hair, (Balter, et.al, Radiology, Volume 254, Number 2, 2010) indicates that below 5 Gray PSD there are only transient erythema and epilation effects. It is only above 10 Gray PSD that more serious long-term or permanent effects are identified. Additionally, The Joint

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Commission has set 15 Gray PSD as reportable Sentinel Event. It is our recommendation that a higher PSD threshold be set reflective of these references for reporting patient harm. In 221.1, SRDL is defined as a radiation level which might produce a clinically relevant injury in an average patient; perhaps this is the terminology which should be used in this section. If, however, reporting patient harm is not the intent, then the rationale for chosing 3 Gray is requested.

Finally, although estimation methods are available, it is currently very difficult to determine with certainty the exact dose delivered to a specific organ by a fluoroscopic beam. This makes both the 3 Gy PSD and especially the 0.5 Gy (50 rad) to a specific organ very difficult quantities to determine with absolute confidence for every diagnostic and interventional procedure. Unless a specific and clear benefit can be articulated for defining reportable events as indicated above, 219.3 ought to be modified so that only major skin events which occur are reportable.

(ii) This section refers to "An unintended dose, other than skin dose, in a single procedure exceeding five times the facility's *established protocol*...there are no established "dose" protocols in high-risk FGI procedures to use as reference, as there are in radiation oncology.

229.229(b)(2) and (3) Other medical reports.

- The difficulties of determining patient exposures, we would request the times for providing the written report to PA-DEP and the clinical summary to the prescribing physician and patient be extended from the 15 days currently in the proposed regulation to 30 days.

Chapter 221. X-Rays in the Healing Arts

General Provisions

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221.2 Definitions

- *CR- computed radiography, DDR- Direct digital radiography* and *DR – Digital radiography*. It seems these definitions are describing the digital receptor technologies as well as the final radiographic image using the same terminology. According to nationally accepted medical physics standards, Direct digital detectors (DDR) are a subset of ALL digital detectors. The DDR definition in the regulations describes both *indirect* and *direct* digital detectors while both direct and indirect digital detectors as well as photostimuable phosphors found in CR systems produce "digital images". Our recommendation is to eliminate the terms CR and DDR in the definition and in the following regulations and use CR *detector systems* and DR *detector systems* with Digital radiography *images* instead of Digital radiography, as alternatives.

- "FGI- Fluoroscopic-guided interventional procedures" – This definition should be expanded to include the differentiation between low-risk and high-risk procedures within this definition. The primary rationale for this request that later in the regulations there are requirements for FGI equipment without reference to patient risk categorization, and these proposed changes are not appropriate for low-risk FGI. Although "High-risk procedure" is defined later in the definitions as any radiological procedure that can exceed 200 rads of potential skin dose, this definition does not agree with nationally recognized standards and is unnecessarily broad. NCRP Report 168 defines "potentially-high radiation dose procedure" as a procedure in which more than 5% of procedures result in greater than 3 Gy (300 rad) air kerma skin dose. Although all fluoroscopic equipment, including that used for FGI procedures, can theoretically deliver patient PSD of 3 Gray or higher, it is the type of procedure and not the equipment which determine the low or high-risk procedure definition. In any case, the "high-risk" definition should be 3 Gray not 2.

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- *Image intensifier*- this definition should be expanded to include flat-panel digital fluoro detectors, in response to current technology

- QE- why is QE defined in 215.2 and how does this differ from QMP? Please clarify or combine QMP with QE and define either in 215.2 or 221.2 and refer to only one definition in Title 25

Administrative Controls

221.11 Registrant responsibilities

- 221.11(c)- With the current digital generator and control technologies, most clinical protocols for a unit are incorporated directly into the controls, precluding the need for physical versions in the vicinity of the control panel. We recommend this be removed or modified to allow digital versions.
- 221.11(l)-Quality assurance program-Eliminate "For CT, each study shall be checked. If an artifact is present, the registrant shall take corrective action as appropriate". This is redundant in that the QA program includes "image quality and artifacts" and QA programs should provide review process for all x-ray modalities, including CT.
- 221.11(n)-What is the purpose for inclusion since this requirement is addressed in 2219.29?

221.16 Training, competency and continuing education

- This section is duplicative of 221.11(a)-(b). Additionally, it provides differing requirements. These two sections should be combined into one section.

Diagnostic Installations General Requirements

We have some general comments about the remaining 221 sections addressing fluoroscopic x-ray systems, CR/DR equipment, CBCT and CT.

