Gryglak, Magdalena

From: Gryglak, Magdalena
Sent: Thursday, January 09, 2020 11:32 AM
To: glong@sfmc.net
Subject: Request to authorize Dr. Keating for use of Yttrium-90 TheraSpheres, NRC license no. 24-00158-03, Saint Francis Medical Center
Attachments: Y90 guidance.pdf

Good morning,

I have reviewed the licensee's request dated 11/12/19 to authorize Dr. Keating for the use of Yttrium-90 ThereSpheres. I need additional information in order to proceed with the request. Specifically, please provide the following:

1) Please provide documentation of Dr. Keating's qualifications as specified in A.1. - A.3 (pages 3 and 4 of the current NRC guidance for use of Yttrium-90 ThereSpheres, Revision 9), which is attached.
2) Please provide the license number and the name of the Authorized User who supervised Dr. Keating during administration of the three Yttrium-90 cases as documented in letter dated 11/10/19.

Please provide the additional information in a signed by management and dated letter by 1/27/2020. You may submit the information directly to me as a pdf document via email.

Please let me know if you have any questions.

Thank you

Magdalena R. Gryglak
Health Physicist
U.S. NRC Region III
630-829-9875

Authorized Individuals

NRC has determined that individuals meeting the guidance provided in both A and B below will be considered qualified and can be authorized for the use of Y-90 microspheres. Applicants may also submit alternative training and experience commitments to be reviewed on a case-by-case basis by NRC staff. The alternative information should include an explanation of why the applicant believes the alternative information demonstrates that the individuals are qualified to be authorized individuals.

Training and Experience

The authorized user for Y-90 microspheres:

A.

1. Is identified as an authorized user for medical uses in 10 CFR 35.400, "Use of sources for manual brachytherapy," or for medical uses in 35.300, "Use of unsealed byproduct material for which a written directive is required," that include the uses described in paragraphs (1), (2), and (3) of 10 CFR 35.390(b)(1)(ii)(G) on one of the following licenses or permits that permit the medical use of byproduct material: A Commission or Agreement State license, a permit issued by a Commission master materials licensee, a permit issued by a Commission or Agreement State specific licensee of broad scope, or a permit issued by a Commission master materials license broad scope permittee; or
2. Meets the training and experience requirements of 10 CFR 35.390 or 10 CFR 35.490; or
3. Meets the training and experience guidelines as follows:

   i.

      a. Board certification in diagnostic radiology and subspecialty certification in interventional radiology by either the American Board of Radiology or the American Osteopathic Board of Radiology; or
      b. Three years supervised clinical experience in diagnostic radiology and one additional year of supervised clinical experience in interventional radiology; and

   ii. has 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, which may be concurrent with training received in accordance with Item A.3.i. in:

      a. Radiation physics and instrumentation;

b. Radiation protection;
c. Mathematics pertaining to the use and measurement of radioactivity;
d. Radiation biology; and

iii. has work experience under the supervision of an AU for Y-90 microspheres or training provided by a Y-90 microsphere manufacturer representative involving:
a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
b. Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
c. Evaluation of each patient or human research subject for the dose and activity of Y-90 microspheres to be administered to each treatment site;
d. Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject;
e. Using administrative controls to prevent a medical event involving the use of byproduct material (Appendix S to NUREG-1556, Volume 9 provides additional guidance on this subject);
f. Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures (Appendix N to NUREG-1556, Volume 9 provides additional guidance on this subject. The procedures should address any special circumstances that may be encountered, such as electrostatic charge of microspheres and proper survey instrument and survey technique for beta emitters); and
g. Follow up and review of each patient's or human research subject's case history for Y-90 microspheres; and

B. has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microsphere for which authorization is sought. This requirement may be satisfied by satisfactory completion of a training program provided by either:

1. (Pathway 1) an AU who is authorized for the type of microsphere for which the individual is seeking authorization. This clinical use experience should include at