

The Nuclear Medicine Technologist's Role in Theranostics: SNMMI-TS Advocacy's Vision

Running Title:

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Introduction

With the approval of Lu-177 PSMA-617, theranostics' presence in nuclear medicine is expanding beyond thyroid cancer and neuroendocrine tumors to higher-incidence diseases. This April (2022), the Journal of Nuclear Medicine (JNM) featured "Joint EANM, SNMMI and IAEA Enabling Guide: How to Set Up a Theranostics Centre."ⁱ The guide provided valuable information to enable interested stakeholders to safely initiate and operate theranostics centers. The article defined the theranostics concept as "using the same target for both imaging and therapy." That is also how we define the theranostics concept as Nuclear Medicine Technologists (NMTs) and SNMMI-Technologist Section (SNMMI-TS) Advocacy governance.

SNMMI-TS Advocacy Committee would now like to expand on that article to answer the following questions and cast a level of opinion on: What training does a nuclear medicine technologist (NMT) need to participate and complete theranostics? What does the SNMMI-TS Advocacy Committee feel are important initiatives to have NMTs fully engaged in theranostics today and in the long-term?

We hope the following article will serve as a springboard for theranostics considerations from the perspective of the NMT.

NMT Theranostics Training

What training does a nuclear medicine technologist need to have to administer and safely treat patients with theranostics?

The SNMMI-TS Advocacy Committee supports best practices in evidence-based science that promote the highest quality in patient care and safety by supporting standards for education and training for NMTs as defined by the Joint Review Committee on Educational Programs in Nuclear Medicine (JRCNMT). Currently, the nuclear medicine technologist is initially trained to get into the field by way of college, graduate school, or certificate curriculum, to gain their certification. After obtaining certification, the NMT must participate in continuing education annually to maintain their NMTCB (Nuclear Medicine Technology Certification Board) or ARRT (The American Registry of Radiologic Technologists) certification. That education is thorough and encompasses radionuclide therapy, including the handling of radiopharmaceuticals, adjunctive medications to support clinical nuclear medicine, and patient care management through capturing patient vitals, monitoring and pre and post procedure patient observation.

Most accredited programs are at the baccalaureate level, and some are converting to a master's level due to the complexity of the field and the volume of material that must be taught to perform nuclear medicine technology. Educational programs require extensive didactic education in the fundamentals of nuclear medicine, radiation biology, radiopharmaceuticals, and radiation physics. Additionally, clinical competency requirements must be successfully completed under the direct supervision of a qualified and certified practicing NMT. It would be extremely challenging to meet all these educational requirements via an apprenticeship model. As a point of reference in 2021, Arizona enacted a lawⁱⁱ that would allow some junior college programs to offer baccalaureate degrees due to the academic rigor and the number of required hours that a student must take (120 hours). Nuclear Medicine Technology was one such program, and as such students that graduate from a Nuclear Medicine associate's program in Arizona are now awarded a baccalaureate degree.

While current NMT training is inclusive of most of the components that go into theranostics *therapy* component of patient care, more training and competency would be helpful to be more competent to access patients' chest vascular ports, lead pre and post patient therapy management, and administration of therapy related adjunctive medications such as amino acids.

Why is radiation safety training so important, particularly in the context of theranostics?

With new technology and evolving radiotherapeutic therapies, it is important for medical professionals to continue to develop a comprehensive knowledge and understanding of radiation biology and safety. The misuse, overuse, and/or inappropriate handling of radiologic technology can be detrimental to both the patient and the NMT. Improper use of equipment can result in faulty images, which in turn, can lead to a misdiagnosis or false interpretation of patient conditions. To prepare knowledgeable, competent, and qualified professionals, the educational content and course competencies are expanding and becoming increasingly complex. Currently, SNMMI is in the process of publishing the 6th edition of the Nuclear Medicine Technology Competency-Based Curriculum Guide that outlines the radiation safety knowledge, skills and experience necessary for Nuclear Medicine Technologists and students to complete a JRCNMT certified program and be ready for the evolving theranostics field. The curriculum guide develops a competency-based education model that is necessary for students to demonstrate understanding of theranostics radiation safety. NMTs must be able to demonstrate and understand the safe handling of radiopharmaceuticals, practice aseptic technique, and the selection and use of proper radiation shielding devices.

