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## General Comment

See attached file(s)

## Attachments

JWF NRN Comments

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Dear Sir/Madam:

I am writing to express my concerns about the liberalizing of the Training and Experience Requirements for Different Categories of Radiopharmaceuticals.

As background, I am board certified by the American Board of Nuclear Medicine, American Board of Radiology with Special Competence in Nuclear Radiology and Certified in Nuclear Cardiology. At the University of Minnesota, I am the program director of the ACGME Nuclear Radiology fellowship, Nuclear Radiology section director of the ACGME Residency in Diagnostic Radiology, Program section Director of Nuclear Cardiology part of ACGME Cardiology Fellowship and Board member and faculty of the Medical Physics training program. I am on the University of Minnesota's radioactive safety committee (University Broad License) and the radioactive subcommittee of the IRB and Medical Center and have experience as an RSO. As the director of nuclear medicine and molecular imaging in a multifacility healthcare system I have a broad exposure handling radioactive materials, experience in training and attesting for various physicians in nuclear medicine, and overall knowledge and wisdom.

In my 35+ years of teaching and responsibility in Nuclear Medicine I have had the opportunity to see the "the good, the bad and of ugly" of handling radioactivity and managing patients, families and the public. Reviewing the materials for this "Public Comments Request" it contains the portrayal of the easy and uncomplicated administration of a radioactive drug. It is easy to focus on the uncomplicated administration but this is not where safety and complications reside. Dealing with dose calculations in complex medical conditions, answering questions for the patient, family, relatives, employers, etc., correcting the misinformation so prevalent in the internet and read by the patient and their family, addressing the questions of nurses and caregivers in the hospital, managing care givers whom are pregnant, dealing with radioactive alarms at public places (i.e., sporting events and public transportation) after giving a patient a radioactive drug or test, handling the body fluids from a radioactive patients, calculating occupancy factors before patients are allowed to be transported home and to return to their home with other occupants, dealing with hotels after some physicians sent their high dose patients (i.e., iodine 131) to recover, etc. is only part of the "bad and ugly" side of practicing nuclear medicine / radiology which has been glossed over by those who may be motivated by financial interests in facilitating lesser trained individuals being allowed to administer radioactive drugs. The following stories are presented to illustrate why we need better and not lesser trained professionals handling radiopharmaceuticals.



This document was electronically signed by Dr. Jerry W. Froelich, M.D.

The practice of physicians sending radioactive patients to hotels to recover because the patient or their family is uncomfortable with the patient being in the home should be a felony violation. The patient is frequently instructed not to disclose that they are radioactive and they should use room service for a day or two does not mitigate the overall contamination of the room, bathroom, linens, dishes, etc. This practice is appalling because I frequently see young females of reproductive age cleaning the rooms and they are extremely vulnerable. Is this practice due to ignorance or malice?

I have copies of lecture notes from "nuclear" endocrinologists who profess to train an endocrinologist in a weekend course to safely handle and administer $I^{123}$, $Tc^{99}$m-pertechnitate and $I^{131}$. I see cardiologists more interested in how many patients then can get through a gamma camera in any given day and not the radiation burden to the patient. Here is an all too common situation; not long ago I uncovered the following procedures in one of the largest cardiology groups in Minneapolis who performed Nuclear Cardiology. They performed a two-day stress protocol where on day one they had 10-15 patients show up for their examination and give each 75 mci of $Tc^{99}$m-MIBI to scan as fast as possible. When the patients returned for the rest study they were given another 75 mci of MIBI and scanned. The international Society standards state that no patient should receive more the 50 mci for a complete MIBI stress study. If I had not reported this practice to the Minnesota Department of Health, who intervened, this practice might not have changed. I have watched Cardiology Attestation Mills for years and was angered that untrained individuals were taking care of patients without proper training in radiation safety and radiobiology.

I have watched Diagnostic Radiology training requirements being watered down with residents training in nuclear medicine / radiology (clinical, physics and safety) being shortened. Few resident's think that nuclear medicine will actually be part of their practice when they leave residency and their goal is to pass their examinations. I have observed that the radiologists focus on nuclear medicine frequently develop years after training when their group requires them to participate in nuclear medicine reads, I am concerned that their usable knowledge of radiation safety is forgotten or out of date.

Interventional radiology serves as a good example as to the correct and incorrect way to manage radioactivity. The $Y^{90}$-Sphere companies are incentivized to sell product and they tell the IR physicians that with an onsite proctor and a few cases they can learn to administer $Y^{90}$-spheres and get added to the radioactive materials license to administer these drugs to patients. My observation of this practice does not contain training or refreshing in radiation safety. A number of sites do everything in IR while other sites may not be equipped and staffed for radiation issues (i.e., spills and other contamination). We have setup a comprehensive program which utilizes the skills and expertise of the different divisions (IR to administer, Nuclear Medicine to manage dose safety, calculations of dosimetry, shunting, total dose, etc. and the Radiation Safety Department (RSO) oversite) to guarantee proper procedures and ultimate safety to patients, family, caregivers and the public.

I practice in the rural upper Midwest and patients have accessibility to advanced nuclear diagnostic and therapeutic agents. As long as the agent is FDA approved, accepted by CMS and deliverable to the region, patients have access to all materials in a safe environment which also address' the concerns of families, caregivers and the public.

In conclusion, the NRC should not be liberalizing the requirements for managing radioactive materials, they should be assuring Americans that mechanisms are in place to protect patients, families, caregivers, the public, etc. It is said that amateurs' practice until they do it right while professionals' practice until they cannot do it wrong. It takes years to become a professional and there appear to be too many amateurs' practicing nuclear medicine today while we need to be sure that only professionals are allowed to practice nuclear medicine.