ABNM: New Requirements for Radiotherapy

George Segall, MD, ABNM Executive Director, and Leonie Gordon, MBChB, ABNM Associate Executive Director

The era of unsealed radionuclide therapy began in 1941 with the treatment of hyperthyroidism with sodium ^{131}I. Radionuclide therapy has been an important part of nuclear medicine practice since the founding of the American Board of Nuclear Medicine (ABNM) in 1971 and currently accounts for an average of 8% of ABNM diplomate practice hours. The ABNM periodically reevaluates radionuclide therapy requirements for initial certification. There has been an evolution of practice since the requirements were last changed in 2014, resulting in fewer radioiodine therapies for benign and malignant thyroid disorders and more parenteral therapies. The ABNM is, therefore, proposing to change the requirements, as summarized in Table 1.

In August of this year, the ABNM asked nuclear medicine training program directors for feedback on the proposal and received responses from the directors of all 38 Accreditation Council for Graduate Medical Education–accredited programs. Fifty-three percent supported the proposal in its entirety, and another 34% supported the proposal with reservations. One reservation was the concern that radioiodine therapies accounted for the majority of therapies at some hospitals and that lowering the minimum number of required therapies would lower standards of competency. Another reservation addressed training with at least 2 different approved FDG radiopharmaceuticals, given the limited number of U.S. Food and Drug Administration (FDA)–approved parenteral therapies used in routine practice at this time.

Four directors (10%) did not support the proposal, citing challenges in providing training opportunities for parenteral therapy resulting from the cost of the agents, limited or noncoverage by medical insurance companies, limited number of FDA-approved radiopharmaceuticals actually used in practice, treatment being performed at dedicated cancer centers, and treatment being performed in radiation oncology rather than nuclear medicine departments.

TABLE 1
ABNM Requirements. Radionuclide Therapy: Current and Proposed

Therapy	Current	Proposed
^{131}I ≤ 33 mCi (benign)	10–15	5+
^{131}I > 33 mCi (malignant)	10–15	5+
Parenteral	5	10+*
Total therapies	35	35

*At least 2 different FDA-approved radiopharmaceuticals, excluding ^{90}Y microspheres.

George M. Segall, MD

Leonie Gordon, MBChB

Suggestions regarding radioiodine therapies included raising the proposed minimum number above 10 (5 for benign plus 5 for malignant thyroid conditions), but a recent SNMMI survey of nuclear medicine program directors indicated that several programs were unable to meet current requirements for a minimum number of 20 radioiodine therapies (10 for benign plus 10 for malignant thyroid conditions). Suggestions regarding parenteral therapies included giving credit for ^{90}Y-microsphere ablation of liver tumors, but the Nuclear Regulatory Commission considers this treatment a form of manual brachytherapy, which is regulated under 10 CFR 35.1000, whereas other parenteral radiopharmaceuticals are considered to be drugs, regulated under 10 CFR 35.396. Another suggestion was to require 10 parenteral therapies with a minimum of 1 FDA-approved radiopharmaceutical (rather than 2) or not to change the requirements until the FDA approves more agents. A summary of the feedback received from nuclear medicine program directors, with ABNM responses, is available at http://ow.ly/WeDV30rgwvv.

Based on the feedback, the ABNM has decided that candidates for initial certification in 2021 and 2022 can fulfill the requirements by using the current criteria in effect since 2014 *or* by using the new criteria. The ABNM will require all candidates to submit a training record that includes dates of treatments, names of treating facilities, radiopharmaceuticals, and administered doses. Based on this information and the state of practice in 2022, the ABNM will reevaluate requirements for radionuclide therapy. The ABNM believes that the new criteria will improve resident training, give nuclear medicine program directors more flexibility in meeting ABNM requirements, and maintain high standards for the specialty.