UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 13, 2018

Dr. Carol S. Marcus
1877 Comstock Avenue
Los Angeles, CA 90025-5014

Dr. Marcus:

I am writing in response to your letter to Irene Wu and Maryann Ayoade of my staff, dated April 30, 2018. Thank you for sharing your perspectives on the training and experience (T&E) requirements for use of unsealed byproduct material in medical applications. As you know, we are currently evaluating these requirements—particularly whether and how tailored training requirements could be established for different categories of radiopharmaceuticals—in response to direction from the Commission. I can assure you that we plan extensive stakeholder outreach before we would recommend to the Commission any changes in the regulations. This outreach will include medical professional societies, such as the Society of Nuclear Medicine and Molecular Imaging, medical specialty boards, universities with nuclear medicine programs, and medical licensees. I would like to offer a perspective in response to a few of the concerns that you shared in your letter.

First, you commented on the length of the time provided for stakeholders to respond to our questionnaire on the evaluation of tailored T&E requirements for different categories of radiopharmaceuticals. Both the scope and time provided to respond to the subject questionnaire were limited given the early stage of our evaluation and the focused scope of this initial outreach effort. We plan extensive stakeholder interactions if we conclude it is feasible to tailor T&E requirements, particularly to solicit feedback on various approaches.

You also commented on the population of external stakeholders that we distributed the questionnaire to as part of this initial outreach. At this early stage, we requested feedback from a small, but representative, sample of stakeholders. These stakeholders included medical organizations such as the American Society for Radiation Oncology, the American Board of Nuclear Medicine, and the Council on Radionuclides and Radiopharmaceuticals, Incorporated. We also reached out to five medical licensees, selected to represent a variety of sizes of medical facilities in different areas of the country. We also sought input from the Commonwealth of Virginia, to gain another regulator's perspective, as well as a number of Army and Navy medical centers, to solicit feedback from Federal organizations that are subject to the T&E requirements. These stakeholders provided valuable input for the staff to consider as we develop our outreach plans going forward.

In addition, you expressed concern that the NRC does not enforce its current T&E requirements for authorized users (AUs). License reviewers for both the NRC and Agreement State regulators verify that AUs meet the T&E requirements in their respective regulations before adding the AUs to a license. The associated documents can also be examined during routine inspections of the licensees.

You also expressed concern that the NRC is not competent in nuclear medicine. To support our regulatory activities, we have multiple medical and health physicists on staff, and we frequently consult with the Advisory Committee on the Medical Uses of Isotopes, which provides substantial expertise from the medical community. You correctly pointed out that currently there are no kits or generators for therapy radiopharmaceuticals that practicing physicians can acquire. We included the possibility of radiopharmaceuticals that require kit preparation in our list of topics given that such a method could be used in the preparation of future therapeutic radiopharmaceuticals.

Finally, you expressed concern that that the NRC's program is dangerous to patients because it allows non-board certified Nuclear Medicine physicians to administer radiopharmaceuticals. The AUs must meet the NRC's T&E requirements in order to administer radiopharmaceuticals. In your letter, you indicated that the NRC's approval of additional AUs results in the NRC collecting additional fees. Increasing the number of AUs on a license does not result in additional fees being collected by the NRC. The NRC's focus is on safety and security of regulated activities. The costs to licensees are considered in the regulatory analysis that would accompany any potential rule change.

We are confident that the regulations developed, and licensing and oversight conducted by the NRC and Agreement States, ensure safety and security of all medical uses of byproduct material. We take concerns expressed by external stakeholders seriously, and as such, we have forwarded your concerns to the NRC's Office of the Inspector General for its evaluation.

If you have any further questions or concerns, please feel free to contact me by e-mail at Marc.Dapas@nrc.gov, or by phone at (301) 415-0595.

Sincerely,

/RA/

Marc L. Dapas, Director
Office of Nuclear Material Safety
and Safeguards

SUBJECT: RESPONSE LETTER TO DR. CAROL MARCUS
DATE: June 13, 2018

DISTRIBUTION:
M. Dapas, NMSS
S. Moore, NMSS
A. Kock, MSST
D. Bollock, MSST

ML18129A086 (P) ML18151A949 (L)

OFC	NMSS/MSST	NMSS/MSST	NMSS	NMSS
NAME	DBollock	TClark	Tech Ed	MDapas
DATE	5/31/18	6/01/18	6/4/18	6/13/18

OFFICIAL RECORD COPY