July 31, 2018

Christopher Palestro, M.D.
Chair, Advisory Committee on the Medical Uses of Isotopes
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Dr. Palestro:

The ABNM has reviewed the February 19, 2018 draft report of the ACMUI Subcommittee on Training and Experience Requirements for All Modalities regarding the current NRC requirements for 700 hours of supervised training and experience for Authorized Users (AUs) of radioactive materials under 10 CFR 35.390 – Training for use of unsealed byproduct material for which a written directive is required. The Subcommittee is considering whether the 700 hour training requirement decreases patient access to alpha and beta emitting therapeutic radiopharmaceuticals, and whether it should recommend changes for the total number of hours of training & experience that is required.

The Subcommittee draft interim report states there are two reasons for reasonable concern for a near-future decline in patient access to care: (1) U.S. Food and Drug Administration’s approval of $^{177}$Lu dotatate for treatment of certain neuroendocrine tumors, and (2) the decrease in the number of first-time candidates sitting for the Certification Examination of the American Board of Nuclear Medicine.

The ABNM welcomes the FDA-approval mentioned above and supports efforts to bring more targeted radionuclide therapies to patients in the U.S.; however, the ABNM strongly believes that the current requirement for 700 hours of supervised training and experience should not be changed and that reducing the minimum requirement for 700 hours of supervised training and experience for unsealed radioisotope therapy raises concern for patient safety. The decrease in the number of nuclear medicine or nuclear radiology qualified AUs is likely overestimated in the Subcommittee draft interim report. The need for fact-driven evaluation before any action was also endorsed by the American College of Radiology (ACR) in comments to the NRC ACMUI sent on July 16. The ABNM fully supports the ACR statement.

The number of initial ABNM certificates issued each year has been relatively constant from 1977 – 2015. The average number of certificates issued each year was 72 during this time (range 50 – 107). The ABNM issued 43 initial certificates in 2016, and 49 certificates in 2017. No data is available for 2018 since the certification examination will not be given until October.
ABNM Letter to ACMUI on Training and Experience

The ABNM has issued a total of 5,744 certificates since the board was incorporated in 1971. There are at least 3,591 active diplomates (not deceased or retired) at the present time.

The Subcommittee draft interim report noted a decrease in the number of ACGME accredited Nuclear Medicine training programs and residents from 57 programs with 161 residents in academic year 2007 – 2008, to 41 programs with 75 residents in 2017 – 2018.

The decrease in the number of programs and trainees is partly due to an increase in the number of Nuclear Medicine physicians who are also certified in Diagnostic Radiology by the American Board of Radiology (ABR). Certification by the ABR decreases the duration of Nuclear Medicine training required for ABNM certification from 36 months to 16 months, creating the appearance of decreasing numbers of residents, when it is the duration of training that is decreasing. Contributing to this trend is the increasing availability of dual training pathways where residents training in Nuclear Medicine are counted as Diagnostic Radiology residents rather than Nuclear Medicine residents, due to the requirements of the ACGME and the ABR. At a recent professional meeting, the ABNM learned that there are at least 35 additional radiology residents engaged in a new program through the ABR aimed at additional qualification in nuclear radiology during the usual length of their diagnostic radiology residency.

The ABNM believes that dual training will result in better-trained physicians to meet the needs of patients in the era of molecular imaging and therapy. The ABNM sees no evidence that workforce issues have decreased patient access to care, and concern for potential future issues has not considered recent positive changes in Nuclear Medicine training. The popularity of the dual training pathways in Nuclear Medicine and Diagnostic Radiology is one of the reasons for the decline in the number of ACGME accredited Nuclear Medicine programs; however total number of residents is not reflected in a similar decline in number of ABNM certificates.

The ABNM urges the subcommittee to re-evaluate the initial estimates of AUs available and those in training to provide the needed services. We also request a re-review of the number of radiation oncology physicians in training as numbers quoted in the draft interim report were erroneously low.

In addition, targeted radionuclide therapies frequently require management by experts in multiple disciplines (surgery, radiation oncology, medical oncology, radiology, nuclear medicine) at centers of excellence; no shortage of AUs has been reported at such institutions. Finally, if the current number of AUs proves to be insufficient to make radionuclides widely available, we believe pursuing approaches to increase the number of properly trained nuclear medicine physicians, nuclear radiologists and radiation oncologists will be better for patient care than lowering the standards for administering radionuclide therapies.

Although the NRC does not oversee the insurance industry, we feel that a larger threat to patient access as compared to the number of AUs in the United States is insurance coverage. Reducing the minimum requirement for 700 hours of supervised training and experience for unsealed radioisotope therapy further jeopardizes patient safety because there is no standardized
assessment of the knowledge, skill and judgment of these physicians who are not certified by the ABNM, or certified by the ABR in the subspecialty of Nuclear Radiology.

In summary, the ABNM strongly believes that the current requirement for 700 hours of supervised training and experience should not be changed and asks the NRC correct the errors in the number of trainees, which we would expect could reduce or end the concern on the number of AUs available to provide these services.

Sincerely,

George M. Segall, M.D.
Executive Director

Daniel A. Pryma, M.D.
Chair

GMS/DAP/mrf