

3169

Kathy Cooper

From: ecomment@pa.gov
Sent: Wednesday, June 21, 2017 11:47 AM
To: Environment-Committee@pasenate.com; IRRRC; eregop@pahousegop.com; environmentalcommittee@pahouse.net; gvitali@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:

Kendall Berry
Fox Chase Cancer Center (kendall.berry@fccc.edu)
333 Cottman Avenue
Philadelphia, PA 19111 US

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IRRC

Comments entered:

219.3 Definitions, Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures...

(i) An unintended peak skin dose to the same area in a single procedure greater than 3 Gy (300 rad).

Unintended dose—A radiation dose in diagnostic or interventional X-ray resulting from an error in procedure or equipment malfunction

Comment:

The intent of the regulation as currently written is not clear, 3 Gy is a dose where skin effects are merely transient and are frequently not even noticed by the patient. What is the BRP's goal with this regulation?

3 Gy seems to be an arbitrarily low PSD value and reporting is based on a completely subjective opinion. I recommend using Joint Commission Sentinel Event threshold of 15 Gy PSD. If 15 Gy PSD is reached there is a root cause investigation conducted without any regard to whether the dose was "unintended" or not.

Subjective regulations are not enforceable and lend themselves to multiple interpretations by regulators and the regulated community.

I suggest following hospital accreditation standards and use wording similar to this:

(i) Prolonged fluoroscopy with cumulative (over the previous 6 months) dose greater than 15 Gy (1500 rads) to a single field.

This will remove any opinion based interpretation of the regulation and the state would learn about all events >15Gy, this is a dose where significant skin effects are expected, however, skin effects are not frequently observed with fluoroscopic cases even at these doses.

§ 221.2. Definitions

High-risk procedure—Any radiologic procedure that utilizes energies of less than 1 million electron volts that could exceed skin doses of 200 rads.

Comment - SI units should be used here for consistency. 2 Gy (200 rads)

§ 221.204. Performance evaluations, routine QC and surveys.

(d) Records. Records of the performance evaluations and surveys shall be maintained for inspection by the Department for at least 5 years. Routine QC records shall be maintained for at least 1 year.

Comment - Please strike the words "at least" before "5 years" and "1 year." Subjective regulations never go well for the regulated community when being inspected by the regulators. No other record keeping requirements described in these proposed changes uses the term "at least" please provide consistency and strike these words in this section.

No attachments were included as part of this comment.

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
P.O. Box 2063
Harrisburg, PA 17105-2063
Office: 717-783-8727
Fax: 717-783-8926
ecomment@pa.gov