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First, all testing requirements should be done by or under the general supervision of a QMP. There is no testing which must always be done by the QMP directly. Secondly, the rapid technological changes occurring in diagnostic images, including computerization and automation, require additional flexibility in these proposed regulations to allow appropriate responses to these ever accelerating changes and improvements. Therefore, we do not agree with the very prescriptive testing requirements detailed in these sections. The QMP expertise should be fully utilized in developing appropriate written testing and QA/QC protocols, inconsistent with manufacturer, nationally-recognized recommendations and the long-accepted image quality metrics of low and high contrast resolution, SNR and CNR and exposure metrics and indicators. There is no need for detailed DEP mandates which will quickly become outdated and irrelevant.

221.35a. – Fluoroscopic X-ray Systems

(a) General requirements- the language is unnecessarily narrow citing that ALL fluoroscopic systems shall use an image intensifier. Because not all fluoroscopic units utilize this technology, this should also include language for flat panel detectors and future fluoroscopic detector technologies.

(b) Operator qualifications

- This section is duplicative of 221.11(a)-(b) and 216 and it provides yet differing requirements. These various sections are very confusing and they should all be combined into one section.

(c) QMP evaluations

- Fluoroscopic equipment shall be evaluated ...under the *general* direction of a QMP
- We disagree with "At a minimum, evaluations shall include all of the following: "It is reasonable to assume that "any maintenance of the [fluoroscopic] system that may affect the exposure rate" would not affect many of the listed required evaluation tasks for fluoroscopic x-ray systems such as contrast or collimation. Instead of requiring

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a full evaluation after any maintenance affecting the output, the QMP should be allowed to make a determination to evaluate those components affected, e.g. only the exposure output in cases when maintenance would not also affect system contrast, collimation, or other system elements.

- We disagree with (c)(1), because no limits are enforced on exposure rates in acquisition, digital subtraction, or cine modes by any regulating or accrediting body, evaluation of these maximum rates is not always recommended. Considering the potential damage to the fluoroscopic tubes and detectors from maximum output operation, and that manufactures have installed fail-safes to disable x-ray production at maximum exposure rates in these modes, evaluation of these maximum exposure rates should not be mandated. Similarly, in 221.35a(c)(3) and 221.35a(c)(5), obligatory evaluation of spot-film modes for high-contrast and low-contrast resolution, beam quality, and collimation should be eliminated because many fluoroscopic clinical practices do not utilize this feature.
  - In 221.35a(c)(1) no compulsory dosimetry system calibration schedule should be enforced (drop "not to exceed 2 years"). Manufacturer recommendations alone should be sufficient for two reasons: manufacturer in-house testing of dosimeters will determine the best calibration schedule and future technological advances may require more or less frequent calibration schedules; we currently see less than 2% changes between calibrations and diagnostic calibrations do not demand the under 2% accuracy of therapy systems. This requirement adds unnecessary costs without adequate benefit.

(d) Additional requirements for facilities performing FGI

- "High risk" should be included before FGI in the above sentence; these additional requirements should not apply to low risk FGI
- (vi) The review of established procedures should be established by the facility and not mandated by DEP.

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- (2) What is the rationale for requiring a justification for revisions of policies or procedures? This should be eliminated.
- The language of 221.35a(d)(3)(iv) and 221.35a(d)(4) is confusing. The regulation mandates recording PSD, cumulative air kerma, or dose area product (DAP) if available on the fluoroscopic unit. Further, the regulation then mentions that four additional pieces of information must be recorded if PSD, cumulative air kerma, and DAP are not available. According to NCRP Report 168 recommendation #13, cumulative fluoroscopy time alone CAN be used as a least preferred method of skin dose estimation without additional recorded information. This method can also be used if use of dose estimation from air kerma, KAP, or PSD is not practical or possible but still available. The language of these sections should be changed to align the regulation with nationally accepted practices of patient dose monitoring and recording.

221.57 Facilities using CR or DR

- This section should be incorporated into 221.11(l) referring to the Quality Assurance/Quality Control program.
- As stated at the beginning of this section, (b) states that facilitis shall establish and image QC program in accordance with the recommendations of a QMP, the system manufacturer or a Nationally-recognized organization and then goes on in (c) to mandate the image quality requirements and include, at a minimum, all of the following:...Section (c) provides vague tests including contrast/noise and workstation monitors. Section (c) should be eliminated as section (b) addresses this adequately.

221.64(a)(2) CBCT

- Performance evaluations are required to be performed under direct supervision of a QMP. This is a higher supervisory standard than even potentially high risk fluoroscopy or CT. This also does not conform to any nationally recognized QC standard and should be changed to general supervision.
- (4) What is the rationale for this requirement? CBCT is typically used for navigational purposes; these are not doing "typical CT

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scans" with typical protocols. There is no need to address deviations from existing protocols.
- (6)(b)(1) Not all CBCT systems have phantoms
- (c) What is the basis for this exemption and the specific operating factors?

