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July 3, 2019

Honorable Kristine Svinicki, Chairman
U.S. Nuclear Regulatory Commission
Office of Administration, Mail Stop: TWFN–7–A60M
Washington, DC 20555–0001
ATTN: Program Management, Announcements and Editing Staff
Re: Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive, Section 10 CFR Part 35.390(b)

Dear Chairman Svinicki:

We value and thank the United States Nuclear Regulatory Commission (NRC) for its history as a strong partner in helping to provide high quality healthcare with consistent high standards for patient safety and public health and public safety. Physicians, patients and the general public all depend upon the careful consideration and judgement and evaluation of the facts of this body when making decisions which affect the safe and effective delivery of medical care using radioisotopes while simultaneously overseeing public safety.

Regarding the current draft approaches for changing the education and training requirements for authorized users of radiopharmaceutical (AUs), we recommend, in the strongest terms possible, that the United States Nuclear Regulatory Commission consider *only one choice* for the training and experience requirements for AUs—that is **"'Status Quo'... no changes to the current T&E requirements for radiopharmaceuticals requiring a written directive under 10 CFR 35.300."**

The physicians of the United States have spoken with one united voice on this issue. During the Annual Meeting of the American Medical Association (AMA), on June 11, 2019, the House of Delegates expressed its concern regarding the draft approaches for changing the education and training requirements for authorized users of radiopharmaceutical (AUs).

The American Medical Association (AMA), the largest association of medical doctors, physicians and medical students in the United States, representing approximately a quarter of a million doctors, voted to oppose any changes to the current requirements. The AMA House of Delegates is composed of physician delegates, representing all 50 state medical societies, all specialties and representative subspecialties of medicine and nearly every established national medical specialty society.

Specifically, of the four options under consideration by the NRC, the American Medical Association (AMA) supports only option A, "Status Quo." The AMA's "House of Medicine" received only supportive testimony for this option and received only negative testimony for other options.

Authorized Users of Radiopharmaceuticals (AUs) serve multiple simultaneous important functions. Highly trained and knowledgeable AUs are not only essential for quality patient diagnosis and therapy, but also are vital for the protection of the public. AUs are responsible for the development of standard operating procedures for the procurement, safe preparation and storage, and proper use and disposal of all radioisotopes. They are therefore comprehensively responsible to the patient, the patient's family members, the AU's co-workers, other hospital personnel and patients, and they also serve as the safeguards for the welfare of the public.

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Any deficiency or short-cutting of training or experience which could compromise the rigorous attention to detail necessary for these important tests and therapies could not only affect the patient being studied or treated, but could also put at risk the technologists and other affiliated medical professionals and staff at a hospital or clinic in addition to endangering the general public.

We also continually advocate that an appropriately trained physician be positioned at the center of patient care and thus directing all patient therapies. We would be adamantly opposed to any consideration that employs a strategy for radionuclide use that employs any protocol where a non-physician would be in charge of any critical aspect of the procedure. For optimal patient and public safety, the physician Authorized User should possess the complete and comprehensive training to oversee all aspects of all medical uses of radioisotopes.

To re-emphasize the above, we urge the United States Nuclear Regulatory Commission to consider *only one choice* for the training and experience requirements for AUs—that is "'Status Quo'… No changes or modifications to the current T&E requirements for radiopharmaceuticals requiring a written directive under 10 CFR 35.300."

We would also like to provide answers to the questions posed for this consideration.

• ***Question 1:*** **If the "Status Quo" is maintained, how should the NRC ready itself for the expected increase in number and complexity of future radiopharmaceuticals?**

The answer to this question lies in the examination of the underlying incorrect assumptions within the expressed concern over the number of AUs as well as to review the history of how the radiologic and nuclear medicine physicians and physician training institutions and organizations have responded to the ever-changing fields of imaging diagnosis and therapies and the manner in which they have met these challenges throughout the history of these specialties.

First of all, there is no current shortage of AUs, and there is no projectable shortage of AUs in the future. The current supply of qualified Authorized Users of Radiopharmaceuticals is, by any reasonable estimation, inexhaustible. All physicians trained in two of the 24 American Board of Medical Specialties (ABMS) designated specialties certified by the American Board of Nuclear Medicine and the American Board of Radiology have already been fully trained to function as AUs. Specifically, this is everyone who has completed, or who will be completing, a residency training program in Diagnostic Radiology or Nuclear Medicine or Radiation Oncology.

