Comment Responses to Revision 2:

§219.3 Definitions for *Medical reportable event for radiation-producing diagnostic or interventional machines* – Use NCRP # 168 notification level of "3 Gy" rather than 2 Gy. The report refers to this level as the "Substantial Radiation Dose Level" for peak skin dose.

(i) **An unintended dose to the skin greater than 3 Gy (300 rads) to the same area for a procedure or series.**

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§219.3 Definitions for *Medical reportable event for radiation-producing machine therapy* – I added "plan" and changed "differs" to "exceed" such as:

(i) An administration of a therapeutic radiation dose to the wrong individual **or using the wrong treatment modality/plan**.

(iv) A dose delivered to all or part of the intended site that exceeds more than 50% from the expected dose for a single fraction of a multi-fraction treatment plan.

Proposed subsection (v) was deleted because it's addressed within the "treatment plan."

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§221.2 Added "ionizing" to the IORT definition.

***Intraoperative radiation therapy (IORT)*— A modality of therapy in which therapeutic levels of ionizing radiation are applied to a target area, such as a cancer tumor, while the area is exposed during surgery.**

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§221.11 Replaced "chart" with "Protocol information."

[(c)](d) [A chart]Protocol information, which specifies the techniques for examinations performed with the system, shall be provided in the vicinity of each diagnostic X-ray system's control panel. **[This chart]The protocol** shall include information pertinent to the particular examination, such as:

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§221.35a Include some additions to the Fluoroscopic X-ray systems section:

(a) Fluoroscopic X-ray systems shall use an image intensifier **or direct-digital receptor** and**,** in addition to the requirements of §§ 221.1—221.34a, shall meet the requirements of §§ 221.36a—221.38a (relating to limitation of useful beam of fluoroscopic equipment; activation of fluoroscopic tube; and entrance exposure rate).

(b) Fluoroscopic X-ray systems shall be equipped with a mechanism to monitor and record patient dose during fluoroscopic operations. Systems incapable of monitoring dose shall have guidelines in place addressing operator requirements, such as beam-on time restrictions and awareness of radiation protection procedures.

(c) All available metrics that describe the total radiation dose from interventional procedures shall be reported in the patient's medical record.

(d) Interventional services shall have policies and processes to ensure that when a specific radiation dose threshold is exceeded, appropriate documentation and follow-up are provided.

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