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COMMENTS on PROPOSED RULEMAKING

ENVIRONMENTAL QUALITY BOARD

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

Radiological Health

[47 Pa.B. 2722]
[Saturday, May 13, 2017]

§ 219.3. Definitions.

Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures—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 unintended peak skin dose to the same area in a single procedure greater than 3 Gy (300 rad).

(ii) An unintended dose, other than skin dose, in a single procedure exceeding five times the facility's established protocol and 0.5 Gy (50 rad) to any organ.

(iii) A dose to the wrong patient or wrong site for the entire procedure and exceeding 0.5 Gy (50 rad) to any organ.

Comment: The intent of the regulation as currently written is not clear and there is no apparent advantage to this reporting requirement. The 3 Gy dose threshold is too low as it likely would not even be noticed by the patient, and will not result in any severe or permanent skin damage. The term "unintended" is subjective and will result in varying interpretations and inconsistent reporting. "Exceeding five times the facilities established protocols" is also vague as fluoroscopic guided interventional procedures do not have a standard protocol time. 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. 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: The wording should be changed to read "that could likely exceed skin doses..."

219.229. Other medical reports.

(a) Within 30 days of the determination by a physician of either actual or suspected acute or long-term functional damage to an organ or a physiological system of a patient exposed to **[therapeutic or diagnostic]** radiation **from a diagnostic or interventional procedure** from a radiation-producing machine, the registrant or licensee shall document the finding and provide a report to the Department and provide a clinical summary to the prescribing physician and the patient. The report shall be retained for at least 5 years. Exempt from this reporting requirement are any events already reported under § 219.228 (relating to reports of medical reportable events for radiation-producing machine therapy) and any functional damage to a patient organ or a physiological system that was an expected outcome when the causative procedures were prescribed.

(b) Upon discovery of a medical event, the registrant or licensee shall:

(1) Notify the Department regarding the medical event within 1 business day.

(2) Provide a written report, including the analysis of the medical event, by the qualified medical physicist, as defined in § 221.2 (relating to definitions), to the Department within 15 business days.

(3) Provide a clinical summary to the prescribing physician and patient within 15 business days.

(4) Maintain a record of the medical event as part of the patient's permanent medical record.

Comment: Part (a) requires actions to be completed within 30 days while Part (b) requires some elements of these same actions to be completed in 1 or 15 business days. The two Parts are not consistent.

Michael Sheetz
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