

RESULTS OF THE EVALUATION OF TRAINING AND EXPERIENCE REQUIREMENTS FOR ADMINISTRATION OF RADIOPHARMACEUTICALS REQUIRING A WRITTEN DIRECTIVE

International Benchmarking

INTRODUCTION:

As part of the U.S. Nuclear Regulatory Commission (NRC) staff's evaluation of the training and experience (T&E) requirements for authorized users of radiopharmaceuticals under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material," Subpart E, "Unsealed Byproduct Material—Written Directive Required," the staff conducted regulatory research and outreach to the international community to understand what T&E is required internationally for physicians to use radiopharmaceuticals.

DISCUSSION:

The NRC staff conducted research and outreach to several countries and one international nuclear medicine society via a questionnaire (ADAMS Accession No. ML19252A116) that covered three main areas: (1) the regulatory framework for physicians that use radiopharmaceuticals; (2) the basic knowledge necessary for administering any type of radiopharmaceutical therapy; and (3) regulations for administering categories of radiopharmaceutical therapies. The questionnaire was transmitted via e-mail to the United Kingdom, Norway, Australia, Japan, Germany, Singapore, South Korea, and the European Association of Nuclear Medicine (EANM); the staff received responses from South Korea, Japan, Germany, and EANM.

The information below briefly summarizes the *medical* training physicians in some international countries must complete to use radiopharmaceuticals—generally, other countries do not separate out radiation safety training from the overall medical training required to use radiopharmaceuticals.

International Training Requirements for Physicians to Use Radiopharmaceuticals

Physicians worldwide using radiopharmaceuticals for diagnosis and therapy are generally physicians in the practice of nuclear medicine, but there is a large disparity in the training pathways available for physicians practicing nuclear medicine. The International Atomic Energy Agency (IAEA) concludes that the operating standards of the practice of nuclear medicine vary considerably from country to country and region to region due to the heterogeneous growth and development of nuclear medicine in the IAEA's member states.¹

Most countries in the European Union (EU) restrict the use of unsealed radioactive material to nuclear medicine physicians, while in some other countries, the use of unsealed radioactive material is authorized for other medical specialties.² Additionally, a double specialization may be acceptable in one EU country and prohibited in another.³ In most European countries, nuclear medicine is an independent specialty with a dedicated training program of four to mostly five years, and radiopharmaceutical therapy procedures can only be performed by fully certified nuclear medicine physicians.⁴ The training for nuclear medicine physicians includes both diagnostic and therapeutic procedures, with the European Union of Medical Specialists requiring

¹ *Nuclear Medicine Resources Manual, STI/PUB/1198*, International Atomic Energy Agency, 2006. Available at https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1198_web.pdf.

² *Nuclear Medicine Training in Europe: "All for One, One for All"*, Journal of Nuclear Medicine, 2017. Available at <http://jnm.snmjournals.org/content/58/12/1904>.

³ Ibid.

⁴ Ibid.

a minimum of four years of training, including at least 100 cases involving radiopharmaceutical therapy.⁵ Italy requires four years of training in nuclear medicine.⁶ Other countries like Germany, France, and Belgium require five years of training in nuclear medicine for radiopharmaceutical administrations.⁷

In Asia, Japan leads the practice of nuclear medicine and its development.⁸ But other countries, such as Mongolia, Myanmar, and Sri Lanka, do not have the resources to expand the practice of nuclear medicine.⁹ In its commitment to promoting nuclear medicine knowledge in Asia, the Asian Regional Cooperative Council for Nuclear Medicine has established the Asian Nuclear Medicine Board to address the growing disparity of the training and practice in nuclear medicine in Asia.¹⁰ Most Asian countries offer a three-year nuclear medicine residency program immediately after graduation from medical school; if the physician-in-training has had prior training in other clinical disciplines, then a two-year program in a nuclear medicine fellowship is required.¹¹