Computed Tomography X-Ray Systems

221.201 Definitions
- Eliminate contrast scale, $CTDI_{100}$, dose profile, elemental area, and MSAD, multiple tomogram system, noise, as they are not referred to in the regulations

221.202 Equipment requirements
- Why is DEP requiring accreditations? If DEP is going to mandate accreditations, then there is no need for detailed CT equipment testing as the site will need to meet the accreditation testing.

221.204 Radiation measurements
- CT dosimetry is in flux due to the multi-detector CT scanners which have invalidated the current CT dose testing methods. Our recommendations are for the regulations to mandate the dosimetry phantom and testing protocols to meet accreditation requirements or other nationally-recognized standards so as not to be locked into the outdated current state of CT dosimetry.
- (3) Eliminate (i) HVL, (ii) MSAD
- (5) Eliminate mR/mAs value determination for head and body

(a) Performance evaluations
- Performed under the *general* supervision of QMP
- (4)(x) This requirement to review and assess the dose of the specified procedures should not be mandated. The ACR and other recognized accrediting bodies do not require submission of specific protocols beyond the adult head and abdomen scans. For example, many clinics do not perform pediatric studies or brain perfusion studies and do not have these clinical protocols set-up to be

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evaluated. The regulation should require only a review and dose assessment of the most generic (adult head and adult abdomen) protocols. Alternatively the regulation could either match the required reviews with those submitted for accreditation or allow the QMP to select a variety of clinically relevant protocols for annual review and assessment.

- (4)(xi) Additional clarification is required in the instruction to "review DRL." Diagnostic reference levels are defined by national guidelines such as NCRP Report 172 as the bottom 75th percentile of diagnostic doses allowing for differences in populations. Specific DRLs reported in such references typically consider a national population. If it is the intent that a review of the DRLs should consider only the national populations and not other, more specific populations, the section ought to specify that requirement. It is also unclear how if at all these DRLs should be interpreted with respect to the notification and alert levels. Furthermore, although XR-29 mandates a reduction in CT study reimbursements for scanners without the capability to set notification levels and alert levels, neither CMS nor any nationally recognized accrediting body has forbidden the operation of such scanners without these capabilities. The regulations should clarify that DRL, notification level, and alert level review are only required for scanners that are XR-29 compliant.

221.204(b)(2), Routine QC

- (2)(c) The procedures mention tracking noise. CT Image quality measurements do not track noise without context to the signal or tube output. Because CT numbers are calculated relative to water attenuation, noise can vary greatly from a number of factors such as slice thickness, tube output, and reconstruction algorithm. Metrics such as CNR and SNR are better performance indicators and should replace "noise" in the regulation.
- (5) specifies that all routine QC be performed only under clinical modes is not recommended by any CT manufacture. These manufactures provide specific phantoms to be run under specific CT

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operating modes which are to be processed by specific QC reconstruction algorithms. Only then can the resulting values be compared to manufacture specifications. Running phantoms, protocols, or reconstruction algorithms that are not specified for QC by the manufacture will not yield the same QC results and will cause incorrect and falsely out-of-tolerance results.

221.205 Operating procedures

- (3)(a) This states a CT system is to be operated only by an individual who has been specifically trained in its operation. During the webinar it was stated this means that all CT techs must be specialty-certified in CT. This is not correct. There are other alternative trainings which can meet this criteria including those detailed in newest The Joint Commission diagnostic imaging standards.
- (c) it is important to note that the role of the QMP is mischaracterized in this section. Under no circumstances can the QMP forbid a physician from scanning or treating a patient if the physician feels the procedure will benefit the patient. Indeed, this is a nuanced qualification. The QMP's role is to act as an advocate for both the safest possible use of radiation and for the best possible diagnostic quality. If the QMP feels that a scan or treatment is not appropriate due to malfunctioning equipment, his/her obligation is to cite acceptable standards of radiation use for diagnostic studies to the staff and physicians and recommend that the procedure be done on a fully functioning unit. The obligation however ends there and any expectation that QMP ought to have a regulated list described in 221.205(c) is inviting conflict with licensed caregivers and exposing the state and hospitals to potential litigation.

A final recommendation is that gender neutral language should be used throughout these regulations instead of the existing male exclusive pronouns used to refer to QMPs and X-ray operators.

Chapters 227-240 - No comments

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We feel strongly that the above comments and suggested changes are in the best interests of the medical physics professionals, the state regulators, and most importantly the public of the Commonwealth of Pennsylvania. It is our expert opinion that addressing the issues in this document is crucial to ensure the adequate protection of radiation workers and the public from the potential harmful effects of radiation. Feel free to reach out to any of the undersigned for any questions, comments, or clarifications of the above. Thank you for your time and consideration.

Sincerely,

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