According to statistics provided by the America College of Radiology, the number of new qualified Authorized Users completing residency programs in these three training programs nationwide, just in June of this year, was 1,579. According to statista.com, there are currently 47,828 diagnostic radiologists in the United States, making it the fifth largest medical specialty. This number does not include the many thousands of additional radiation oncologists and nuclear physicians. The number of well-trained, qualified, potential authorized users is vast.

The specialty of Nuclear Physician deserves special mention in this context. Nuclear Medicine Residency training programs are designed to be specifically ultra-focused programs for the training of specialists in nuclear medicine, the graduates of which are known as Nuclear Physicians. These residencies have been

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overproducing Nuclear Physicians for decades in long anticipation of the time when clinical nuclear medicine imaging and therapies would proliferate. Every year the number of graduates from these programs well exceeds the job openings. There are hundreds of these specially trained nuclear medicine experts potentially awaiting job openings in their chosen profession. Now that these days are imminent, this group of physicians stands especially prepared to help deliver the newly approved and expected future approvals of therapeutic and theranostic agents.

The United States Nuclear Regulatory Commission should not be lessening the training and experience requirements for existing or new radiopharmaceuticals. The moment when the field is becoming more complex is precisely the moment when we should remain vigilant and consistent regarding the training and experience requirements. For these reasons, we, and the AMA, advocate for the choice of "Status Quo."

The physicians in Diagnostic Radiology and Nuclear Medicine and Radiation Oncology, with their extensive and in-depth training in all types of imaging and nuclear medicine, have constantly navigated the ever-changing field of diagnostic imaging and imaging-related therapies. Over the past years and decades, there have been continual changes in and advances in patient care utilizing imaging modalities. Technological advancements in Computed Tomography (CT), and Magnetic Resonance Imaging (MRI) and Ultrasound imaging have resulted in numerous new ways to identify, diagnose and treat diseases.

For example, the utilization of CT and MRI and ultrasound has notably escalated over the past decades. This is largely due to the multiple quantum shifts in the speed and imaging resolution of these machines. The improvements in these imaging modalities have also changed the way in which biopsies of almost all organs and tumors are performed, usually with the utilization of CT, or ultrasound or MRI directed guidance of these procedures. During this same time period, the need and demand for plain x-ray radiography and diagnostic fluoroscopy has significantly decreased.

It is the nature of the specialty of Diagnostic Radiology to continually adapt to these new realities. Radiologists and radiology groups constantly update the way they practice in order to meet the changing needs of patients and their ordering physicians. These changes are expected and anticipated.

It will occur likewise regarding the new expected increase in number and complexity of future radiopharmaceuticals; the groups of imaging and therapy professionals will make the necessary adjustments in imaging and therapy personal to meet the needs of our patients and ordering physicians, just as they have always done with the other new technologies and image-guided therapies. There does not, *and should not*, be a lessening of the training and experience requirements for these radiopharmaceuticals.

• ***Question 2:*** **Is there a challenge with the current T&E requirements—such as concerns regarding patient access to radiopharmaceuticals—that should be addressed through a rulemaking?"**

We do not see the development of these new promising radiopharmaceutical agents as posing any new challenge to patient care or access. As detailed above in the answer to Question 1, the community of specialists in diagnostic radiology and nuclear medicine and radiation oncology stand ready to take care of America's patients with new and emerging radiopharmaceuticals. We oppose any alteration to the tailoring training and experience based on categories of radiopharmaceuticals in favor of maintaining the

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highest quality standard of utilizing authorized users who are completely trained in the handling and administration of all types of medical radioisotopes.

Delegates of the American Medical Association (AMA) spoke last week emphasizing that they welcome the expected increase in number and complexity of future radiopharmaceuticals to treat the patients throughout the United States. The NRC need do nothing additional to ready our physicians for this progress in patient care. The current fully trained individuals qualified as authorized users, and those in training to be future AUs, will be the best and most qualified physicians for the development of new respective patient safety and general public safety guidelines for new and emerging radiopharmaceuticals. This process is one that occurs naturally and continually in academic nuclear medicine circles.

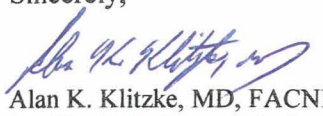
As is the case with the introduction of any new medical or surgical therapy, access to the new treatment is not universally uniform from the outset. The introduction of the new treatment or diagnostic test tends to occur first at large hospitals and academic centers and then spread to community hospitals and clinics from there. Medical imaging and therapy seem to show a more rapid history of market saturation than do new surgical treatments and procedure algorithms. It should be expected that new radiopharmaceutical imaging and therapeutic agents would assume similar natural market saturation over a similar relatively short predictable period of time.

