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Road to becoming Y-90 authorized user as an integrated vascular and interventional radiology resident (NRC alternate pathway)

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ABSTRACT

Yttrium-90 (Y-90) radioembolization, also called transarterial radioembolization (TARE), is a catheter-directed therapy for direct delivery of internal radiation to tumors in the form of microspheres. It is currently available in two forms, either as a constituent of glass microspheres called TheraSphere® (BTG Ltd., London, UK [now Boston Scientific, Marlborough, MA, USA]) or as a biocompatible resin-based microsphere called SIR-Spheres® (Sirtex Medical Ltd., Woburn, MA, USA). Once these microspheres are delivered to the tumor through an arterial pathway, they are embedded within the tumor microcirculation and emit β-radiation at therapeutic levels. TARE is a commonly used treatment for unresectable primary or secondary hepatic malignancies and has led to improved survival rates and increased success rates in downstaging patients before liver resection or transplantation. Immediately following the pre-treatment angiogram, each patient undergoes a nuclear medicine study, otherwise known as technetium (^{99m}Tc) macroaggregated albumin scan, to determine the amount of radiotracer that has accumulated in the lungs (lung shunt fraction). Finally, after several calculations, the appropriate radiation dose to be delivered to the tumor is determined. While the technical aspects of radioembolization are quite complex, the collective clinical experience presented in the literature supports the use of Y-90 radioembolization for unresectable hepatic malignancies. Those ordering and administering radioembolization particles must be deemed an authorized user (AU) by the Nuclear Regulatory Commission (NRC). The NRC defines an AU as the individual responsible for ensuring that radioactive materials are handled and used safely and following NRC regulations and the terms and conditions of the NRC license. The NRC has published licensing guidance on Y-90 brachytherapy with the 10th revision released on November 8, 2019. This guidance has outlined specific requirements for obtaining a license for the use of TheraSphere and SIR-Spheres. Following the revised licensure guidelines from the NRC on Y-90 usage, a conditional authorization has been obtained at our institution by the PGY-6 interventional radiology/diagnostic radiology (IR/DR) resident. While the full guidelines and extensive alternative requirements can be found online, we will highlight the specific guidelines applicable to and fulfilled by IR/DR residents. The traditional ABR pathway takes approximately 18 months after graduation, including passing the ABR certification examination to become an AU. With the proposed alternate pathway, trainees will potentially become AU immediately after graduation. The primary aim of this submission is to describe the process for obtaining conditional authorization for Y-90 microspheres for PGY-6 IR/DR residents.

Keywords: Interventional oncology, Radioembolization, Y-90 authorized user

INTRODUCTION

Yttrium-90 (Y-90) radioembolization, also called transarterial radioembolization (TARE), is a catheter-directed therapy for direct delivery of internal radiation to tumors in the form of

microspheres. It is currently available in two forms, either as a constituent of glass microspheres called TheraSphere® (BTG Ltd., London, UK [now Boston Scientific, Marlborough, MA, USA]) or as a biocompatible resin-based microsphere called SIR-Spheres® (Sirtex Medical Ltd., Woburn, MA, USA). Once these microspheres are delivered to the tumor through an arterial pathway, they are embedded within the tumor microcirculation and emit β-radiation at therapeutic levels.[3] This process allows for a high concentrated dose of radiation to be delivered directly to the tumor without affecting other parts of the body and thus minimizing the potential for organ toxicity, which is a common side effect in standard external beam radiation therapy. TARE is a commonly used treatment for unresectable primary or secondary hepatic malignancies and has led to improved survival rates and increased success rates in downstaging patients before liver resection or transplantation.[3] The liver receives most of its blood supply through portal venous system. On the contrary, liver tumors receive the bulk of their blood supply from the hepatic arteries. Immediately following the pretreatment angiogram, each patient undergoes a nuclear medicine study, otherwise known as a technetium (^{99m}Tc) macroaggregated albumin scan, to determine the amount of radiotracer that has accumulated in the lungs (lung shunt fraction). Finally, after several calculations, the appropriate radiation dose to be delivered to the tumor is determined. While the technical aspects of radioembolization are quite complex, the collective clinical experience presented in the literature supports the use of Y-90 radioembolization for unresectable hepatic malignancies. Those ordering and administering radioembolization particles must be deemed an authorized user (AU) by the Nuclear Regulatory Commission (NRC). The NRC defines an AU as the individual responsible for ensuring that radioactive materials are handled and used safely and in accordance with NRC regulations and the terms and conditions of the NRC license. The NRC has published licensing guidance on Y-90 brachytherapy with the 10th revision released on November 8, 2019. This guidance has outlined specific requirements for obtaining a license for the use of TheraSphere and SIR-Spheres. Following the revised licensure guidelines from the NRC on Y-90 usage, a conditional authorization has been obtained at our institution by the PGY-6 interventional radiology/diagnostic radiology (IR/DR) resident. While the full guidelines and extensive alternative requirements can be found online, we will highlight the specific guidelines applicable to and fulfilled by IR/DR residents at our institution. Traditional ABR pathway takes approximately 18 months after graduation which includes passing the ABR certification exam to become an AU.[1] With the proposed alternate pathway, trainees will potentially become AU immediately after graduation. The primary aim of this submission is to describe the process for obtaining a conditional authorization for Y-90 microspheres for PGY-6 IR/DR residents.