The SNMMI is currently working on theranostics based badges that will be purchasable in 2023. The Molecular & Therapy Task force is heading the efforts to develop the theranostics badges which includes Xofigo, Lutathera, Azedra and more. The plan is also to have the badges be CEU based for NMT formal training. These badges do not take the place of certification but are more so a way to promote the field and the work NMTs do.

Radiation safety training plays an integral aspect of administering theranostics to ensure safety to the occupational workers, NMT and patient. The NMT must understand the radiation emission of the isotopes used in theranostics to select the correct means of following ALARA (as low as reasonably achievable). Selecting the correct shielding, means of delivery and proper distance from the patient are all considerations that come from proper training. In some theranostics administrations, proper preparation is key to minimize residual radioactivity exposure and contamination, i.e. prepping the bathroom on Lutathera administrations. For the NMT and ancillary staff, training from the vendor specific to therapy, and the knowledge acquired during school training is essential to ensuring the safety of all involved. In regard to Lutathera and even high-dose I-131 administrations, knowing how to handle emesis during & post-administration is also essential in conducting successful radiotherapy.

The Theranostics Care Team

Now is the time most critical to make sure that the nursing and nuclear medicine technologist groups work together to assure that we have enough healthcare providers to serve the growing population of

patients who are going to require theranostics treatments. The list of available theranostics today includes thyroid cancer, neuroendocrine tumors, prostate cancer; and this list will grow significantly with time, as other imaging-therapy radionuclide packages come to market. Just recently, an analysis from McKinsey and company found a potential shortage of 200,000 to 450,000 nurses not available for patient care in the short-term.ⁱⁱⁱ The same analysis mentioned that by 2025, there could be half a million shortage of nurses throughout the United States.

Today, our nursing partners play a pivotal collaborative role in the provision of theranostics therapy, where much of the patient management and appropriate adjunctive medications for therapy are administered by nurses. The shortfall of nurses puts a larger strain on our healthcare system and the provision of theranostics, as nurses may not be available to support the nuclear medicine technologists and authorized users to provide patients with this incredibly important therapy. Therefore, the SNMMI-TS Advocacy Committee feels that a focus on nuclear medicine technologist training and further evaluation and possible expansion of the Nuclear Medicine Technologist curriculum to include all components of theranostics is crucial. Furthermore, developing a collaborative training process with the nursing professionals is essential to make sure that theranostics will have enough healthcare personnel to provide this patient essential therapy, and NMTs can safely and effectively participate in all components of theranostics care delivery.

Another important member of the nuclear medicine care team is the Nuclear Medicine Advanced Associate (NMAA). The NMAA is a master's level and board certified professional that serves as a physician extender or mid-level provider with specialization in all areas of Nuclear Medicine. The NMAA performs duties and responsibilities in a manner consistent with our mission, values, guiding principles and AHA/NMTCB service standards within the scope of an NMAA practice.^{iv} In the theranostics setting (as in diagnostics), NMAAs work under the supervision of a licensed physician and serve as an adjunct between the physician and other healthcare professionals (including NMTs) to enhance patient care.

SNMMI-TS Advocacy Theranostics Future Plans

Engagement with the Nuclear Regulatory Commission (NRC) and The Joint Commission (TJC)

It is immensely important to SNMMI-TS and the nuclear medicine community that our regulators are aware of what theranostics is. For this reason, in the fall of 2021, the SNMMI-TS Advocacy Committee met with the U.S. Nuclear Regulatory Commission staff to refine language on the NRC webpage of what "nuclear medicine is and is not". On that same page, we proposed that the NRC include the following, under common nuclear medicine procedures: "Theranostics for targeted radioactive imaging and therapy for various cancers and diseases. Theranostics uses targeted imaging to tailor patient treatment."

