3169

Kathy Cooper

From:	ecomment@pa.gov
Sent:	Friday, June 23, 2017 5:00 PM
To:	Environment-Committee@pasenate.com; IRRC; 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:

John Niemkiewicz
(john.niemkiewicz@rcn.com)
1240 S. Cedar Crest Blvd.
Schnecksville, PA 18078 US

Comments entered:

I am the Chief Physicist in Radiation Oncology at Lehigh Valley Hospital in Allentown, PA and have been in this position for thirteen years. I gave my personal address and email above since my comments are mine alone and do not represent the opinion of Lehigh valley Hospital.

Comments attached.

Thanks,
John

These links provide access to the attachments provided as part of this comment.

Comments Attachment: Comments on PA DEP Proposed Rulemaking by the Environmental Board June 23 2017.docx

Please contact me if you have any questions.

Sincerely,
Jessica Shirley

Jessica Shirley
Director, Office of Policy
PA Department of Environmental Protection
Rachel Carson State Office Building

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 23, 2017

Proposed amendments to § 219.3 (relating to definitions) clarify the definition of "medical reportable event for radiation-producing machine therapy" by including actual criteria.

Comment: If the intent of the regulations in this chapter is to monitor and ensure the safety of the public who are having radiation therapy treatments, I believe the appropriate events to report are those that have clinical significance. I believe the current definition of 'Medical reportable event for radiation-producing machine therapy" is an attempt to capture those events. In that light, the proposed changes seem to me to create confusion because they are redundant and are poorly written. Certainly, if a person not planned to be given a radiation treatment is given a radiation treatment by mistake, that is a significant clinical event. That circumstance is covered in (i) as is. A radiation treatment delivery to the wrong treatment site is covered in existing (ii) and would also be covered in the proposed (ii). Similarly, a radiation treatment using a treatment delivery intended for another individual resulting in a clinical significant is covered in (ii). Also, the new (ii) (B) omits the reference to fractionated treatment (to which it applies) making it less clear. Also, the phrases "from the prescribed dose" and "from the intended prescribed dose" are used twice in the same sentence and should not be. I propose the following:

Medical reportable event for radiation-producing machine therapy—The administration to a human being, except for an administration resulting from a direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

(i) An administration of a therapeutic radiation dose to the wrong individual.

(ii) An administration of a **therapeutic radiation dose identified in a written directive that differs from the intended prescribed dose for the treatment site, or for any other organ, by one of the following:**

(A) More than 20% of the prescribed total dose.

(B) More than 30% of the prescribed weekly dose of a multi-fraction plan.

(C) More than 50% of the prescribed single-fraction dose of a multi-fraction plan.

I believe this would adequately cover clinically significant events, and would be significantly easier to properly interpret compared to the proposed changes.

Proposed § 221.63 (relating to therapy imaging guidance systems) adds technical requirements for procedures using this new type of guidance system, such as QC procedures and methods addressing radiation safety.

Comment (a): The AAPM publishes guidelines on many topics including QA of CT Simulators. These guidelines clearly state that they are for guidance only and it is the responsibility of the assigned medical physicist and/or a departmental quality assurance committee to establish QA procedures that apply to a particular site. I am concerned that the way the proposed rule for 221.63 (a) is worded that it can be interpreted by a PA state inspector that a site is expected to follow all of the QA procedures described in a document published by a national organization and by the device manufacturer. I suggest: "The QMP shall develop QC procedures and tolerances for therapy imaging guidance systems using Nationally-recognized standards or those recommended by the manufacturer for guidance."

Proposed § 221.64 (relating to CBCT) adds QC and evaluation requirements for cone beam computed tomography (CBCT) to address radiation safety. Radiation measurements for these units shall be evaluated annually and as soon as practical following any component repair. The operator shall have instructions on performing routine QC.

Comment (a)(2) and (a)(3): As above.
Comment (a)(4): I am not sure of the need for this. Operators properly trained should be able to operate the CBCT system in a safe and appropriate manner. How the CBCT is used does vary since patient anatomy varies. This would add additional workload to create a variety of protocols and to document deviations from them.
Comment (b)(2): There is not a need for an operator to know the full extent of the schedule for QC. They only need to know the ones they are expected to perform.
Comment (b)(4): It is not clear what is being sought here. The operator needs to evaluate the results of their QC tests and take appropriate action. Otherwise, the QC results need to be reviewed by the QMP.

Proposed amendments to § 228.11a (relating to licensee responsibilities) add qualification requirements for operators of accelerators used in the healing arts to address radiation safety. This includes operators who need additional instruction including certification in the applicable specialty.

Comment: Does this restrict the operation of a linac by a student even if they are under the supervision of a trained and certified operator? If so, this is a bit restrictive. Also, there are times an accelerator needs to be operated by service personnel and others for testing. This does not seem to be accounted for in proposed additional language.

Proposed amendments to § 228.73 (relating to selection of stationary beam therapy or moving beam therapy) clarify that this section refers to devices capable of stationary beam therapy or moving beam therapy, or both.

Comment: The proposed change does not make sense in this section since the rules apply only to linacs capable of BOTH stationary AND moving beam therapy.

Respectfully submitted,

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Lehigh Valley Health Network

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