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Kathy Cooper

From: ecomment@pa.gov
Sent: Friday, June 23, 2017 5:56 PM
To: Environment-Committee@pasenate.com; IRRRC; eregop@pahousegop.com; environmentalcommittee@pahouse.net; regcomments@pa.gov; apankake@pasen.gov
Cc: ra-epmsdevelopment@pa.gov
Subject: Comment received - Proposed Rulemaking: Radiological Health



Re: eComment System

The Department of Environmental Protection has received the following comments on Proposed Rulemaking: Radiological Health.

Commenter Information:

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Comments entered:

215.35a, (c) (1) - Clean up language regarding calibrated dosimetry system. I think the intention is: "a dosimetry system that has been calibrated within the prior 2 years according to manufacturer's recommendations".

215.35a (c) (3) - Replace "spot-film modes" with "radiographic modes". Spot-film is an outdated term.

215.35a (c) (4) - Recommend eliminating evaluation of 5-minute timer. The 5-minute timer contributes to "alarm fatigue" without offering any advantage for radiation safety and protection. It's original intention may have been good but with modern radiation metrics, it has outlived its usefulness.

215.35a (d) (1) (ii) - Monitoring actual patient dose during FGI is not practical. I recommend monitoring cumulative dose to a standard location in space (eg, the Interventional Reference Point, or IRP).

215.35a (d) (4)(i) - In practice, the fluoroscopic mode may change during the course of a FGI procedure. Some systems do not report the various modes that were used during a procedure.

215.57 (a) - To implement a process to investigate consistent deviations from established exposure indicator ranges requires some method to electronically record and analyse the exposure indicator data. Some CR & DR manufacturers may not provide such capability as an integral part of their systems. Is the facility going to be expected to create such a system/method on their own? This could be a great burden. I recommend that wording be added to allow an exemption from this requirement if the necessary tools are not an inherent capability

of the CR or DR system.

215.57 (c) - I believe that requiring quarterly testing of CR/DR systems is unnecessary. For large institutions that may have many (hundreds) of CR image plates, this is also impractical. Most DR systems include software that forces the user to perform a self-test or calibration on a regular basis (approximately monthly). Creating a regulatory requirement to force all CR and DR users to meet this standard is extremely burdensome.

215.57 (c) - Many DR systems now come with self-test procedures that analyze uniform ("flat-field") images for sensitivity, uniformity, artifacts, and noise. These self-tests are often performed with a uniform beam filter. It's purpose is to harden the beam like a patient. Would this filter be considered a "phantom"? In addition, these self-tests do not evaluate spatial resolution or detector contrast. For electronic DR systems consisting of a matrix of fixed detector elements, the detector contrast and the detector resolution does not change over time so testing spatial resolution on a routine basis is unnecessary. I suggest removing (2) Spatial resolution.

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?

221.64 (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) I recommend that CT scanners that are intended for non-diagnostic use (eg, treatment planning/simulation, attenuation correction) be exempt from the accreditation requirement. I also recommend exempting CBCT for oral/maxillofacial/ENT, extremity imaging, etc. The ACR CT accreditation program does not support these types of CT devices.

No attachments were included as part of this comment.

Please contact me if you have any questions.

Sincerely,
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