Additionally, the SNMMI-TS Advocacy Committee embarked on a multi-year effort to oppose the further dilution of the training and experience (T&E) requirements for unsealed byproduct materials (10 CFR Part 35). In 2020, NRC staff recommended that the Commission pursue regulatory changes to the T&E requirements for radiopharmaceuticals, moving to using solely board certification for determining and obtaining AU status. Specifically, NRC staff indicated they planned to modify the board certification

criteria to allow for additional medical specialty boards, beyond nuclear medicine and radiation oncology, to qualify for meeting the T&E requirements. In practice, this would necessitate weakening the already robust, yet flexible, board recognition criteria. Thankfully in January 2022, the Commission disapproved of their staff's recommendations, preserving the T&E status quo.^v

In the last year, NRC has been busy supporting novel PET diagnostic radiopharmaceuticals, and will play a direct role in creating regulations involving proposed rules on Rb-82 generators and other new emerging medical technologies (EMTs). The Commission approved of their staff proceeding with rulemaking in January 2022 due to the anticipated increase in the number of emerging medical technologies licensed by the NRC.^{vi} As the use of medical applications of radioisotopes continues to increase and new advancements in medical technologies are expected, we anticipate the NRC will continue to be busy in this segment of radiopharmaceuticals. Proactively, to address these challenges, the NRC staff recommended updating Part 35 to establish generally applicable, performance-based requirements for emerging medical technologies that would focus on the essential, safety-related elements necessary to ensure radiation safety for workers, patients, and the general public. The revised regulation would also include performance-based requirements for rubidium-82 generators, GSR units, and Y-90 microspheres.^{vii}

In the staff's rule-making plan^{vii}, "radiotheranostics' that merge molecular-targeted diagnostic imaging agents with molecular-targeted radiopharmaceutical therapy" is an example of new EMTs that currently would require licensing under 10 CFR 35.1000. SNMMI and the SNMMI-TS Advocacy will engage in providing comment to the proposed rule, along with participating in stakeholder calls during the 90-day comment period in March 2023.

The support of not only the NRC, but the Joint Commission (TJC), a national accrediting body, is essential in having nuclear medicine technologists fully participate in the delivery of theranostics. There are currently regulations within the NRC that allow the nuclear medicine technologist to perform all actions of therapeutic radiopharmaceutical administration under the guidance of the Authorized User.^{viii} The SNMMI-TS Scope of Practice and Performance Standards (SOP) updated in 2022, as written allows the NMT to perform and participate in all elements of theranostics care delivery.^{ix} The SNMMI-TS Advocacy Committee understands and further welcomes guidance and/or rulemaking on the various NMT roles in radiopharmaceutical therapies, in order for the technologist to be properly supported, licensed and prepared to safely deliver all components of such therapies. Adjustment of policies and standards are common when you evaluate the history of NRC and TJC, and over the next three to five years it is reasonable to see these changes happen with the support and collaboration between these and other appropriate accrediting and governing groups.

State and Local Collaboration

SNMMI-TS Advocacy plays a significant role to ensure that State rules and healthcare facility policies allow NMTs to practice to their standardized scope, practice standards, and training. This oversight is pivotal in NMTs playing a fully-encompassing role in theranostics therapy. The SNMMI-Technologist Advocacy Group Committee (TAG) has been effectively collaborating throughout most of the States in

the United States (in addition to the District of Columbia and Puerto Rico) to make sure that nuclear medicine technologists are properly licensed to deliver all components of nuclear medicine in their published Scope of Practice (SOP). While this is an ongoing effort, today almost 80% of our states license nuclear medicine technologists to practice to their training in their respective states. As NMT role expands with theranostics, licensure will need to keep up with curriculum and scope of practice changes. These changes will need to evolve and be incorporated into State regulations to have NMTs participate and lead in all aspects of theranostics therapy. This is a tall task and one that will require consistent work by the TAG and State governments, working together. The Advocacy committee will continue to use the SNMMI Model Practice Act (MPA) to equip States with legislative support and a thorough understanding of the NMT scope, so proper licensure and regulation is in place to support the evolving skills needed to provide safe handling and administration of radiopharmaceuticals used for theranostics. Furthermore, the SNMMI-TS Advocacy Committee is currently considering creating one MPA for the field by collaborating with organizations such as the Conference of Radiation Control Program Directors (CRCPD) and the Organization of Agreement States (OAS).

