# PUBLIC SUBMISSION

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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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## Submitter Information



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## General Comment

See attached file(s)

## Attachments

Comments for NRC

To whom it might concern:

My opinions, stated below, are based on almost 40 years of experience as an academic Nuclear Medicine physician, as well as experience in obtaining a PhD degree in biophysics with an emphasis in normal tissue radiation injury. I am currently Professor of Radiology, Director of Nuclear Medicine at the University of Iowa and am a past President of the Society of Nuclear Medicine and Molecular Imaging. I am an AU and have personal experience and extensive expertise in all radiopharmaceuticals used for therapy.

My answers to the questions are below in **bold**.

*A. Tailored Training & Experience Requirements*

*A1. Are the current pathways for obtaining AU status reasonable and accessible?*
**The current pathway for obtaining AU status for Nuclear Medicine ABNM-certified physicians is completely reasonable and accessible, since all residents get repeated experience in parenteral therapy during the residency training. Such experience will almost certainly increase as more parenteral therapy is offered in the near future as new agents become available.**

**The current pathway for obtaining AU status for Radiation Oncology ABR-certified physicians is also reasonable and accessible, these residents get repeated experience in treating patients with high-dose radiation and with I-131. Parenteral radiolabeled therapy experience will almost certainly increase as more parenteral therapy is offered in the near future as new agents become available.**

**The current pathway for obtaining AU status for Radiology ABR-certified physicians with one or more extra years of nuclear medicine training is also reasonable and accessible, and completely adequate.**

**The current pathway for obtaining AU status for Radiology ABR-certified physicians <u>without</u> one or more extra years of nuclear medicine training is <u>inadequate</u>. These people only have 4 months of training in basic nuclear medicine and have participated in 3 administrations of low-dose radio-iodine and 3 administrations of high-dose radio-iodine. Most have never seen parenteral administration, with the exception of Y-90 microspheres for liver metastases.**

*2. Are the current pathways for obtaining AU status adequate for protecting public health and safety?*
**The current pathways for Nuclear Medicine, Radiation Oncologists, and Radiologists with extra Nuclear Medicine training are completely adequate for protecting public safety, as explained above. However, Radiologists with minimal Nuclear Medicine training are not.**

*3. Should the NRC develop a new tailored T&E pathway for these physicians?*
**No. There are sufficient numbers of Nuclear Medicine physicians and Radiation Oncologists to provide the administration of parenteral radionuclide therapy and necessary follow-up these patients. The specialty societies, SNMMI and ASTRO are developing training programs for nuclear medicine physicians and radiation oncologists to assure they have all the necessary skills. Such training programs will build on the extensive experience these physicians will already have in radiation safety and in managing patients who have been injected with radionuclides.**

*4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?*
**If such a pathway were to be offered, it would have to be fairly rigorous, with an understanding of radiobiology, radiation safety, and the management of patients who have been treated with targeted radioactive agents. Such an experience might be obtained in a busy center in about 3 months.**

*5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?*
**See my answer to #4 above.**

*B. NRC's Recognition of Medical Specialty Boards*
*1. What boards other than those already recognized by the NRC could be considered for recognition for medical uses under 10 CFR 35.300?*
**No other boards are appropriate.**

*2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?*
**The board recognition criteria are adequate, except for the radiologists who have had minimal training in nuclear medicine.**

*C. Patient Access*
*1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300?*
**No.**

*2. Are there certain geographic areas with an inadequate number of AUs?*
**No.**

*3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals*
**No.**

*4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine?*
**No.**

*D. Other Suggested Changes to the T&E Regulations*
*1. Should the NRC regulate the T&E of physicians for medical uses?*
**Yes. The NRC should continue to regulate the T&E for physicians that administer radioactive drugs to patients.**

*2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?*
**No.**

*3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?*
**As the use of targeted radioactive drugs increases, there will be a shift to increased use of quantitative dosimetry. Training requirements will need to be changed once this becomes common practice. The NRC should monitor the field and may need to modify regulations as medical practice evolves.**