To be qualified to use radiopharmaceuticals in Japan, physicians must complete two years of post-graduate clinical training, followed by three years of general training at a training facility approved by the Japan Radiological Society, and complete a radiologist examination.¹² Following successful completion of that examination, a qualification in either radiotherapy or diagnostic radiology can be obtained by completing an additional two years of specialist training and successfully completing either the radiotherapist or the diagnostic radiologist examination.¹³ The Japanese Ministry of Health, Labor, and Welfare has oversight for the medical use of radiopharmaceuticals, and there are no regulations regarding training for physicians to use radiopharmaceuticals. However, the Ministry does require physicians take a training course on safety management guidelines for Iodine-131 and Radium-223 published by the Japanese Society of Nuclear Medicine.

In Australia and New Zealand, only nuclear medicine physician specialists can use radiopharmaceuticals. The practice of nuclear medicine is an advanced specialty consisting of a three-year advanced training program following a fellowship of either the Royal Australasian College of Physicians or the Royal Australian and New Zealand College of Radiologists.¹⁴ A

⁵ *Training Requirements for the Specialty of Nuclear Medicine, European Standards of Postgraduate Medical Specialist Training*, European Union of Medical Specialists, 2017. Available at http://uems.eanm.org/fileadmin/user_upload/UEMS_European_Training_Requirements__NUCMED_final_May17.pdf.

⁶ *Nuclear Medicine Training in Europe: "All for One, One for All"*, Journal of Nuclear Medicine, 2017. Available at <http://jnm.snmjournals.org/content/58/12/1904>.

⁷ Ibid.

⁸ *The Asian Nuclear Medicine Board (ANMB); Why Do We Need It?*, Asia Oceania Journal of Nuclear Medicine and Biology, 2013. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4927045/>.

⁹ Ibid.

¹⁰ Ibid.

¹¹ *Challenges of developing a pan-Asian curriculum: lessons for global nuclear medicine training*, Nuclear Medicine Communications, 2012. Available at https://journals.lww.com/nuclearmedicinecomm/Citation/2012/11000/Challenges_of_developing_a_pan_Asi_an_curriculum__1.aspx.

¹² Tokyo Medical and Dental University, *Diagnostic Radiology and Nuclear Medicine Education*. Available at <http://www.tmd.ac.jp/english/dept/medhospital/mrad/index.html>.

¹³ Ibid.

¹⁴ The Royal Australian and New Zealand College of Radiologists, *Nuclear Medicine Training*. Available at <https://www.ranzcr.com/trainees/clinical-radiology/nuclear-medicine-training>.

qualified medical practitioner must complete seven to eight years of training (fellowship and advanced training program) to become a nuclear medicine specialist.¹⁵

The Australian Radiation Protection and Nuclear Safety Agency's Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation establishes the regulatory requirements for the use of ionizing radiation in medicine, and sets forth that the Responsible Person ensure that a Radiation Management Plan is in place and addresses amongst other things, the training, qualifications and supervision of the staff of the medical facility—including nuclear medicine specialists—and their roles and responsibilities.¹⁶

CONCLUSION:

Feedback from South Korea, Japan, Germany, and the EANM, coupled with additional research by NRC staff indicates that in many international countries: (1) therapeutic radiopharmaceuticals are primarily used only by nuclear medicine specialty physicians, and the amount of specialty medical training required varies from country to country, (2) there are no regulations that specifically address radiation safety training requirements, and (3) there are no regulations that address training for different categories of radiopharmaceuticals.

¹⁵ Australasian Association of Nuclear Medicine Specialists, *Nuclear Medicine Specialty*. Available at https://www.aanms.org.au/index.php?option=com_content&view=article&id=8&Itemid=3.

¹⁶ *Radiation Protection in the Medical Applications of Ionizing Radiation, Radiation Protection Series Publication No. 14*, Australian Radiation Protection and Nuclear Safety Agency, 2008. Available at <https://www.arpansa.gov.au/sites/g/files/net3086/f/legacy/pubs/rps/rps14.pdf>.