



## CHRISTIANA CARE HEALTH SERVICES

### Nuclear Medicine

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**Re: Proposal to alter training and education requirements to allow additional alternate pathways for therapeutic radiopharmaceuticals**

**Docket ID NRC-2018-0230**

Dear NRC Commissioners,

Thank you for the opportunity to comment on the proposal to establish "alternate" training and education requirements to allow practitioners not otherwise qualified to administer unsealed therapeutic radiopharmaceuticals. I am a nuclear medicine physician with about 20 years' experience. I work in the nuclear medicine section at Christiana Care Health System in northern Delaware where we administer  $^{131}\text{I}$ ,  $^{223}\text{Ra}$  dichloride (Xofigo),  $^{177}\text{Lu}$  DOTATATE (Lutathera), and, in collaboration with interventional radiology,  $^{90}\text{Y}$  SIR-Sphere and  $^{90}\text{Y}$  TheraSpheres.

My colleagues and I strongly believe that allowing physicians without training in nuclear medicine to administer therapeutic radiopharmaceuticals would be a grave mistake which would endanger patients and ultimately discredit the NRC. The whole rationale for having training and education requirements for radiopharmaceutical use and administration is precisely that extensive, focused training—the training nuclear medicine physicians receive—is necessary to achieve the effective and safe use of unsealed radioactive materials. Safe and appropriate nuclear medicine practice involves daily use of this training and its underlying principles. Application of these principles and their nuances are necessary for all radiopharmaceutical procedures, not just specific therapeutic agents.

The argument that a shortage of nuclear medicine physicians will limit patients' access to treatments is not compelling. The number of nuclear medicine diplomates has actually remained fairly constant. There are nuclear medicine physicians throughout the country and the world who are ready and willing to make the newest treatments available to patients. For many years, patients have come to regional centers where particular expertise or procedures are available; there is no difference between therapeutic radiopharmaceutical administration and any other procedure. Regarding the perceived "shortage" of nuclear medicine physicians, what has hurt nuclear medicine practice is sparsity of new procedures nuclear medicine physicians are uniquely qualified to perform. This has created difficulties in recruiting new physicians to the field and caused nuclear medicine physicians to pursue additional training and seek other careers. New, exciting therapeutic procedures are emerging which will allow nuclear medicine physicians to bring great value to patient care and promise to attract new practitioners to the field. Many believe that therapeutic procedures and the emerging field of "theranostics" is the future of nuclear medicine practice. For this reason, allowing other physicians to perform nuclear

medicine procedures—thereby taking these procedures away from qualified nuclear medicine practitioners—would be counterproductive as well as potentially unsafe.

We understand that the proposal is motivated in all respects by money. Drug companies want to sell as many doses of their new pricey drugs as quickly as possible, so of course they want as many administration sites as possible. Practitioners from various branches of medicine see an opportunity to profit by cutting out nuclear medicine physicians and administering radiopharmaceutical therapies themselves, whether or not they are qualified. Finally, the NRC itself, which is supported by licensing fees, has an interest in licensing as many Authorized Users as possible. While these motivations are understandable, for the NRC to allow therapeutic radiopharmaceutical administration—where the stakes and risks are highest—by occasional users who are only quasi-qualified and not fully trained in radioactive material safety and use would be a huge mistake which would imperil safe and appropriate use of radioactive materials and the future of the nuclear medicine specialty itself.

Thank you for your consideration,

A handwritten signature in black ink, appearing to read 'T. Manzone', with a stylized flourish at the end.

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