Like the evolution of the NMT SOP, healthcare facilities themselves will also need to adjust their practices and determine what components of care they can transition from licensed nurses to nuclear medicine technologists. Hospitals have policies in place for patient monitoring, patient management and medication administration. These are policies that will need to be evaluated, reevaluated, and updated to allow nuclear medicine technologists to provide full care to radiopharmaceutical-*therapy* patients. Some of this training will be done by Clinical Education Units (CEU), on the job training, and supplementary material from certification boards and badging options described earlier. The relationship and collaboration between nurses and nuclear medicine technologists is essential to make sure that the technologists can learn and practice in the safest and most patient efficient way. The action of training Radiology Technologists from other healthcare providers like nurses has historically been successfully in various scopes in thousands of hospitals and clinics throughout the United States, and the transition to nuclear medicine technologists doing all aspects of theranostics therapy under proper guidance and policy management will be no different. With expected severe nursing shortages, the sharing and training is utmost important now, to make sure that access to theranostics for patients is not compromised. The Advocacy Committee plans to continue to engage with hospitals and other healthcare facilities to further the field of nuclear medicine and NMTs to support the continued growth of theranostics. This continued work and attention to licensure and regulation should allow the NMT to stay front-and-center in theranostics delivery and further create pathways for new NMTs to get into the field and be available to support our patients as the demand grows.

Incorporation of Theranostics into the Scope of Practice

Immediate recommended actions of the SNMMI-TS Advocacy committee include the continuous evaluation of the SNMMI-TS NMT SOP, to be amended and revised to cover all components of therapy. Some considerations that the Advocacy team is considering are inputting the addition of the term “**theranostics**” to the *Technologist Qualified to Perform Nuclear Medicine Procedures* section.

1. Under the supervision of an authorized user, the nuclear medicine technologist is responsible for the safe use of ionizing and non-ionizing radiation and molecular imaging for diagnostic, therapeutic, [**theranostics**,] and research purposes.

2. A certified nuclear medicine technologist is qualified to perform general nuclear medicine procedures, nuclear medicine therapy, [**theranostics**,] nuclear cardiology procedures, nuclear breast procedures, positron emission tomography (PET) procedures, and CT attenuation correction and localization, and administer radioactive, adjunctive, and imaging medication at entry-level.

Adding "**theranostics**" into the Scope of Practice achieves the goal of exposing the NMT profession and scope to the rapidly emerging field and puts the practice standards and scope as a reference point to the NMT having a fully inclusive role in this therapy delivery. As NMT curriculum and training increases to fully encompass all components of the delivery of theranostics by the NMT, the SOP will continue to expand and become more specific to each element.

The Advocacy Committee is also looking to amend the Model Practice Act (MPA) for Nuclear Medicine Technology and look to add the **theranostics** definition to the document to start exposing states to the NMT role in these therapies. As NMT education and training expands, so will the MPA, referencing all tasks that the NMT should be allowed to conduct while providing theranostics-therapy care to patients.

Conclusion

The Nuclear Medicine Technologist profession is evolving at a rapid pace. How will current nuclear medicine technologists prepare for these new roles? Because of their position, their education, and the respect they have earned, nuclear medicine technologists are well-positioned to take an active lead in theranostics growth and advancement.

NMTs need to initiate the conversation for policy and process changes locally, with their clinic leaders and the local governments so they can start building a stake in this exciting emerging therapy available to our patients in the US. NMTs leading and being a fully contributing members to the interdisciplinary theranostics teams may require some nuclear medicine technologists to step out of their comfort zone and gain more training, but this effort will not only allow the NMT scope and profession to expand, but it will also lead to a significant improvement in patient access for these integral therapies.

The work by SNMMI and SNMMI-TS over the next several years will be to continue to build on and further launch a comprehensive theranostics awareness campaign to highlight its importance as a professional-growth pathway and encouraging NMTs to be front-line healthcare providers in the delivery of all radiopharmaceutical therapies. This will require collaborative work among healthcare professionals and various departments in healthcare and will ultimately help patients have better access to receive the care that they require to live better and longer lives.

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