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July 27, 2023

U.S. Nuclear Regulatory Commission  
Region III  
Materials Licensing Branch  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

**Via Fax: 630-515-1078**

Dear Reader:

Re NRC License Number 24-00128-03

We request the authorization of Dr. Abel Belay for medical use of Y-90 glass microspheres, as permitted by 10 CFR 35.1000 in a TheraSphere dose delivery system.

Amendment 15 of our license provided conditional authorization of Dr. Abel A. Belay for medical use of Y-90 glass microspheres, as permitted by 10 CFR 35.1000 in a TheraSphere dose delivery system. Since that time, we have learned that Dr. Belay had previously obtained training and experience in the use of Y-90 TheraSpheres during his fellowship in Interventional Radiology at University of Iowa. The attached letter from his program director at University of Iowa provides documentation of his performance of three hands-on clinical cases under the supervision of an AU for TheraSpheres. It also includes attestation of Dr. Belay's ability to independently fulfill the radiation safety-related duties as an AU for TheraSpheres.

If you have any questions regarding this application, please feel free to call me at 573-519-4710 (office) or 573-270-7492 (mobile).

Sincerely,

A handwritten signature in black ink that reads "Sam S. Hancock PhD".

Sam S. Hancock, PhD  
Radiation Safety Officer

Enclosures:

- Attestation letter from Univ. of Iowa

cc: Mariellena Sudak, VP, COO  
Mark Gates, MD, RSC Chairman

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**Department of Radiology**

Roy J. and Lucille A.  
Carver College of Medicine  
Department of Radiology  
200 Hawkins Drive 3884 JPP  
Iowa City, IA 52242  
medicine.uiowa.edu/radiology

To whom it may concern:

Dr. Abel Belay, has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for Theraspheres. The clinical use training included three (3) hand-on patient cases for the medical use of Theraspheres under the supervision of an Authorized User for TheraSpheres.

I believe Dr. Abel Belay has satisfactory completed training and work experience in accordance with the U.S. Nuclear Regulatory Commission's Microsphere Brachytherapy Sources and Devices Guidance (Rev 10.2, April 20, 2021) section A and B to become an AU for TheraSpheres and that Dr. Abel Belay is able to independently fulfill the radiation safety-related duties as an AU for TheraSpheres.

I affirm the attestation above represents the consensus of the residency program faculty where at least one faculty member is an AU for Theraspheres who concurs with the attestation provided.



**Mohammad Amarnah**  
Clinical Assistant Professor of Radiology and Pediatrics  
Director, Vascular and Interventional Radiology  
Program Director, Interventional Radiology Residency  
University of Iowa Carver College of Medicine

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