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August 9, 2018

Independent Regulatory Review Commission
333 Market Street
14th Floor
Harrisburg, PA 17101



Re: Comments on Proposed Rulemaking: Radiological Health #7-499 (IRRC# 3169)

Avid Radiopharmaceuticals ("Avid") appreciates the opportunity to provide additional comment on the 25 PA. Code Chapter 223 proposed rulemaking published on May 13, 2017 and scheduled for the August 16, 2018 IRRC Public Meeting. We understand Avid's type of use is small compared to the number of veterinarians using x-ray and appreciate the change that has already been made to the proposed regulations. However, Avid believes one of our comments, seeking exemption of cabinet x-ray units from certain requirements, may have been overlooked. If the regulations are implemented in its current form, it will create a burden on cabinet x-ray users using animals without providing any additional level of radiation safety.

The current proposed Chapter 223.1 Purpose and Scope, added "research on animals" to the Veterinary Medicine section. Due to this change, our Siemens Inveon Multimodal PET/CT unit, a cabinet x-ray unit, will be subject to this chapter of the rules. This chapter of the rules is primarily intended for a much larger group of users (veterinarians) with open beam x-ray units. While we agree that Chapter 223 would be the most appropriate chapter of the rules for inclusion of our Siemens unit, we do not want to see application of new unnecessary rules to our cabinet x-ray system the same way they apply to the typical open beam x-ray unit used by veterinarians.

Our Siemens PET/CT unit is a cabinet x-ray system with integral shielding for use in uncontrolled areas, just like airport x-ray systems used for baggage inspection. This type of unit provides adequate protection from exposure to radiation for any operator of the unit. Therefore, based on Siemens installation guides and our own radiation measurements on the outside of the PET/CT, the operator sits immediately beside the PET/CT unit, just like an airport TSA agent sits immediately beside the baggage inspection x-ray.

However, despite adequate radiation controls provided by the Siemens unit, Avid would be required to use additional controls that Avid believes are unnecessary. The current proposed Chapter 223.31(d)(3) states "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." As this reads, our operator would be required to wear a leaded apron or we would need to install additional shielding of 0.25 millimeter lead equivalent. Although the proposed regulation would allow the operator to be 2 meters from the unit, the operator needs to remain close to the PET/CT unit to monitor the unit and animal. In any event, even if the operator could operate the unit from a distance from the unit, the current room size and arrangement does not allow the operator to be 2 meters from the PET/CT.

August 9, 2018

We understand why and how this chapter applies to veterinarian use of open beam x-ray units, but believe this chapter should not be applied to a cabinet x-ray such as our PET/CT that already includes adequate controls for health and safety of the operator. The useful x-ray beam and image receptor of the PET/CT is totally enclosed and shielded. Requiring any additional shielding, such as leaded aprons or shielded panels, is unnecessary and will create ergonomic and tripping hazards. Accordingly, we propose that Chapter 223.31(d)(3) be revised to exempt cabinet x-ray units from this chapter.

If you need further details please contact Stan Hampton, Corporate Radiation Safety Officer, Eli Lilly and Company, 317-276-7862 or shampton@lilly.com.



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