DISCUSSION

Training and experience

The NRC requires specific criteria to be met by integrated IR/DR residents to qualify for a conditional AU license for Y-90 treatment.[2] Table 1 displays the NRC requirements and suggestions of the ways that integrated IR/DR residents can fulfill those requirements. All listed criteria must be met for licensure eligibility. Requirements have been paraphrased from the original document. After all appropriate documentations are sent to the NRC, the conditional AU license is provided to the PGY-6 integrated IR/DR resident. The conditional AU can administer Y-90 microspheres under the supervision of a full AU who can provide immediate assistance as needed. Broad Scope Radioactive Materials License states that the Radiation Safety Committee of the hospital has the responsibility and power to approve and maintain a list of all AUs. Our system of providing "conditional" AU status to the PGY-6 integrated IR/DR residents was presented to state inspectors during the most recent inspection, who have provided us with a very positive response without objections. The "conditional" AU license is valid until the day of graduation from integrated IR/DR residency and may be converted to a full AU license if the said trainee continues under the same radioactive materials license (at the same institution) or by process of license transfer to another practice/institution.

Table 1: NRC Y-90 licensure requirements and IR/DR resident requirement fulfillment.

Requirements for Y-90 licensure[2]	IR/DR resident requirement fulfillment
Experience in DR	Three years of supervised clinical experience in DR completed in PGY 2–4
Experience in IR	Twelve months of supervised clinical experience in IR completed in PGY 5/6
Eighty hours of classroom and laboratory training in byproduct material requiring a written directive, applicable to Y-90 microspheres, which may be concurrent with training received in radiation physics and instrumentation, radiation protection, mathematics pertaining to use and measurement of radioactivity, and radiation biology.	Completed as part of the standard DR curriculum, as confirmed by DR program director in writing

(Contd...)

Table 1: ***(Continued).***

Requirements for Y-90 licensure[2]	IR/DR resident requirement fulfillment
Has work experience under AU supervision for Y-90 microsphere brachytherapy or training provided by a Y-90 microsphere manufacturer representative involving; ordering, receiving, and unpacking radioactive materials safely, performing quality control procedures on instruments used to determine the activity of Y-90 microspheres, calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient, and using procedures to control and to contain spilled byproduct material, including Y-90 microspheres.	Completed in PGY 4-5, as confirmed by IR program director and radiation safety officer in writing
Has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for the type of Y-90 microspheres for which authorization is sought.	Completed in PGY-4, as confirmed by the IR program director in writing. *To keep consistent with current conditional AU process, any conditional AU must be supervised by a full AU
Has obtained written attestation that the individual has satisfactorily completed the requirements in the above criteria and is able to independently fulfill radiation safety-related duties as an AU for the type of Y-90 microspheres requested. The attestation must be obtained from a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is a physician who is an AU for the type of Y-90 microsphere brachytherapy being authorized and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education.	Completed in PGY-5, as confirmed by the IR program director in writing

NRC: Nuclear regulatory commission, Y-90: Yttrium-90, AU: Authorized user, DR: Diagnostic radiology, IR: Interventional radiology

CONCLUSION

Conditional to a full AU license will provide a significant advantage to the IR/DR resident during their transition to an attending physician role at a same or new institution. Conventionally, through the ABR pathway, one can obtain AU license after board certification (minimum 18–24 months from graduation). With this alternate pathway, IR/DR resident will potentially become AU right after graduation from residency. This would be particularly useful for trainees going to practices with limited local resources to fulfill requirements through traditional pathway. Programs with limited local resources and lower volume centers will be able to avoid logistical and scheduling challenges of bringing in proctors. Joining the practice as an AU can be vital at centers that want to start a Y-90 program by transfer of license which can be done by the local radiation safety officer. At the other end of the spectrum, high-volume centers would also benefit by having an AU on day 1 of recruitment as it brings scheduling advantages and ease of workflow in busy environment. With an increasing number of IR/DR residents graduating in the coming years and many practices performing Y-90 treatments, we hope to shed light on this available pathway for obtaining a conditional AU license, with potential to convert to full AU license depending on local radiation safety committee or state radioactive materials regulating body by process of transfer of license as early as immediately after graduation.

IRB Approval

No IRB approval was required for this article as no human or animal subjects, or patients were involved.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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