Whenever novel treatments become available, there are outset periods when patients desiring such medical treatments must travel greater distances than average for these services than for established types of care. We do not believe that lessening or changing the training or education requirements for Authorized Users would do anything to upgrade that reality, with patient outcome in mind. There is always awareness and drive to try to provide better medical care access to more rural portions of the country, where travel for medical care can be significant. We consistently stand opposed to mechanisms which would endeavor to provide medical care to portions of the country by individuals with lesser degrees of training or experience than the national accepted standards for that care. The potential provision of less trained and educated individuals to more underserved areas would only serve to provide a lesser standard of care and to endanger these patients and general public communities in which they live and work. All patients deserve the same standard of care and safety.

In summary, we, along with the American Medical Association, the largest association of medical doctors, physicians and medical students in the United States, strongly advocate that the United States Nuclear Regulatory Commission leave the training and education requirements for authorized users of radiopharmaceutical (AUs) as "Status Quo."

Thank you for your time and attention to this important matter for our patients and for our public safety.

Sincerely,



Alan K. Klitzke, MD, FACNM
Staff Radiologist and Nuclear Physician
Roswell Park Comprehensive Cancer Center, Buffalo, NY
Past President, American College of Nuclear Medicine
Past President, Society of Nuclear Medicine & Molecular Imaging Eastern Great Lakes Chapter
Assistant Professor of Oncology, Roswell Park Comprehensive Cancer Center
Assistant Professor of Radiology and Nuclear Medicine, SUNY Buffalo

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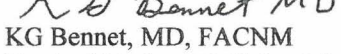
Thomas A. Hope, MD
Associate Professor in Residence
Department of Radiology and Biomedical Imaging, University of California, San Francisco



KG Bennet, MD, FACNM
Head of Nuclear Medicine, Elmhurst Memorial Hospital
Past President, American College of Nuclear Medicine

Mark Tulchinsky, MD, FACNM, FSNMMI, CCD
Professor of Radiology and Medicine
Associate Director, Nuclear Medicine, Penn State University
Milton S. Hershey Medical Center, Hershey, PA

Andrew Quon, M.D.
Professor, Department of Molecular and Medical Pharmacology
Division of Nuclear Medicine
David Geffen School of Medicine at UCLA

Robert S. Miletich, MD, PhD, FAAAS
Chair, University at Buffalo Faculty Senate
Professor and Chair and Residency Program Director
Department of Nuclear Medicine
Jacobs School of Medicine and Biomedical Sciences, SUNY Buffalo

Hossein Jadvar, MD, PhD, MPH, MBA, FACNM, FSNMMI
Associate Professor of Radiology (tenure), Keck School of Medicine of the University of Southern California
Associate Professor of Biomedical Engineering, Viterbi School of Engineering of USC
Past President, American College of Nuclear Medicine
Past President, Society of Nuclear Medicine and Molecular Imaging
Distinguished Investigator, Academy of Radiology and Biomedical Imaging Research

Christopher Gribbin, MD
Clinical Associate Professor of Radiology
Rutgers Robert Wood Johnson Medical School
Past President, Medical Society of New Jersey

Giuseppe Esposito, MD, MBA
Professor of Radiology
Chief of Nuclear Medicine, Medstar Georgetown University Hospital
Washington, DC 20007

Mark J. Adams, MD, MBA, FACR
Professor and Associate Chair of Imaging Sciences
University of Rochester Medical Center

Bital Savir-Baruch, MD
Assistant Professor of Radiology
Department of Radiology, Division of Nuclear Medicine
Loyola University Medical Center, IL

Bonnie Litvack, MD, FACR
Medical Director, Women's Imaging Center
Northern Westchester Hospital
Past President, New York State Radiological Society
President-Elect, Medical Society of the State of New York

Yang Lu, MD, PhD
Associate Professor, Medical Director, Clinical Nuclear Medicine
Department of Nuclear Medicine
MD Anderson Cancer Center

Ankit Agarwal, MD, MBA
PGY-4, Radiation Oncology, UNC Health Care
ARRO Executive Committee, Vice-Chair

Gregory C. Ravizzini, MD
Associate Professor, Department of Nuclear Medicine
Medical Director (Ad Int), Center for Advanced Biomedical Imaging
MD Anderson Cancer Center, Houston, TX

Gary L Dillehay, MD, FACNM, FACR, FSNMMI
Professor of Radiology
Director of Nuclear Medicine, Northwestern Memorial Hospital, Chicago, IL
Past President, American College of Nuclear Medicine
Past President, Society of Nuclear Medicine and Molecular Imaging

