



National Institutes of Health  
Bethesda, Maryland 20892  
www.nih.gov

November 16, 2018

License: 19-00296-10 *103001786*

U.S. Nuclear Regulatory Commission  
Division of Radiation Safety and Safeguards  
2100 Renaissance Blvd  
King of Prussia, PA 19406

Dear Sir or Madam:

In response to your email dated November 8, 2018 regarding our license amendment request dated September 24, 2018 for the addition of Y-90 TheraSpheres® for clinical use under 10 CFR 35.1000, below are the answers to each of your questions:

1. Confirm that if the CAU is obtaining training and experience by a Y-90 microsphere manufacturer (Pathway 2), the clinical use experience will include at least three supervised hands-on *in-vitro* simulated cases, followed by three supervised patient cases in the physical presence of the manufacturer's representative or CAU. *In-vitro* simulated cases should demonstrate issues that are encountered during Y-90 microsphere administration procedures.

NIH Response:

Q1) We confirm that when Pathway 2 is followed for CAU approval for the medical use of Y-90 microspheres, the CAU will complete at least three *in-vitro* simulated cases provided by the Y-90 microsphere manufacturer, subsequently followed by at least three supervised patient cases in the physical presence of the manufacturer's representative.

2. Confirm documentation of the training and experience will be maintained. For individuals obtaining clinical use experience under Pathway 1, documentation must include the clinical use cases. For individuals obtaining clinical use experience under Pathway 2, documentation must include the *in-vitro* simulated cases and a commitment that each individual will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative.

NIH Response:

Q2) We commit to maintaining documentation of the CAU's training and experience on this therapy. Documentation of clinical use experience will include the first three hands-on patient cases supervised by an approved CAU (if Pathway 1 is followed), and the three *in-vitro* simulated cases obtained through the Y-90 microsphere manufacturer, as well as the three clinical use cases performed in the physical presence of a manufacturer representative, (if Pathway 2 is followed). We will submit documentation from the manufacturer within 30 days of when these three supervised patient cases have been satisfactorily completed.

3. Confirm training will be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

*Rec'd. in LAT-11/19/2018*

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NNSC/RGN MATERIALS-002

NIH Response:

Q3) We confirm that all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres will receive training commensurate to their duties. This includes but is not limited to: dosimetry, infusion techniques, clinical considerations, waste disposal, and radiation safety issues.

4. Confirm documentation of the revised TheraSphere® Y-90 program will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change. In addition, confirm that a record of each change will be maintained for five years.

NIH Response:

Q4) We confirm that documentation of the revised Therasphere Y-90 program will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change. A record of each change will be maintained for a minimum of five years.

If you have any questions or need additional clarification on this amendment request, please contact me at 301-594-1303 or via e-mail at [cribaudo@nih.gov](mailto:cribaudo@nih.gov).



Catherine A. Ribaudo  
NIH Radiation Safety Officer

cc: Dr. Bradford Wood, Chair, NIH Radiation Safety Committee  
Dr. Michael Gottesman, Deputy Director for Intramural Research, NIH