3169

Comments on PA DEP Proposed Rulemaking by the Environmental Board

[25 PA. CODE CHS. 215—221, 223, 225, 227, 228, 230 AND 240]

June 26, 2017

219.3 (i) – The definition for 'unintended dose' does not appear in regulations until 221.2 Definitions. Recommend that the definition should be contained within the chapter 219. Also, the 3 Gy peak skin dose level should be reconsidered as this is at a generally low level that would not be very likely to cause skin effects.

221 – No requirements for ongoing QMP evaluations of radiographic equipment, only for fluoroscopic and CT systems. Was this an oversight or intentional?

221.11 (c) – References protocol information in the vicinity of the control panel. Since most modern x-ray control panels allow for storage of techniques, suggest referencing an allowance for the electronic storage of pre-programmed techniques.

221.11 (l) – Not clear as to what type if any documentation is required for daily ongoing evaluation of CT systems for artifacts.

221.16 is the new section on Training and Continuing Education. Will this still support the "List of Resources Satisfying initial and continuing Education Requirements..." that supplements the old technical guidance document #291-4200-001 (the document our policy is based off of?). The "List" includes ABR MOC participation right now... Obviously the old technical guidance document will be N/A, but I am wondering if this "List" will be reworked into the new 221.16.

221.16 (a)(2) For operators of hybrid imaging devices (PET/CT and SPECT/CT) where the CT is used for attenuation correction and localization only, is ARRT(CT) required or would other certification such as NMTCB be acceptable?

221.16 (b)(1) – Continuing education required for high and low risk users every 2 / 4 years respectively. Will more detailed guidance be provided as to number of hours or how inspectors will determine what is adequate?

221.35a (b)(1) – Operation of fluoroscopic systems: would like clarification on "licensed practitioner working within his scope of practice". It seems that Physician Assistants (except Radiology PAs?) can no longer be trained to utilize fluoroscopy, since their "Professional and Vocational Standards" do not cover operation of fluoroscopic equipment. Is this accurate?

221.35a (c)(3) – Replace "spot-film modes" with "radiographic modes" or "digital spot radiographic modes"

221.35a (c)(6) An evaluation of the availability and accuracy of technique indicators... The only technique indicator we evaluate is kVp. We assume this is acceptable!

221.35a (d) (1) (ii) – Should reference monitoring dose as indicated by cumulative air kerma meter, ie. dose to interventional reference point or other practical means.

221.57 (a) – Establishing an acceptable range for exposure indicators can be a burdensome process. Some units report EI, others REX, etc. Also, clinical factors greatly impact the exposure indicator such as collimation, patient centering, etc. While it is agreed that monitoring EI is important, we still need more support and guidance from the system manufacturers. Implementation and enforcement of this section will need more clarification from the Bureau.

221.57 (c) – Requiring quarterly phantom evaluations of CR/DR systems seems to be excessive. Perhaps requiring manufacturer's recommended QC (with phantoms if supplied by mfr), or simpler evaluation for artifacts would be more reasonable. Exposure indicator consistency tracking is also difficult as per above comment for 221.57 (a).

221.64 (a)(2) In other areas of the proposed regulations, test intervals not to exceed 14 months are allowed, but in this section it is 12 months. Please be consistent at 14 months.

221.202 (a) – Diagnostic CT systems must be accredited by an organization 'recognized by the Department'. Some more clarification is needed as to which accrediting bodies will be acceptable.

221.204 (a)(3) – Requires initial performance evaluation of CT system prior to patient use. This should be consistent with requirements for x-ray, fluoroscopic, and other systems.

221.204 (b)(4) The Routine QC for CT looks like it is only required weekly? Several manufacturers recommend daily QC with their supplied phantom. We would most likely stick with this routine.

Respectfully submitted,

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