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Todd M. Hertzberg, MD
Women's Imaging & Radiology/Medical Consulting
3-J Imaging, PC, 441 Hartwood Trail
Pittsburgh, PA 15238

Patrick M. Colletti, MD, FACNM, FSNNMI
Professor of Radiology
Keck School of Medicine of USC
Past President, American College of Nuclear Medicine

Richard S Pieters, MD, Med
Professor of Radiation Oncology and Pediatrics
University of Massachusetts Medical School

Benjamin Franc, MD, MS, MBA
Clinical Professor of Radiology
Nuclear Medicine Section
Stanford University School of Medicine

Twyla B. Bartel, DO, MBA, FACNM
Co-Owner, Global Advanced Imaging, PLLC
Little Rock, AR 72223
Past President, American College of Nuclear Medicine

Sheila Rege, MD, FACRO
Radiation oncologist
Washington State

Ryan Niederkohr, MD
Chair of Nuclear Medicine
Permanente Medicine - The Permanente Medical Group
Kaiser Permanente, Northern California Region
President, SNMMI PET Center of Excellence

Olga P. Molchanova-Cook, MD PhD
Chief of Nuclear Medicine and Body Imaging
Imaging Associates of New Mexico
Las Cruces, NM

Samuel Mahgerefteh, MD
President, Nuclear Medicine Resident Organization
American College of Nuclear Medicine

Robert Jaffe, MD
Diplomats ABNM, ABR
University Radiology
AU, RWJ Somerset Medical Center

Thomas M Anderson, MD, FACR
Diplómate: ABR, ABNM
Professor of Clinical Radiology
University of Illinois at Chicago

Mohamed K. Khan, MD, PhD, MBA
Division Chief of Radiation Oncology
Banner MD Anderson ~~Cancer~~ Center – Service Line
Adjunct Professor Radiation Oncology, University of Texas- MD Anderson Cancer Center
Gilbert, AZ 85234

Murray D. Becker, MD, PhD, FACR
Associate Clinical Professor of Radiology
Rutgers Robert Wood Johnson School of Medicine

Hongming Zhuang, MD, PhD, FACNM
Professor of Radiology, Perelman School of Medicine the University of Pennsylvania
Chief of Division of Nuclear Medicine and Director of PET/CT
The Children's Hospital of Philadelphia

Bruce J. Barron MD, MHA, FACNM
Professor of Radiology
Emory University

Jeffrey S. Kempf, MD, FACR
Chief, Nuclear Radiology, Robert Wood Johnson University Hospital
Program Director, Rutgers RWJMS, Diagnostic Radiology Residency, ESIR, and Nuclear Radiology
Clinical Associate Professor of Radiology, Rutgers, Robert Wood Johnson Medical School
New Brunswick, NJ 08901

Dennis Galinsky, MD, FACR, FACRO
Radiation Oncologist
Chicago, IL

Cory P. Daignault, MD
Staff Nuclear Radiologist
Radiation Safety Officer
Minneapolis VA Medical Center
Adjunct Assistant Professor of Radiology University of Minnesota

Anca M. Avram, MD, FACNM
Professor of Radiology
Director, Nuclear Medicine Therapy Clinic
University of Michigan Medical Center

Aria Razmaria, MD, MSc
Nuclear Medicine
UCLA Medical Center

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Martin Allen-Auerbach, MD
Medical Director
UCLA Nuclear Medicine

Daniel H. Silverman, MD, PhD
Professor, Molecular and Medical Pharmacology, UCLA
Past President, Society of Nuclear Medicine, Pacific Southwest Chapter

Denise D Collins MD FACR
Henry Ford Health System
Vice Chair Radiology
Chief Radiology at HFWBH
Section of Pediatric Radiology

Ermelinda Bonaccio, MD
Chair, Diagnostic Radiology
Roswell Park Comprehensive Cancer Center
Buffalo, NY 14263

Simin Dadparvar, MD, FACNM
Professor of Radiology
Temple university hospital
Philadelphia, PA 19140

David Ng, MD, FACNM, FACP
Nuclear Medicine Department
Kaiser Permanente Sacramento

Steven Wang, MD, MBA
Chief of Service, Radiology
Kern County Kaiser Permanente

Jeremie Calais MD
Assistant Professor
UCLA Nuclear Medicine and Theranostics

Lesley Flynt, MD

Carl Odom, MD, MS

Alan Klifeke, MD FACNP
83 Bryant St, #5A
Buffalo, NY 14209

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