

Comment Responses to Revision 1:

§215.22 Deleted (a) and (b), but kept the following:

No person may operate or maintain within this Commonwealth devices or machines which use fluoroscopic, X-ray or radiation principles for human non-medical use without prior written approval of the Department.

(1) A person requesting the Department to approve the non-medical human use of radiation shall submit in writing information describing the proposed use to the Department for evaluation.

(2) The Department will consider efficacy as a factor when evaluating the proposed non-medical human use of radiation.

§216.2 Revised the section

(a) A person possessing a radiation-producing machine shall:

(1) Register with the Department within 30 days after acquisition. Registration shall be completed on forms furnished by the Department and shall contain information required on the form and accompanying instructions.

(2) Designate on the registration form an individual to be responsible for radiation protection.

(3) Notify the Department in writing within 30 days of a change [of] in name, address, owner or [radiation safety officer] the individual designated under §216.2(a)(2) to be responsible for radiation protection.[number of machines].

(4) Maintain a written inventory to include at a minimum the type and location of all radiation-producing devices.

(5) Notify the Department of the date and location where imaging services will be performed before the registrant may provide mobile services. The registrant is exempt from this reporting requirement in instances when immediate mobile services are necessary.

§219.3 Definitions for *Medical reportable event for radiation-producing machine therapy* – I deleted “overdose” and will simply use “dose”, such as:

(v) An unintended dose to normal organs, tissues or skin.

§221.25 Beam quality – delete current Table II and replace with CRCPD’s SR-F table (the new SR-F table addresses both certified and non-certified devices, while the former table only addressed non-certified units).

§221.38a.

Revised “quarterly” to “annually” for devices that exceed 2 Gy, per RPAC recommendation. Eliminating “quarterly” results in all devices, regardless of output, having the same frequency of measurements, therefore the addition will be deleted.

(c) *Frequency of output measurements.* Output measurements to show compliance with this section shall be made at least annually and after maintenance that could affect the output of the machine. **Devices used to perform procedures that could exceed 200 rads (2 Gy) shall have output measurements recorded annually or after any repair or change that may affect the performance of the device.**

§221.64

In subsection (a)(ii) substitute "Output" measurements instead of "CTDI" measurements. CTDI is not appropriate for CBCT or OBI device measurements.

NOTE: The entire “Computed Tomography X-Ray Systems” section (§221.201 - §221.205) has been revised and included in the package.

Chapter 223 Veterinary Medicine

I deleted a portion of §223.31(d)(3)

(1) Each person shall be positioned so that no part of the body will be struck by the useful beam unless protected by at least 0.5 millimeter lead equivalent material. The lead equivalent of the material shall be determined at 60 kV.

(2) Each person shall be protected from stray radiation by protective aprons or whole protective barriers of at least 0.25 millimeter lead equivalent or shall be positioned so that no person is in the direct line of the useful beam and the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(3) No individual, other than the animal being examined, may be positioned in the useful beam, unless required to conduct the procedure.